Improving Risk Assessment Approaches and Ensuring Consistency in Risk Assessment

Thomas A. Burke, PhD, MPH
Professor and Associate Dean
Director, Risk Sciences and Public Policy Institute
Johns Hopkins Bloomberg School of Public Health

2nd International Conference on Risk Assessment
Brussels
26 January,2011

SCIENCE AND DECISIONS: ADVANCING RISK ASSESSMENT

National Research Council

Committee on Improving Risk Analysis Approaches Used by EPA

Board on Environmental Studies and Toxicology

Risk assessment has become a dominant public policy tool for making choices, based on limited resources, to protect public health and the environment. It has been instrumental to the mission of the U.S. Environmental Protection Agency (EPA) as well as other federal agencies in evaluating public health concerns, informing regulatory and technological decisions, prioritizing research needs and funding, and in developing approaches for cost-benefit analyses.

However, risk assessment is at a crossroads. Despite advances in the field, risk assessment faces a number of significant challenges including lengthy delays in completing complex risk assessments; lack of data leading to significant uncertainty in risk assessments; and many chemicals in the marketplace that have not been evaluated and emerging agents requiring assessment.

Science and Decisions makes practical scientific and technical recommendations to address these challenges. This book is complement to the widely used 1983 National Academies book, *Risk Assessment in the Federal Government* (also known as the Red Book). The earlier book established a framework for the concepts and conduct of risk assessment that has been adopted by numerous expert committees, regulatory agencies, and public health institutions. The new book embeds these concepts within a broader framework for risk-based decision-making. Together, these are essential references for those working in the regulatory and public health fields.

Also of Interest:

Risk Assessment in the Federal Government: Managing the Process
978-0-309-03349-7 • 191 pages • 6 x 9 • paperback (1983)

Environmental Health Sciences Decision Making: Risk Management, Evidence, and Ethics: Workshop Summary
978-0-309-12454-6 • 92 pages • 6 x 9 • paperback (2009)

Toxicity Testing in the 21st Century: A Vision and a Strategy
978-0-309-10992-5 • 216 pages • 6 x 9 • hardcover (2007)

NATIONAL RESEARCH COUNCIL

SCIENCE AND DECISIONS

SCIENCE AND DECISIONS

Advancing Risk Assessment

THE NATIONAL ACADEMIES
Advisers to the Nation on Science, Engineering, and Medicine

The nation turns to the National Academies—National Academy of Sciences, National Academy of Engineering, Institute of Medicine, and National Research Council—for independent, objective advice on issues that affect people's lives worldwide.
www.national-academies.org

THE NATIONAL ACADEMIES PRESS

NATIONAL RESEARCH COUNCIL
OF THE NATIONAL ACADEMIES

Is risk assessment broke?

- Credibility is being challenged by stakeholders
- Easy target for raising doubts
- Surrogate for conflicts over risk management costs
- Disconnect between available data and needs of decision makers
  - Inconsistency??
- Appropriate for new challenges, sustainability?

The NAS EVALUATION

Two broad elements:

- Improving ***technical analysis*** entails the development and use of scientific knowledge and information to promote more accurate characterizations of risk.

- Improving ***utility*** entails making risk assessment more relevant to and useful for risk-management decisions.

CONCLUSIONS AND RECOMMENDATIONS

- Design of risk assessment
- Uncertainty and variability
- Selection and use of defaults
- A unified approach to dose-response assessment
- Cumulative risk assessment
- Improving the utility of risk assessment
- Stakeholder involvement
- Capacity-building
- Also…greater consistency throughout the process

UNCERTAINTY

- The level of detail for characterizing uncertainty is appropriate only to the extent that it is needed to inform specific risk-management decisions appropriately.

- Inconsistency in the treatment of uncertainty among components of a risk assessment can make the communication of uncertainty difficult and sometimes misleading.

