

TOOLKIT FOR DETECTING MISUSED EPIDEMIOLOGICAL METHODS THAT UNDERMINE HEALTH POLICY AND DERAIL THE ADVANCEMENT OF SCIENCE

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AT THE INTERFACE OF GOVERNANCE AND INTEGRITY

ASSUMPTIONS:

- Science is used to inform policy
- Scientists are expected to operate with integrity in the application of the scientific method

BUT:

- If the scientist lacks integrity, what then is produced to inform rational policy?
Distorted science undermines health policy and derails the advancement of science

EPIDEMIOLOGY

- **The study of population health and disease**
- **An applied interventionist science**
- **Epidemiologists study where diseases occur, what causes them, and how to prevent them**
- **Knowledge derived from epidemiological evidence is not used solely for discovery purposes. It is also applied to control and prevent health problems and used to restore, promote, and protect population health across all levels of society**
- **By virtue of their focus on protecting the public's health, epidemiologists, as a profession, are expected to serve the public, with the public interest trumping all others**

THE INEP MISSION



INTERNATIONAL NETWORK FOR
EPIDEMIOLOGY IN POLICY
INTEGRITY, EQUITY, AND EVIDENCE IN POLICIES IMPACTING HEALTH

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.

INEP'S POSITION STATEMENT

CONFLICT-OF-INTEREST AND DISCLOSURE IN EPIDEMIOLOGY

Released and launched on January 5, 2021

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 member organization **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
- Distorted science undermines health policy and derails the advancement of science

WHAT IS IN THE INEP POSITION STATEMENT ON *CONFLICT-OF-INTEREST AND DISCLOSURE IN EPIDEMIOLOGY?*

<https://epidemiologyinpolicy.org/coi-d-position-statement>

- Recent high-profile cases **exemplifying the misuse of epidemiologic research and the failure to disclose COI reported in the media and scientific literature**
- 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 AJPB 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

BRIEF FOCUS ON TWO EXAMPLES OF COI

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.” The exposé exposed Dr. Julie Goodman giving expert testimony, citing inappropriately conducted 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 derailment of science, policy delays, and injustice in tort actions.

A TOOLKIT OF EPIDEMIOLOGY DIRTY TRICKS – RECOGNIZE THE METHODS *A COMMENTARY ON THIS COMPONENT HAS JUST BEEN ACCEPTED FOR PUBLICATION*

A compendium of misapplied methods, often demonstrated in tort actions, the toolkit can be used:

By peer-reviewers as a checklist of what to look out for

- To train epidemiologists and others on how epidemiology can be distorted
- To review the literature for inappropriately conducted science or for uninformative studies (e.g., as in underpowered studies)
- To identify who is misusing / abusing epidemiology
- *NINE CO-AUTHORS*

TABLE: TOOLKIT OF INAPPROPRIATE APPLICATIONS OF THE EPIDEMIOLOGICAL METHOD

PART A: EPIDEMIOLOGY-SPECIFIC METHODS/TECHNIQUES USED TO FOMENT UNCERTAINTY AND CAST DOUBT ABOUT CAUSE-AND-EFFECT [through biased study designs/measurements producing invalid science]

PART B: ARGUMENTS USED TO DELAY ACTION, MAINTAIN THE STATUS QUO, AND CREATE DIVISIONS AMONG SCIENTISTS [imposing inappropriate standards and methods of suppression]

PART C: TACTICS INVOKED TO MISDIRECT POLICY PRIORITIES THROUGH INFLUENCE [imposing undisclosed values from the positions taken by special interests]

--- PART A ---

**EPIDEMIOLOGY-SPECIFIC METHODS/TECHNIQUES USED TO FOMENT
UNCERTAINTY AND CAST DOUBT ABOUT CAUSE-AND-EFFECT**
[through biased study designs and measurements producing invalid science]

Item #	METHOD/TECHNIQUE	EFFECTS	REFERENCE(S)
A1	Relying on statistical hypothesis testing; Using “statistical significance” at the .05 level of probability as a strict decision criterion to determine the interpretation of statistical results and drawing conclusions	Increases the probability of Type-II error; highly dependent upon sample size and statistical power; common strategy for dismissing study results that are indeterminate because of low power, or yield elevated risk ratios but do not reach an arbitrary level of statistical significance.	[64, 65]
A2	Conducting statistically under-powered studies; Ignoring Type-II errors	Sample size too small to detect an adverse effect, or adverse effect is too rare to be detected by a statistical study; asserting that a “negative” study (even if $RR > 1$) is proof of no effect. This can be addressed transparently by providing a power calculation. Token studies are undertaken as a delay tactic..	[59, 62, 66, 67]

