LINKING PROBLEM FORMULATION TO DOSE-RESPONSE ASSESSMENT

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OUTLINE

- Science & Decisions (Silver Book)
- Problem Formulation
- Value of Information (VOI)
  - Value of Methods (VOM)
  - Value of Information Systems (VOIS)
  - Why VOI is rarely used in practice
- Model-Based Reasoning in PF
What are the relative health or environmental benefits of the proposed options?
How are other decision-making factors (technologies, costs) affected by the proposed options?
What is the decision, and its justification, in light of benefits, costs, and uncertainties in each?
How should the decision be communicated?
Is it necessary to evaluate the effectiveness of the decision?
If so, how should this be done?

Stage 1: Planning
- For the given decision-context, what are the attributes of assessments necessary to characterize risks of existing conditions and the effects on risk of proposed options? What level of uncertainty and variability analysis is appropriate?

Stage 2: Risk Assessment
- Hazard Identification
  What adverse health or environmental effects are associated with the agents of concern?
- Dose-Response Assessment
  For each determining adverse effect, what is the relationship between dose and the probability of the occurrence of the adverse effects in the range of doses identified in the exposure assessment?
- Risk Characterization
  What is the nature and magnitude of risk associated with existing conditions?
  What risk decreases (benefits) are associated with each of the options?
  Are any risks increased? What are the significant uncertainties?
- Exposure Assessment
  What exposures/doses are incurred by each population of interest under existing conditions?
  How does each option affect existing conditions and resulting exposures/doses?

Stage 3: Confirmation of Utility
- Does the assessment have the attributes called for in planning?
- Does the assessment provide sufficient information to discriminate among risk management options?
- Has the assessment been satisfactorily peer reviewed?

FORMAL PROVISIONS FOR INTERNAL AND EXTERNAL STAKEHOLDER INVOLVEMENT AT ALL STAGES
- The involvement of decision-makers, technical specialists, and other stakeholders in all phases of the processes leading to decisions should in no way compromise the technical assessment of risk, which is carried out under its own standards and guidelines.
THE DESIGN OF RISK ASSESSMENTS

• Risk Assessment = **Process** + Product

• A Risk Assessment, at its outset, is a design problem
  • *Multiple, Competing Objectives*
  • *Resource Constraints (\$, time, expertise)*
Problem Formulation

- Discussion
  - With Decision-Makers
  - With Stakeholders
  - Among analysts

- Leading to Decisions
  - Decision Context – Scope of Analysis
  - Decision Options to be Explored
  - Essential Qualities of the RA
Step 1: Problem Formulation
Preliminary identification of risk management options and the scope of the problem being considered (which hazards, which pathways, which receptors, which outcomes, to whom, where and when).

Step 2: Hazard Identification
Characterization of various properties of the hazard and evidence for the causal linkage between a hazard and outcomes of interest.

Step 3: Exposure Assessment
Estimate the probability and extent of exposure to the hazard.

Step 4: Exposure - Consequence Assessment
Estimate the frequency or probability of consequences given an event, or a certain level of exposure.

Step 5: Risk Characterization
Derivation of summary measures of risk that integrate the frequency and extent of exposure with the consequences of these exposures. Characterization of uncertainty in estimates.

Assessing the Risk Reduction Impact of Risk Management Options
To estimate the benefits of specific decision-making options, a range of risk management options is selected for evaluation and comparison, against each other and against the baseline scenario. This step simply repeats the risk characterization step for a selection of decision options, and focusses attention upon the differences in the level of risk among the various options and as compared to a baselines scenario (for example, the status quo).
PROBLEM FORMULATION QUESTIONS

- What exactly is the product of problem formulation?
- Should there be a quantitative component to problem formulation?
- Should it be iterative, and what would trigger iteration?
VALUE OF INFORMATION (VOI)

• Decision-centric valuation of the benefit of new information that would reduce uncertainty.
• How does new information generate benefit?
• Information reduces the likelihood and severity of adverse outcomes from decisions
WHAT VOI IS NOT

• VOI ≠ Interesting or Publishable

• VOI ≠ Scientific Importance

• Important versus Informative
  • A 30-person telephone survey on use of consumer products
  • A two-generation primate reproductive study
Value-of-Information Analysis

Uncertain Information R1
Uncertain Information R2
Uncertain Information R3
Uncertain Information R4
Uncertain Information C1
Uncertain Information C2
Uncertain Information C3

Uncertain Information Opportunities
- Survey (R1)
- Capital Cost Study (C1)
- Expert Elicit. (R2)
- Operating Cost Study (C2)
- Bioassay (R3)
- Control Effectiveness (C3)

Baseline Risk Model
Risk Reduction & Cost Model
Decision Support Model

Preferred Option

Additional Information X1
Additional Information Xn

Net Benefit Metric

Net Benefit of Information
Simulated Impact of Information on Preferred Option and Net Benefit
Estimate of Unc. Reduction
Indirect Risks and Costs of Study
Direct Costs of Information

Decision-Maker’s Valuation of Risk and Cost Outcomes
VALUE OF INFORMATION SYSTEMS (VOIS)

• The exact same concept extends naturally to information systems

• Decision → Class or Series of Decisions

• Information → Information Systems
  • Resolution, Timeliness, Quality
WHY VOI IS RARELY USED IN PRACTICE

• The Missing Link for Formal VOI
  • You can’t do VOI if you don’t know what options the decision-makers is contemplating.
  • You can’t do VOI if you don’t know how the decision-maker chooses among the options
FROM FORMAL TO INFORMAL

• Silver Book Committee recommended adoption of informal VOI
  • Requiring a clear causal link between a particular piece of information, the magnitude of uncertainty reduction, and the reason why the decision-maker is likely to make a better and different choice.

• The Goal: stopping criteria for risk assessment
A PROPOSED SOLUTION: MODEL-BASED REASONING

• Construction of a class of Decision-Context Models which serve as a sandbox for exploring the value of information, the value of complex model components, and the impact on the (phantom) decision-maker.

• At the onset of a Risk Assessment
  • Choose the right decision context model
  • Tune it with crude approximations
  • See what is truly necessary to support the decision-maker
VOI EXPLORATION

Graph 1: Control Cost ($/yr) vs. Emissions Reduction

Graph 2: Excess Deaths (d/yr) vs. Emissions Reduction
VOI for Toxicity as a Function of Exposure
SUMMARY

• Design of Risk Assessment
• Value Of Information (VOI)
  • VOM (For Complexity and Process)
  • VOIS (For Classes of Decisions)
  • Informal VOI (Causality)
• Model-Based Reasoning in Iterative PF