



SCHOOL OF PUBLIC HEALTH BLOOMINGTON

From Study Conception to Study Dissemination: How Do We Assure Rigor of Research, Rigor of Communication, and Communication of Rigor

David B. Allison, Ph.D.

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Why rigor is important: truth and human interest are at stake

The American Journal of Clinical Nutrition

<https://doi.org/10.1016/j.ajcnut.2023.03.010> ↗

Effectiveness of lactation cookies on human milk production rates: a randomized controlled trial

Ana M. Palacios^{1,*}, Michelle I. Cardel^{2,3}, Erik Parker⁴, Stephanie Dickinson⁴, Valerie R. Houin⁴,
Bridget Young⁵, David B. Allison^{4,**}



“This study found no evidence for the effect of consuming lactation cookies on human milk production rate, perceived insufficient milk, or breastfeeding self-efficacy in exclusively breastfeeding parents with an overall adequate perceived milk supply. Recommendations to consume LCs for increasing objective or subjective milk supply may deliver false hope and unnecessary financial costs at a vulnerable time.”



Communication Challenges: Multiple Players, Multiple Perspectives, Lack of Clarity of Procedures, Standards, and Objective.



Challenges with the model:

- Lack of rigor in definitions/measurement methods in nutrition/obesity research
- Lack of standardized guidelines for interpretation/synthesis of nutrition/obesity literature
- Difficulty integrating findings from multiple disciplines



Headlines vs. Studies

Headlines

Skipping breakfast to lose weight **makes you fatter** - and far more likely to raid the vending machine.

Diet Soda Leaves Your Gut Unsatisfied, **Contributes To Obesity**.

US Farm Subsidy Policies Contribute To **Worsening Obesity** Trends, Study Finds.

Drinking 5 cups of coffee everyday may **lead to obesity**: study.

Wrong amount of coffee **could kill you**.



Studies

MRI results and observations of how much subjects ate at lunch after skipping breakfast. **No body weight**, no vending machines.

Assessment of metabolic responses to different carbohydrates loads of bacteria in vitro. Humans, **diet soda, and obesity were not studied**.

There is no study – paper is an author's commentary/review on farm subsidies.

A study of mice, involving a substance found in coffee, but no coffee, showed no significant weight gain, and **reported no deaths**.

