A Decision Analytic Framework for Considering the Economic Value of Improved Risk Assessment Data

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Overview of Presentation

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- Objective: Explore the potential value of improved risk assessment data and methods in the context of environmental regulation
- Nature of the problem
- Analytical framework
- Examples –Regulatory Case Studies
    - Lead Regulation
    - Mobile source related air toxics requirements
- Implications for ARA Framework

Nature of the Problem – Evaluating Improvements in Risk Assessment

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- There are numerous sources of uncertainty in risk assessment that may be addressed (at least partially) by improved risk assessment methods and/or data:
  - Improving methods for evaluating the potential risks of chemicals – e.g., mode of action or other dose-response assessment methods.
  - Identifying susceptible populations and characterizing factors that may place them at higher risk.
  - Understanding how chemicals move and change along pathways from sources to potentially exposed populations.
- Advances in these areas seem of value, but are they likely to lead tangible changes in regulatory decisions that have quantifiable net benefits for society?

Value of Information Analysis

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- Value of information (VOI) represents the improvement in the expected value of a decision outcome that would result from collecting additional information about one or more factors affecting a decision.
- Decision analysis approaches can quantify the value of collecting additional information before making a specific decision, or the value of adopting improved methods of data analysis.
- Involves comparison of the expected outcomes of a suite of alternative regulatory choices made with and without information believed critical for the issue.

Why is VOI Important?

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- Can help decision-makers make better decisions
  - identifies key decision inputs
  - helps minimize expected loss / maximize expected gain
  - increases chances of good outcome
  - makes explicit the "costs" of uncertainty
- Results provide a measure of social willingness-to-pay for new research
- Helps set priorities so that resources can be allocated efficiently

Evaluations of VOI as a Tool

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- NRC's *Science and Decisions: Advancing Risk Assessment* (2009)
  - Discusses VOI as a tool for understanding the tradeoffs between timely decision-making and the desire to refine the underlying science
  - Barriers to applying formal VOI broadly
  - Underlying concepts and structure still valuable: linkages between information, decision-maker behavior, and decision making objectives
  - Recommends informal VOI or value of methods analyses to inform risk assessment design

Evaluations of VOI as a Tool (cont'd)

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- 2010 Report of EPA's Board of Scientific Counselors (BOSC) decision analysis workshop with ORD/NRMRL
  - VOI can be valuable, but is challenging to implement
    - Need extensive data, including probabilities for decision options & how probabilities change conditional on new information
  - Nonetheless, VOI cited as possible method to inform several case studies – e.g., regulations of chemicals with biomarker data, prioritizing IRIS evaluations
  - Benefits of VOI are the net improvements in decision outcomes minus the costs of obtaining improved information

VOI Analytic Framework

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- Decision analysis approaches can quantify the value of collecting additional information before making a specific decision
- Involves comparison of the expected outcomes of a suite of alternative regulatory choices made with and without information believed critical for the issue
- Framework in a regulatory context can be illustrated using two types of diagrams:
  - Influence diagram - showing the role of toxicity data and other inputs in estimating NSB
  - Decision tree – can depict a choice among (for example):
    - Taking no further regulatory action
    - Instituting additional control measures based on current information
    - Collecting additional dose-response information prior to deciding whether to institute new controls

