



# 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**

- 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?

**PHASE II:  
PLANNING AND CONDUCT  
OF RISK ASSESSMENT**

**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?

• *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

**PHASE III:  
RISK MANAGEMENT**

- 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?

YES

**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

**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 baseline 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)

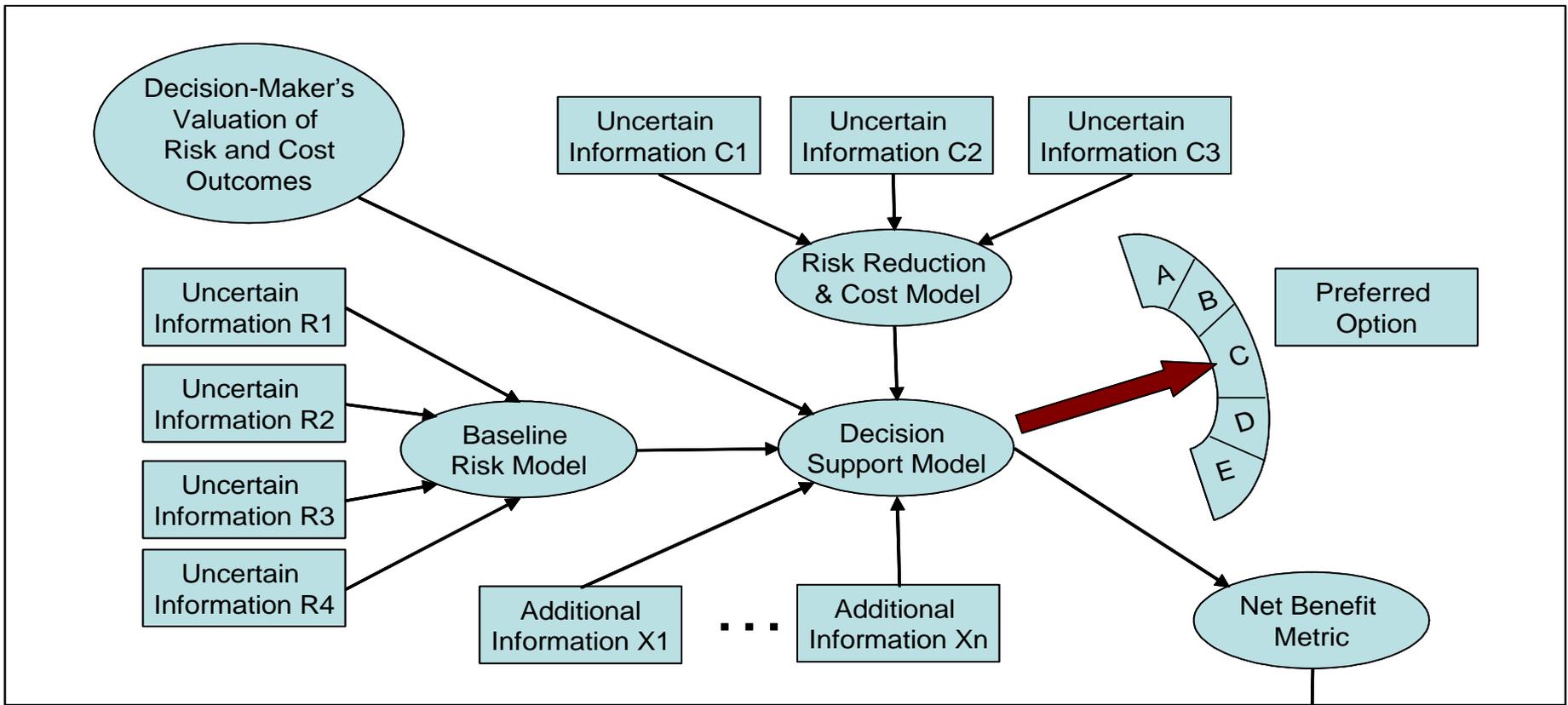


- **Decision-centric valuation of the benefit of new information that would reduce uncertainty.**
- **How does new information generate benefit?**
- **Information reduces the *likelihood* and *severity of adverse* outcomes from decisions**

