



Challenges in Risk-Based Approaches to Nutrition Policy

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Nutritional Risk Assessment: Bridging Perspectives, Sharing Methodologies, Identifying Data Challenges



Outline

- ◆ Risk Assessment: Why Bother?
- ◆ Defining 'Risk-Based'
 - ◆ Risk Assessment and Safety Assessment
- ◆ Valuation Models for Multiple Outcomes
- ◆ Maturation of Risk Communication



Practical Rationale for Formal Risk Assessment

- ◆ Management of Overwhelming Complexity
 - ◆ Probability Calculations quickly overwhelm the human brain
 - ◆ Multi-hazard, Multi-pathway, Multi-agent
 - ◆ Multi-outcome, cascading events
- ◆ Links to the Appropriate Toolboxes:
 - ◆ Probability provides multidisciplinary language
 - ◆ Decision Sciences
 - ◆ Risk and Reliability Sciences



Public Policy Rationale for Formal Risk Assessment

- ◆ Rationality
- ◆ Meeting the Reasonableness Test
- ◆ Accountability



Risk Assessment Essentials

- ◆ Evidence is processed in order to generate statements of probability of individual events which are combined to determine the probability of an adverse outcome of interest.
- ◆ The primary value-added feature is in the inference of the probability of adverse outcomes by appropriately combining a formal representation of the risk generating system with the rules of inferring probability.



Safety-Based Standard-Setting

- ◆ No estimate of the probability of harm
 - ◆ No Exposure Assessment
 - ◆ Can't use it to predict risk even if exposure assessment were completed

- ◆ Final number includes:
 - ◆ Uncertainty
 - ◆ Variability
 - ◆ Uncertainty about Variability
 - ◆ Value Judgements

- ◆ Can be an adequate Risk Management tool
 - ◆ But it's not risk assessment



The Essence of 'Risk-Based'

- ◆ Decisions are based on explicit knowledge and description of full risk-generating system (hazards, pathways, outcomes)
- ◆ Measured on dimensions of likelihood and magnitude of consequences
- ◆ Decisions are made and optimised based on their capacity to REDUCE risk at reasonable cost



Top Down vs. Bottom Up

- ◆ Top Down Risk Assessment is based on surveillance and attributing risk to causes after the fact.
- ◆ Bottom Up Risk Assessment is based on predictive models of risk including prediction of the impact of system changes, before the fact.



Top Down vs. Bottom Up

- ◆ Fundamentally, 'risk-based' is bottom-up.
- ◆ Top-Down complements bottom-up by providing validation and system feedback.
- ◆ Ideally, decisions are made at the 'sweet-spot' between top-down observations and bottom-up predictions.



Risk Assessment

- ◆ Hazard Identification
 - ◆ What can go wrong?
 - ◆ What makes the entire system safer or less safe?
- ◆ Exposure Analysis
 - ◆ How likely are events that can lead to adverse events?
 - ◆ What is the combined likelihood of the adverse events?
- ◆ Exposure-Consequence Analysis
 - ◆ What are the consequences of adverse events?
 - ◆ How does the risk manager value them?