VOI Framework

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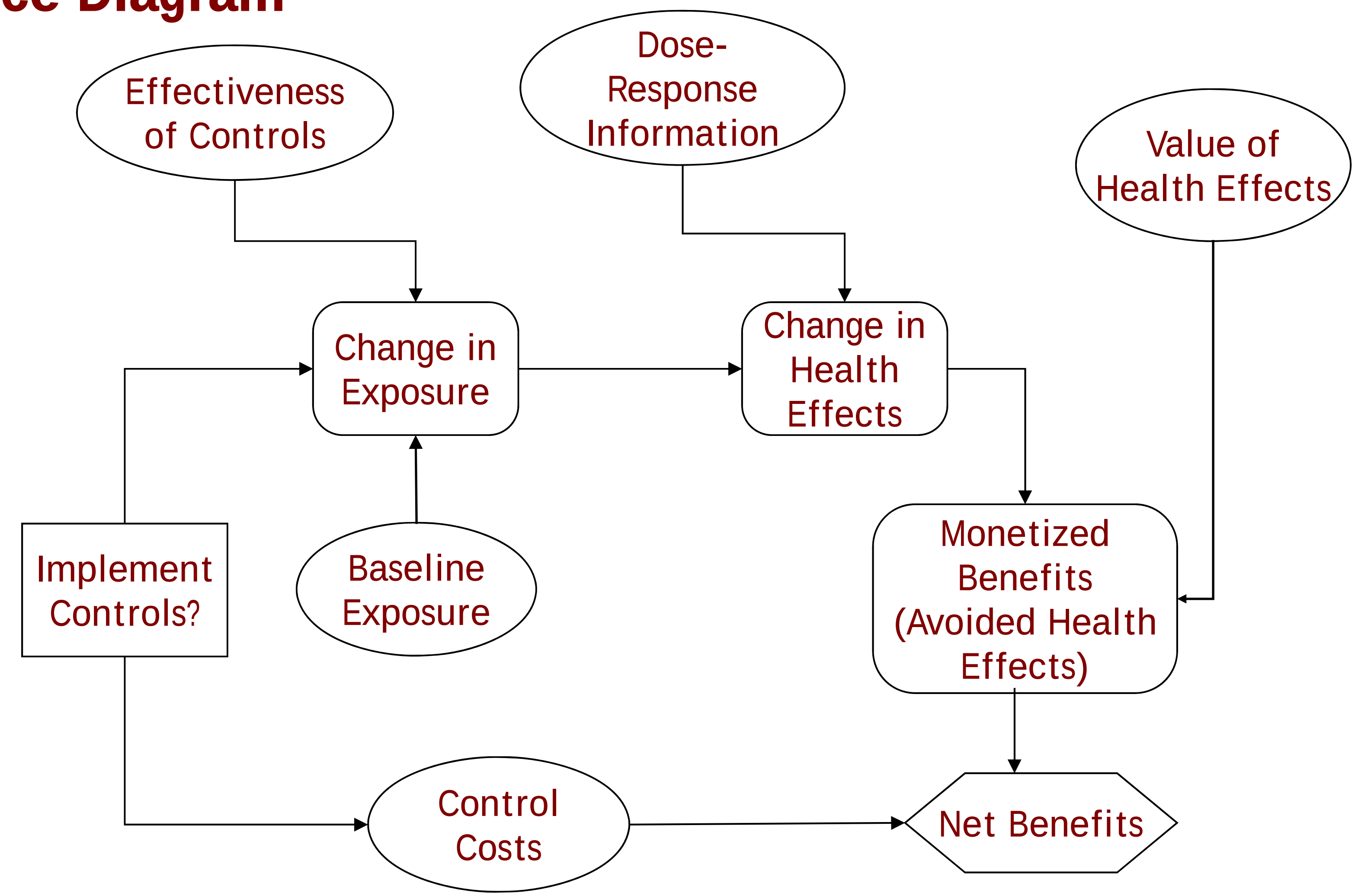
Influence Diagram



VOI Framework (continued)

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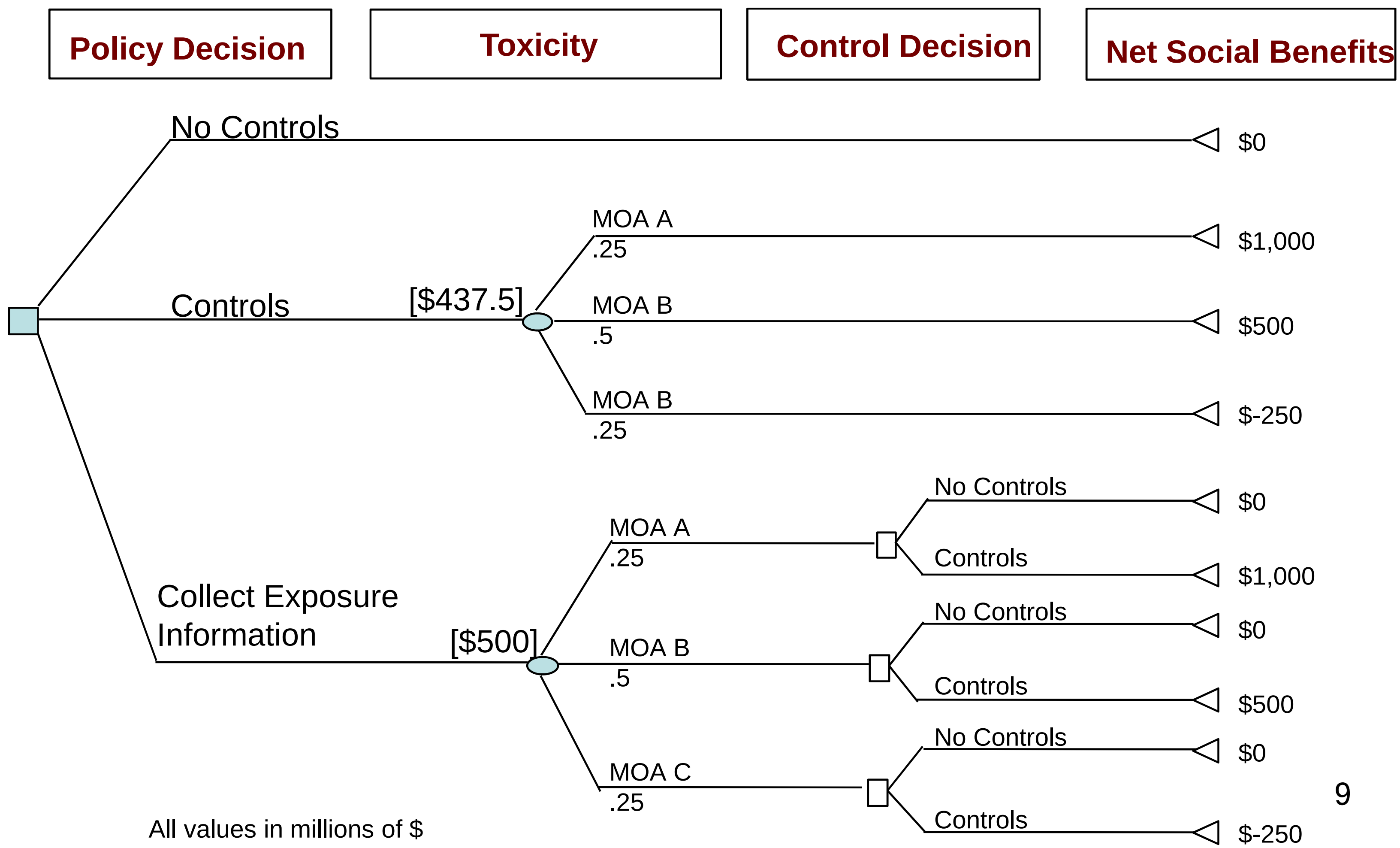
Hypothetical Decision Tree: VOI = $500 - $437.5 = $62.5



