Evidence Regarding the Potential Influences of Non-financial Biases

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Overview

- What are some non-financial biases?
- What is white hat bias?
- Where do we see white hat bias?
- Examples of non-financial and white hat biases
- Suggestions for improving truthfulness of scientific reporting so that WHB is alleviated.
What is Non-financial Bias?

Personal, Political, Academic, Ideological and Religious
Isn’t it all about Financial Conflicts?

“We agree that financial conflict is not the only cause of bias. ... long-standing scientific viewpoints, career considerations, and even political opinions might color study design or interpretation.”-Lesser, PLoS Med, 2007

“...academic progression rests squarely on peer review publications in leading journals [which is] aided by positive findings”
-Pyke, Pharm Stats, 2011

“...science, which has begun facing a veritable inquisition, both in the academic and popular press, for sloppy thinking, cherry picking data, systemic bias and, in some cases, outright fraud.”
-Butterworth, Forbes Magazine, 2010

-Most non-financial interest (conflicts) are not reported in publications
White Hat Bias:
Truthful Reporting of Scientific Data

White hat bias: examples of its presence in obesity research and a call for renewed commitment to faithfulness in research reporting

White hat bias: the need for authors to have the spin stop with them

White hat bias: a threat to the integrity of scientific reporting
What is White Hat Bias?

- Bias leading to distortion of research-based information in the service of what may be perceived as righteous ends.
Do Individual Biases “Cancel Out”? 

“...individual biases tend to cancel themselves out...We contend that financial conflict of interest is qualitatively different, producing selective bias that acts consistently in one direction over time.” -Lesser, *PLoS Med*, 2007

“Using quantitative evidence...WHBs do not ‘cancel out’ over the long run...WHB seemed to be consistently pushing conclusions in a single direction and systematically distorting the research record.” -Cope, *Acta Paed*, 2010
Where do we see WHB?

- Citing Results from Previous Publications Inaccurately/Incompletely
  - Described as ‘unbalanced citations’ by Atkinson and Macdonald (2010)
- Publication Bias-Published Based on Outcome
- Inappropriate Inclusion/Exclusion of Information/Data in Literature Reviews
- Miscommunications in the Media/Magazines/Press Releases
  - especially headlines
No significant change in BMI; fewer children in intervention group were obese at the end of the intervention (out of 165 papers: 84% cited only the positive outcome; 12% were accurate; and 4% cited only the non-significant)
Citing Results from Previous Publications Inaccurately


No significant change in BMI; children in intervention group who were in the top tertile lost more than control in top tertile (out of 41 papers: 49% cited only the positive outcome; 24% were accurate; 10% cited only the negative and 17% were not-scored)
Miscommunications in the press—especially headlines

James et al.
**Paper**
“After 12 months there was no significant change in the difference in body mass index (mean difference 0.13, -0.08 to 0.34) or z score (0.04, -0.04 to 0.12).”

**Press Release**
“Discouraging children from drinking fizzy drinks can prevent excessive weight gain, according to new research available on bmj.com.”

Ebbeling et al.
**Paper**
“change in body mass index (BMI) was the primary end point. The net difference, 0.14±0.21 kg/m², was not significant overall”

**Press Release**
“In randomized trial, a simple beverage-focused intervention led to weight loss”
Publication Bias - published based on outcome

- Breastfeeding example (no industry funded publications in WHO report)

  “the strong PB in the literature pertaining to breastfeeding and its relationship to obesity seems because of the behavior of non-industry funded scientists and does not appear to be fueled by industry interests.”

Critical review of the World Health Organization’s (WHO) 2007 report on ‘evidence of the long-term effects of breastfeeding: systematic reviews and meta-analysis’ with respect to obesity

Cope MB and Allison DB. Obesity Rev, 2008; 9:594-605
Inappropriate Inclusion/Exclusion of Data in Literature Reviews

- Tailoring reported results to enhance intended message
  - “we cited several examples where careful study of some of the original papers revealed that WHO authors selectively included some values from certain primary papers and thereby generated stronger associations of breastfeeding with reduced obesity risk and excluded less impressive values from the same papers without explanation.”-Cope, 2010

Critical review of the World Health Organization’s (WHO) 2007 report on ‘evidence of the long-term effects of breastfeeding: systematic reviews and meta-analysis’ with respect to obesity
An Unbalanced Citation

- FDA docket (Registry F. FDA Docket. 2010;75:39026–8)
  - ‘the availability of nutritional information through menu labeling would provide Americans the opportunity to exercise personal responsibility and make informed choices about their diets. Studies show that providing nutrition information at restaurants can help people make healthier choices [Howlett, Journal of Consumer Research 2009 36(3): 494-503]’.

- Study actually reported that parents will choose slightly lower calorie food options for their children in a restaurant setting; however, the parents did not choose lower calorie foods for themselves.

- An more accurate statement from the study would have been ‘A single study (but not all studies) showed that providing nutrition information at restaurants can help people make healthier choices when they choose food for other people, but not when they choose food for themselves.’
Inappropriate Inclusion/Exclusion of Information in press release

http://article.wn.com/view/2012/06/27/Kaiser_Permanente_Study_Finds_Students_Eat_Healthier_When_Sc/

“Tailored programs could reduce obesity, help implement federal wellness policies”

http://www.ijbnpa.org/content/9/1/80/abstract

Changes in rates of obesity for intervention school (28% baseline, 27% year 1, 30% year 2) were similar to those seen for control school (22% baseline, 22% year 1, 25% year 2) children.
Men’s Health
- Silo effect (one case study)

Men’s Fitness
- Totality of evidence
What We Can Do To Improve Scientific Rigor and Truthful Reporting

- Emphasize the idea of science as a discipline and vocation.
- Develop a culture that unequivocally condemns personal attacks in science.
- Develop a set of ‘meta-methods’ which will collectively ensure the implementation of the fundamental scientific methods that already exist.
Examples of Meta-Methods

- Public contracts with standard clauses regarding mandatory publishing
- Registration of studies (Design, Implement, Report)
- Searchable IRB and IACUC databases
- Peer-Reviewed Press Releases
- Public or Open Data Antidote (see Allison, Science, 2009)
Good News!

