Recent initiatives to improve research reporting fidelity

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The opinions presented are my own and do not necessarily reflect those of ILSI, UAB, or the NIH.

The discussion of a particular entity or topic does not constitute endorsement or rejection of said entity or topic.
“Unfortunately advances in scientific medicine are frequently heralded as being of much more value and importance than they can possibly prove to be.”
Existing Common Checks and Balances

- Review panels
- Study Registration
- Review Boards
- Review Boards
- Peer Review

Funding
Project Development
Project Execution
Writing
Publication
Post-publication

Study Registration
Peer Reviewed Methods
Guidelines/Checklists
Portable Peer Review
2 Phase Peer Review
Data Sharing
Post-publication
Peer Review
Reproducibility Initiatives

Proposed or Recent Improvements
<table>
<thead>
<tr>
<th>Year</th>
<th>Event</th>
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| 1997 | • Food and Drug Administration Modernization Act of 1997 (FDAMA)  
      • Requires Trial Registration for INDs |
| 2000 | • NIH Releases ClinicalTrials.gov |
| 2005 | • International Committee of Medical Journal Editors (ICMJE) requires trial registration |
| 2006 | • WHO Establishes Trial Registration Policy  
      • Launches International Clinical Trials Registry Platform (ICTRP) |
| 2007 | • Food and Drug Administration Amendments Act (FDAAA) requires more trials to be registered, more information reported, and penalties for noncompliance. |
| 2013 | • European Clinical Trials Database (EudraCT) expands |

http://clinicaltrials.gov/ct2/about-site/history
Compliance with mandatory reporting of clinical trial results on ClinicalTrials.gov: cross sectional study

Andrew P Prayle NIHR doctoral research fellow, Matthew N Hurley Wellcome Trust paediatric clinical research fellow, Alan R Smyth professor of child health

Number of trials subject to mandatory reporting which had reported results, grouped by funder of study

<table>
<thead>
<tr>
<th>Funder</th>
<th>No with results</th>
<th>Total</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Industry</td>
<td>126</td>
<td>317</td>
<td>40</td>
</tr>
<tr>
<td>Mixed</td>
<td>25</td>
<td>265</td>
<td>9</td>
</tr>
<tr>
<td>NIH/government</td>
<td>4</td>
<td>48</td>
<td>8</td>
</tr>
<tr>
<td>Other</td>
<td>8</td>
<td>108</td>
<td>7</td>
</tr>
<tr>
<td>Total</td>
<td>163</td>
<td>738</td>
<td>22</td>
</tr>
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NIH=National Institutes of Health.
Fisher’s exact test for effect of funder influencing proportion of trials with results: P=2.2×10^{-16}.
2011

- PROSPERO systematic review registry is launched

University of York
Centre for Reviews and Dissemination

PROSPERO International prospective register of systematic reviews

- 2678 registrations as of 16 January 2014.

- National Institute of Health Research requires all NIHR funded systematic reviews to be registered

- Supported by the EQUATOR network
  (Enhancing the QUALity and Transparency Of health Research)

http://www.crd.york.ac.uk/PROSPERO/news.asp
“We fear that these bureaucratic impositions are creeping up on us whether we like it or not. And, frankly, we like it not.”
Primary outcomes: All-cause mortality and/or cardiovascular events (fatal and non-fatal).

Analysis of subgroups or subsets: Exploration of subgroups will be based on meta-regression models and/or relevant clinical rationale.

