Linking Problem Formulation to dose-Response Assessment

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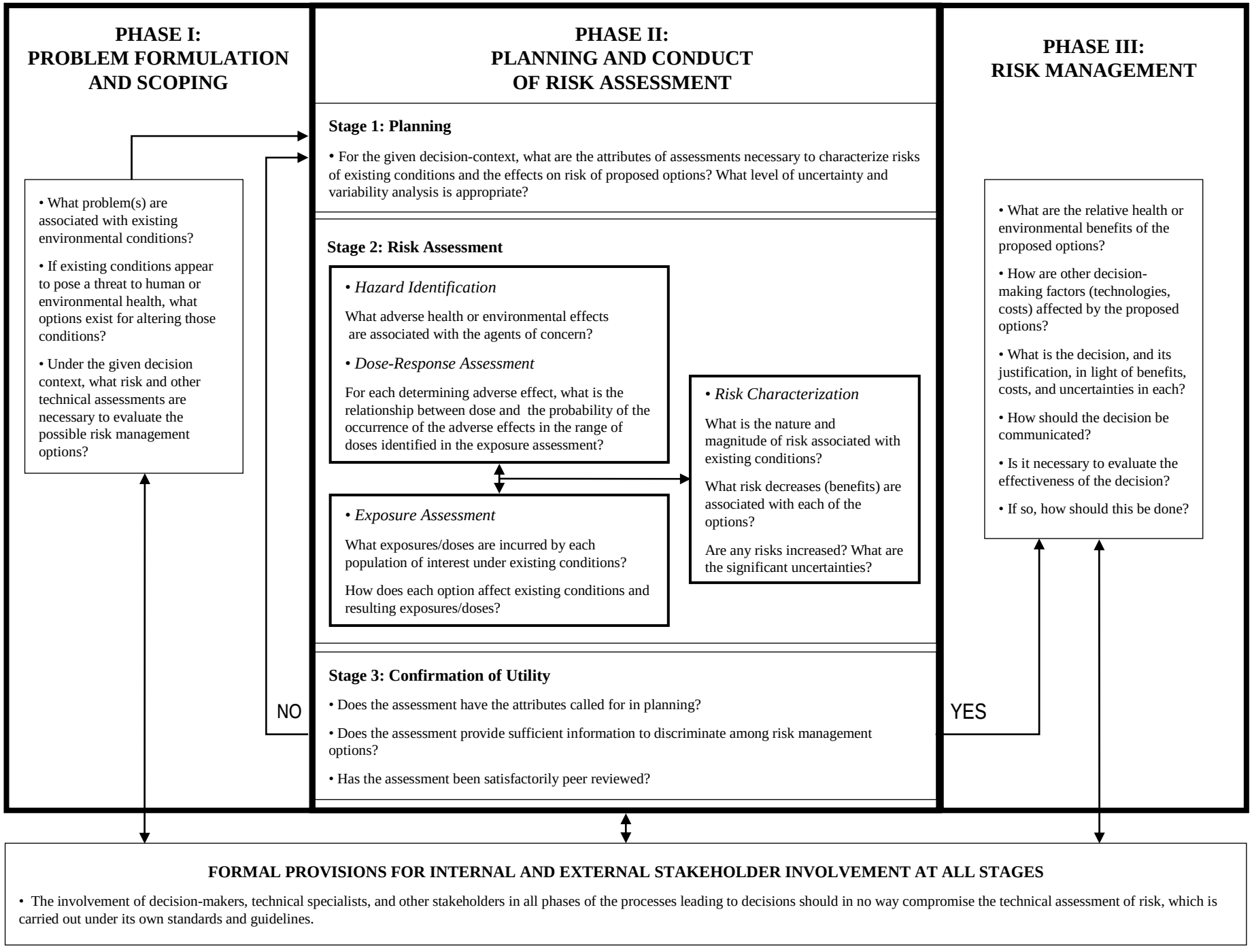
OUTLINE

- 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


PHASE I:
PROBLEM FORMULATION
AND SCOPING
PHASE II:
PLANNING AND CONDUCT
OF RISK ASSESSMENT
PHASE III:
RISK MANAGEMENT
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?
• What problem(s) are associated with existing environmental conditions?
• If existing conditions appear to pose a threat to human or environmental health, what options exist for altering those conditions?
• Under the given decision context, what risk and other technical assessments are necessary to evaluate the possible risk management options?
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?
• 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?
• 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?
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?
NO
YES
• 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?
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.