OEO

Obesity and Energetics
Offerings
IU SPHB / UAB NORC



Where things go wrong: 'hidden' Information

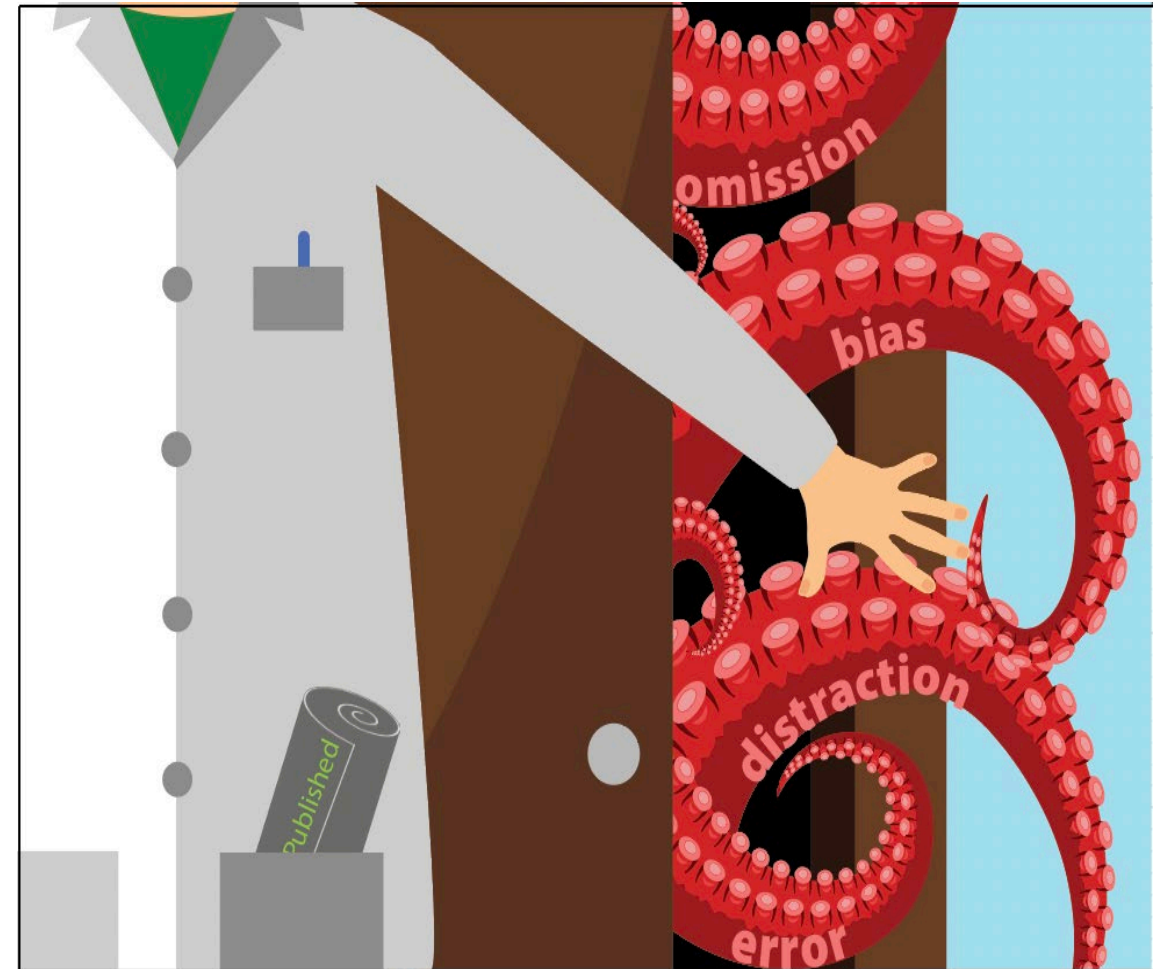
Scientists sometimes intentionally engage in distraction and omission and hide elements of the whole truth.

1. *Distracting the reader or “spinning” the data.*
2. *Outcome switching.*
3. *Undisclosed model selection or sampling.*
4. *Creating a false impression about the magnitude or consequence of the results.*

Other Sources of Hidden Information.

1. *Failure to include all observations.*
2. *Proprietary elements of studies are not disclosed.*
3. *Failure to share data.*
4. *Failure to report null results.*
5. *Failure to report unsuccessful studies.*
6. *Retraction for non-scientific reasons.*

Siddique ... & Allison. Hidden: A Baker's Dozen Ways In Which The Scientific Community Falls Short of and Can Better Fulfill Einstein's Principle of The Whole Truth (manuscript in preparation)