Results: Subgroup analysis showed a modest, significant association between ‘metabolically healthy’ obesity and increased mortality and/or CV events (1.24; 95% CI 1.02-1.55)

Conclusions: “… there is no healthy pattern of increased weight.”
Rationale for registration of clinical trials and application to observational studies

<table>
<thead>
<tr>
<th>Rationale</th>
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<tr>
<td>Respect for human participants</td>
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<tr>
<td>Evidence-based medicine</td>
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<tr>
<td>Mitigation of publication bias and detection of deviations</td>
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<tr>
<td>Clear documentation of prespecified study design</td>
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<tr>
<td>Identification of gaps in research</td>
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<tr>
<td>Avoidance of duplication</td>
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<tr>
<td>Public record</td>
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Observational Study Registration

Because existing registries (e.g., ClinicalTrials.gov) accommodate observational studies, and the rationale and benefits of registration are similar, we ask the scientific community and other stakeholders to consider the systematic, prospective registration of observational studies.
The BMJ publishes a large amount of observational research and has an important stake in its quality. We are now actively supporting the registration of observational study protocols and results in publicly accessible registries.

The Lancet family of journals believes that when feasible, investigators should register observational studies on a WHO-compliant registry before they begin.
“At its best, epidemiology is a process of synthesizing evidence within data sets and across populations, with due respect for biologic plausibility and a skeptic’s eye for alternative explanations... On such matters, registration has no bearing.”
Single-blinded peer review: authors do not know who reviews the paper.
Double-blinded peer review: neither authors nor reviewers know the identity of the other party.

Open-names peer review: similar to traditional peer review with reviewer identification.
Open-process peer review: interested parties are invited to join the peer review process that takes place before an article is accepted for a journal or other similar venue; also called community peer review.
Published peer review: the referee comments are published.

Post-publication peer review: formal or informal peer-review after publication.

Two stage/phase peer review: any of a number of configurations of dual stage peer review such as:

Stage 1: Methods reviewed prior to study completion.
Stage 2: Paper is published given faithful completion of methods.

Stage 1: Submit paper to open-process peer review.
Stage 2: Paper is subsequently sent for typical peer-review.

http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3282940/
Why Focus on Peer Review?

- Peer review is considered the hallmark of scientifically valid results.
- A few scientists decide the fate of a paper indefinitely.
- Value of peer review estimated at $400.
- Often considered combative instead of constructive.

Peer review ‘burden’ per scientist:

\[
\frac{\text{manuscripts}}{\text{authors}} \times \text{submissions} \times \frac{\text{reviews}}{\text{submission}}
\]

Example:

- 10 manuscripts in a year
- Average of 4 authors per manuscript
- Average of 3 submissions (including revisions) per manuscript
- Average of 3 reviewers per submission

Created an average burden of 22.5 reviews in a year.
Between 1 June and 30 September 2006, invited authors of papers that survived the editorial assessment to have them hosted on an open server for public comment.

1369 Papers Reviewed

- 71 Participated
- 33 Received No comments
- 38 Received Comments
- 92 Total Comments
- 1298 Did Not
Editors rated each comment for technical value and editorial value.

1. Actively unhelpful
2. Reasonable comments, but no useful information
3. Valid minor points and/or details
4. Major points in line with solicited reviewers' comments
5. Directly influenced publication over and above reviewers' comments

- No comments rated 5; only 4 rated at 4.
- Average scores were: editorial 2.6; technical 1.8.
- "No editor reported that comments influence their decision on publication."

Despite enthusiasm for the concept, open peer review was not widely popular, either among authors or by scientists invited to comment.
2 Stage Peer Review

Our Model

- Article submission
- In-house pre-publication check
- Publication + Data repository
- Open refereeing + User commenting
- Article revision
- Indexing

Final Submission to Publication DAYS

Atmospheric Chemistry and Physics
An Interactive Open Access Journal of the European Geosciences Union

- Every discussion paper and interactive comment remains archived and citable.
- Three years after launch, ranked twelfth out of 169 journals in 'Meteorology and Atmospheric Sciences' and 'Environmental Sciences' by Impact Factor
“BMC’s *Genome Biology* accepts around 10% of submitted papers, but passes on 40% of those it rejects to other BMC journals together with the peer reviews; of those, around 50% are published somewhere within the BMC group.”

http://www.nature.com/news/company-offers-portable-peer-review-1.12418

EMBO Press rejected papers are encouraged to transfer referee reports between selected partner journals for further consideration.

http://www.embo.org/embo-press
Stage 1. Submission and Reviews  
(suggested duration: 14 days)
Stage 2. Peer-review-of-peer-review  
(suggested duration: 7 days)
Stage 3. Manuscript revision upload, or withdrawal for re-submission  
(suggested duration: 21 days)
Stage 4. Final evaluation of the revised manuscript  
(suggested duration: 7 days)

Publishing

The peer review process is available concurrently to all subscribing journals.