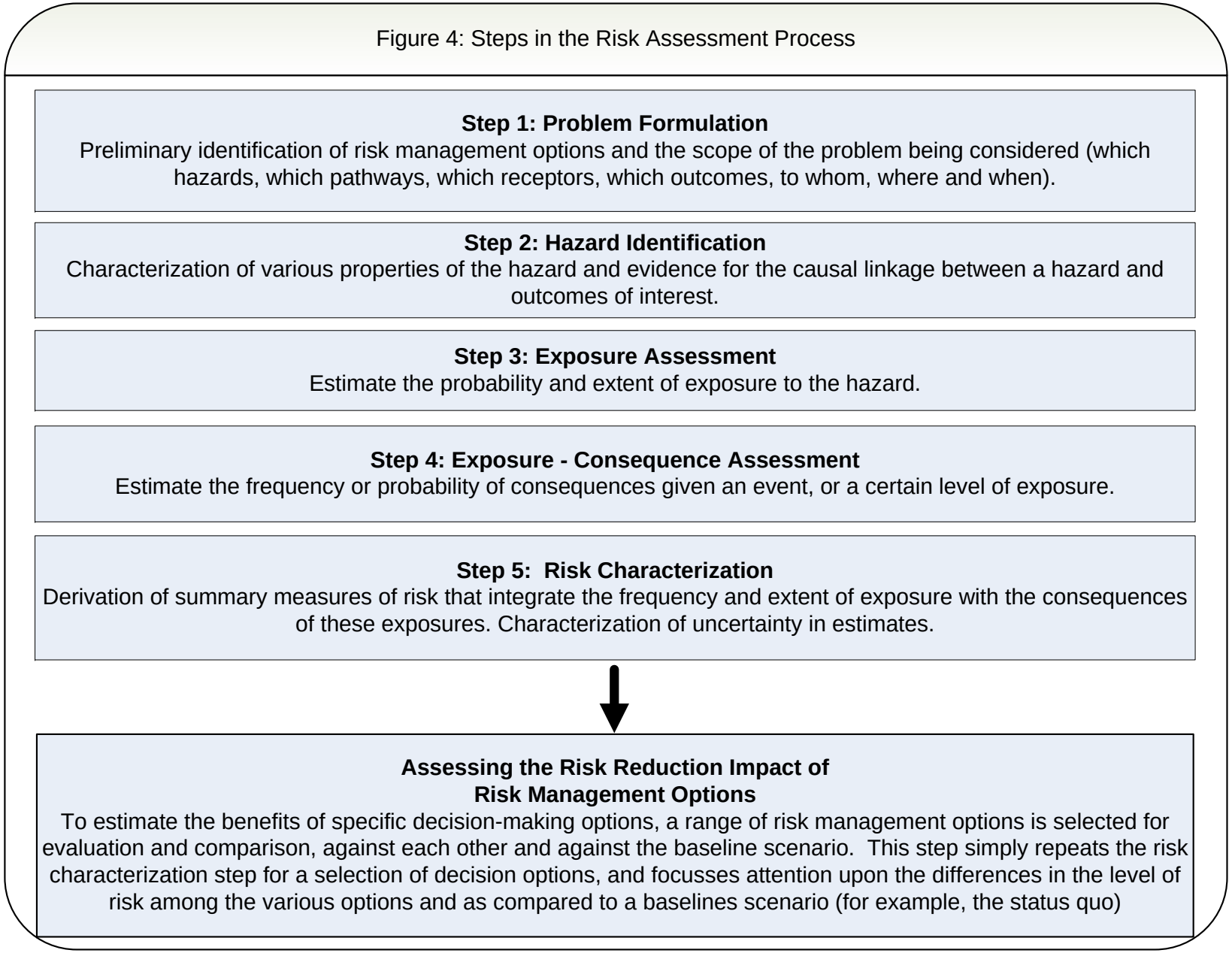
The Design of Risk Assessments

- 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***

Figure 4: Steps in the Risk Assessment Process



Problem Formulation Questions

