

Integrating Evidence

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NAAQS Process for Causal Determination

Step	Description
1	Literature search
2	Selection of studies for inclusion
3	Consideration of general limitations of each study type
4	Use of modified Bradford Hill aspects to aid in judging causality
5	Evaluate evidence for major health outcome categories
6	Integrate evidence from across disciplines and across health endpoints
7	Weight alternative views on controversial issues
8	Characterize strength of evidence into casual conclusions
9	Assess adversity of effects

Bradford Hill “Criteria”

- Strength of association
- Consistency
- Specificity
- Temporality
- Exposure-Response
- Biological plausibility
- Coherence
- Experiment
- Analogy

“[I]s there any other way of explaining the set of facts before us, is there any other answer equally, or more, likely than cause and effect?”

- Bradford Hill

IOM vs. NAAQS Framework

IOM Causation Categories

Sufficient

Equipoise and above

Below equipoise

Against

NAAQS Causal Framework

Causal

Likely causal

Suggestive

Inadequate

Not likely causal

EPA's Causal Determinations

Health Outcome	Short-term Exposure		Long-term Exposure	
	2008 Review	2015 Review	2008 Review	2015 Review
Respiratory effects (including mortality)	Causal	Causal	Suggestive	Likely to be causal
All-cause mortality	Suggestive	Likely to be causal	Little evidence	Suggestive
Cardiovascular effects (including mortality)	Suggestive	Likely to be causal	No conclusion	Suggestive

Evidence Integration Frameworks

**Critical Reviews
in Toxicology**

<http://informahealthcare.com/txc>
ISSN: 1040-8444 (print), 1547-6898 (electronic)

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REVIEW

A survey of frameworks for best practices in weight-of-evidence analyses

Lorenz R. Rhomberg¹, Julie E. Goodman¹, Lisa A. Bailey¹, Robyn L. Prueitt¹, Nancy B. Beck², Christopher Bevan³, Michael Honeycutt⁴, Norbert E. Kaminski⁵, Greg Paoli⁶, Lynn H. Pottenger⁷, Roberta W. Scherer⁸, Kimberly C. Wise², and Richard A. Becker²

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REVIEW ARTICLE

Evaluation of the causal framework used for setting National Ambient Air Quality Standards

Julie E. Goodman, Robyn L. Prueitt, Sonja N. Sax, Lisa A. Bailey, and Lorenz R. Rhomberg