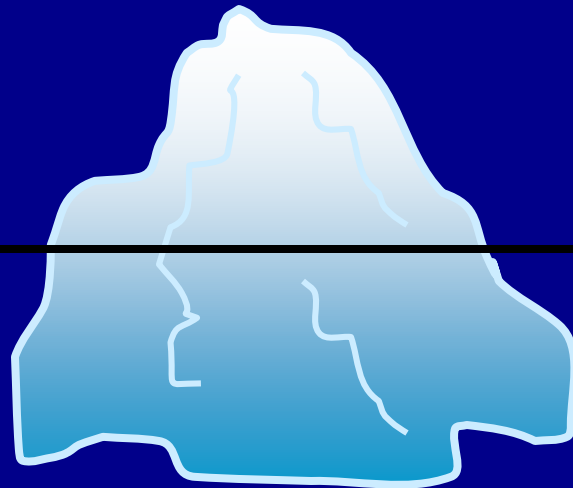


Measuring Foodborne Risks



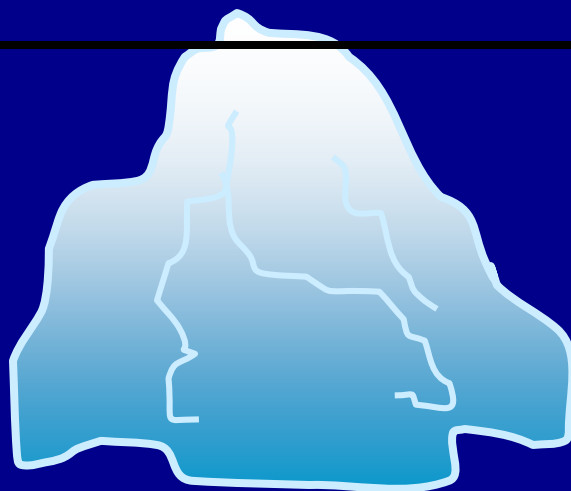


Microbial



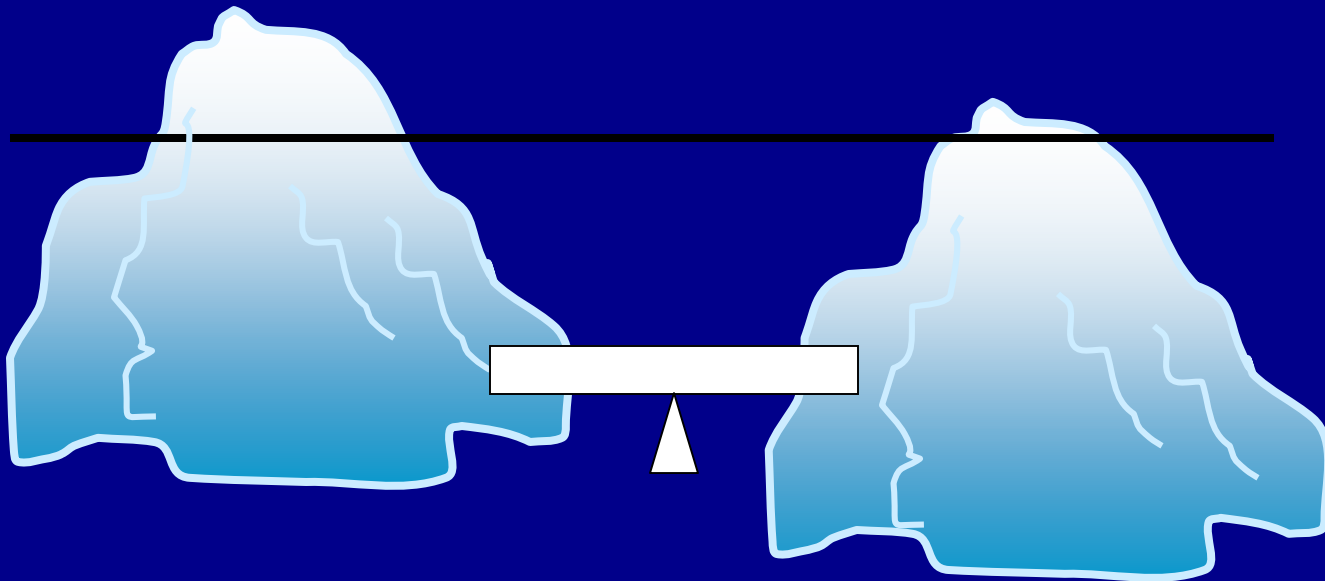


Chemical





Nutritional





Moving Toward Risk-Informed





Reactive Model

Observable

Reactive

Near-Miss Zone

Unobservable

Predictive





Improvement ...

Observable

Reactive

Near-Miss Zone

Unobservable



Predictive



Risk-Informed Steady-State

Observable

Reactive

Near-Miss Zone

Unobservable

Predictive





Disability Adjusted Life-Years (DALY)



