HOW TO REDUCE WASTE AND INCREASE TRANSPARENCY IN HEALTH RESEARCH

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RDC WEBINAR
DISCLOSURES

- No conflicts of interest

- Affiliations at uOttawa & University of Stirling

- Member of EQUATOR Canada

- Ambassador for Centre for Open Science 🌸
LEARNING OBJECTIVES

- Understand the problem of waste in health research
- Discuss how to enhance the transparency of health research
- Discuss how to move towards open science
A PROBLEM IN BIOMEDICINE:

- The combination of a strong bias toward statistically significant findings and flexibility in data analysis and results reporting can lead to irreproducible research
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- The combination of a strong bias toward statistically significant findings and flexibility in data analysis and results reporting can lead to irreproducible research.
(Fanelli, 2010; PLoS One)
Key reason negative and null results don’t get published is because researchers don’t write them up (Franco, Malhotra, Simonovits, 2014; Nature)

PUBLICATION BIAS

- Size of study (# of participants)
- Favours treatment
- Favours control
- Effect size
- Missing: small studies favouring control

Prepared by Professor Amanda Burls and available from http://openaccess.city.ac.uk/id/eprint/13488Amanda.Burls.1@city.ac.uk
INCOMPLETE EVIDENCE
A PROBLEM IN BIOMEDICINE:

- The combination of a strong bias toward statistically significant findings and **flexibility in data analysis and results reporting** can lead to irreproducible research
GARDEN OF FORKING PATHS

+ incentives and rewards

Outliers?

Controls?

Sex/Gender?

Hypothesis: “Does X affect Y?”

Gelman and Loken, 2013
Selective outcome reporting

Re-prioritization of outcomes (primary outcome becomes secondary and vice versa)
“There seem to be no formal guidelines in science as to when study results should or should not be published. The decision as to what to include in a publication and whether to publish is largely personal, although dictated by the fashion of the times to a certain extent.”

-Kay Dickersin JAMA, 1990
A PROBLEM IN BIOMEDICINE:

- The combination of a strong bias toward statistically significant findings and flexibility in data analysis and results reporting can lead to **irreproducible research**

Baker, 2015; Nature
IRREPRODUCIBLE RESEARCH

- Why do patients partake in research?
- Why do governments fund research?
- Why do researchers study health topics?
MacLeod et al., 2014; Lancet

Are research decisions based on questions relevant to users of research?
- Low priority questions addressed
- Important outcomes not assessed
- More than 50% studies designed without reference to systematic reviews of existing evidence

Appropriate research design, methods, and analysis?
- Adequate steps to reduce bias not taken in more than 50% of studies
- Inadequate statistical power
- Inadequate replication of initial findings

Efficient research regulation and management?
- Complicit with other sources of waste and inefficiency
- Disproportionate to the risks of research
- Regulatory and management processes are burdensome and inconsistent

Fully accessible research information?
- More than 50% of studies never fully reported
- Biased under-reporting of studies with disappointing results
- Biased reporting of data within studies

Unbiased and usable research reports?
- More than 30% of trial interventions not sufficiently described
- More than 50% of planned study outcomes not reported
- Most new research not interpreted in the context of systematic assessment of other relevant evidence
WHAT IS THE SOLUTION TO THIS PROBLEM?

- The combination of a strong bias toward statistically significant findings and flexibility in data analysis and results reporting can lead to irreproducible research

Transparency
RESEARCH WASTE CONTRIBUTES TO IRREPRODUCIBILITY

MacLeod et al., 2014; Lancet

JOURNALOLOGY
SOLUTION: TRANSPARENT PREREGISTRATION

- A time-stamped, read-only version of your research plan created before you begin data collection.

It contains:

- Hypothesis
- Data collection procedures
- Manipulated and measured variables
- Statistical model
SOLUTION: TRANSPARENCY

1. What was planned?
   - Linking to protocols

2. What was done?

3. What is different between 1. and 2. and why?

4. What is the supporting evidence of 1., 2. and 3.?
WHAT PROBLEMS WOULD REGISTERED PROTOCOLS FIX?

1. Publication bias and selective outcome reporting

2. P-hacking: Unreported flexibility in data analysis

3. HARKing: Hypothesizing After Results are Known
When the research plan undergoes **peer review before results are known**, the preregistration becomes part of a Registered Report.
Preregistration makes the distinction between **confirmatory** (hypothesis testing) and **exploratory** (hypothesis generating) research more clear.