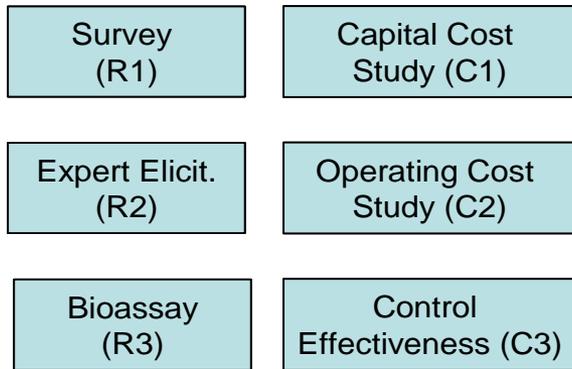
# WHAT VOI IS NOT



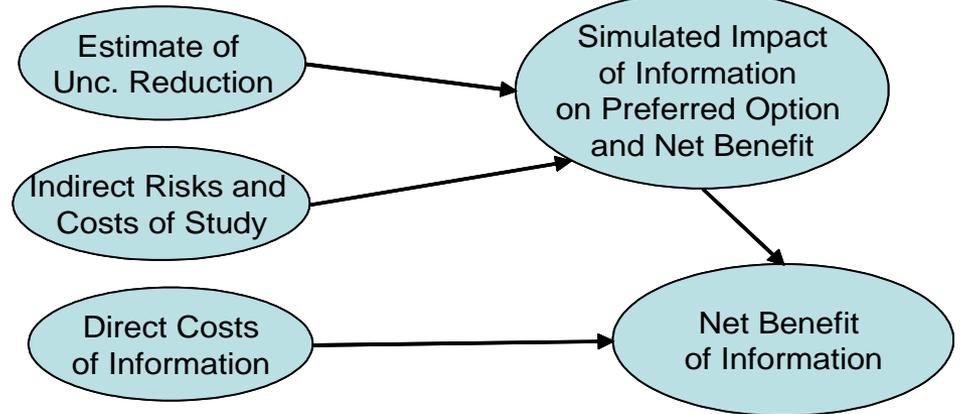
- **VOI  $\neq$  Interesting or Publishable**
- **VOI  $\neq$  Scientific Importance**
- **Important versus Informative**
  - *A 30-person telephone survey on use of consumer products*
  - *A two-generation primate reproductive study*