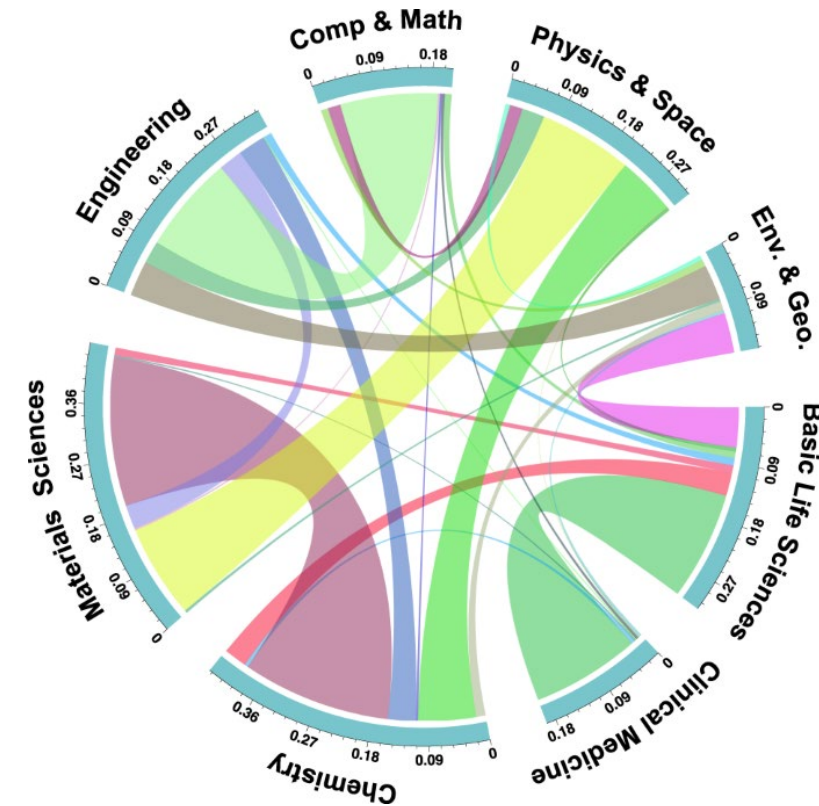


Where things go wrong: hidden bias

Scientists also engage in hiding elements of the whole truth without intention

1. *Omissions stemming from errors of interdisciplinarity*

- Occurs when a project involves knowledge from more than one disparate discipline and investigator(s) may have such limited knowledge of matters of one of the disciplines involved, that they do not even know enough to be aware of their ignorance
- Laboratory investigators who use mouse models
- Studying things like senescent cells, GPS coordinates, mitochondrial measurements, socioeconomic status, and so on, even though we may lack a full understanding of how all those things are measured.



Siddique ...& Allison. Hidden: A Baker's Dozen Ways In Which The Scientific Community Falls Short of and Can Better Fulfill Einstein's Principle of The Whole Truth (manuscript in preparation)



Scientists also engage in hiding elements of the whole truth without intention

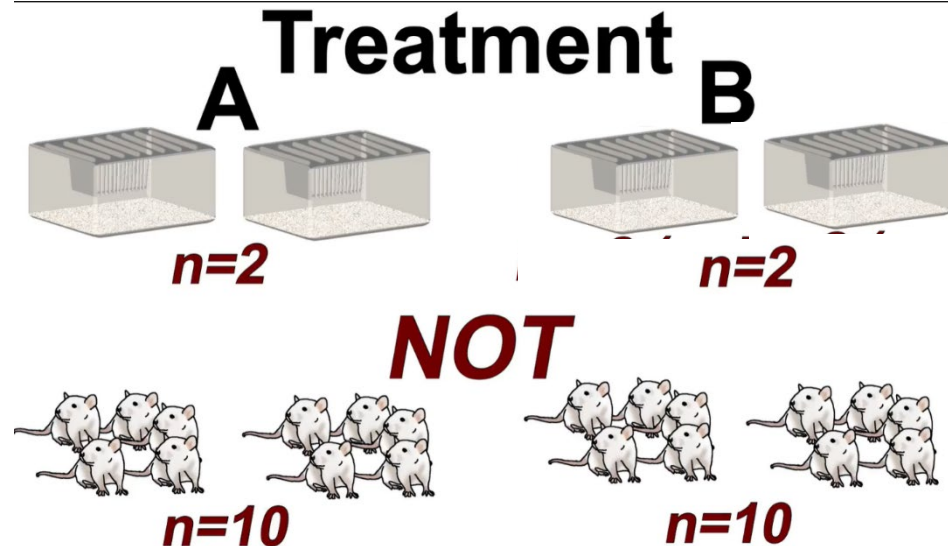
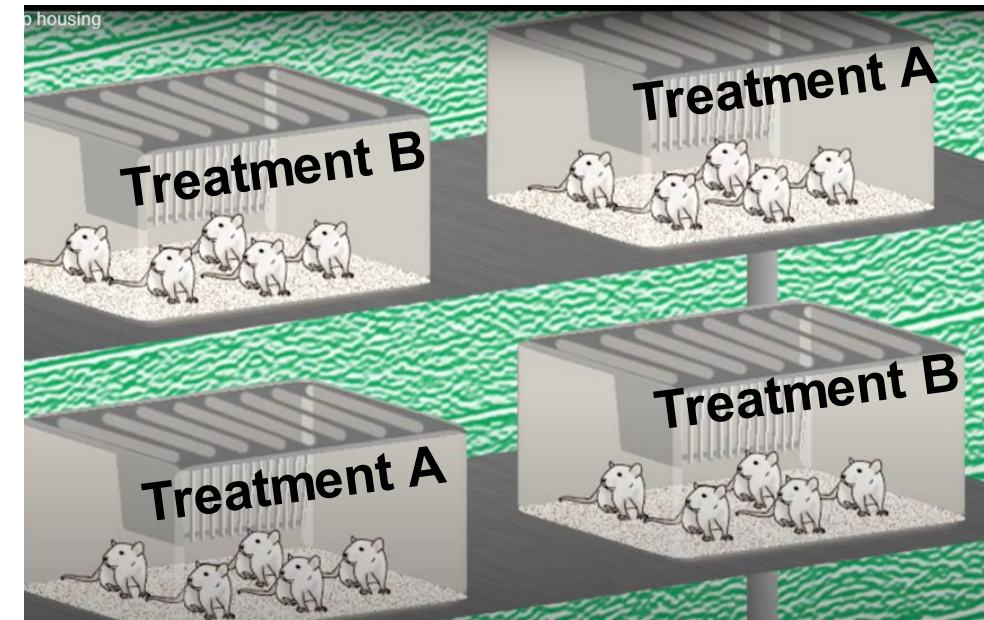
2. Error in Incorrectly or Incompletely Described Procedures, e.g., Randomization.