VOI Framework (continued)

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- Variations in complexity of analysis:
  - Value of perfect information -- assumes that collection of information will eliminate all uncertainty in exposure
  - Value of imperfect information -- examines the potential that addition of information will resolve some, but not all of the uncertainty in exposure
  - Value of partial information -- considers the impact of uncertainty in other inputs to the decision (e.g., for the previous hypothetical example - toxicity)

Lead Case Study - Background

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- Decision we analyzed (retrospectively): regulating lead in residences under TSCA Section 403
- Rule sets three standards: floor dust loading (µg/ft^2); window sill dust loading (µg/ft^2); and soil concentration (ppm). Violation triggers abatement
- Economic and risk analysis supporting the rule looked at 1000 combinations of these three standards
- Risk and economic estimates ultimately based on two alternative models for relationship between environmental lead and children's blood lead:
  - IEUBK: more sensitive, says regulate stringently
  - The "Empirical" model: much less sensitive, says do not regulate
- November 1998 proposed standards reflect EPA's balancing of these two exposure outcomes

VOI Case Study - Lead Exposure

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COMPARISON OF NET BENEFITS, DUST STANDARDS, AND SOIL STANDARDS FOR TWO LEAD UPTAKE MODELS		
	Standards that Maximize Net Benefits IEUBK Model	**Proposed Standards**
Floor Dust Standard Window Sill Dust Standard Soil Standard Total Cost Total Benefit Net Benefit	40 $\mu g/ft^2$ 100 $\mu g/ft^2$ 250 ppm \$100.4 billion \$273.6 billion ***\$173.2 billion***	50 $\mu g/ft^2$ 250 $\mu g/ft^2$ 2,000 ppm \$52.8 billion \$160.1 billion ***\$107.2 billion***
	Standards that Maximize Net Benefits Empirical Model	
Floor Dust Standard Window Sill Dust Standard Soil Standard Total Cost Total Benefit Net Benefit	80 $\mu g/ft^2$ 310 $\mu g/ft^2$ 4,350 ppm \$44.0 billion \$35.1 billion ***-\$8.9 billion***	

Lead Rule RIA Influence Diagram

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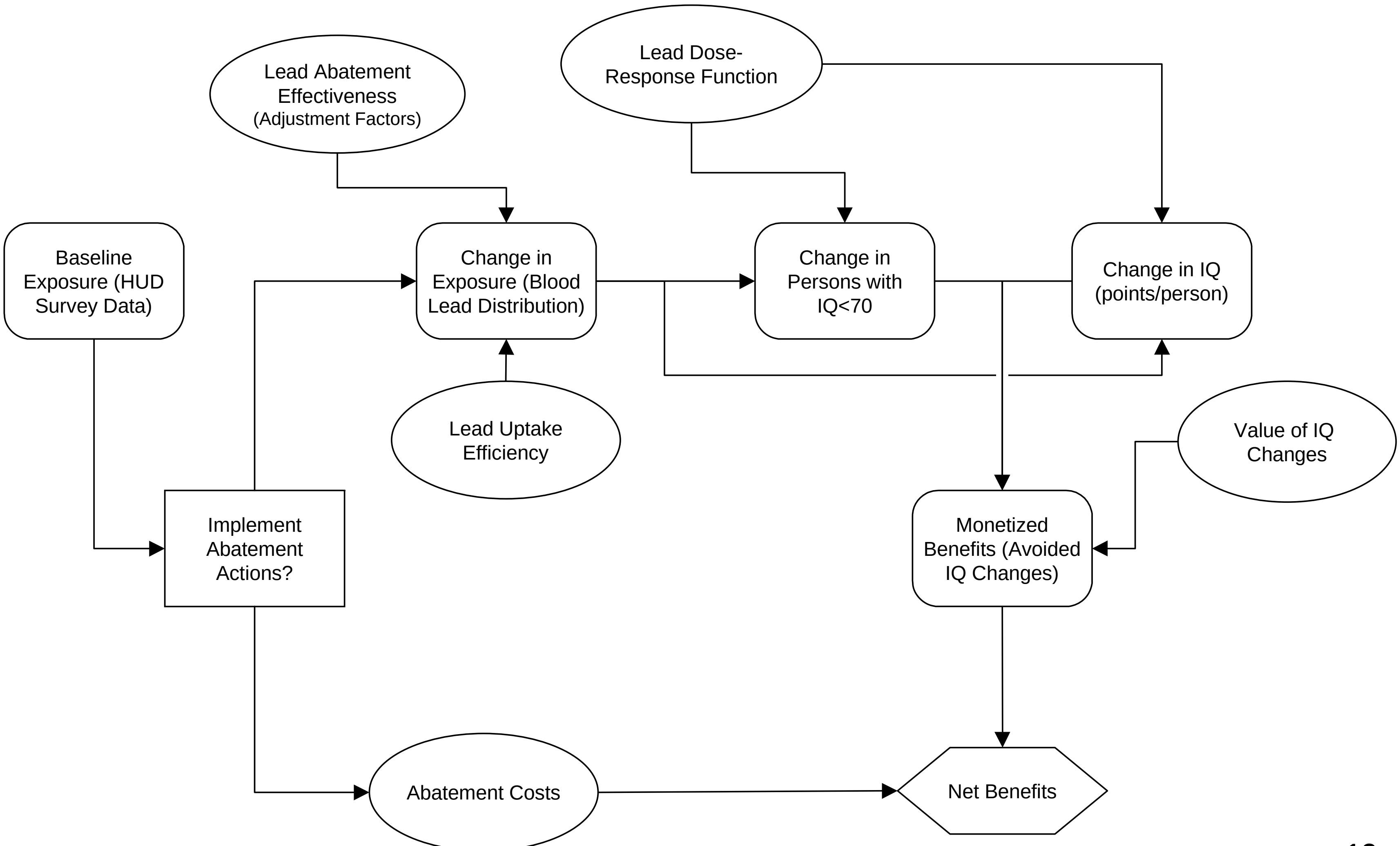

