

Moving from Observational Studies to Clinical Trials: Why Do We Sometimes Get It Wrong?

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Premises for the workshop:

1. Causal and non-causal associations are often confused by the medical science community, the media, the public, and policy makers.
2. This can have important consequences:
 - a) large randomized trials can be launched based on insufficient information
 - b) large randomized trials can be delayed (or not launched) based on unjustified inferences
 - c) ineffective or harmful health policy or practice can be instituted or continued

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Underlying question for the workshop:

How can mistakes be avoided when deciding whether or not to launch large “definitive” clinical or community trials?

Specifically:

1. What are the traditional tools to help us judge an intervention or a body of evidence?
2. What new methodologies are available (or are needed) to judge evidence in today's research environment?
3. What are research directions for validating methods to distinguish between causal and non-causal chains of evidence?

Prioritization Criteria for Launching a Large Randomized Clinical Trial

- Therapeutic equipoise among health professionals
- Strength of evidence: not too strong, not too weak
- Magnitude of potential health benefits or contribution to scientific understanding
- Portfolio balance
- Window of opportunity: potential for “runaway” practice
- Social, political context/pressures

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Sessions:

- I. Background
- II. Distinguishing Causal From Non-causal Associations
- III. Evaluating and Grading Strength of Evidence
- IV. Evaluating Study Outcomes: Biomarkers, Intermediate Endpoints, and Surrogate Endpoints
- V. Expressing Study Results to the Professional and Public Communities
- VI. The Data and Safety Monitoring Board: Should This Trial Be Stopped?
- VII. Putting It All Together: Translating Data Into Health Policy

“The investigation of truth is in one way hard, in another easy”

Aristotle, Metaphysics II