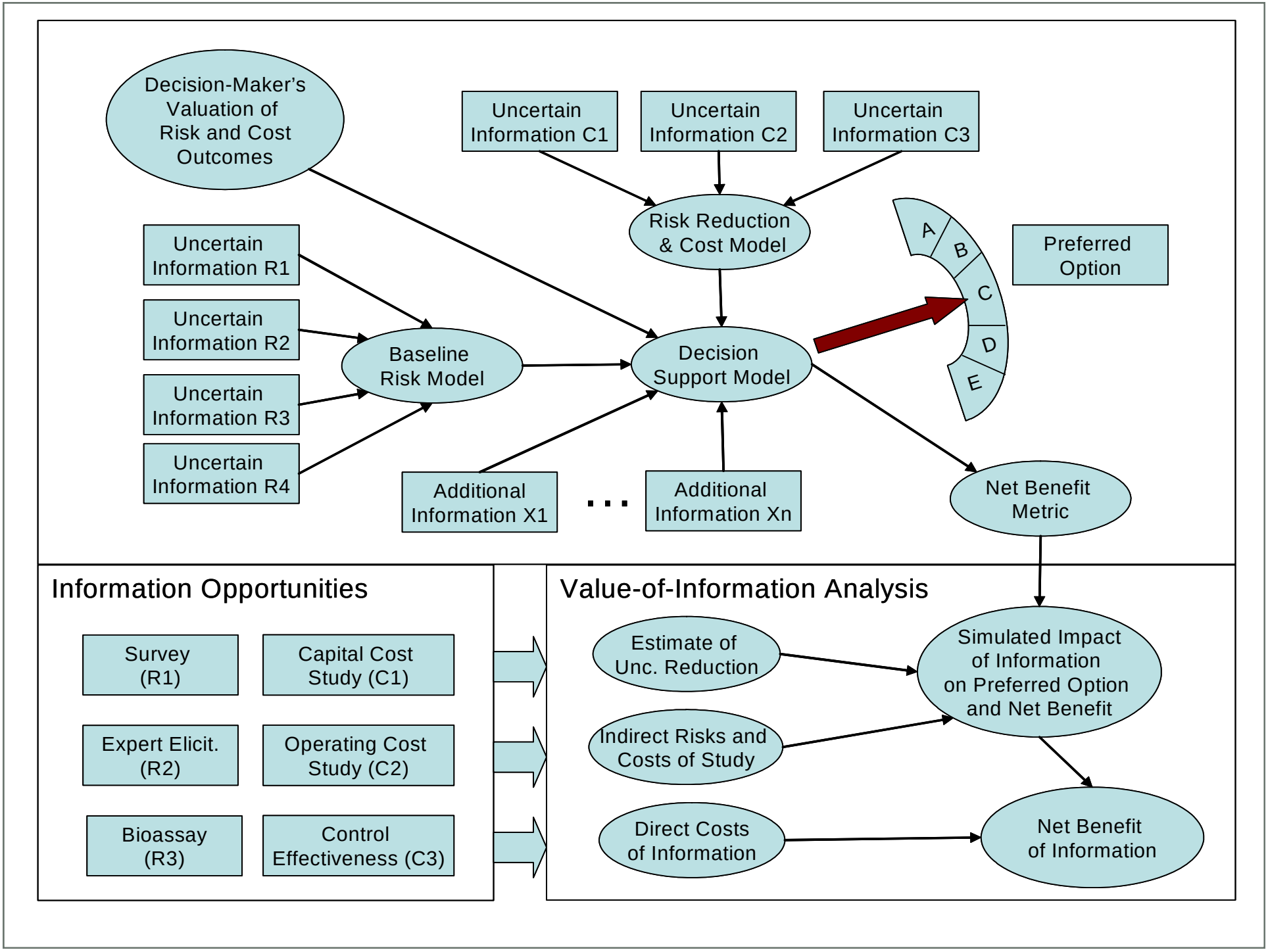
- What exactly is the product of problem formulation?
- Should there be a quantitative component to problem formulation?
- Should it be iterative, and what would trigger iteration?

