

WCRI 2024



BEYOND BIAS

Toward Aggregate Approaches to COI Policy

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CONFLICT OF INTEREST IN MEDICAL RESEARCH, EDUCATION, AND PRACTICE



INSTITUTE OF MEDICINE
OF THE NATIONAL ACADEMIES

Evidence synthesis

Ten years later: a review of the US 2009 institute of medicine report on conflicts of interest and solutions for further reform

Trevor Torgerson ,¹ Cole Wayant ,¹ Lisa Cosgrove ,²
Elie A Akl,³ Jake Checketts,¹ Rafael Dal Re ,⁴ Jennifer Gill,⁵
Samir C Grover,^{6,7,8} Nasim Khan,⁹ Rishad Khan,^{6,7}
Ana Marušić,¹⁰ Matthew S McCoy,¹¹ Aaron Mitchell,¹²
Vinay Prasad,^{5,13,14} Matt Vassar¹

- Sunshine Act, Open Payments Database, MedEd COI policies
- Minimal changes for biomedical research and regulatory spaces.

A conflict of interest is a set of circumstances that creates a risk that professional judgment or actions regarding a primary interest will be unduly influenced by a secondary interest. (IOM, 2009)

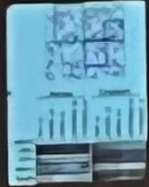


**DO NOT
THROW ROCKS
AT THIS SIGN**

Self-Serving Cognitive Bias

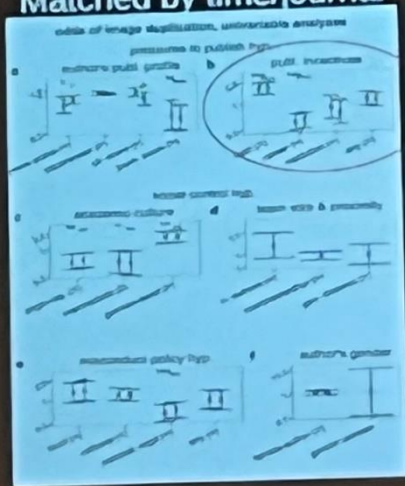
- 90% of Americans believe they are better than the average driver
- 16% of medical residents believe they are affected by industry relationships
- 61% of medical residents believe their colleagues are affected by industry relationships

Effects of incentives, publication pressures etc. vary by country



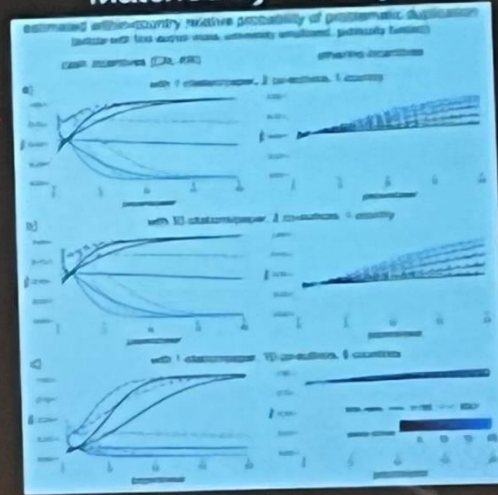
(Bik et al. 2016, mBio)

Matched by time/journal



(Fanelli et al. 2018, Sci Eng Ethics)

Matched by country



(Fanelli et al. 2022, PloS ONE)



TABLE 2 Common COI wedges, definition, and example formulations.

Wedge type	Definition	Example formulation in COI discourse
Epistemic	Disruption of questions of facts; challenging of available evidence.	While others might be biased by COI, I am not. There is insufficient evidence regarding the harms of COI.
Terminological	Strategic re-definition of terms in use.	There's no COI here because I'm not acting with ill intent (i.e., the conflation of fraud and COI).
Moral	Attempt to leverage values to circumscribe policy efforts.	Limiting COI will limit innovation.
Jurisdictional	Attempt to limit the discussants in argument through appeals to experience and/or expertise.	Only biomedical researchers who work with industry should be allowed to comment on the effects of COI.



RESEARCH ARTICLE

Beyond bias: Aggregate approaches to conflicts of interest research and policy in biomedical research

S. Scott Graham ✉ Kimberly R. Harrison, Jade C. Shiva Edward, Zoltan P. Majdik, Joshua B. Barbour, Justin F. Rousseau

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Metastudies of sponsorship bias & COI

- Lund et al., 2012 (48 papers)
- Lund et al., 2017 (27 more papers)
- Graham et al., 2022 (92 additional papers)

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Studies in health technology and informatics

