Risk Assessment & Risk Management

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JOHNS HOPKINS BLOOMBERG SCHOOL OF PUBLIC HEALTH
Risk and Risk Management

\[
\text{Risk} = \text{Likelihood} \times \text{Impact}
\]

\[
\text{Inherent Risk} - \text{Managed Risk} = \text{Residual Risk}
\]
Risk-Based Decision Making

**PHASE I: PROBLEM FORMULATION AND SCOPING**

- What problems 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 effect in the range of doses identified in the exposure assessment?

- **Risk Characterization**
  - What is the nature and magnitude of risk associated with existing conditions?
  - To what extent do risks vary as a result of uncertainties 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?

**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?

**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 option?
- 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.
Steps of Risk Assessment

1. Hazard Identification
2. Dose-Response Assessment
3. Exposure Assessment
4. Risk Characterization

Stage 2: Risk Assessment

- **Hazard Identification**
  - What adverse health or environmental effects are associated with the agents of concern?

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  - For each determining adverse effect, what is the relationship between dose and the probability of the occurrence of the adverse effect in the range of doses identified in the exposure assessment?

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- **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?
Hazard Identification

Evaluation of the scientific literature (human and animal studies) that informs whether an agent poses a health risk (hazard) and under what settings.

- Incorporates uncertainty
- Identifies extrapolation
  - Animal to human
  - One setting to another
**LD\textsubscript{50}**

LD\textsubscript{50} is the dose of a toxic agent required to kill 50% of the population (i.e. the more sensitive half).

<table>
<thead>
<tr>
<th>Agent</th>
<th>LD\textsubscript{50} (mg/kg)</th>
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<tbody>
<tr>
<td>Sucrose</td>
<td>30,000</td>
</tr>
<tr>
<td>Ethanol</td>
<td>10,000</td>
</tr>
<tr>
<td>Aspirin</td>
<td>1,000</td>
</tr>
<tr>
<td>Phenobarbital</td>
<td>150</td>
</tr>
<tr>
<td>Caffeine</td>
<td>192</td>
</tr>
<tr>
<td>DDT</td>
<td>113</td>
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<tr>
<td>Strychnine</td>
<td>16</td>
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<tr>
<td>Sodium cyanide</td>
<td>6</td>
</tr>
<tr>
<td>Nicotine</td>
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</tr>
<tr>
<td>Tetrodotoxin</td>
<td>0.1</td>
</tr>
<tr>
<td>Dioxin</td>
<td>0.001</td>
</tr>
<tr>
<td>Botulism toxin</td>
<td>0.000001</td>
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</tbody>
</table>
Sources of data on hazards

• Human studies
  • Case reports
  • Epidemiologic studies
• Animal studies (in vivo studies)
  • Toxicity studies
  • Animal models
• In vitro studies
  • Cell culture
  • Model systems
Limitations of animal studies

- Animal-to-human extrapolation (biology not always the same)
- Route of administration (e.g. intratracheal v. inhaled)
- Dose selection
- Study duration
- Timing of study relative to life stage
- Sex (e.g. studies with only male rodents)
  - Use of both sexes requires better segregation of male and female animals
- Health endpoints of interest
Alternatives to Animal Testing

The three “Rs” —

- **Reduction**: improvements in experimental design to limit the number of animals required
- **Refinement**: use of organisms at a lower phylogenetic level or improvements to protocols to limit pain
- **Replacement**: substitution of animal use via *in vitro* or other methods that do not require living host

The “fourth R”

**Reproducibility**: ability to identify the same results given repetition of an experiment (by the same or a different individual)
Dose-Response Assessment

The process of quantifying a dose and evaluating its relation to the risk or magnitude of adverse health effects.
Cancer Endpoints

Regulate to an “acceptable” level of risk, typically 1 in a million.
Non-Cancer Endpoints

Assumes a threshold or safe dose, so regulate to zero risk.

\[ RfD = \frac{NOAEL}{UFs} \]

LOAEL: lowest observable adverse effects level (lowest tested dose that produced an effect)
NOAEL: no observable adverse effects level (highest tested dose that did NOT produce effect)
Estimation of “safe” level

\[
\frac{\text{NOAEL or LOAEL}}{\text{Uncertainty Factors}} = \text{“Safe Level”}
\]

Uncertainty factors:
10 for human variability
10 for extrapolation from animal studies to humans
10 for use of less than chronic data
10 for use of LOAEL instead of NOAEL
Exposure Assessment

The quantitative or qualitative assessment or estimation of the magnitude, duration, and route of human exposure.

Exposure = Intensity \times Frequency \times Duration
Steps of Risk Assessment

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Risk Characterization

An integration and summary of hazard identification, dose-response assessment, and exposure assessment.

- Focus on assumptions and uncertainties.

<table>
<thead>
<tr>
<th>Risk Assessment Uncertainties</th>
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<tbody>
<tr>
<td>Hazard Identification</td>
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<tr>
<td>Dose-Response Assessment</td>
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<td>Risk Characterization</td>
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**Phase III of Risk Assessment**

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Risk Management

Interventions (e.g. government or company policy) to reduce risk:

• Reduce exposure
  – Engineering controls (ventilation)
  – Administrative controls (limit contact with agent)
  – Substitution (use a less hazardous agent)
  – Personal protective equipment (PPE)

• Promote healthy behaviors and access to healthcare
  • Health education
  • Improve access to health-related services
Risk Communication

Interactive process of exchange of information and opinion among individuals, groups, and institutions.

- Messages about risk
- Messages about legal and institutional arrangements related to risk
- Messages expressing concern or opinion
Steps of Risk Communication

1. Establish message
2. Define audience
3. Select venue (e.g. radio, TV, social media)
4. Frame the message
5. Market the message (i.e. maximize “reach”)
6. Evaluate the impact
 Perception and risk

Adapted from Paul Slovic, *Science* 1987

- Controllable
  - Limited harm
  - Not global in threat
  - Non-fatal
  - Individual harm
  - Low risk to future generations
  - Easily reduced
  - Voluntary

- Uncontrollable
  - Great harm
  - Global in threat
  - Fatal
  - Catastrophic harm
  - High risk to future generations
  - Not easily reduced
  - Involuntary

- Not observable
  - Unknown to those exposed
  - Delayed effect
  - New or unknown risk

- Observable
  - Known exposure
  - Immediate effect
  - Well-characterized, known risk

- More Acceptable
- Less Acceptable
Risk perception and policy

• Public perception and interventions to reduce risk
  • **Underprotection**: perceived risk and policy interventions do not provide adequate protection from risk
  • **Overprotection**: perceived risk and policy interventions are disproportionate to the level of risk
• Importance of economic, political and social considerations to interventions to reduce risk and public perception
Interested in the Risk Sciences?

Risk Sciences and Public Policy

OVERVIEW

Risk professionals are under increased pressure to interpret complex environmental and health situations in creative ways. The certificate program provides multidisciplinary education designed to increase awareness of the scientific underpinnings of risk assessment and provide a bridge between science and policy that allows innovative public health solutions to complex problems. Risk assessment methods are applied to address a wide range of environmental and public health issues including chemical, microbiological, radiological exposures, natural and man-made disasters, and to evaluate new technologies. Risk assessors are employed in academic, governmental and non-governmental organizations across multiple sectors such as agriculture, energy, environmental protection, armed forces, public health, and transportation.

• Certificate program
• Coursework