Decision Tree for Lead Regulatory Decision

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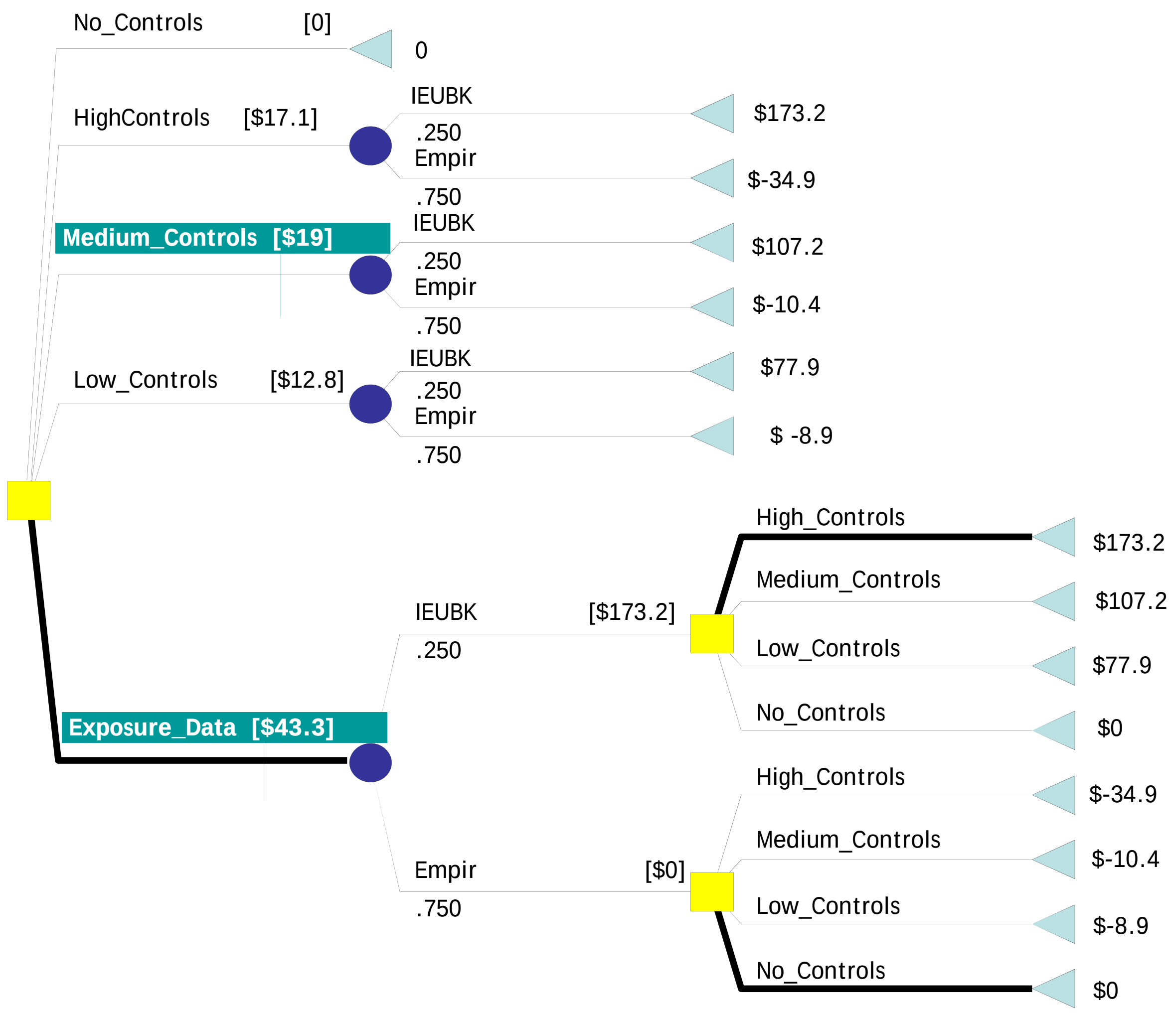
VOI = $43.3b - $19b = $24.3b