- In many circumstances, cluster randomization was not disclosed but was actually done
- In some situations, individual randomization was incorrectly described as cluster randomization,
- In other situations, non-randomization was described as randomization,
- An extraordinary number of other incorrect or incomplete descriptions of purported randomization.

3. Inconceivably consequential details.

- What extent of details constitute the “whole truth,” is unclear.

Siddique ... & Allison. Hidden: A Baker's Dozen Ways In Which The Scientific Community Falls Short Of And Can Better Fulfill Einstein's Principle of The Whole Truth (manuscript in preparation)



Where things go wrong: Non-Mathematical Thinking

CHILDHOOD OBESITY
February 2014 | Volume 10, Number 1
© Mary Ann Liebert, Inc.
DOI: 10.1089/chi.2013.0082

Modeling Potential Effects of Reduced Calories in Kids' Meals with Toy Giveaways

Maysoun Y. Freij, PhD, MPH,¹ Randall L. Sell, ScD,² Anne K. Bozack, MPH,¹
Linda J. Weiss, PhD,¹ and Ana C. Garcia, MPA³

calculation is based on the fact that a pound of body fat equals approximately 3500 calories. Therefore, a child who eats a kids' meal with a toy twice per week would avoid approximately 132 calories per week if he or she consumed an NPLAN-like regulated kids' meal in place of an unregulated kids' meal. This equals approximately 6864 calories per year (132 calories $\times$ 52 weeks) or approximately two pounds per year averted. A lower calorie limit

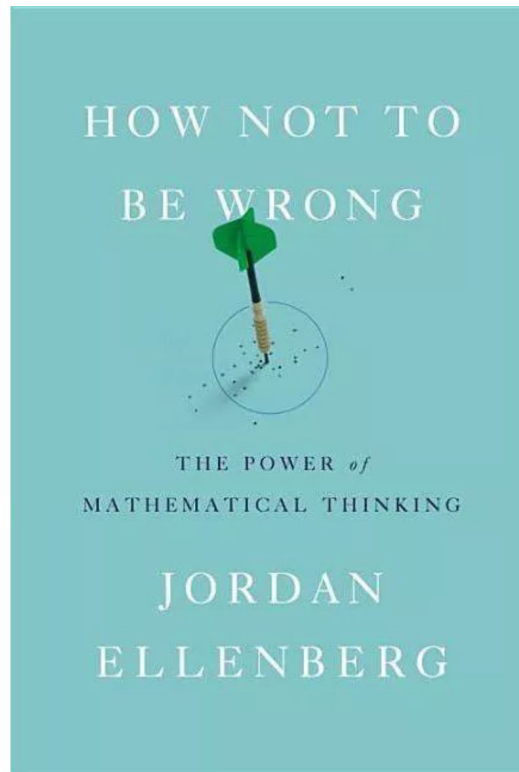
nance). Calculations in the model include children who are estimated to eat fast food four or more times per day. Though rare, such children could theoretically expect to avert weight gain of 27 pounds per year if an NPLAN-like toy ordinance were fully implemented.

