Reference Materials for Risk Assessment and Communication Module

Video RA-1 Reference Materials
Human Health Risk Assessment - Toxicology Education Foundation

Video RA-2 Reference Materials
Risk Assessment | US EPA

Risk Analysis, Assessment, Communication, Evaluation, and Management | Risk (cdc.gov)

Chapter 2: Public Health Assessment Overview | PHA Guidance Manual | ATSDR (cdc.gov)

Risk Assessment | Ready.gov

Risk Assessment in the Federal Government: Managing the Process | The National Academies Press (nap.edu)

Science and Decisions: Advancing Risk Assessment | The National Academies Press (nap.edu)

Video RA-3 Reference Materials
Risk Assessment | US EPA

Risk Assessment in the Federal Government: Managing the Process | The National Academies Press (nap.edu)

Science and Decisions: Advancing Risk Assessment | The National Academies Press (nap.edu)

Video RA-4 Reference Materials
Chapter 2: Public Health Assessment Overview | PHA Guidance Manual | ATSDR (cdc.gov)

Public Assessments & Health Consultations | ATSDR (cdc.gov)

Risk Analysis, Assessment, Communication, Evaluation, and Management | Risk (cdc.gov)

Risk Assessment | Ready.gov

Risk Assessment in the Federal Government: Managing the Process | The National Academies Press (nap.edu)

Science and Decisions: Advancing Risk Assessment | The National Academies Press (nap.edu)

Video RA-5 Reference Materials
Science Policy Council Handbook on Risk Characterization (epa.gov)

Risk Assessment: Guidance for Superfund Volume 1 Human Health Evaluation Manual (Part A) (epa.gov) – See Chapter 8 for Risk Calculations. Long document, but an excellent resource for EPA risk assessments.

Video RA-6 Reference Material

Risk Management | US EPA

Risk Communication | US EPA

Risk Analysis, Assessment, Communication, Evaluation, and Management | Risk (cdc.gov)

Additional useful materials

Bonano, EJ, GE Apostolakis, PF Salter, A Ghassemi, and S Jennings (2000), 'Application of risk assessment and decision analysis to the evaluation, ranking and selection of environmental remediation alternatives', *Journal of Hazardous Materials*, 71 (1-3), 35-57.

Lee, Jung Dae, Joo Young Lee, Seung Jun Kwack, Chan Young Shin, Hyun-Jun Jang, Hyang Yeon Kim, Min Kook Kim, Dong-Wan Seo, Byung-Mu Lee, and Kyu-Bong Kim (2019), 'Risk Assessment of Triclosan, a Cosmetic Preservative', *Toxicological Research*, 35 (2), 137-54.

White, Avian V., David W. Wambui, and Lok R. Pokhrel (2021), 'Risk assessment of inhaled diacetyl from electronic cigarette use among teens and adults', *Science of The Total Environment*, 772 145486.

Corburn, J (2002), 'Environmental justice, local knowledge, and risk: the discourse of a community-based cumulative exposure assessment.', *Environ Manage*, 29 (4), 451-66.

Ashford, Nicholas A (2007), 'The legacy of the Precautionary Principle in US law: the rise of cost benefit analysis and risk assessment as undermining factors in health, safety and environmental protection',

Patterson, Jacqueline, PJ Bert Hakkinen, and Andrea E Wullenweber (2002), 'Human health risk assessment: selected Internet and World Wide Web resources', *Toxicology*, 173 (1-2), 123-43.

Robson M. and Toscano W. 2007. Risk assessment for Environmental health. Wiley ISBN: 9780787983192.