Effect of Delay on VOI

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- Delay scenarios assume:
  - Benefits are delayed if “collect exposure data” option is chosen.
  - Discounted over delay period at 3 percent annually.
- Results:
  - Perfect VOI, no delay: $24.3 billion
  - Perfect VOI, five-year delay: $18.4 billion
  - Perfect VOI, ten-year delay: $13.2 billion.

Value of Imperfect Information

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- Value of imperfect information analysis asks: What if improved data cannot completely resolve uptake uncertainty?
- Looked at best and worst case scenarios for power of NHEXAS-like data to resolve IEUBK/Empirical uncertainty (from 50 percent predictive accuracy to 90 percent predictive accuracy)
- Results show VOI remains substantial when improved data achieves a high level of predictive accuracy and the prior likelihood that IEUBK is correct is less than 50 percent

Expected Value of Imperfect Lead Exposure Information

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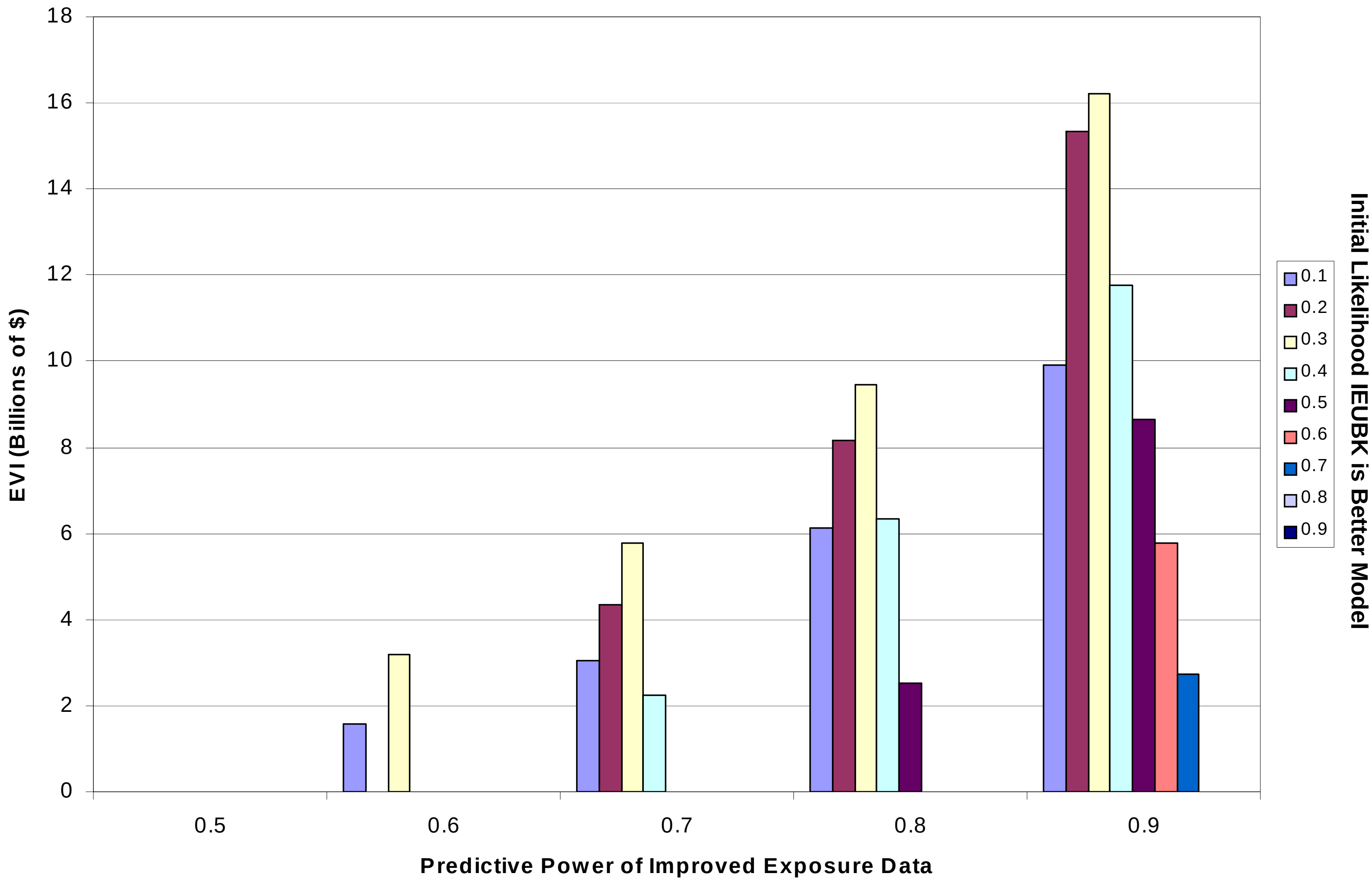

Conclusions of Lead Case Study

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- Value of exposure information could be very high; under best case conditions, a national exposure survey could have value in the tens of billions of dollars.
- Effect of delay in provision of information is to reduce VOI, but value of perfect information remains substantial even with 10-year delay.
- Improved exposure information must achieve a predictive accuracy of 80 to 90 percent certainty in forecasting the "correct" lead uptake model for VOI to remain substantial (e.g., no more than a 20 percent chance of predicting IEUBK if the empirical model is correct); lower levels of certainty quickly erode VOI.

