INEP's Position Statement on Conflict-of-Interest and Disclosure in Epidemiology

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THE INEP MISSION

INEP works at the interface of research and policy to maintain and protect the public's health… by:

- creating and disseminating evidence-based knowledge about epidemiology,
- supporting capacity-building of experts to translate research and science into policy, and
- recognizing and highlighting the misuse of data and potential corruption of the science practiced by epidemiologists.

ON THE SHOULDERS OF OTHERS

INEP's Position Statement was:

- Started in 2014 and written by CLS with 9 co-authors, 8+ contributors, and 6 external reviewers
- Adapted from the work of several professional organizations
- Unanimously approved by the INEP Board on September 16, 2020
- Exceeded its required endorsement threshold on December 24, 2020; released on January 5, 2021

HOW AND WHY CONFLICT-OF-INTEREST?

- **What is conflict-of-interest (COI)?**

  If a scientist has a vested interest in how TRUTH is presented, they can distort the truth

  A scientist with a COI may have her/his objectivity compromised

- **What drives COI?**

  A scientist's vested interests, which could include benefiting financially, promotions, prestige, and so on

HOW DO COI PRACTICES AFFECT EPIDEMIOLOGY?

- Rather than an impartial analysis, scientists can produce and disseminate misinformation or suppress data
- The association between cause-and-effect can be obscured and denied
- Scientific integrity can be undermined
- Public trust in the science of epidemiology can be eroded
- Workers, the public, and the environment can be harmed

WHAT IS IN THE INEP POSITION STATEMENT on *Conflict-of-Interest and Disclosure in Epidemiology?*

- Recent high-profile cases
- Recent COI examples developed by INEP co-authors and contributors
- A compendium of common practices used to distort and misapply epidemiological sciences
- INEP recommendations for COI management by: Identification, Avoidance, Disclosure, and Recusal
- Appendices that cover responses to the breadth, scope and growing sophistication of COI

TO FIX IT YOU HAVE TO RECOGNIZE IT!

CASE EXAMPLES: COI IDENTIFICATION, DISCLOSURE, AND GUIDANCES

1. Medical Research, Education and Practice
2. Tobacco Industry
3. Food Safety Panel
4. 2015 INEP Policy to Avoid COI through Donations

5. Recent Epidemiology-specific Examples of COI and Disclosure Issues ("a" to "l"; n=12)

TWELVE RECENT EXAMPLES ILLUSTRATING THE BREADTH, SCOPE, AND GROWING SOPHISTICATION OF THE PROBLEM

a) 2016 CPI COI Exposé: "Science for Sale" on Scientific Boards, Councils, and Review Panels

b) 2018 Collegium Ramazzini Statement: COI-related Principles for Safeguarding the Integrity of Research in Occupational and Environmental Health

c) 2019 Commentary: How can the integrity of occupational and environmental health research be maintained in the presence of conflicting interests?

d) 2019 Acquavella Commentary that COI Disclosure Harms Epidemiology: INEP member response

e) 2020 Graziosi Article: Political COI of False Hurricane Claims

f) 2020 Kaplan et al Article: COVID Pandemic Lapses in COI and Disclosure

g) 2020 Unbalanced and Conflicted Science in AJPH Special Issue on E-Cigarettes

h) 2020 Heindel Article: Undeclared COI in Biased Editorial Duplicated in 8 Toxicology Journals

i) 2020 Hardell, Rivasi, and Buchner Letters / Reports: RF-EMF Hazard and COI of ICNIRP Analyses and Leadership

j) 2015-2020 Caldwell-Soskolne Analysis of COPE Failure: Articles and Journal COI for Drinking Water Carcinogenicity

k) COI and Improper Influence through Meeting/Conference Sponsorship by Vested Interests: ISEE Guidelines for Donor Support

l) 2020 COI and Hill's 1965 Viewpoints Used in Testimony for Causation in Civil Litigation

