Research funders and research reporting

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Disclaimer

- The following represents the opinion of the speaker only

…“some thoughts on the way in which research funders could address the issue of research reporting”…

Funder

- Those who fund competitive research grants
  - Charitable institutions
  - Government agencies
  - Philanthropic organizations

Why should funders address the issue of research reporting?

- A double-blind, placebo-controlled, randomized, factorial study using a daily oral administration of 30 mg beta-carotene and/or 500 mg vitamin C was conducted in 141 women with colposcopically and histologically confirmed minor squamous atypia or cervical intra-epithelial neoplasia (CIN) I.
- Over approximately 2 years of follow-up, 43 lesions regressed to normal and 13 progressed to CIN II. The regression rate was slightly higher, but not significantly so, in those randomized to beta-carotene compared to no beta-carotene (hazard ratio = 1.58, 95% CI: 0.86-2.93, *P* = 0.14) and slightly lower, but not statistically significant, for those randomized to vitamin C compared to no vitamin C (hazard ratio = 0.65, 95% CI: 0.35-1.21, *P* = 0.17). In a model with no interaction, the progression rate was slightly higher in those randomized to beta-carotene (hazard ratio = 1.75, 95% CI: 0.57-5.36, *P* = 0.32) and also in those randomized to vitamin C (hazard ratio = 2.40, 95% CI: 0.74-7.80, *P* = 0.13). Neither of these were statistically significant.

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“Registration of all interventional trials is a scientific, ethical and moral responsibility”

WHO ICTRP Secretariat, Nov 2005

~~Registration~~ *Reporting the findings* of all interventional trials is a scientific, ethical and moral responsibility

Declaration of Helsinki

27. Both authors and publishers have ethical obligations. In publication of the results of research, the investigators are obliged to preserve the accuracy of the results. Negative as well as positive results should be published or otherwise publicly available. Sources of funding, institutional affiliations and any possible conflicts of interest should be declared in the publication. Reports of experimentation not in accordance with the principles laid down in this Declaration should not be accepted for publication.

World Medical Association

2008 Review of the DoH

30. Authors, editors and publishers all have ethical obligations with regard to the publication of the results of research. Authors are accountable for the accuracy of the results. They have a duty to make publicly available the results of their research on humans. In so doing they should adhere to accepted guidelines for ethical reporting. Negative as well as positive results should be published or otherwise made publicly available. Sources of funding, institutional affiliations and conflicts of interest should be declared in the publication. Reports of research not in accordance with the principles of this Declaration should not be accepted for publication.

Why should funders address this issue?

- Scientific, ethical and moral responsibility
  - To be sure they are funding research that complies with key ethical principles

Why should funders address this issue?

- Good business
  - Limited resources
  - The public good
    - Use of public funds means accountability to the public
  - Is the research necessary?
    - Is it addressing an question that has not already been answered?
  - Will the research contribute to knowledge?

How should funders address the issue of research reporting?

Funders should… 1. *take responsibility*

- Acknowledge that publicly reporting research findings is a scientific, ethical and moral responsibility
- Not enforce restrictions on reporting in contracts or agreements

- Nov 2001 - Jan 2002, officials at 108/122 U.S. medical schools interviewed about provisions in their institutions' agreements with industry sponsors of multicenter clinical trials.

Schulman et al (NEJM 2002)

"Our findings suggest that academic institutions routinely participate in clinical research that does not adhere to ICMJE standards of accountability, access to data, and control of publication. These standards address long-standing concern about the integrity of research published in biomedical journals. We found that academic institutions rarely ensure that their investigators have full participation in the design of the trials, unimpeded access to trial data, and the right to publish their findings."

Funders should… 1. *take responsibility*

- Require safeguards to research integrity
  - eg an independent data safety monitoring committee
  - eg an independent publications committee

Funders should… 2. *ensure trials are conducted and interpreted in context*

- Ensure that research results are reported in context
  - Of other relevant research
  - Preferably systematic reviews
- Ensure systematic reviews
  - are part of the justification for performing a new trial
  - are part of the discussion and interpretation of the results of a study

Interpretation in context

"We recommend that at a minimum, authors should discuss the results of their trial in the context of existing evidence. This discussion should be as systematic as possible and not limited to studies that support the results of the current trial. Ideally, we recommend a systematic review and an indication of the potential limitation of the discussion if this cannot be completed."

Interpretation in context

- Assessment of reports of RCTs published May 2005 in 5 general medical journals
- 18 reports
  - Systematic review referred to in:
    - Introduction section 5 = (27%)
    - Discussion section = 0

Clarke M, Hopewell S, Chalmers I JRSM 2007

Funders should… 3. *create and implement research (protocol and) reporting policies*

- Require prospective registration as a condition of receiving funding
  - Funds not transferred until evidence received by funding agency
- Ensure that protocols for funded research complies with accepted minimum standards

Funders should… 3. *create and implement research (protocol and) reporting policies*

- The findings of currently funded (and completed) research must be made publicly available as a condition of receiving further funding
  - Including research grants, travel grants and other awards
- The findings of the funded research must be made publicly available before final payment is made
- Funders should have policies on:
  - Minimum reporting standards
  - Open access
    - Eg MRC

Funders should… 4. *ensure compliance with research reporting policies*

- Should have monitoring and other processes in place to ensure compliance with policies
- Ensure appropriate “peer” review of "non-traditional" publications
  - Eg to avoid misinformation or misinterpretation
- Ensure compliance with minimum reporting standards

Funders should… 5. *advocate*

- Advocate for public reporting as an ethical requirement
- Advocate for responsible reporting
- Advocate for public reporting as a legal requirement

Funders should… 6. *support methodological research*

- into the methods of reporting research

What methodological research in this area could funders support?

- Does making raw data publicly available improve or negatively impact on decision making
  - By consumers
  - By policy makers
  - By clinicians, etc
- What do consumers want/need to know in order to make an informed decision?
  - In what format?
    - Eg decision aids

Montori et al (Guide to avoid being misled by biased presentation and interpretation of data)

Linguistic spin

- Where the objectivity of the research is confronted by the subjectivity of authors
  - Authors may emphasize one point of view more than another
  - Considered by some to be essential to scientific communication
    - opportunity for scientists to speculate and formulate new hypotheses
- Challenge
  - To distinguish opinions and conclusions from advocacy or promotion
  - Is it preferable to leave the users of the findings to draw their own conclusions and form their own opinions of what the findings of a trial mean for them and their decision making?

What methodological research in this area could funders support?

- Do policies on reporting clinical trials lead to improvements in
  - the quality of reporting
  - The quality of decision making?
- Funders should give researchers enough funds to pay for adequate statistical and methodological support

How should ethics committees address the issue of research reporting?

What can ethics committees do?

- Require prospective registration as a requirement for ethics approval
- Require commitment to publish in protocol
- Require a systematic review of the existing evidence as part of the justification for a new study

What can ethics committees do?

- Require the researchers to provide evidence that the results of previously approved (and completed) research has been made public when approval is sought to conduct new research
- Monitor and ensure compliance with existing publication and other reporting policies
- Require the results of a trial to be interpreted in the context of the existing evidence
  - As described in the protocol plus other evidence arising in interim