--- PART B ---

ARGUMENTS USED TO DELAY ACTION, MAINTAIN THE *STATUS QUO*, AND CREATE DIVISIONS AMONG SCIENTISTS

[imposing inappropriate standards and methods of suppression]

Item #	ARGUMENT	EFFECTS	REFERENCE(S)
B1	Insisting on the erroneous application of “criteria” for causation proposals (e.g., Bradford-Hill viewpoints or aspects) in interpreting the weight of evidence in a causation analysis to infer causation	Guidelines in the form of “viewpoints” or “aspects” proffered for interpreting causation, including Bradford-Hill, have been erroneously interpreted as required criteria, thereby leading to the dismissal of the weight of evidence that should properly be considered in health-protective policies. Despite outright errors in the Bradford-Hill suggested guidelines, and his own expressed caveats about his proposed guidelines, the Bradford-Hill guidelines are still cited by regulatory agencies, in legal proceedings, and by epidemiologists and healthcare professionals as a requirement for causation.	[62, 87, 88]
B2	Failing to disclose a conflict-of-interest in the presence of a financial conflict-of-interest, financial control of agenda-driven funders, political influences, or vested interest goals (see C6 below)	The absence of objectivity / impartiality resulting in the application of a biased design or analysis, or selective interpretation of the findings.	[10, 11]

--- PART C ---

TACTICS INVOKED TO MISDIRECT POLICY PRIORITIES THROUGH INFLUENCE

[imposing undisclosed values from the positions taken by special interests]

Item #	TACTIC	EFFECTS	REFERENCE(S)
C1	Assuming that “no data” equates to “no risk”	Lack of research about a public health issue—and a paucity of data—does not equate to “no risk.” However, the absence of data (because of the failure to conduct studies) is often invoked or misinterpreted as evidence of no risk. The absence of scientific research, including the absence of epidemiological research, does not equate to “no risk.” Mechanistic and toxicological data can be sufficient evidence to indicate human risk.	[7, 64, 84, 97, 98]
C2	Failing to study a critical public health issue because of political influence, financial interests, or influence of special interest groups resulting in a Repression Bias. We should not lose sight of the fact that some studies are never done because approval for them was, for some reason, not granted. Sometimes the reason is because the topic is repressed	Critical public health threats, including climate change, firearm violence, obesity/diet, and others have not been properly addressed due to the improper influence of special interests. Repression Bias arises in situations in which a line of inquiry is not pursued because the researcher is, consciously or subconsciously, aware that pursuing such a research question would upset the dominant culture/paradigm, or the funding agency. The research question may never be investigated because funding is not.	[1, 11, 15, 84, 99]

SUMMARY OF TECHNIQUES AND DEFENSES

Techniques to manufacture and cast doubt (i.e., irrational skepticism), targeted at policymakers and consumers through the misapplication of the epidemiological method, claim that:

- The science is unclear
- There is dissent (where the evidence is clear)
- The data are inconclusive
- Scientists are biased / You can't trust scientists
- Regulation is unjustified—"It's a slippery slope."

This is achieved through:

- Delaying action
- Influencing policy decisions—risk factors for bias
 - Pulls: Vested interest (stand to gain personally)
 - Pushes: Lobbying.

Defenses that work against epidemiology being misapplied include:

- Correctly applying and clarifying the methods of statistical inference
- Exposing undisclosed COI
- Recognizing erroneous and misleading interpretations of underpowered studies
- Acknowledging the scientific assessment of uncertainty
 - Bias; Statistical (aleatoric) uncertainty; Epistemic uncertainty
 - Model uncertainty; parameter uncertainty
 - Expected value = (value of outcome) X (probability of outcome)
 - Uncertainty intervals
- Highlighting when the logic of an argument is invalid
 - False premises
 - Invalid argument
 - Misapply conclusions
- Exposing the motives of researchers, journal editors, peer reviewers, decision makers and other stakeholders in the policy process
- Critically appraising the evidence as presented
- Publishing standards for good practice, e.g., the INEP Position Statement
- Calling out malpractice.

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 (financial stakes, liability protection, political interests, self-advancement, etc.)**
 - 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 it [in the public interest](#)

GOING FORWARD: INEP-SPECIFIC RECOMMENDATIONS FOR COI

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

DISCUSSION

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This PPT presentation will be

accessible at www.colinsoskolne.com