VARIABILITY

- Variability in human susceptibility has not received sufficient or consistent attention in many EPA health risk assessments although there are encouraging exceptions, such as those for lead, ozone, and sulfur oxides.

- The committee encourages EPA to move toward the long-term goal of quantifying population variability more explicitly in exposure assessment and dose-response relationships.

UNCERTAINTY AND VARIABILITY

Recommendation:

- EPA should encourage risk assessments to characterize and communicate uncertainty and variability in all key computational steps—for example, exposure assessment and dose-response assessment.

- Uncertainty and variability analysis should be planned and managed to reflect the needs for comparative evaluation of the risk management options.

- In the short term, EPA should adopt a “tiered” approach for selecting the level of detail to be used in the uncertainty and variability assessments, and this should be made explicit in the planning stage.

- EPA should develop guidance to determine the appropriate level of detail needed in uncertainty and variability analyses to support decision-making and should provide clear definitions and methods for identifying and addressing different sources of uncertainty and variability.

SELECTION AND USE OF DEFAULTS

Recommendation:

- EPA should continue and expand use of the best, most current science to support and revise default assumptions.

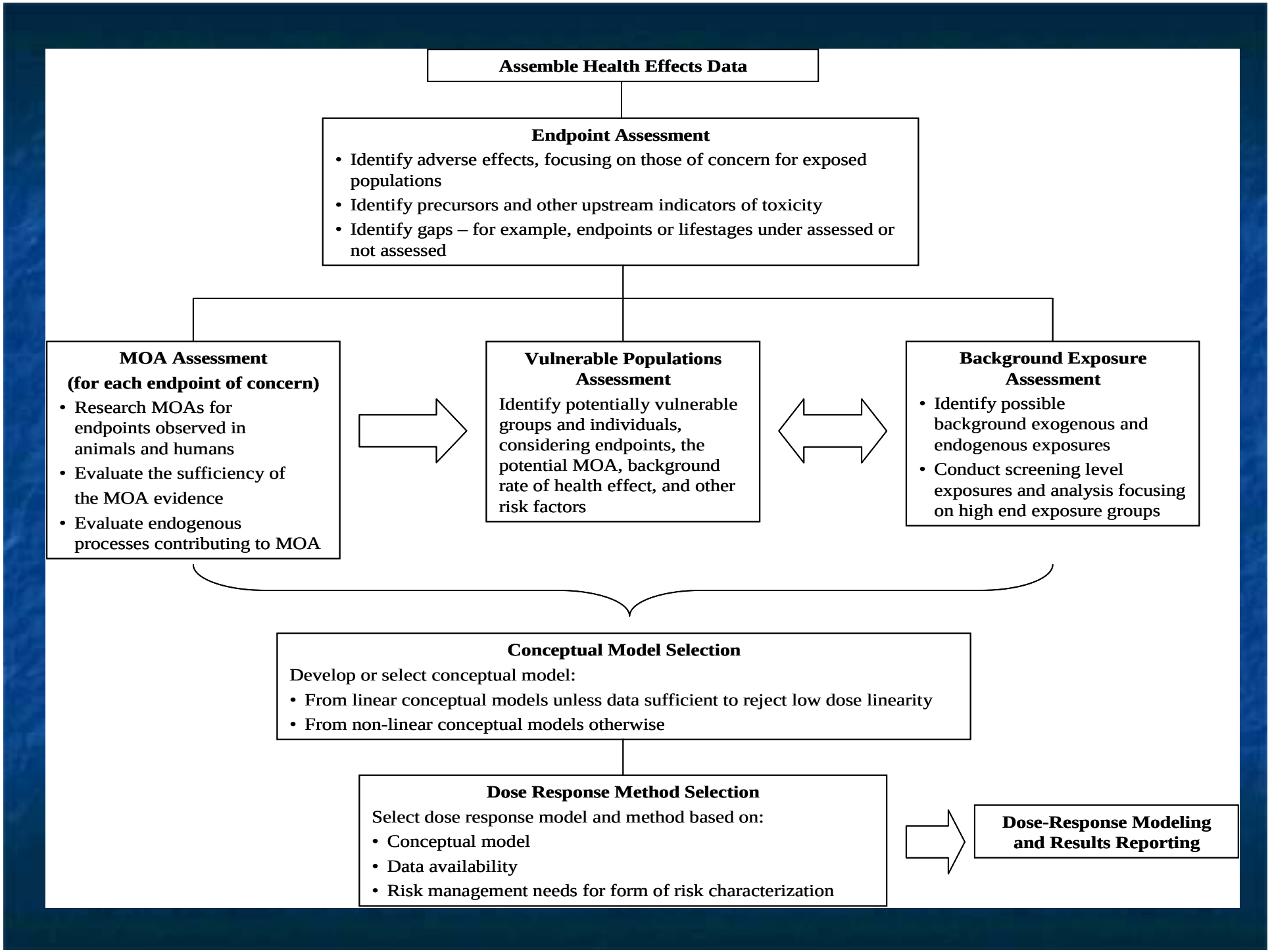
- EPA should develop clear, general standards for the level of evidence needed to justify the use of alternative assumptions in place of defaults.