Focus on a few recent INEP examples of COI (1 of 3)

a) 2016 Center for Public Integrity (CPI) COI Exposé: "Science for Sale" on Scientific Boards, Councils, and Review Panels; David Heath, investigative journalist with the CPI, published a series of articles entitled "Meet the 'rented white coats' who defend toxic chemicals." They exposed Dr. Julie Goodman giving expert testimony, citing junk science, and financially benefiting from vested interests of her employer, Gradient. Gradient has long been associated with scientists employed to manufacture doubt and foment uncertainty about scientific evidence

d) The 2019 Acquavella Commentary that COI Disclosure Harms Epidemiology; Soskolne and co-authors refuted him. Dr. John Acquavella, a career Exxon-Mobil and Monsanto employee, published a commentary in the *Annals of Epidemiology in 2019* entitled "Conflict of Interest: A Hazard for Epidemiology." In it, he rearticulated the approach often used by vested interests to underplay the role of financial COI in science by invoking other sources of bias. Acquavella ignored the role of financial COI in documented cases of derailed science, policy delays, and injustice in tort actions

Focus on a few recent INEP examples of COI (2 of 3)

h) **2020 Heindel Article: Undeclared COI in Biased Editorial Duplicated in 8 Toxicology Journals: On 10 July, 2020, Heindel described in *Environmental Health News* how an editorial written by a group of 19 toxicologists had been published verbatim in eight toxicology journals over the prior four months**

The group of 19 toxicologists had no expertise in the endocrine-disrupting chemical scientific field that they were writing about. Heindel described the editorial as an unethical attempt to present views of the chemical industry as an impartial review of the science and that the editorials were timed to occur just before the European Parliament's vote on the EU's resolution on Chemicals Strategy for Sustainability

Also, six of the eight journals are published by Elsevier Publishing Company and those six journal editors were among the 19 editorial co-authors. Elsevier is supposed to follow COPE guidelines that should disclose such COI and ethics violations

Focus on a few recent INEP examples of COI (3 of 3)

I) **2020 COI and Hill's 1965 Viewpoints Used in Testimony for Causation in Civil Litigation: Neutra et al. in 2019 described some major shortcomings exhibited by U.S. court decisions involving use of the Hill viewpoints.**

Hill's seminal presidential address published in 1965, became a set of guidelines to assist in drawing causal inferences from statistical associations

These 9 viewpoints were labeled as criteria and were invoked in U.S. law as a canonical set of nine criteria that experts can utilize to support their testimony for causation in civil litigation. They have been misused to dismiss epidemiological findings of potential health risk by industrial interests, and described–even defined–as "good epidemiological practice"

A TOOLKIT OF EPIDEMIOLGY DIRTY TRICKS – RECOGNIZE THE METHODS!

A compendium of misapplied methods → junk science as demonstrated in tort actions. Useful:

- By peer-reviewers as a checklist of what to look for
- To train epidemiologists and others on how epidemiology can be distorted
- To review the literature for junk science or uninformative studies
- Identify who is misusing/abusing epidemiology

IN PREPARATION IS A COMMENTARY ON THIS COMPONENT

REVIEW

- Never has **TRUTH** been under such assault and needed more to protect the public's health
- Science can be misused either intentionally, through error, or from bias
- For centuries, intentional distortion of scientific methods, evidence, and miscommunication have been associated with Conflict-of-Interest (COI)
- COI-associated misuse of science can result from self-interest
- Increasing levels of sophistication are being employed that include coopting regulatory bodies, scientific panels, and communication forums

→ INEP recognizes this and recommends ways to better manage the problem in the public interest

GOING FORWARD: INEP-SPECIFIC RECOMMENDATIONS FOR COI

a. Identification
b. Avoidance
c. Disclosure
d. Recusal

WHAT ABOUT EXPANDING UPON THE INEP EXAMPLE?

- Issues not covered:
  (1) What if someone is using a non-disclosure agreement to shield their COI?
  (2) Is the chair of a scientific review panel to be held to a higher standard than the panel members?

- Use the INEP document as a launching pad to write other documents … to extend the reach of INEP's Position Statement

DISCUSSION

Address any questions to:
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This presentation will be accessible at www.colinsoskolne.com