VOI Case Study: Mobile Air Toxics

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- Retrospective analysis of VOI of exposure data for benzene and 1,3-butadiene, two air toxics regulated under the 1990 CAAA.
- Developed estimates of exposure and risk in 2000 both with and without control programs -- based on information available as rules were promulgated.
- Other inputs: control costs (over $2 billion annually); other benefits of air toxics reductions (about $850 million annually).
- Estimate value of improved information for mobile source air toxics relative to improvements in other key uncertain inputs (e.g., toxicity).

Mobile Source Air Toxics - Exposure Uncertainty

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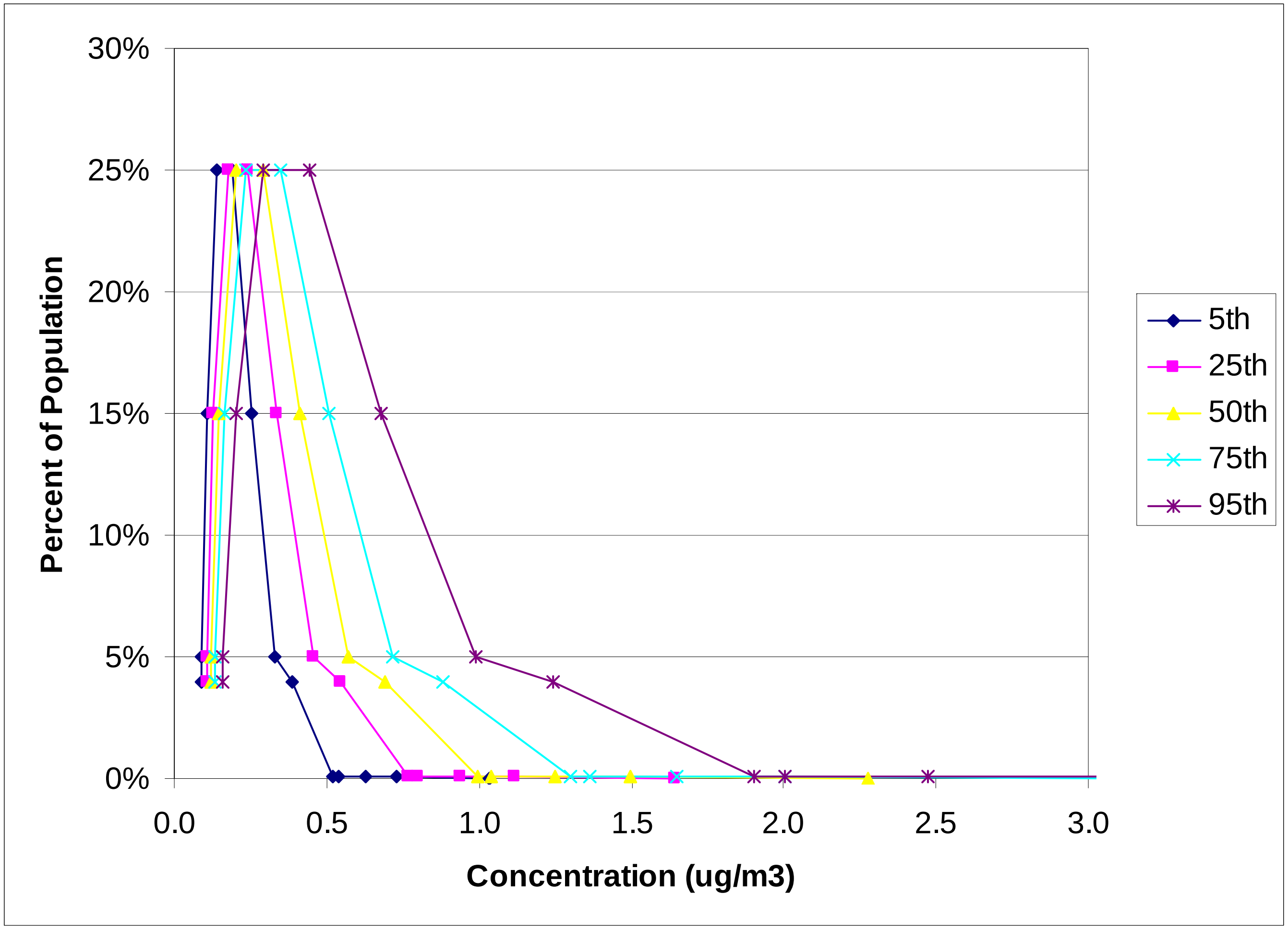
Alternative Exposure/Distributions for 1,3-Butadiene