- EPA should work toward the development of explicitly stated defaults to take the place of implicit defaults.

UNIFICATION APPROACH TO DOSE-RESPONSE ASSESSMENT

- The committee recommends a consistent, unified approach for dose-response modeling that includes formal, systematic assessment of background disease processes and exposures, possible vulnerable populations, and modes of action that may affect a chemical's dose-response relationship in humans.

- Redefines the RfD or RfC as a risk-specific dose that provides information on the percentage of the population that can be expected to be above or below a defined acceptable risk with a specific degree of confidence.


Assemble Health Effects Data
Endpoint Assessment
• Identify adverse effects, focusing on those of concern for exposed populations
• Identify precursors and other upstream indicators of toxicity
• Identify gaps – for example, endpoints or lifestages under assessed or not assessed
MOA Assessment
(for each endpoint of concern)
• Research MOAs for endpoints observed in animals and humans
• Evaluate the sufficiency of the MOA evidence
• Evaluate endogenous processes contributing to MOA
Vulnerable Populations Assessment
Identify potentially vulnerable groups and individuals, considering endpoints, the potential MOA, background rate of health effect, and other risk factors
Background Exposure Assessment
• Identify possible background exogenous and endogenous exposures
• Conduct screening level exposures and analysis focusing on high end exposure groups
Conceptual Model Selection
Develop or select conceptual model:
• From linear conceptual models unless data sufficient to reject low dose linearity
• From non-linear conceptual models otherwise
Dose Response Method Selection
Select dose response model and method based on:
• Conceptual model
• Data availability
• Risk management needs for form of risk characterization
Dose-Response Modeling and Results Reporting

CUMULATIVE RISK ASSESSMENT

- There has been little consideration of nonchemical stressors, vulnerability, and background risk factors.

- Because of the complexity of considering so many factors simultaneously, there is a need for simplified risk-assessment tools (such as databases, software packages, and other modeling resources) that would allow screening-level risk assessments and could allow communities and stakeholders to conduct assessments.

IMPROVING THE UTILITY OF RISK ASSESSMENT

Recommendation:

To make risk assessments most useful for risk management decisions, the committee recommends that EPA adopt a framework for risk-based decision-making that embeds the Red Book risk assessment paradigm into a process with initial problem formulation and scoping, upfront identification of risk-management options, and use of risk assessment to discriminate among these options.

KEY MESSAGES

- Enhanced framework
- Formative focus
- Four steps still core
- Matching analysis to decisions
- Clearer estimates of population risk
- Advancing cumulative assessments
- People and capacity building

The Silver Book

- Consistent with the goals and efforts of the Global Risk Assessment Dialogue
- A lens for our discussions
- Identifies key challenges and addresses need for consistency
- Focuses upon informing and improving decisions