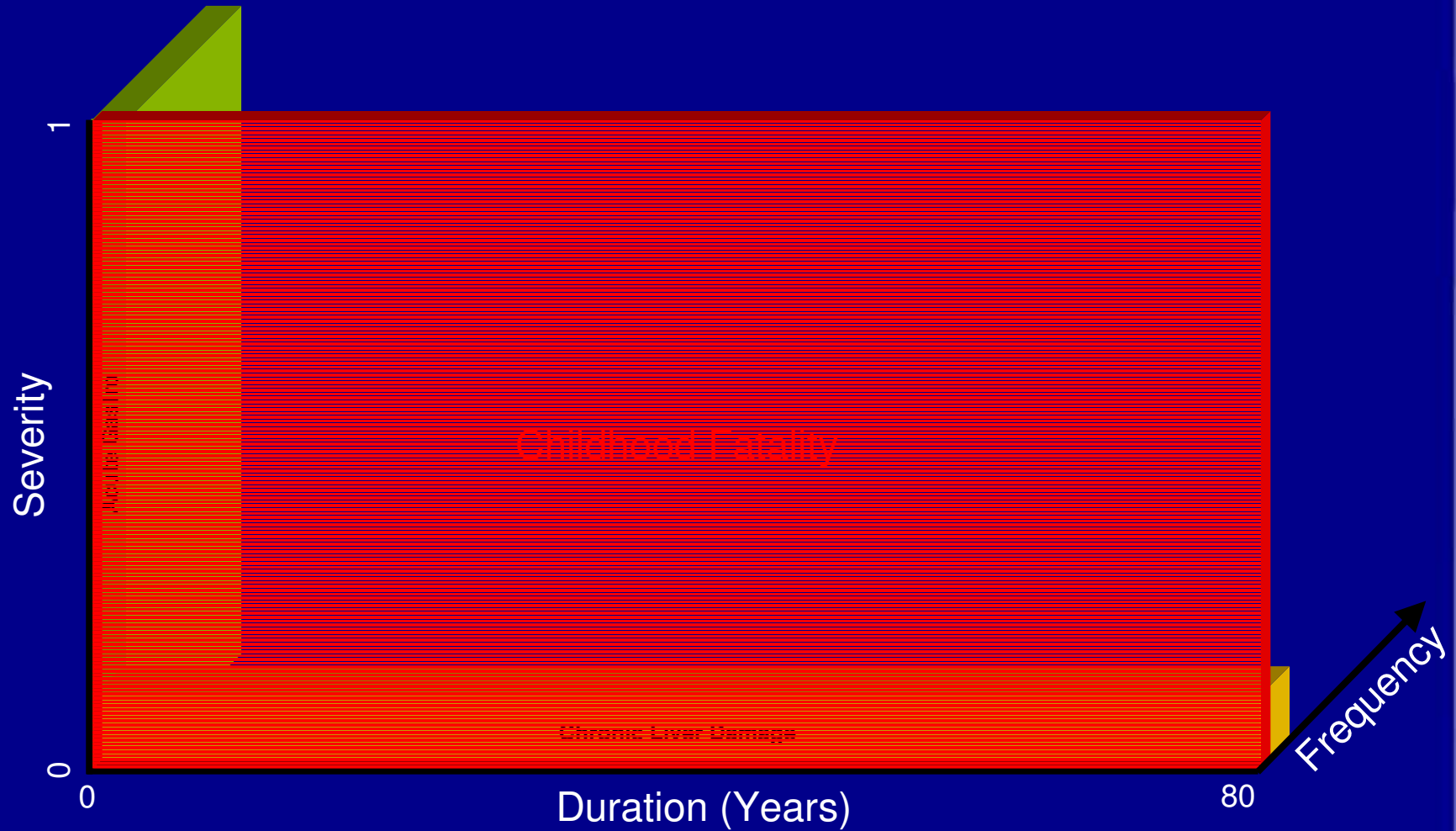


Burden of Disease Metric

- ◆ Translates a spectrum of outcomes into a single abstract measure of burden
- ◆ Inevitably it imposes a societal valuation of states of health
- ◆ Many strong ethical and valuation assumptions will be embedded.



Incorporating Frequency





Pseudo-DALYs

- ◆ Broad categories of health impacts reduce the characterization burden while providing common metric
- ◆ Each combination assigned a pseudo-DALY value

Categories	
Duration	Impact
Short-term (2D)	Mild (0.01)
Medium-duration (30D)	Moderate (0.05)
Long-term (20Y)	Severe (0.3)



Duration

Long-term, mild impact (0.2)	Long-term, moderate impact (1)	Long-term, severe impact (6)
Medium-duration, mild impact (8E-04)	Medium-Duration, moderate impact (4E-03)	Medium-duration, severe impact (2E-02)
Short-term, mild impact (5E-05)	Short-term, moderate impact (3E-04)	Short-term, severe impact (2E-03)