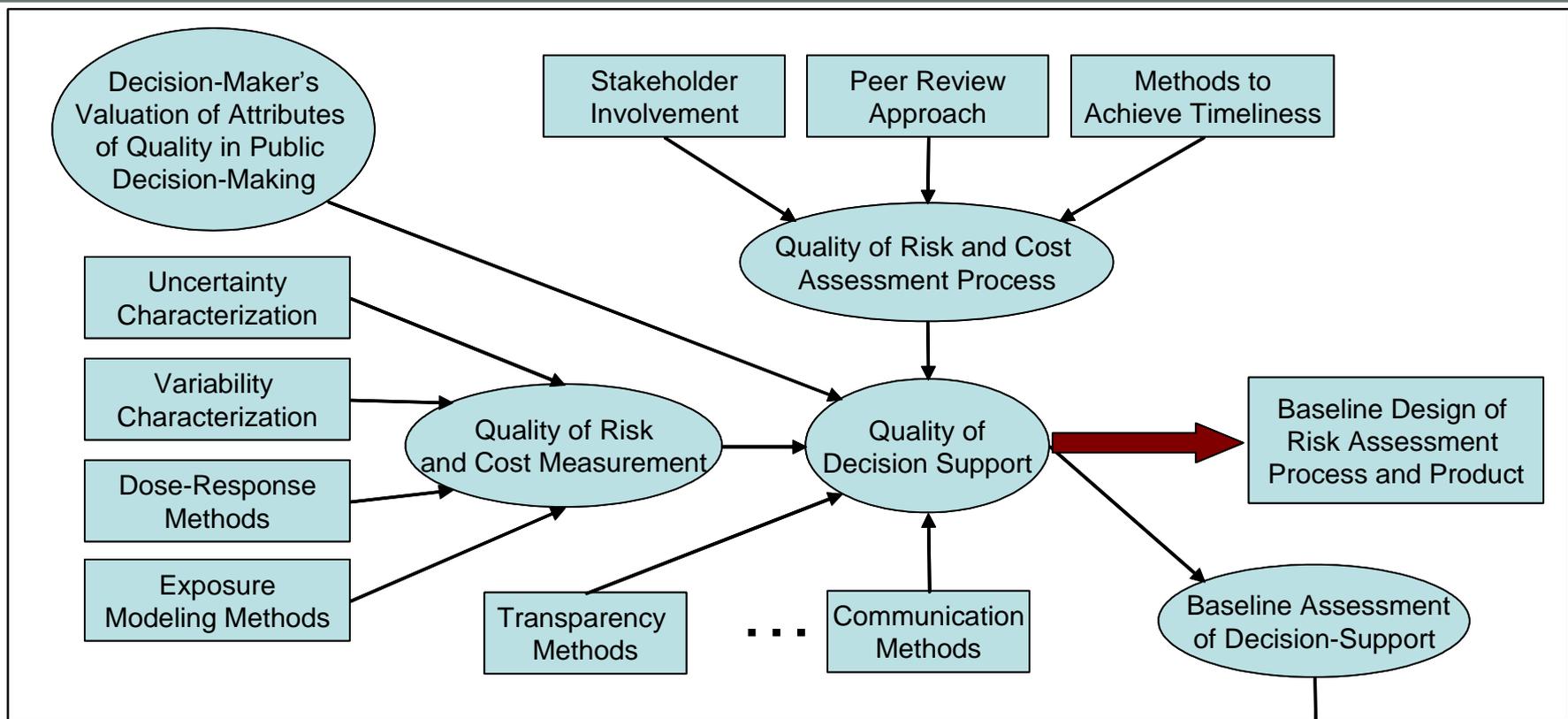


### Information Opportunities

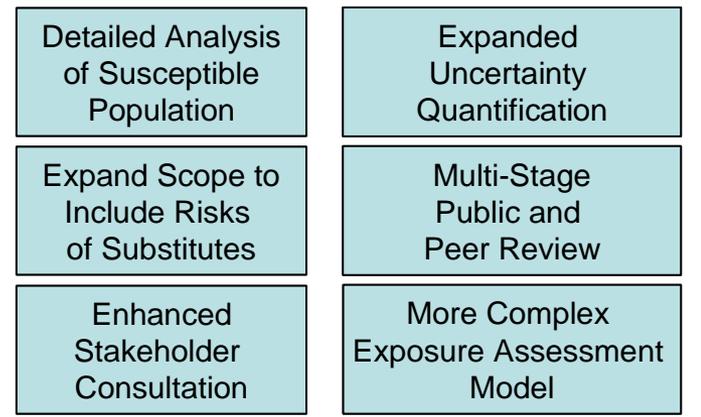


### Value-of-Information Analysis

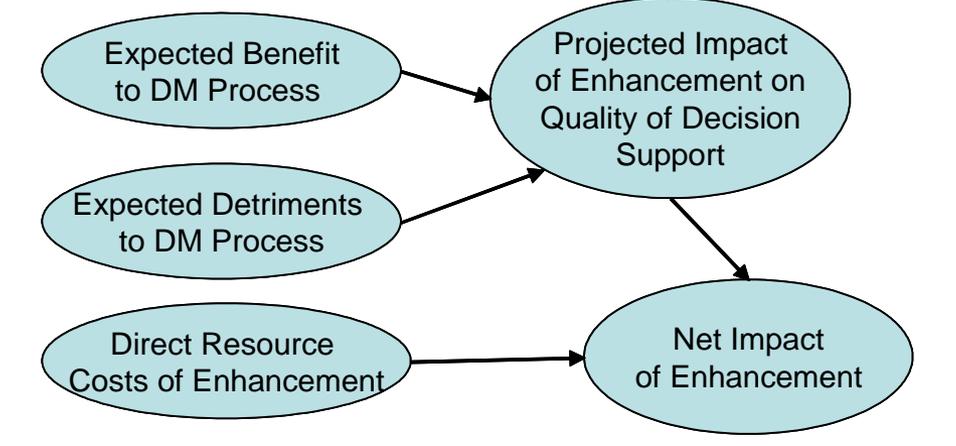




### Enhancement Opportunities



### Value-of-Methods Analysis



# 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



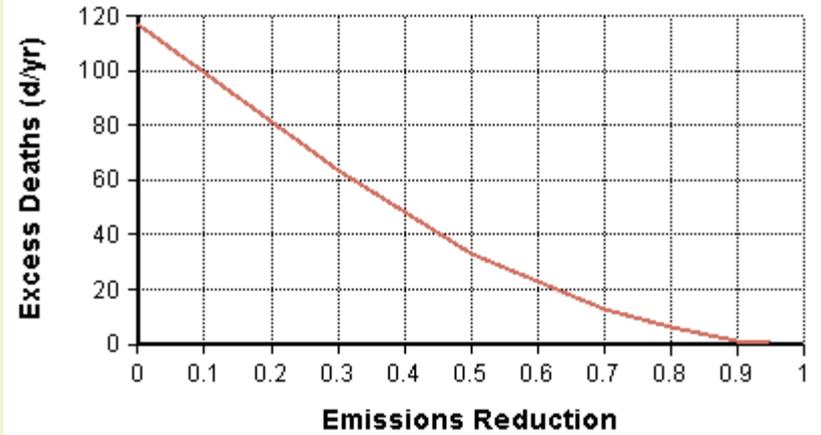
