The dark side of Evidence Based Medicine

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Disclosure
Hervé Maisonneuve

I have the following potential conflicts of interest to report:

- Consultant in medical writing
- Editor of La Presse Médicale
- Editor of www.redactionmedicale.fr, a blog on medical writing
The Medical Decision

- Individual Clinical Expertise
- Best External Evidence
- Patient Values & Expectations
Medical decision

Where to find the evidence?
Evidence versus experts’ opinions

Best external evidence

What is the value of journals we usually read?

What is the value of the few papers that are selected to produce clinical practice guidelines?
Quality of literature is poor

- Research reports are not available
- Articles published in peer-reviewed journals are used to assess the research data:
  1. Positive data are published many times when negative results are not published!
  2. Beautification of data is frequent: more than 50% of papers?
  3. Reproducibility of published data is very poor
  4. Conflicts of interests are poorly managed
Beautification in surgical RCTs

327 randomized controlled trials (2007/2012)
152 had a registered protocol before the end of the trial

- 75 / 152 (49%) « showed some evidence of discrepancies between outcomes registered and the outcomes published, most often related to omitting or introducing a primary outcome »
Beautification: massage/torture of data

<table>
<thead>
<tr>
<th>Category</th>
<th>All</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. papers, n (%)</td>
<td>152 (100)</td>
</tr>
<tr>
<td>Number of papers with discrepancies between trial registration and publication, n (%)</td>
<td>75 (49.3)</td>
</tr>
<tr>
<td>Registered primary outcome reported as secondary outcome in text*</td>
<td>8 (5.3)</td>
</tr>
<tr>
<td>Registered primary outcome omitted in text*</td>
<td>32 (21.1)</td>
</tr>
<tr>
<td>New primary outcome introduced in text*</td>
<td>24 (15.8)</td>
</tr>
<tr>
<td>Published primary outcome described as secondary outcome in registry*</td>
<td>14 (9.2)</td>
</tr>
<tr>
<td>Different timing of assessment of primary outcome*</td>
<td>9 (5.9)</td>
</tr>
<tr>
<td>Papers with discrepancies in primary outcome favoring statistically significant results, n (%)</td>
<td>21 (28.0)</td>
</tr>
</tbody>
</table>
Beautification of RCTs’ data*

* Seror R, Ravaud PH. Embellissement des données : fraude à minima, incompétence ou un mélange des deux. La Presse Médicale 2012, septembre
Reproducibility is very poor

A Survey on Data Reproducibility in Cancer Research Provides Insights into Our Limited Ability to Translate Findings from the Laboratory to the Clinic

Aaron Mobléy¹, Suzanne K. Linder², Russell Braeuer¹, Lee M. Ellis¹,²*, Leonard Zwelling⁴*

237 (54.6 %) out of 434 physicians declared not being able to reproduce data published in high-impact journals

There are many objective data confirming poor reproducibility in fundamental research

PLOS ONE, May 2013
Conflicts of interests

- Financial COIs: authors underdisclose
- Non-financial COIs: hidden schools of thought, and dominating mode of thinking

From Disclosure to Transparency
The Use of Company Payment Data
Sasato Chemoreos, PhD; Zachary Freech, BA; David J. Rothman, PhD


A Randomized Study of How Physicians Interpret Research Funding Disclosures
Aaron S. Kesselheim, M.D., J.D., M.P.H., Christopher T. Robertson, Ph.D., J.D.,

NEJM, 2012;367:1119
Research: Improve value, decrease waste

1. 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

2. 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

3. 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

4. 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

5. 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

Research waste

Series of 5 papers (10 pages/paper), Lancet, online first, January 8, 2014
Conclusion

Literature being flawed, should experts’ opinions be considered? (if conflicts of interests are monitored)

EBM should not be Evidence-B(i)ased-Medicine

EDITOR’S CHOICE

Evidence based medicine: flawed system but still the best we’ve got

BMJ, 2014, Jan 22
Questions?