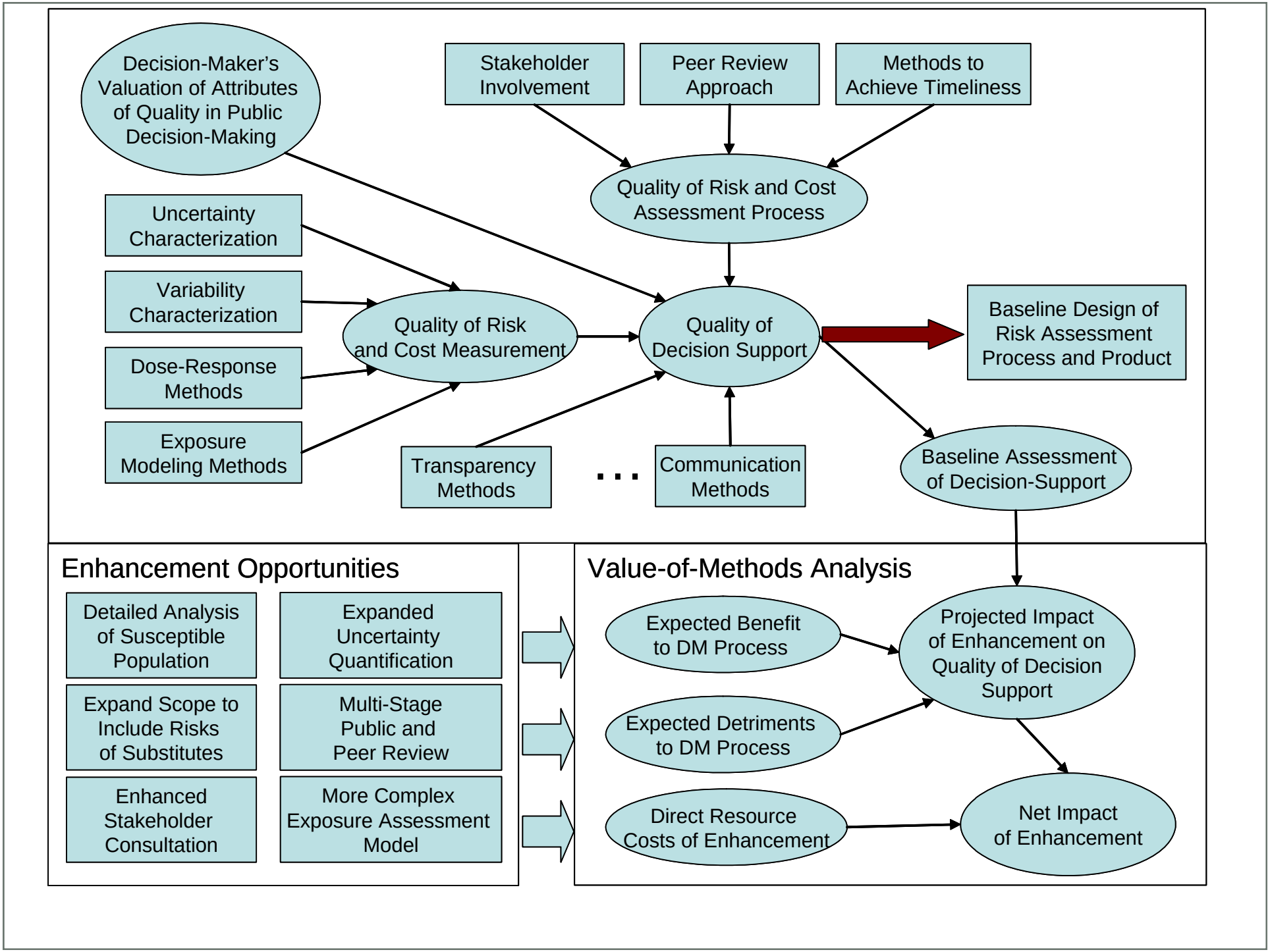
Value of Information (VOI)

- 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***


Decision-Maker's Valuation of Risk and Cost Outcomes
Uncertain Information C1
Uncertain Information C2
Uncertain Information C3
Risk Reduction & Cost Model
Uncertain Information R1
Uncertain Information R2
Uncertain Information R3
Uncertain Information R4
Baseline Risk Model
Decision Support Model
A
B
C
D
E
Preferred Option
Additional Information X1
...
Additional Information Xn
Net Benefit Metric
Information Opportunities
Survey (R1)
Capital Cost Study (C1)
Expert Elicit. (R2)
Operating Cost Study (C2)
Bioassay (R3)
Control Effectiveness (C3)
Value-of-Information Analysis
Estimate of Unc. Reduction
Indirect Risks and Costs of Study
Direct Costs of Information
Simulated Impact of Information on Preferred Option and Net Benefit
Net Benefit of Information