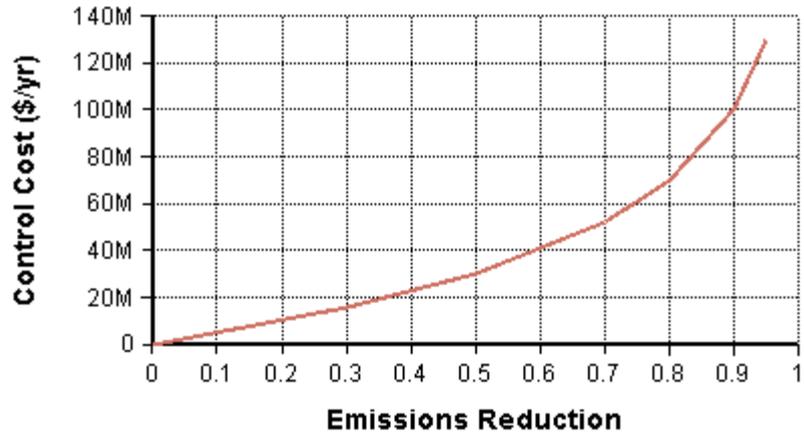
- **Silver Book Committee recommended adoption of informal VOI**
  - Requiring a clear causal link between a particular piece of information, the magnitude of uncertainty reduction, and the reason why the decision-maker is likely to make a better and different choice.
  - **The Goal: stopping criteria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