Presenting exploratory results as confirmatory increases the publishability of results **at the expense of credibility of results.**
WHY PREREGISTER?

- Make your research stand out
- Reduce waste
- Comply with policy (certain designs)
STUDY REGISTRATION: CLINICAL TRIALS

- Clinical trials:
  - http://apps.who.int/trialsearch/

Article 11.3 TCPS2

- All clinical trials shall be registered before recruitment of the first trial participant in a publicly accessible registry that is acceptable to the World Health Organization (WHO) or the International Committee of Medical Journal Editors (ICMJE).
POLICIES NEED TO BE ENFORCED

On average, each trial reported just 57.5% of its specified outcomes. And on average, each trial silently added 5.2 new outcomes.

53 letters sent
5 letters published
13 letters unpublished after 4 weeks
8 letters rejected by editor

STUDY REGISTRATION: SYSTEMATIC REVIEWS

https://www.crd.york.ac.uk/PROSPERO/
*health related outcomes; currently only clinical research; no scoping reviews
STUDY REGISTRATION: OTHER DESIGNS

- Open Science Framework
- Free, immediate, protocol registration

https://osf.io/
The effects of chocolate on graduate student happiness

Contributors: Jolene Esposito

Affiliated institutions: Center For Open Science

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ost.io/xt34a

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Not Personal Health Information Protection Act (PHIPA) compliant
STUDY REGISTRATION: OTHER DESIGNS

- Institutional repositories

http://ruor.uottawa.ca/
WILL I BE SCOOPED?

1. Date-stamped preregistrations make your claim verifiable.

2. By the time you’ve preregistered, you are ahead of any possible scooper.

3. Embargo your preregistration.
“The objective is to expand the impact of brain research and accelerate the discovery of ground-breaking therapies to treat patients suffering from a wide range of devastating neurological diseases.”
Badges to Acknowledge Open Practices: A Simple, Low-Cost, Effective Method for Increasing Transparency


Published: May 12, 2018 • http://dx.doi.org/10.1371/journal.pbio.1002458
## TRANSPARENCY AND OPENNESS PROMOTION GUIDELINES

### Summary of the eight standards and three levels of the TOP guidelines

Levels 1 to 3 are increasingly stringent for each standard. Level 0 offers a comparison that does not meet the standard.