Decision-Maker's Valuation of Attributes of Quality in Public Decision-Making
Stakeholder Involvement
Peer Review Approach
Methods to Achieve Timeliness
Quality of Risk and Cost Assessment Process
Uncertainty Characterization
Variability Characterization
Dose-Response Methods
Exposure Modeling Methods
Quality of Risk and Cost Measurement
Quality of Decision Support
Baseline Design of Risk Assessment Process and Product
Transparency Methods
...
Communication Methods
Baseline Assessment of Decision-Support
Enhancement Opportunities
Detailed Analysis of Susceptible Population
Expanded Uncertainty Quantification
Expand Scope to Include Risks of Substitutes
Multi-Stage Public and Peer Review
Enhanced Stakeholder Consultation
More Complex Exposure Assessment Model
Value-of-Methods Analysis
Expected Benefit to DM Process
Expected Detriments to DM Process
Direct Resource Costs of Enhancement
Projected Impact of Enhancement on Quality of Decision Support
Net Impact of Enhancement

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***

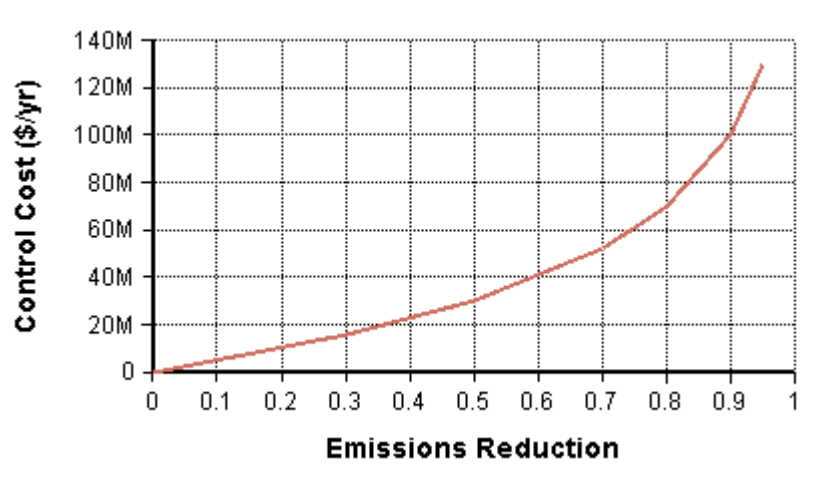
From Formal to Informal

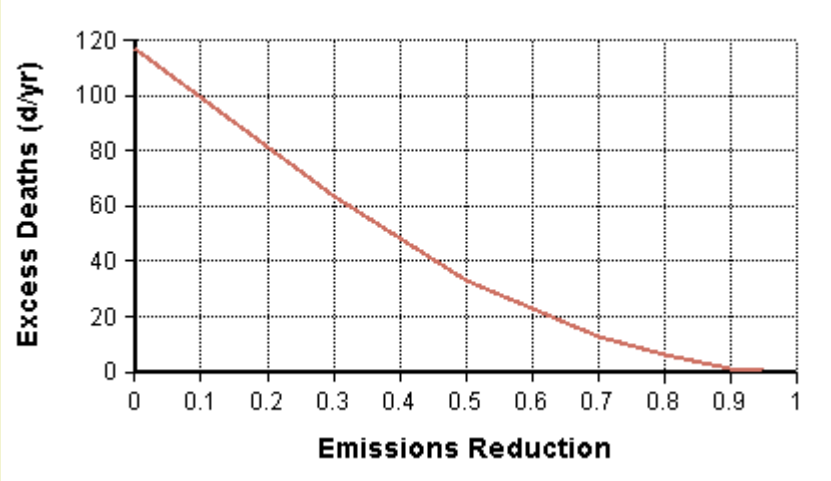
- **Silver Book Committee recommended adoption of informal VOI**
  - **Requiring a clear causal link between a particular piece of information, the magnitude of uncertainty reduction, and the reason why the decision-maker is likely to make a better and different choice.**
  - **The Goal: stopping criteria for risk assessment**

