Overcome failure to Publish negative findings: The OPEN project

For the OPEN Consortium

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ACT now: Accuracy, Completeness, and Transparency in health research reporting
11 – 12 October 2012
www.equator-network.org
Disclosures

• It is not exactly about reporting quality
• But, nevertheless important
• I am a systematic reviewer, so I am affected by non-publication of research findings
• I am a clinician (pediatrician & pediatric hematologist/oncologist), so I am concerned about not being able to provide the best treatment to my patients
Non-publication of research findings: ...just one example

N=677 Trials

Results:

Published data overestimated the benefit of reboxetine versus placebo by up to 115% and reboxetine versus SSRIs by up to 23%, and also underestimated harm.
EC Policy Initiatives on OPEN Access

July 2012: Communication on a reinforced European Research Area partnership for excellence and growth (72KB)

- Communication Towards better access to scientific information: Boosting the benefits of public investments in research: (en, fr, de.)

- Recommendation on access to and preservation of scientific information: (en, fr, de, other languages)

- Commission staff working document accompanying the Recommendation on access to and preservation of scientific information (Executive Summary of Impact Assessment)

January 2012: Results of the public consultation on scientific information in the digital age (4MB)

- Commission staff working document accompanying the Recommendation on access to and preservation of scientific information (Impact Assessment) (738KB)

November 2011: Proposal for open access in Horizon 2020
The Call

the different partner institutions should follow the networking that already occurs at the scientific level in EU-funded projects. As a result, an increase in quality and quantity of the communication actions, a better coordination of resources and messages, and a proper acknowledgement of the European dimension of collaborative health research should be achieved.

**HEALTH.2011.4.1-2 Targeting publication bias. FP7-HEALTH 2011 single-stage.** The objective is to explore, identify and overcome failure to publish negative results, especially from clinical trials. Failure to publish negative results or unsuccessful experiments has major ramifications for the health of EU citizens and there is an ethical imperative and a significant challenge to ensure that finite health research resources are better used, avoiding replication of previous experiments leading to better use of resources. Applicants should propose well-structured, innovative approaches to define and evaluate publication bias and the impact it has on research. These approaches should include the inventory of existing sites and publications, presentation of current data on impact of the failure to published negative results via surveys and/or analysis of literature, evaluation of study protocols, conference abstracts and discussions with key opinion leaders and stakeholders, such as research journal publishers, study registries, research institutions, funding bodies, regulators and industry. Interaction with major journals and international groups acting in medical publication should be sought in order to identify ways to change practice and provide insights on how to avoid duplication of research efforts and allow a more effective funding of health research. **Note:** Limits on the EU financial contribution apply. These are implemented strictly as formal eligibility criteria.

**Funding scheme:** Coordination and Support Action (supporting section).

**Requested EU contribution per project:** Maximum EUR 500 000.

One or more proposals can be selected.

**Expected impact:** Publication bias is commonly understood as the failure to publish entire studies with negative results, particularly referring to clinical trials. Although the importance of bias is increasingly being recognised, more empirical evidence is needed to gain insight into this issue, in order to evaluate an important primary source of information on planned studies. The supporting action should assess the impact and seek ways to detect effectively and reduce the impact of non-publication of negative studies and study results, and provide insights on how to avoid duplication of research efforts and allow a more effective funding of health research.
OPEN: Overcome failure to Publish Negative findings

- Project co-funded by the European Commission
- 7th Framework Programme HEALTH.2010.3.1-1: Grant agreement n° 258583
- Financial volume: 499‘989,- Euro
- Duration: 24 months
- Starting date: 01.11.2011
## Consortium

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<th>Participant no.</th>
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<td>1</td>
<td>University Medical Centre Freiburg</td>
<td>Meerpohl/Antes and Team</td>
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<td>University of Tuebingen</td>
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<td>Research Institute of the Hospital of Santa Creu and Sant Pau, Barcelona</td>
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Co-funded under European Union Seventh Framework Programme (FP7 – HEALTH.2011.4.1-2) under grant agreement n° 285453.
Advisory Board

• Doug Altman, Centre for Statistics, Oxford, UK
• Kay Dickersin, John Hopkins School of Public Health, Baltimore, USA
• An-Wen Chan, Women’s College Research Institute, Toronto, Canada
• Fujian Song, School of Medicine, University of East Anglia, UK
• Wim Weber, Editor, BMJ, UK
Keypoints I

- OPEN will bring together key opinion leaders from across Europe to address the issue of non-publication of research findings
- To conduct a series of systematic reviews to assess the current state of the literature on publication bias
- To assess/evaluate policies and procedures in place for preventing publication bias by the main parties involved in funding, conducting and publishing clinical research including:
  - Funding agencies
  - (Pharmaceutical) Industry
  - Research ethics committees
  - Research institutions
  - Researchers (authors and reviewers)
  - Trial registers
  - Biomedical journals
  - Regulatory agencies
  - Benefit assessment agencies
Graphical representation of the components showing their interdependencies

WP 14 Project management

- WP 1 Systematic reviews to assess publication bias
- WP 2 Evaluate funding agencies
- WP 3 Evaluate (pharmaceutical) industry
- WP 4 Evaluate ethic boards
- WP 5 Evaluate research institutions
- WP 6 Evaluate researchers, authors and reviewers
- WP 7 Evaluate trial registers
- WP 8 Evaluate biomedical journals
- WP 9 Evaluate regulatory agencies
- WP 10 Evaluate impact on benefit assessment process
- WP 11 Impact of publication bias on network metaanalysis

WP 12 Evaluation of findings and formulation of recommendations

WP 13 Dissemination and exploitation of results
Keypoints II

• OPEN will hold an European Workshop and develop recommendations using the findings of the work packages.