<table>
<thead>
<tr>
<th>Standard</th>
<th>Level 0</th>
<th>Level 1</th>
<th>Level 2</th>
<th>Level 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Citation standards</td>
<td>Journal encourages citation of data, code, and materials—or says nothing.</td>
<td>Journal describes citation of data in guidelines to authors with clear rules and examples.</td>
<td>Article provides appropriate citation for data and materials used, consistent with journal’s author guidelines.</td>
<td>Article is not published until appropriate citation for data and materials is provided that follows journal’s author guidelines.</td>
</tr>
<tr>
<td>Data transparency</td>
<td>Journal encourages data sharing—or says nothing.</td>
<td>Article states whether data are available and, if so, where to access them.</td>
<td>Data must be posted to a trusted repository. Exceptions must be identified at article submission.</td>
<td>Data must be posted to a trusted repository, and reported analyses will be reproduced independently before publication.</td>
</tr>
<tr>
<td>Analytic methods (code) transparency</td>
<td>Journal encourages code sharing—or says nothing.</td>
<td>Article states whether code is available and, if so, where to access them.</td>
<td>Code must be posted to a trusted repository. Exceptions must be identified at article submission.</td>
<td>Code must be posted to a trusted repository, and reported analyses will be reproduced independently before publication.</td>
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<td>Research materials transparency</td>
<td>Journal encourages materials sharing—or says nothing.</td>
<td>Article states whether materials are available and, if so, where to access them.</td>
<td>Materials must be posted to a trusted repository. Exceptions must be identified at article submission.</td>
<td>Materials must be posted to a trusted repository, and reported analyses will be reproduced independently before publication.</td>
</tr>
<tr>
<td>Design and analysis transparency</td>
<td>Journal articulates design transparency standards.</td>
<td>Journal articulates design transparency standards.</td>
<td>Journal requires adherence to design transparency standards for review and publication.</td>
<td>Journal requires and enforces adherence to design transparency standards for review and publication.</td>
</tr>
<tr>
<td>Preregistration of studies</td>
<td>Journal says nothing.</td>
<td>Journal encourages preregistration of studies and provides link in article to preregistration if it exists.</td>
<td>Journal encourages preregistration of studies and provides link in article and certification of meeting preregistration badge requirements.</td>
<td>Journal requires preregistration of studies and provides link and badge in article to meeting requirements.</td>
</tr>
<tr>
<td>Preregistration of analysis plans</td>
<td>Journal says nothing.</td>
<td>Journal encourages preregistration of analysis plans and provides link in article and certification of meeting preregistration badge requirements.</td>
<td>Journal requires preregistration of studies with analysis plans and provides link and badge in article to meeting requirements.</td>
<td></td>
</tr>
<tr>
<td>Replication</td>
<td>Journal discourages submission of replication studies—or says nothing.</td>
<td>Journal encourages submission of replication studies.</td>
<td>Journal encourages submission of replication studies and conducts blind review of results.</td>
<td>Journal uses RegisteredReports as a submission option for replication studies with peer review before observing the study outcomes.</td>
</tr>
</tbody>
</table>
“The lead author* affirms that this manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned (and, if relevant, registered) have been explained.”
## CRediT

<table>
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<tr>
<th>Contributor Role</th>
<th>Role Definition</th>
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<tbody>
<tr>
<td>Conceptualization</td>
<td>Ideas; formulation or evolution of overarching research goals and aims.</td>
</tr>
<tr>
<td>Methodology</td>
<td>Development or design of methodology; creation of models.</td>
</tr>
<tr>
<td>Software</td>
<td>Programming, software development; designing computer programs; implementation of the computer code and supporting algorithms; testing of existing code components.</td>
</tr>
<tr>
<td>Validation</td>
<td>Verification, whether as a part of the activity or separate, of the overall replication/reproducibility of results/experiments and other research outputs.</td>
</tr>
<tr>
<td>Formal Analysis</td>
<td>Application of statistical, mathematical, computational, or other formal techniques to analyze or synthesize study data.</td>
</tr>
<tr>
<td>Investigation</td>
<td>Conducting a research and investigation process, specifically performing the experiments, or data/evidence collection.</td>
</tr>
<tr>
<td>Resources</td>
<td>Provision of study materials, reagents, materials, patients, laboratory samples, animals, instrumentation, computing resources, or other analysis tools.</td>
</tr>
<tr>
<td>Data Curation</td>
<td>Management activities to annotate (produce metadata), scrub data and maintain research data (including software code, where it is necessary for interpreting the data itself) for initial use and later reuse.</td>
</tr>
<tr>
<td>Writing – Original Draft Preparation</td>
<td>Creation and/or presentation of the published work, specifically writing the initial draft (including substantive translation).</td>
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WHY FOLLOW THESE TRANSPARENCY PRACTICES?

- Allow your work to be audited and prevents duplication
- Ensures work is useable
- Provides open access account of the study
  - Not all publications are open access; duty to public; duty to patients
- Increasing requirement to share data and materials
  - E.g., ICMJE, Tri-Agency, institutional guidelines, journal policies
  - Data preservation not new, but this facilitates open data re-use
  - Budget time (and money) to complete a comprehensive data and materials management plan
THE SYSTEM OF INCENTIVES AND REWARDS PROMOTES WASTE

- Academics face a pressure to publish
  - Publish or perish
- Institutions and funders often value quantity over quality
  - E.g., # of publications
- Metrics used to assess researchers may not promote the best possible science
  - E.g., DORA initiative calls for institutions to move away from impact factor as a means of assessing researchers
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