Weight-of-Evidence Evaluation Approach

1 Define causal question
Develop study selection criteria



2 Develop and apply criteria for review of
individual studies

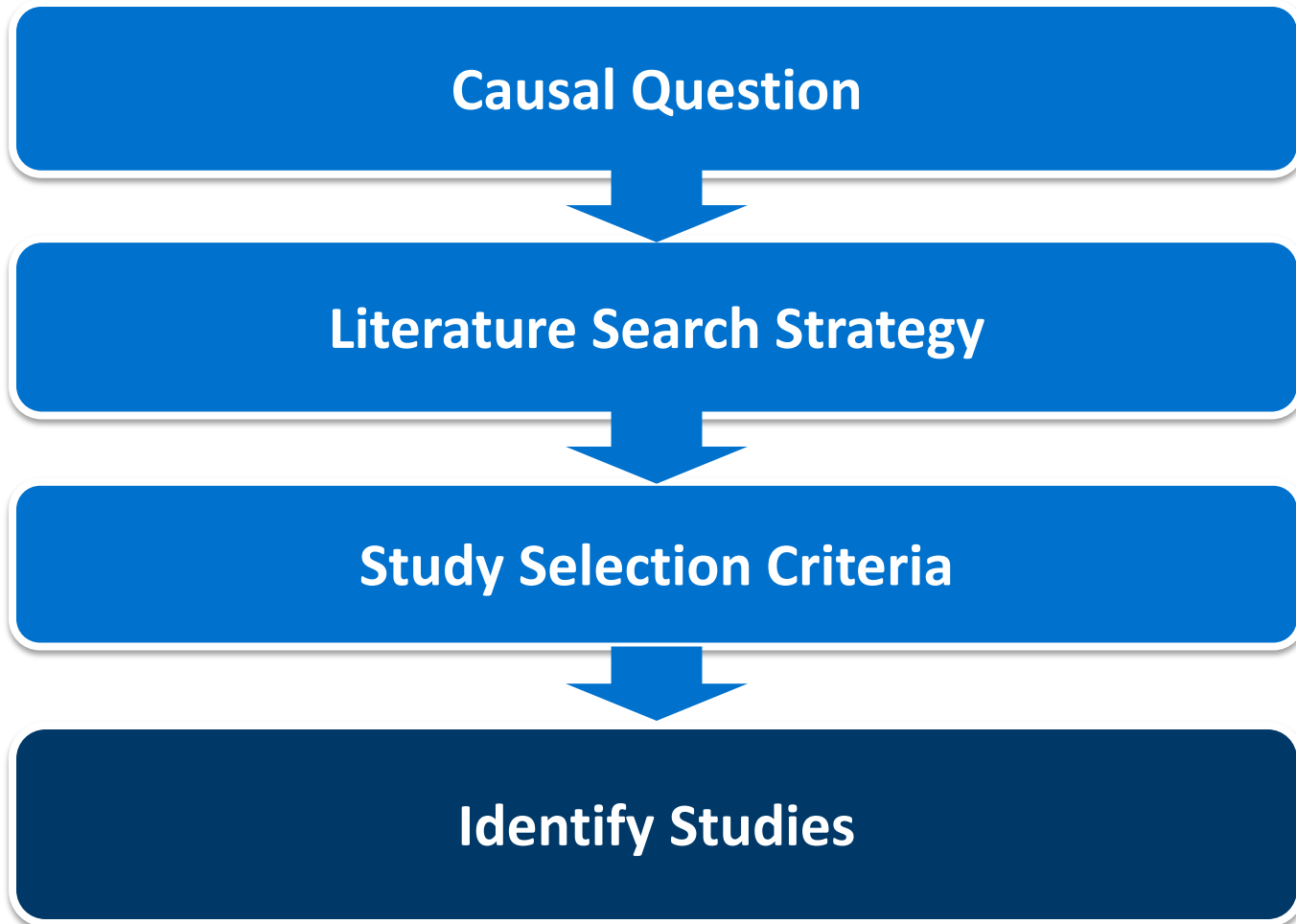


3 Integrate and evaluate evidence



4 Draw conclusions based on inferences

Short-term Ozone and Asthma

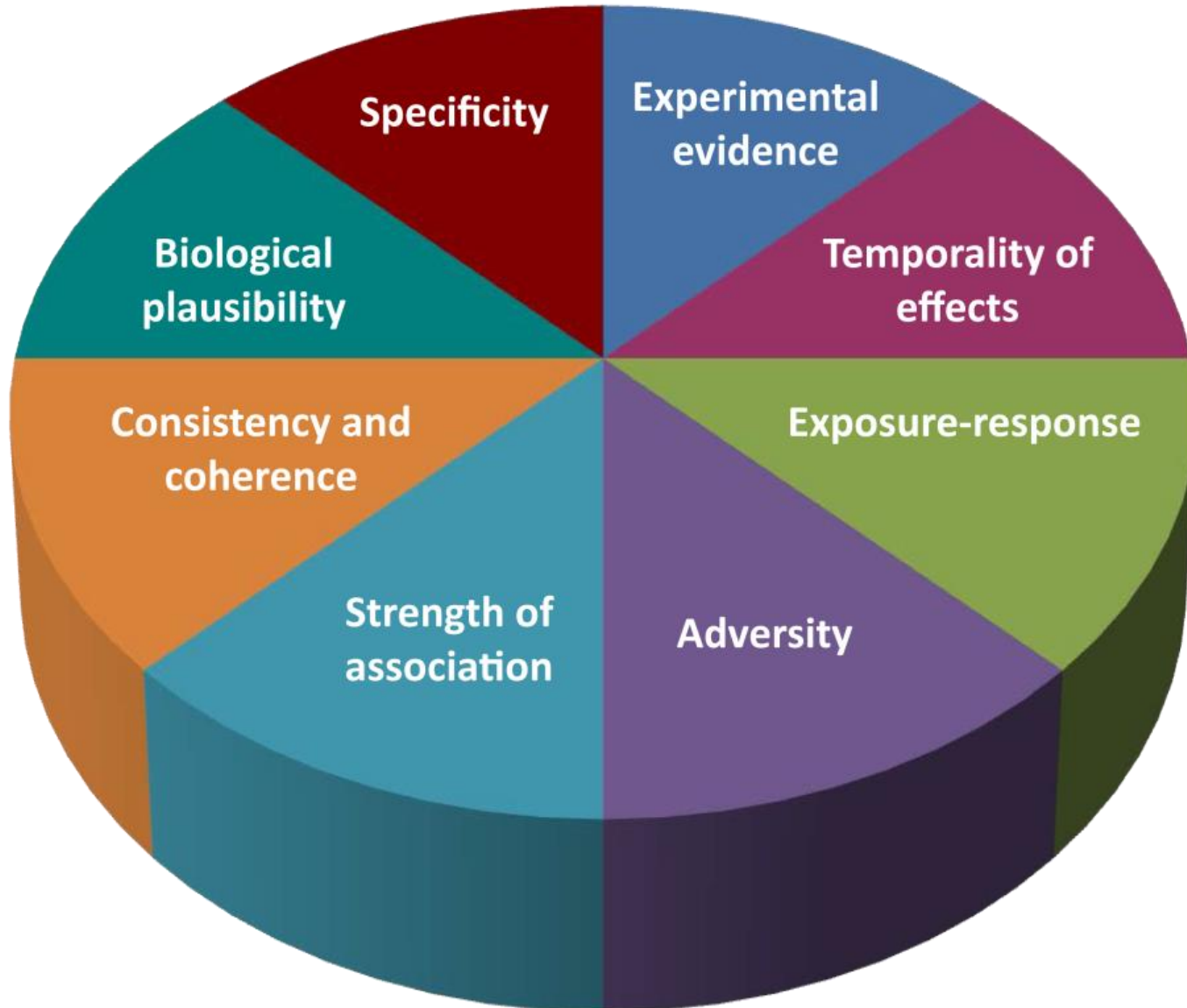


Study Quality Evaluation

Epidemiology	Controlled Human Exposure	Animal
Study design	Selection bias	Randomization
Study size	Blinding	Study size
Selection bias	Exposure method	Exposure monitoring
Exposure assessment	Study design	Experimental animals, housing, and husbandry
Outcome assessment	Smoking	Control groups
Statistical models	Subject inclusion/exclusion criteria	Assay reproducibility
Confounding	Exposure monitoring	Transparent reporting
Adjustment for pollen	Outcome assessment	Statistical methods
Multiple lag times	Data analysis	
Sensitivity analysis	Statistical methods	

All studies classified as Tier I or Tier II.

Evidence Integration and Evaluation



Draw Conclusions