• The expected results of OPEN will be evidence-based recommendations for initiating the implementation of adequate measures to control publication bias and limit its effects on clinical decision-making.
# Work plan

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Next steps

• February 2013, Barcelona:
  – Internal workshop with all partners and advisory board to discuss findings from and implications of different workpackages

• May 2013, Freiburg:
  – Workshop with involvement of external key stakeholders
  – Aim:
    • to develop recommendations aiming at better detection and prevention of non-publication
    • to explore strategies for implementation of recommendations
OPEN

To Overcome failure to Publish nEgative fiNdings

Welcome

is a 24-month project (running from November 1, 2011 to October 31, 2013) co-funded by the European Commission under the Seventh Framework Programme.

Project Objective

“To Overcome failure to Publish nEgative fiNdings”

Background

Results from clinical studies are an essential factor determining clinical decision making. It is therefore important that the results of all studies are presented in an unbiased and easily accessible manner. Health professionals and policymakers should make healthcare decisions based on the entire relevant research evidence, not on partial or skewed evidence. This, however, can frequently not be achieved, to a large part because a considerable amount of research findings are not published; this phenomenon is called publication bias.

Publication bias results from the tendency of authors to submit, and of journals to accept, manuscripts for publication based on the direction or strength of the study findings. If manuscripts are not published because of an undesirable direction or perceived lack of strength of its findings, that evidence will not contribute towards advancing science. However, patients who participate in clinical research and the funding bodies who provide financial support do so with the clear understanding that their contributions will add to the progress of scientific knowledge. Publication bias therefore wastes considerable human and financial resources and skews the evidence base.

Objectives
Your chance to contribute!

- Ana Marusic and Mario Malicki from Split are conducting structured interviews to learn about views on publication bias of
  - Researchers
  - Authors of research reports

- If you are interested contact either
  - anyone of them or
  - go to room „Künstlergarderobe“ during poster sessions
What is OPEN?

It is a 24-month project (running from November 1, 2011 to October 31, 2013) co-funded by the European Commission under the Seventh Framework Programme.

The German Cochrane Centre at the University Medical Center Freiburg coordinates the OPEN Project addressing publication bias in biomedical research. The objective of the OPEN Project is "To Overcome failure to Publish nEgative fiNdings".

Background
UNCOVER

Evaluation and development of measures to uncover and overcome bias due to non-publication of clinical trials

September 2011 – February 2014 (30 months)

http://www.ait.ac.at/uncover
Project partners

1. Austrian Institute of Technology (AIT)
   • Coordinating partner
   • Dirk Holste, Manuela Kienegger, Joachim Klerx, Petra Wagner-Luptacik, Eva Buchinger, Brigitte Palensky, Edgar Schiebel

2. Danube University, Krems (DUK)
   • Gerald Gartlehner, Ludwig Grillich, Kylie Thaler, Ursula Griebler, Christina Kien, Michaela Strobelberger

3. University of North Carolina at Chapel Hill (UNC)
   • Shrikant Bangdiwala, Visali Peravali
Aims

1. **UNCOVER aims to**
   - apply established and develop novel methods to uncover non-publication bias,
   - engage with stakeholders and identify strategies, barriers, and facilitating factors to overcome non-publication and its consequences; and
   - synthesize lessons learned and recommend feasible measures to deal with the publication bias.

2. **UNCOVER treats the issues of the publication bias**
   - with an multidisciplinary approach
   - with quantitative, qualitative and participatory methods
Activities

1. **Framing** the publication bias in terms of EBM and system theory (incl. stakeholder mapping)

2. **Identification** of key opinion leaders and stakeholders inside and outside the scientific community through bibliometric analysis and automated WWW site searches

3. **Systematic review** on the effectiveness of interventions to counter publication bias

4. **Interviews** with editors and other stakeholders on publication policies and practices especially with respect to compulsory trial registration of RCTs

5. **Open-source software programme** to estimate the potential impact of missing data / unpublished studies on the results of a given meta-analysis

6. **Recommendations** for the implementation of viable policy measures to overcome non-publication
Summary

• Two EC co-funded project on non-publication of research findings
• Co-operation between projects to ensure optimal output and avoidance of duplicate work
• First results will be available in 2013
Questions ??

Or for UNCOVER: Gerald Gartlehner, Danube University Krems, Austria

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