A Proposed Solution: Model-Based Reasoning

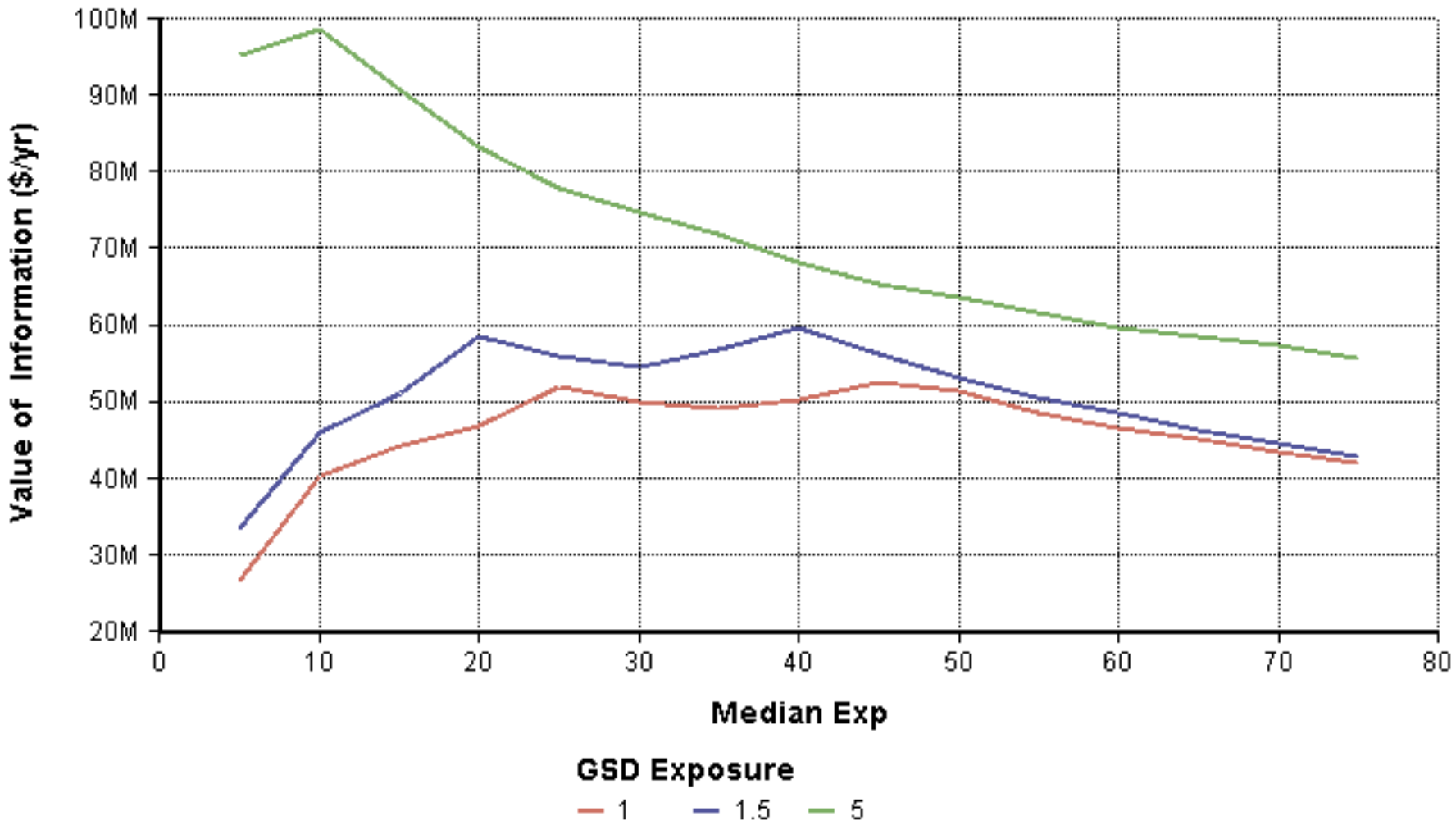
- Construction of a class of Decision-Context Models which serve as a sandbox for exploring the value of information, the value of complex model components, and the impact on the (phantom) decision-maker.
- At the onset of a Risk Assessment
  - *Choose the right decision context model*
  - *Tune it with crude approximations*
  - *See what is truly necessary to support the decision-maker*

VOI Exploration





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