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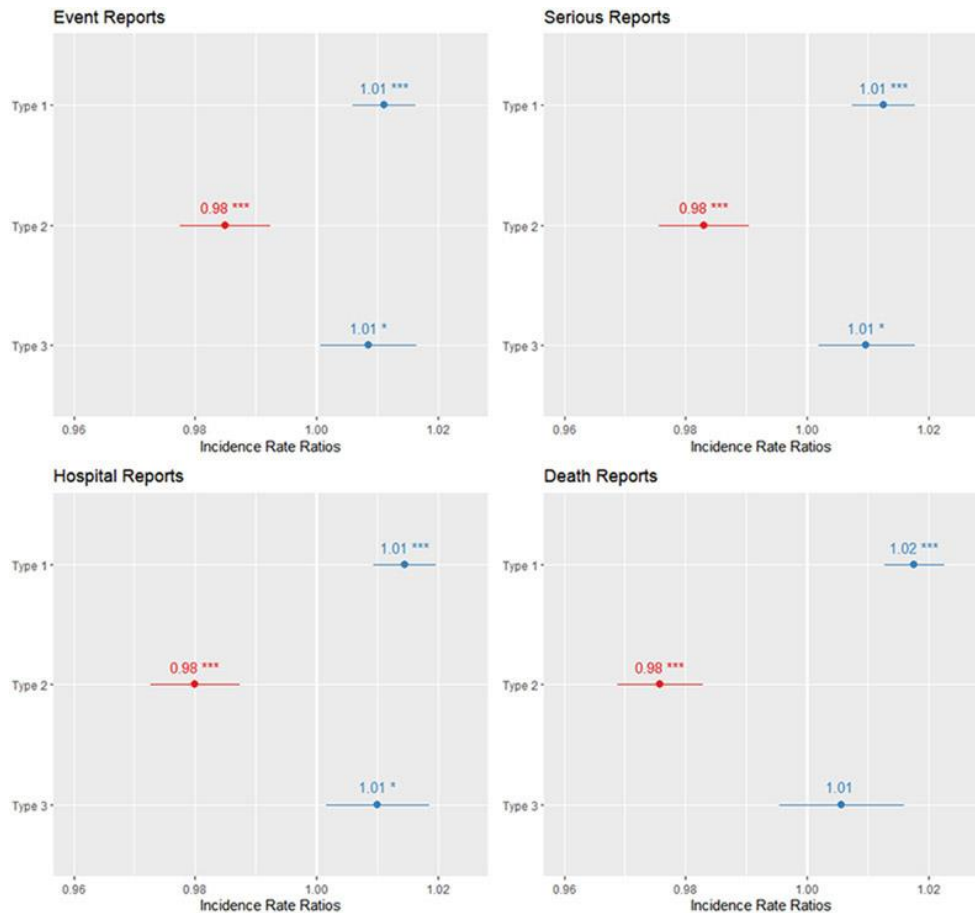
Associations Between Aggregate NLP-extracted Conflicts of Interest and Adverse Events By Drug Product

S. Scott Graham, Zoltan P. Majdik, [...], and Justin F. Rousseau

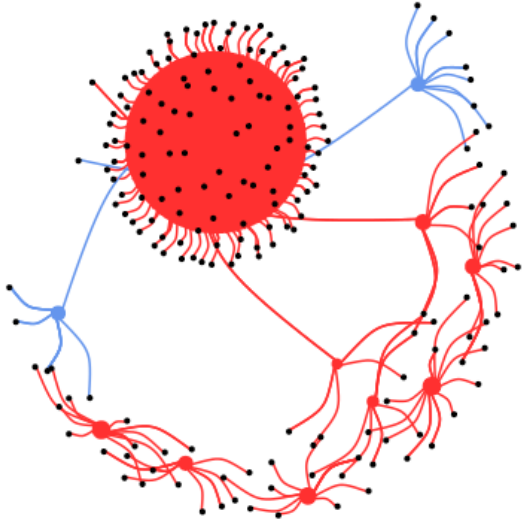
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Abstract

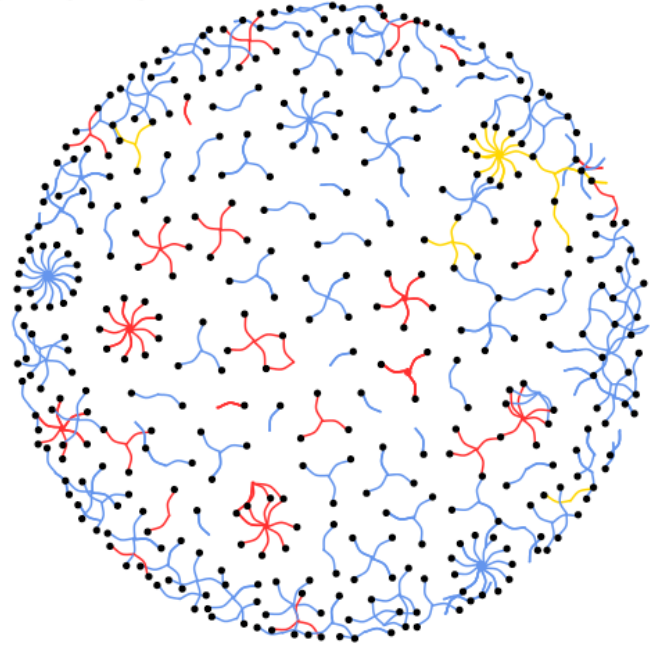
This study evaluates associations between aggregate conflicts of interest (COI) and drug safety. We used a machine-learning system to extract and classify COI from PubMed-indexed disclosure statements. Individual conflicts were classified as Type 1 (personal fees, travel, board memberships, and non-financial support), Type 2 (grants and research support), or Type 3 (stock ownership and industry employment). COI were aggregated by type compared to adverse events by product. Type 1 COI are associated with a 1.1-1.8% increase in the number of adverse events, serious events, hospitalizations, and deaths. Type 2 COI are associated with a 1.7-2% decrease in adverse events across severity levels. Type 3 COI are associated with an approximately 1% increase in adverse events, serious events, and



● RCTs ● Industry ● US Fed ● Other



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