From Kevin Hall: "I used the 'rule of thumb' equations relating excess body weight to excess energy intake ...[from PMID: 24349967]. I came up with about 0.5 kg of excess weight ... by increasing daily intake by 19 kcal/d from 7 to 12 years."

So, the original investigators were off by a factor of about 9.



Where things go wrong: Non-Mathematical Thinking



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World Journal of Acupuncture-Moxibustion (WJAM)
Vol. 25, No.1, 30th Mar. 2015



Letter to the Editor: Exceptional Data in Paper on “The effect of meridian massage on BM, BMI, WC and HC in simple obesity patients: a randomized controlled trial”

Diana M. Thomas¹, Andrew Brown², John A Dawson³, Peng Li², Steven B. Heymsfield⁴, & David B. Allison²

- Massage intervention group **lost over 7 kg** (>9%) in 8 weeks
- Adults would have grown an average of 6.5 cm over **8 weeks for BMI to be correct**



Egregious examples of miscommunication about findings in nutrition and obesity research

Author Driven



Pediatric OBESITY WORLD OBESITY

Original Research | [Full Access](#)

LA sprouts randomized controlled nutrition, cooking and gardening programme reduces obesity and metabolic risk in Hispanic/Latino youth

N.M. Gatto  L.C. Martinez, D. Spruijt-Metz, J.N. Davis

First published: 22 February 2016 | <https://doi.org/10.1111/ijpo.12102> | Citations: 39

THIS ARTICLE HAS BEEN RETRACTED

Retracted: LA sprouts gardening programme youth

Funder Driven



New Study Shows that Combating Childhood Obesity in Schools Works

Posted in: [Health](#) | June 5, 2015



- “Analyses showed no difference between Healthy School Program schools and control schools in overweight and obesity prevalence”
- “Healthy School Program appears to be an important means of supporting schools in reducing obesity...”

Media Driven



FOOD NEWS, HEALTH & MEDICAL NEWS

Thanks to calorie-counting menus, fewer Americans are dying of obesity-related cancers



NEWS RELEASE 18-APR-2023

Menu calorie labels estimated to save U.S. billions on cancer care

A study from researchers at the Friedman School of Nutrition Science and Policy of Americans' eating behaviors suggests tens of thousands of cancer diagnoses and deaths could be prevented



Editor/Journal Driven

- Authors made ad hominem remarks in reply to letter
- Editor therefore refused to publish both letter and reply



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How can things improve?

The Value of Raw Data Sharing

Article

Nutrition Journal

Impact of weight loss diet associated with flaxseed on inflammatory markers in men with cardiovascular risk factors: a clinical study

Letter

Inappropriate statistical method in a parallel-group randomized controlled trial results in unsubstantiated conclusions

[Rositsa B. Dimova](#) & [David B. Allison](#) 

“Cassani et al. should be commended for making their raw data publicly available and for noting this in their article.”

Retraction Watch

Nutrition study pulled after statistical flaws emerge

A paper that suggested that eating flaxseed could reduce inflammation in men at risk of heart disease has been retracted, after researchers pointed out the paper's flaws.

The retraction is part of a large initiative on the part of nutrition researcher David Allison and colleagues to clean up the literature, which we've previously covered.

Nutrition
Journal



 BioMed Central
The Open Access Journal

Science

The Antidote to Bias in Research

[DAVID B. ALLISON](#)



How can things improve?

