

HESI SUBCOMMITTEE ON EVALUATING CAUSALITY IN EPIDEMIOLOGIC STUDIES

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HESI Subcommittee Co-Chair

The views expressed in this presentation are those of the presenter and do not necessarily reflect the view or policies of the U.S. EPA



HESI Subcommittee on Evaluating Causality in Epidemiologic Studies

Mission: To stimulate a dialogue on the methods and issues related to evaluating causality and interpreting evidence from published epidemiological studies

Objective: Strengthen the value and impact of epidemiologic studies in quantitative health risk assessments by fostering agreement on what constitutes clear and relevant epidemiological evidence for causation

Goal: Organize a workshop with published proceedings to address the mission related to evaluating causality from epidemiological studies

Subcommittee Steering Team

INDUSTRY

- Carol J. Burns (Dow Chemical Company) – ***Co-chair***
- J. Morel Symons (DuPont)

ACADEMIA

- James E. Klaunig (Indiana University) – ***EIC Science Advisor***
- Leonard Ritter (University of Guelph)

GOVERNMENT

- J. Michael Wright (US EPA - National Center for Environmental Assessment) – ***Co-chair***

Subcommittee Participation

ACADEMIA (n=6)

Aarhus University Hospital
Harvard School of Public Health
Indiana University
University of Guelph
MRC/University of Leicester
Wake Forest University

GOVERNMENT (n=4)

CDC / ATSDR
US FDA CDER
US EPA OPP
US EPA NCEA

INDUSTRY (n=8)

Bayer CropScience
Dow
DuPont
ExxonMobil Biomedical Sciences
Monsanto
Procter & Gamble
Shell Health
Syngenta

CONSULTANTS (n=1)

DLW Consulting Services

US EPA Research Areas of Emphasis

Sustainability - served as the structural paradigm for re-scoping EPA research programs; focus is on protection of human health (and future generations) and the environment, while also addressing social and economic considerations

Cumulative Risk Assessment - increased consideration of chemical and non-chemical stressors and buffers, including environmental justice considerations (Epidemiological studies examine many of these factors to a large degree, when examining confounding & effect modification)

National Academy of Sciences Recommendations for EPA's IRIS Program

Ongoing EPA efforts to:

- 1) Increase clarity and readability of IRIS documents
- 2) Increase Transparency
- 3) Use a standardized approach for study selection
- 4) Discuss determinants used for weight of evidence considerations

Causal Inference for Risk Assessments

- Quantitative risk assessments should examine weight of evidence across available data sources including toxicological, clinical and epidemiological studies
- Continued need to address (and quantify) sources of uncertainty in risk assessments

Integration of Epidemiology in Risk Assessments

- Epidemiologic data often considered more relevant to characterizing risk in human populations
- Sources of uncertainty resulting from epidemiologic data can be less than that due to extrapolation based on other data types
- Epidemiologic data can be challenging due to a variety of factors; such as potential bias due to confounding, selection and information bias

Modern Epidemiologic Methods

- Epidemiologic methods to ascertain and quantify potential sources of bias have been developed
 - Yet, it is often hard to elucidate the likelihood of false positives and false negatives (e.g., the impact of systematic and random error)
- Further development of Innovative Methods is still needed. For example, the use of causal diagrams to identify confounding factors and other potential sources of bias.

Subcommittee Activities (2010-11)

Fall 2010

- Project proposal (Evaluating Causality in Epidemiological Studies) selected through the HESI Emerging Issues process
- Steering Team formed

2011

- Steering Team meetings and teleconferences
- Full subcommittee meeting in Washington DC to formulate next steps (October 19, 2011)
- Scoping Meetings for 2012 workshop
- Symposia proposal submitted for August 2012 International Society for Environmental Epidemiology Conference

Subcommittee Work Plan

- Participation in the 2012 International Society for Environmental Epidemiology Conference, with Dr. Morel Symons co-leading a symposia entitled “Improving Reviews, Methods, and Transparency in Environmental Epidemiology to Inform Timely Public Health Decision-Making.”
- Workshop planned for Research Triangle Park, North Carolina, October 21-22, 2012
- Manuscript for publication in a peer-reviewed journal (2013)
- Possible training in epidemiological methods for interested parties (post-publication)

Workshop –October 2012

Purpose: The purpose of the workshop is to stimulate a dialogue on evaluating causality in epidemiologic studies in a risk assessment context by bridging the gap between theory and practice and engaging multi-disciplinary experts from the epidemiology, medical, and toxicology communities

Discussion Topics: 1) Modern Epidemiologic Methods; 2) Uncertainty of Epidemiologic Data in Application in Risk Assessments; 3) Exposure Assessment

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Thank You!