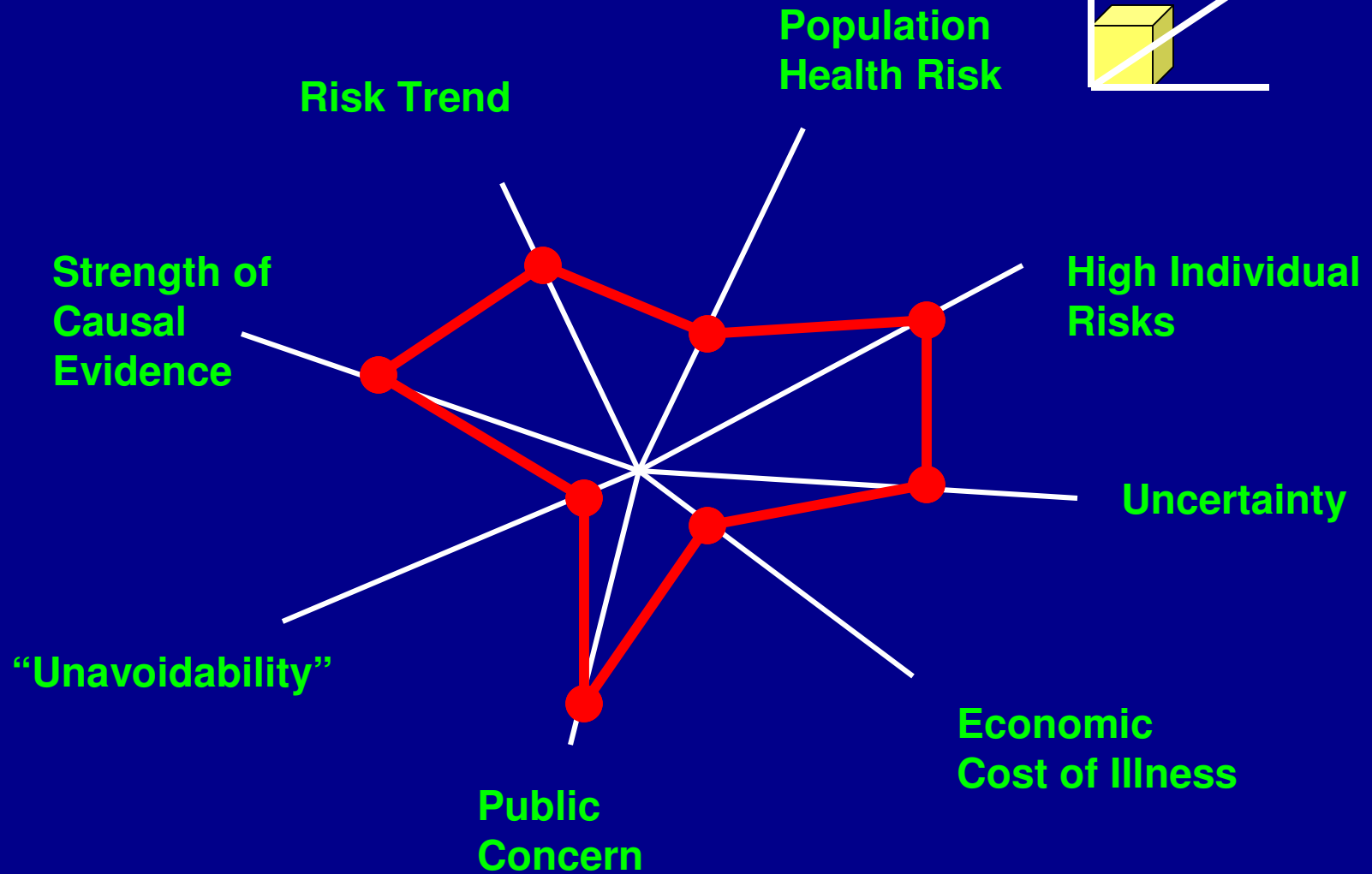
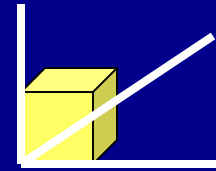
Impact