- **Scientific method** is a Bias Reduction Technique
- Ethics is an integral part of scientific training
- Primary research methods are improving
- Reporting standards are increasingly used and formalized
- Evidence-based reviews are increasingly used and formalized
- Trial registration and public data depositing are becoming more common.

The Glass is More Than Half Full…
Whether WHB is intentional or unintentional, and whether it stems from a bias toward anti-industry results, significant findings, feelings of righteous indignation, results that may justify public health actions, or yet other factors, is unclear. Future research should study approaches to minimize such distortions in the research record. We suggest that authors be more attentive to reporting primary results from earlier studies rather than selectively including only a part of the results, to avoiding PB, as well as to ensuring that their institutional press releases are commensurate with the studies described. Journal editors and peer reviewers should also be vigilant and seek to minimize WHB. Clinicians, media, public health policy makers and the public should also be cognizant of such biases and view the literature on NSBs, breastfeeding and other obesity-related topics more critically.
Responsibility as Scientists

- Regularly read scientific studies (carefully)
  - Read the press releases as well
- Understand *how* to read scientific studies
  - Review limitations/strengths of study
- Assess value of the study in the “Bigger” world context
  - Develop message based on **Body of Evidence** – not Just a single study
- Respond to media appropriately
  - Convey results accurately
Conclusions

- Non-financial bias is a reality
  - WHB is prevalent in nutrition research
- Research should be evaluated closely especially when there may be WHB present
- Knowing *How* to interpret research is our scientific responsibility
- Questioning *questionable* reporting of outcomes is a professional responsibility
Thank You!
Personal Bias

- Previous body of work
- Personal goals for achievement
- Achieving peer recognition
- Ethical or values-based
- Philosophical
- Publish or perish
- Financial incentives, gifts, etc

Funding food science and nutrition research: financial conflicts and scientific integrity\(^1-4\)  
Rowe, et al.
“…resulted in greater gains in FBFM (lean mass) and type II muscle fiber area. Increases in type I muscle fiber area were greater in the Milk and the Soy groups than in the control group. All groups showed increased strength as a result of the training program; however, there were no between-group effects.”

Hartman et al. (2007)

“Results indicated all three groups increased muscle fiber size and muscle mass, but subjects in the milk group experienced the greatest gains in muscle fiber size and muscle mass.”

-National Dairy Council Summary
Authors address an issue with different methods
- Silo effect (one case study)

- Totality of evidence
“All-natural protein” is often code for soy, which research shows may cause gynecomastia—the abnormal enlargement of the mammary glands in men. When you consume soy protein, you’re actually courting the Mr. Hyde side of two organic compounds: genistein and daidzein. Both act so similarly to estrogen that they’re known as phytoestrogens (plant produced estrogen). Eat enough of the stuff, and you open up the potential for hormonal havoc.”

– -Men’s Health (http://www.menshealth.com/nutrition/soys-negative-effects/page/2)

“The condition (gynecomastia) can be brought on by obesity, excessive alcohol, pot smoking, and steroids—in other words, by simply acting stupid.”

– -Men’s Health (http://www.menshealth.com/health/roid-rage)
“I should point out that searching "soy and gynecomastia" in the National Institute of Health database only spews out three articles, but you'll be happy to know that the reproductive tracts of male macaques were not adversely affected by ingesting soy. There is one interesting case report of a 60-year-old man who developed big ol' hooters and presented to a gland clinic for an answer. His gynecomastia eventually went away when they discovered he was drinking 3/4 of a GALLON of soy milk A DAY and told him to cut it out. With all the millions of people who ingest soy daily (there are countries where soy is a staple of the "normal" diet) the fact that there is one case report of one guy whose breast tissue was sensitive to soy products is reassuring to me.”

- Men’s Fitness

(http://www.mensfitness.com/nutrition/abs-health/does-soy-really-cause-man-boobs)
Soy Protein Does Not Lower Testosterone

Clinical studies show no effects of soy protein or isoflavones on reproductive hormones in men: results of a meta-analysis

Jill M. Hamilton-Reeves, Ph.D.,* Gabriela Vazquez, Ph.D.,a,b,c Sue J. Duval, Ph.D.,b William R. Phipps, M.D.,d Mindy S. Kurzer, Ph.D.,e and Mark J. Messina, Ph.D.f,g

15 placebo-controlled treatment groups were included in this meta-analysis

“The results of this meta-analysis indicate that neither soy protein nor isoflavones affect reproductive hormone concentrations in men regardless of age or cancer status.”
Totality of Evidence

- **Design bias**
  - Animal studies have shown negative effects of isolated compounds on a variety of outcomes

- **Several drawbacks of animal studies**
  - Dose is not equivalent to human consumption
  - Route of administration
  - Form of ‘food’ provided (component vs total food)
  - Model: Rodents metabolize isoflavones differently from humans

Interpret results from animal studies with caution
ADA Evidence Analysis Process

Step 1: Formulate Question
- Develop the Question

Step 2: Gather Research
- Gather and Classify the Research

Step 3: Appraise Articles
- Critically Appraise Each Article

Step 4: Summarize
- Summarize the evidence in an Overview Table and Evidence Summary

Step 5: Grade
- Develop Conclusion Statement and Grade the Strength of the Supporting Evidence