Authors may accept a publishing offer from subscribing journal, or export the peer reviews to any journal of their choice.

For Authors and Reviewers, the submission and peer review process in Peerage of Science is free of any charges.

http://www.peerageofscience.org/
Portable Peer Review Services

Three Fee Options: $500, $600, or $700
Are fast food restaurants an environmental risk factor for obesity?
Andrew Brown  5 days ago    1 of 1 people found this helpful
This article was corrected in 2006, but does not appear to be linked in PubMed. Correction: Are fast food restaurants an environmental risk factor for obesity?  http://www.ijbnpa.org/content/pdf/1479-5868-3-35.pdf

Prenatal diagnosis of ventriculo-coronary communications in a second-trimester fetus using transvaginal and transabdominal color Doppler sonography.
Brett Snodgrass  6 days ago    edited    0 of 1 people found this helpful
Thank you for an excellent article.
The fistula between the right ventricle and right coronary artery is probably consistent with a vessel of Wearn.
"Critical assessment of the evidence for striped nanoparticles"
Julian Stirling, Ioannis Lekkas, Adam Sweetman, Predrag Djuranovic, Quanmin Guo, Josef Granwehr, Raphaël Lévy, Philip Mortarty, arxiv, 1312.8812v1 (2013)

Comments (101):

Peer 1:  (January 3rd, 2014 2:07pm UTC)
This paper should finally lay to rest the whole striped nanoparticles controversy. It is accompanied by a blog post
http://raphazid.wordpress.com/2013/12/26/open-science-to-settle-stripy-controversy/

According to Moriaty
http://raphazid.wordpress.com/2013/12/26/open-science-to-settle-stripy-controversy/#comment-2269
it has been submitted to PLOS One. This is a really sad indictment of science today. Dressing up poor experimental technique and wonky analysis in a fantastical conclusion pays off with multiple papers in high-impact journals. However, when the work is done carefully, the reward is a PLoS One and embarrassed silence from those "top" journals.

That said, the paper really, really should have been submitted to Nature Materials, who ran the original story and whose editor supported it to the hilt. Anyway, I'm sure Pep Pamies will read it with interest and hopefully he will write the nice editorial it deserves.

Peer 2:  (January 3rd, 2014 2:48pm UTC)
INDEPENDENT REVIEW
During the Independent Review phase, the review editors assess the paper independently from each other and the authors, according to a standardized review template.

INTERACTIVE REVIEW
During the Interactive Review phase, authors and Review Editors can interact with each other through real-time comments in the discussion forum. The Associate Editor and if required the Specialty Chief Editor can also enter the Review Forum and oversee this review process.
Registered Replication Reports

- Psychological science should emphasize findings that are robust, replicable, and generalizable.
- Direct replications are necessary to estimate the true size of an effect.
- Well-designed replication studies should be published regardless of the size of the effect or statistical significance of the result.

Submit Protocol to Original Authors → Original Authors Review → Post Protocol → Publish Results

http://www.psychologicalscience.org/index.php/replication
“If your study is chosen, the results of the validation studies will be provided to you in confidence and you will have the option to publish the replicated results...”

https://www.scienceexchange.com/reproducibility
The risks of the replication drive

The push to replicate findings could shelve promising research and unfairly damage the reputations of careful, meticulous scientists, says Mina Bissell.
To Register or Not To Register

Jonathan M. Samet

Arguably, this should have been the leading recommendation: the gathering and analysis of evidence to establish the dimensions and characteristics of the problem to be addressed through registration.

Epidemiology • Volume 21, Number 5, September 2010
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