Causality and Epidemiology
Role of HESI

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- Senior Epidemiologist, 1995 -
  - The Dow Chemical Company, Midland, Michigan
- Adjunct epidemiology professor, 2009 -
  - Davenport University
- > 60 publications in peer reviewed journals
- Leadership in industry trade associations and American College of Epidemiology
- Interest area in exposure assessment and occupational epidemiology
Outline

• Nature of issue
• Why now
• What HESI provides
• Value of project
Issue of causality

Pros-cons of epidemiology

**PRO**

- Human (not animal)
- Real life exposures
- Longitudinal follow-up
- Address multiple hypotheses at once

**CON**

- Subject to bias, confounding
- Exposure misclassification
- Hypothesis generating
- Multiple comparisons
Issue of causality

Causality as a CONCEPT

• Not universal agreement
  – “Causality” itself is not well defined
• Must agree before used in weight of evidence

Causality in PRACTICE

• Are results true or false positive?
  – Are results true or false negative?
  – Science is shades of gray, probability
• Emotions can overwhelm the process
An emerging issue: government and industry

- EPA’s OPP intends to employ epidemiology studies into its human health risk assessment [2010 FIFRA SAP meeting]
- OPP is evaluating how epidemiology studies can be integrated into risk assessments
- Recent President’s Cancer Panel report

OPP: Office of Pesticide Programs, SAP: Science Advisory Panel
An Emerging Issue: scientific community

Integration of Toxicological and Epidemiological Evidence to Understand Human Risk
- a theme for the 2011 Annual Meeting of Society of Toxicology
An emerging issue: scientific community

Why Most Published Research Findings Are False (John P. A. Ioannidis)

False-Positive Results in Cancer Epidemiology: A Plea for Epistemological Modesty
Paolo Boffetta, Joseph K. McLaughlin, et al.

Epidemiology, Public Health, and the Rhetoric of False Positives
Aaron Blair, Rodolfo Saracci, Paolo Vineis, et al.

Epidemiological Methods: About Time
Helena Chmura Kraemer
An emerging issue: public

• Critical of PMRA’s regulatory decisions because at the time PMRA did not have an epidemiologist on staff

• Call to use Agricultural Health Study results in risk assessment

PMRA: Pest Management Regulatory Agency, Canada
What HESI provides: a forum

- Reduces WE – THEY mentality
  - Stakeholders and study authors don’t always agree
- Can bring together epidemiologists on a neutral setting
- Structure to organize them
What HESI provides:

less conflict of interest

• Brings credibility to all participants through tripartite approach

• Promotes cross-disciplinary activity
  – different perspectives
  – different expertise
What HESI provides: funding

• Methodology research is orphaned
  – Industry supports business related
  – Public grants support public health impact
What is the value

• Recognition of problem
  – We can’t evaluate causality well
• Forum to discuss the problem
  – Initiating conversation on the principles
  – Working creatively toward a solution
• Disseminate solutions and compromises
Conclusion

- Proposal: 3 phase process to discuss evaluating causality in epidemiology studies
- Emerging need for improved consensus among epidemiologists and stakeholders
- HESI is well positioned to support this
Questions and discussion

1. Identify a work group
   - 10 leaders in epidemiology
   - Teleconferences to structure symposium

2. Conduct a symposium
   - Broader, larger symposium group
   - 2-day meeting
   - Open debate

3. Publish proceedings
   - Consensus statement
   - Peer-reviewed journal