Calculation of Net Social Benefits

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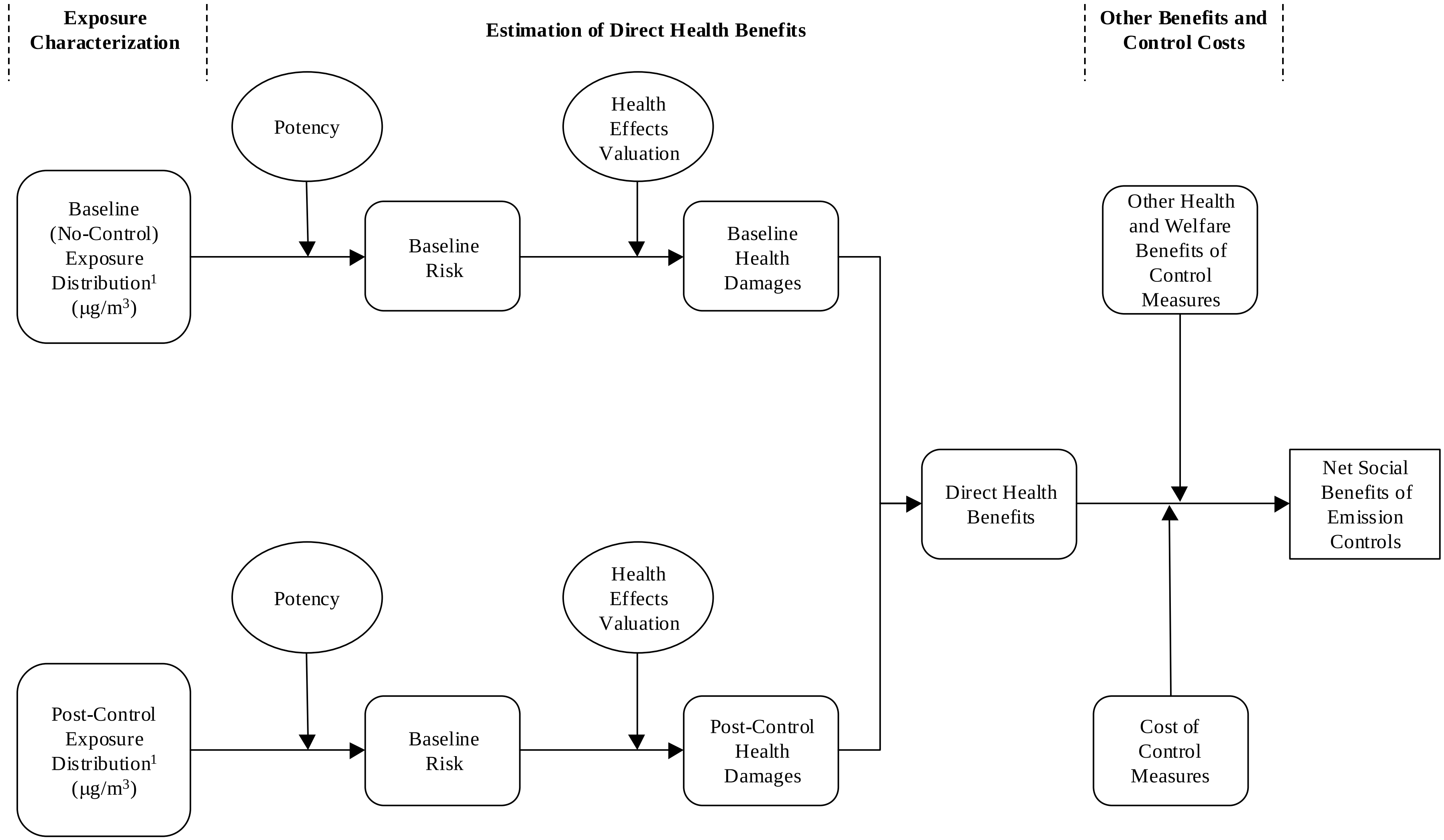
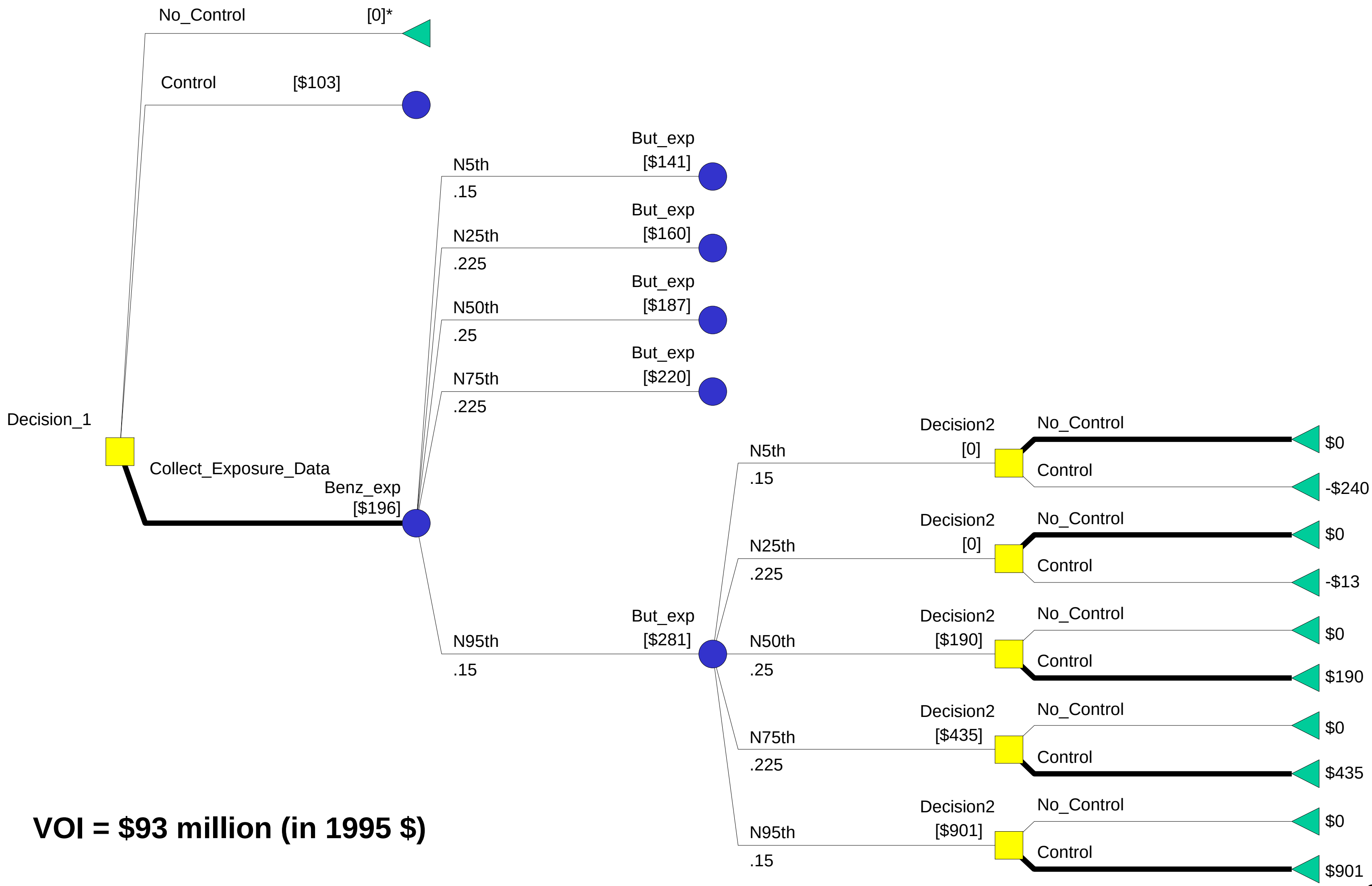