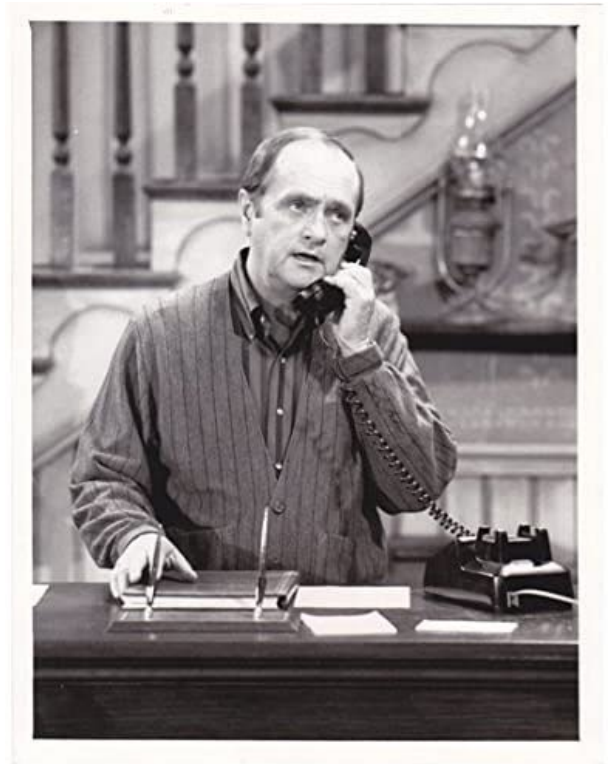
Take **Professional** Statistical Expertise More Seriously

A neurosurgeon phones the statistical consulting department to inform them,

"I'm doing a study, and I'd rather just do my own statistics. So I don't need your help; I just wonder if you can suggest a good statistics text."

The consulting statistician says, "I'm so glad you called! I've always wanted to do brain surgery; can you suggest a good text on that?"

- As told by David Norris



How can things improve? Need Workflow Checklists

Erratum to “Correlation not Causation: The Relationship between Personality Traits and Political Ideologies” *American Journal of Political Science* 56 (1), 34–51

Correction: The Relative Safety of Ephedra Compared with Other Herbal Products FREE

Inpatient pediatric psychology consultation-liaison practice survey.

“The interpretation of the coding ... **was exactly reversed.**”

“... the company realized that data on some products, which contain ephedra and other herbs but which the company classifies as vitamins/supplements or grocery items rather than herbal products, **had not been provided to the authors.**”

“The retraction is at the request of the authors. One section of the article reported data on psychologist impressions of consultation liaison practice. **These data were not reverse scored as intended prior to analyses.**”



Retraction Watch

Authors used wrong dataset in study on shock therapy, exercise in depression



“Check me”



We thank...

David B. Allison, Ph.D., Andrew W. Brown, Ph.D., Stephanie L. Dickinson, M.S., and Lilian Golzarri-Arroyo, M.S., of the Indiana University School of Public Health–Bloomington for reviewing and verifying the statistical methods and results of this project.



"I think you should be more explicit here in step two."

Katzmarzyk, P. T. ... & Springgate, B. (2020). *Weight Loss in Underserved Patients- A Cluster-Randomized Trial*. The New England Journal of Medicine, 383, 909–918. <https://doi.org/10.1056/NEJMoa2007448>



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How can things improve?

Detect and correct errors at early stages of the publication process



EDITORIAL

A practical decision tree to support editorial adjudication of submitted parallel cluster randomized controlled trials

Yasaman Jamshidi-Naeini, Andrew W. Brown, Tapan Mehta, Deborah H. Glueck, Lilian Golzarri-Arroyo, Keith E. Muller, Carmen D. Tekwe, David B. Allison 

