



Causality and Epidemiology

Role of HESI

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Carol J. Burns, PhD, MPH

- 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