[1] This includes characterizing the uncertainty in the exposure description.

Decision Tree for Motor Vehicle Air Toxics IEc



VOI = $93 million (in 1995 $)

* Numbers in brackets are expected values of net social benefits at decision or chance nodes.

Conclusions of Mobile Sources Case Study

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- Expected value of perfect information = $93 million.
- Explored value of partial information by considering impact of uncertainty in toxicity of 1,3-butadiene and benzene.
  - Value of exposure information decreases to $9 million.
  - Value of toxicity information is greater, $118 million.
- Explored impact of varying dollar value of a statistical life (VSL).
  - Exposure information has value across a wide range of VSL (approximately $3 million to $7 million).

Applications / Requirements

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- VOI framework can be applied to variety of issues (pollutant regulation, global warming) and focus on different inputs (exposure, toxicity, economic valuation)
- A key constraint for formal quantitative VOI is data availability. Need data to:
  - estimate outcomes (ideally, net social benefits) in dollars
  - characterize quantitatively decision inputs (e.g., costs, population exposure, toxicity) *and how they change post-information*
  - quantify uncertainty either discretely or using distributions *pre- and post-information* -- may require expert elicitation

Identifying Decisions Where VOI May be High IEc

- High Stakes, sufficient variance in outcomes across choices
- Decision expected to be sensitive to health outcomes and not dictated by non health-related factors
- Uncertainty can be represented using small number of scenarios (e.g., alternative MOAs) and associated probabilities
- Additional research (e.g., improved PBPK modeling, interpretation of biomarker data, MOA research) can change beliefs about likelihoods of key decision factor values/states
- Uncertainty in other decision inputs does not dominate uncertainty in input for which information is collected

VOI and the ARA Framework

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- Potential approaches for a case study in the context of the ARA Framework
  - Full quantitative VOI
    - Can be challenging and resource intensive
    - Best reserved for quantitative, in-depth assessments for decisions with substantial impacts
  - Informal, qualitative VOI (as discussed in Science & Decisions)
    - Must establish causal link between research/methods and reduced uncertainty in toxicity AND link between reduced uncertainty and decision-maker's choice
    - Explore how to operationalize this for qualitative assessments or quantitative screening assessments
  - Are there existing case studies that can serve as foundation for a VOI analysis

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