First published: 23 February 2022 | <https://doi.org/10.1002/oby.23373>



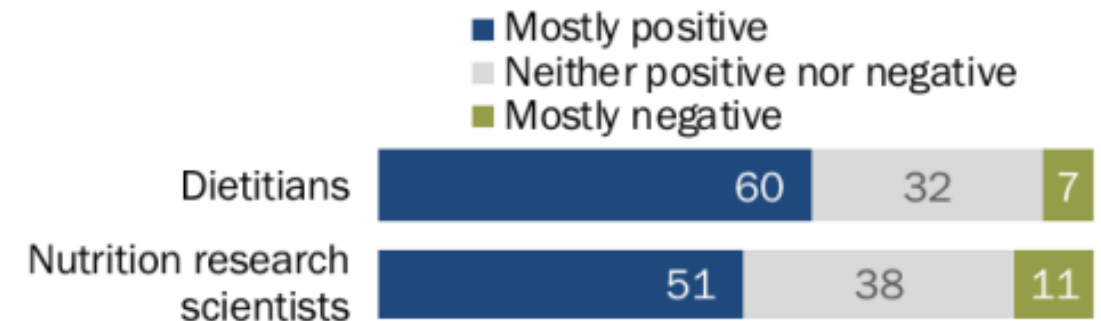
Nutrition science needs to foster trust

"Fads like microbiome mania wax and wane, but there's one field of research that consistently generates more hype, inspires more media interest and suffers more from the deficiencies outlined in this book than any other. It is, of course, nutrition" - **Stuart Ritchie in 'Science Fictions'**

"One may wonder if we should stop nutritional research altogether until we can get it right." - **Scott Lear**

Most Americans have a positive view of dietitians

% of U.S. adults who say they have a ____ view of ...



Note: Respondents who did not give a response are not shown.

Source: Survey conducted Jan. 7-21, 2019.

"Trust and Mistrust in Americans' Views of Scientific Experts"

PEW RESEARCH CENTER

<https://www.pewresearch.org/science/2019/08/02/americans-trust-dietitians-more-than-nutrition-researchers-but-are-skeptical-of-both-groups-transparency-accountability/>



Communicating uncertainty when synthesizing research: the case study of red meat

The New York Times

That Perplexing Red Meat Controversy: 5 Things to Know

It may be the most unexpected dietary finding to come along in years.

Dr. David Allison, dean of the Indiana University School of Public Health — Bloomington, said there is a difference “between evidence for drawing a scientific conclusion, and making or recommending an action.”

“The standards of evidence for the former are scientific matters and should not depend on extra scientific considerations” he added. “The standards of evidence for the latter are matters of personal judgment or in some cases legislation.”

His advice: “People should be aware of the uncertainty and make their decisions based on that awareness.”

<https://www.nytimes.com/2019/09/30/health/red-meat-questions-answers.html>



Trust based on trustworthiness

- We should not ask people to trust science in blind faith
- Trustworthiness is demonstrated through our methods

PNAS

AT THE NATIONAL ACADEMIES | SOCIAL SCIENCES | 

The Strategic Council for Research Excellence, Integrity, and Trust

Marcia McNutt  , France A. Córdova, and David B. Allison [Authors Info & Affiliations](#)

October 5, 2021 | 118 (41) e2116647118 | <https://doi.org/10.1073/pnas.2116647118>



Conceptual things that can improve communication of uncertainty

- Uncertainty and certainty to be states of mind that need not follow objective rules.

“We all have a stake in ensuring that scientists...understand and express the uncertainty inherent in their conclusions” - NASEM
 - But the probability, risk, heterogeneity, and probability distributions represent objectively verifiable measures that imbue science with trustworthiness and inform uncertainty judgements.

“Whatever way uncertainty is approached, probability is the only sound way to think about it.” - Dennis Lindley
- ✓ The quantitative uncertainty informative data (QUIDs) can be used to assess the trustworthiness of research processes.
 - ✓ Uncertainty cannot be encapsulated easily in a single measure.
 - ✓ Studies should be accompanied by multiple QUIDs that describe the different dimensions of a study, such as the effects of sample sizes, the odds of a causal relationship, or recommendations that will have a meaningful impact.





“...let us take this path through the woods...”

~ Jean-Jacques Rousseau

謝謝您



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