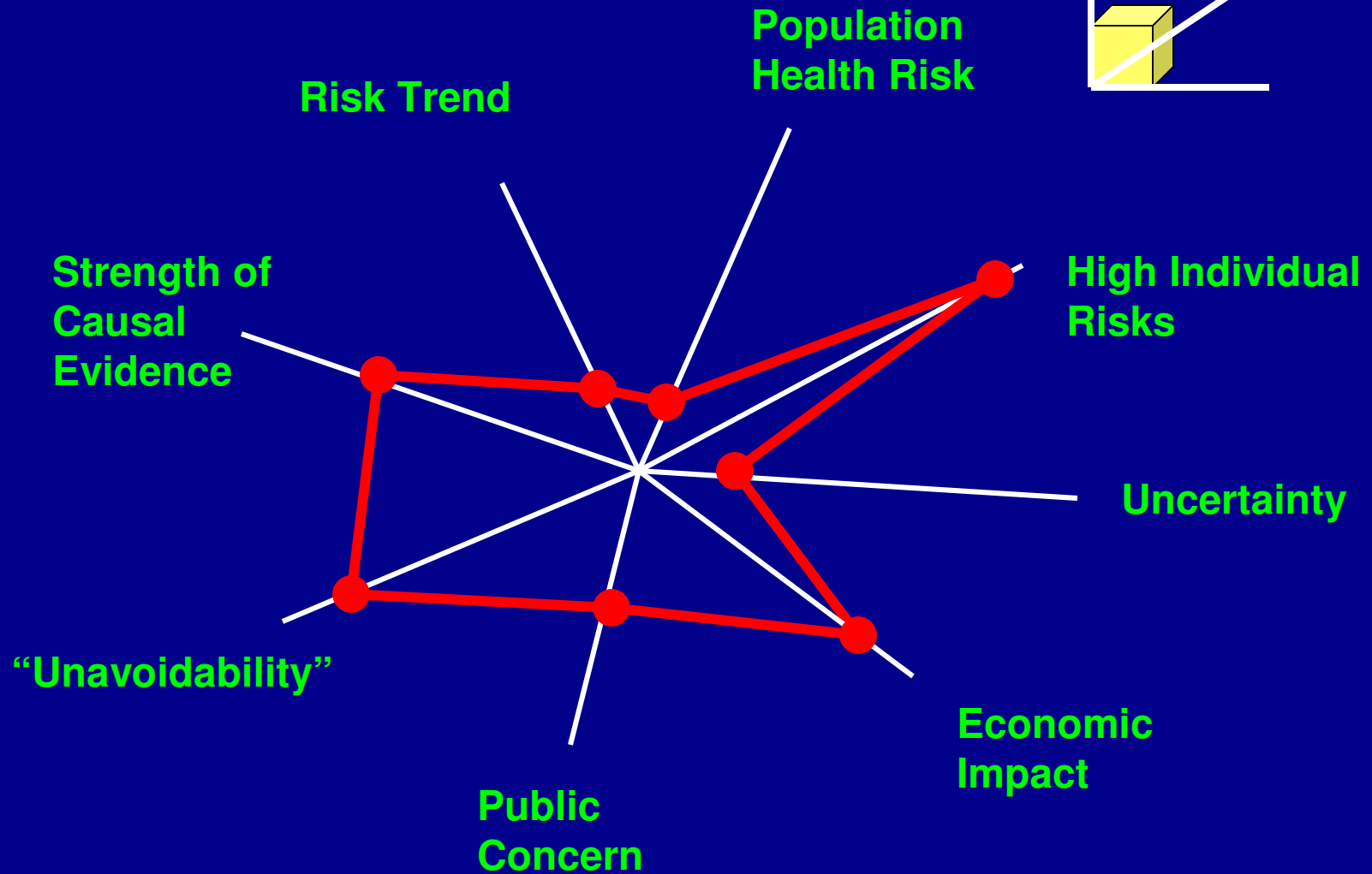
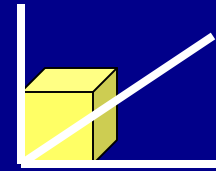


Pseudo-DALYs

- ◆ Determine pDALY for hazard by combining appropriate health impacts (per exposure or per year)

Health Impact	pDALY/case	Cases/yr	Annual pDALY
short-term, mild	5E-05	1000	0.05
short-term, moderate	3E-04	100	0.03
long-term, severe	6E-00	10	60
Total Annual pDALY:			60.08







Risk Communication

- ◆ A Drug Analogy
- ◆ When risk mitigation is actually achieved primarily through communication products, we need to extend the risk assessment paradigm to include an estimate of risk reduction via risk communication.



Summary of Risk Assessment

- ◆ 'Reasonableness' is a complex combination of Evidentiary, Managerial, and Obligatory aspects of decision-making processes.
 - ◆ Risk Assessment provides a structure for meeting these requirements in a defensible way.
- ◆ Opens up a large Multi-disciplinary Toolkit for analysis, decision-making and knowledge encapsulation