# A PROPOSED SOLUTION: MODEL-BASED REASONING

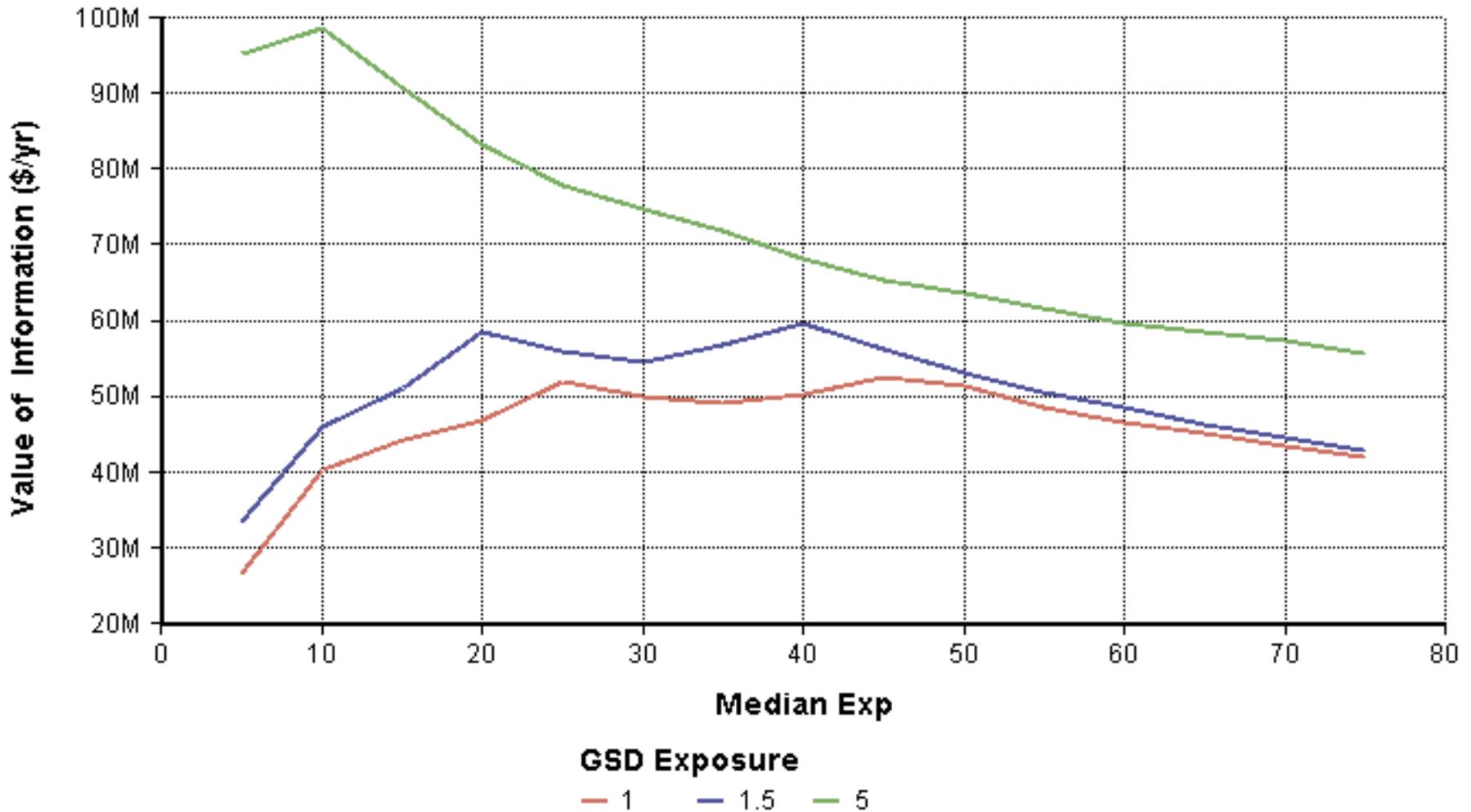


- **Construction of a class of Decision-Context Models which serve as a sandbox for exploring the value of information, the value of complex model components, and the impact on the (phantom) decision-maker.**
- **At the onset of a Risk Assessment**
  - *Choose the right decision context model*
  - *Tune 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**