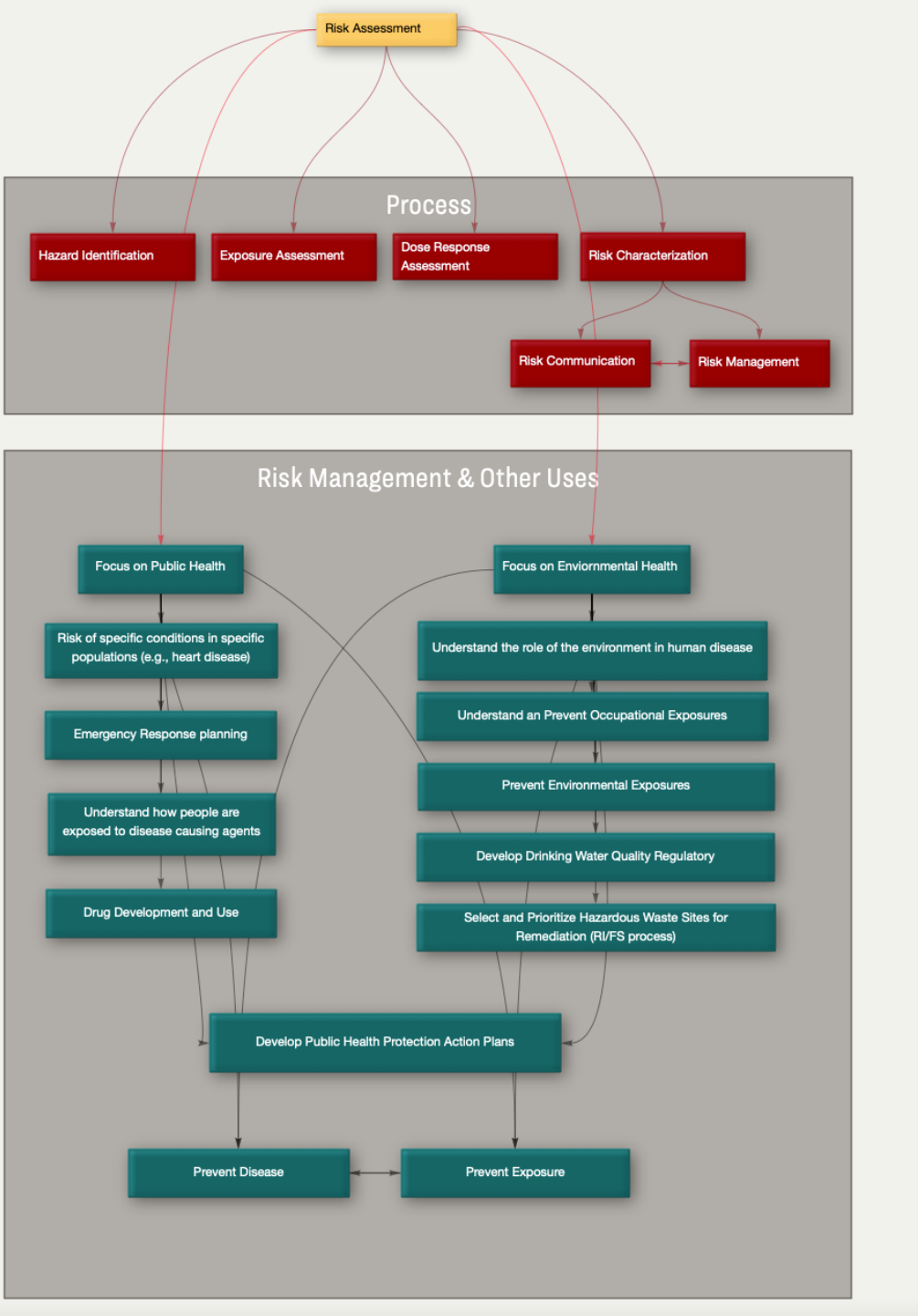
Public Health Assessment & Risk Assessment Frameworks

Outline

- Describe the origins of risk assessment in public and environmental health
- Describe the Risk Assessment Process
- Describe the Health Assessment Process

National Research Council of the National Academy of Sciences Framework

- In 1983 the NAS published Risk Assessment in the Federal Government: Managing the Process | The National Academies Press (nap.edu)
  - Provided the basic framework of Hazard Identification, Exposure Assessment, Toxicity Assessment, Risk Characterization
- In 2009 the NAS published Science and Decisions: Advancing Risk Assessment | The National Academies Press (nap.edu)
  - Provided suggestions for improvement to the process
- ATSDR and the USEPA use these documents as guidance for the development and conduct of Public Health Assessments and Risk Assessment.


Risk Assessment
Process
Hazard Identification
Exposure Assessment
Dose Response Assessment
Risk Characterization
Risk Communication
Risk Management
Risk Management & Other Uses
Focus on Public Health
Focus on Enviornmental Health
Risk of specific conditions in specific populations (e.g., heart disease)
Understand the role of the environment in human disease
Emergency Response planning
Understand an Prevent Occupational Exposures
Prevent Environmental Exposures
Understand how people are exposed to disease causing agents
Develop Drinking Water Quality Regulatory
Drug Development and Use
Select and Prioritize Hazardous Waste Sites for Remediation (RI/FS process)
Develop Public Health Protection Action Plans
Prevent Disease
Prevent Exposure

ATSDR

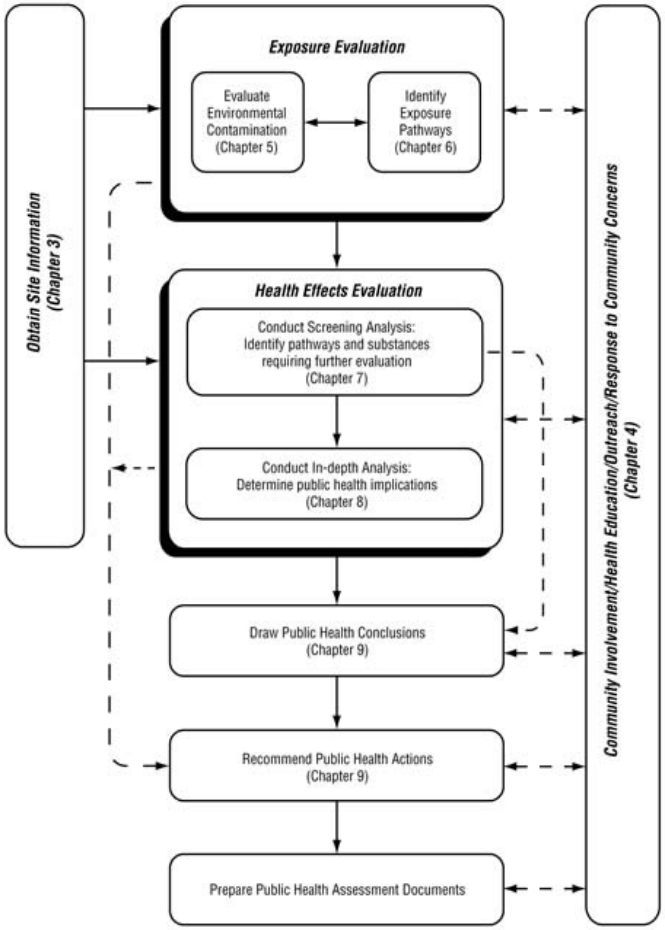
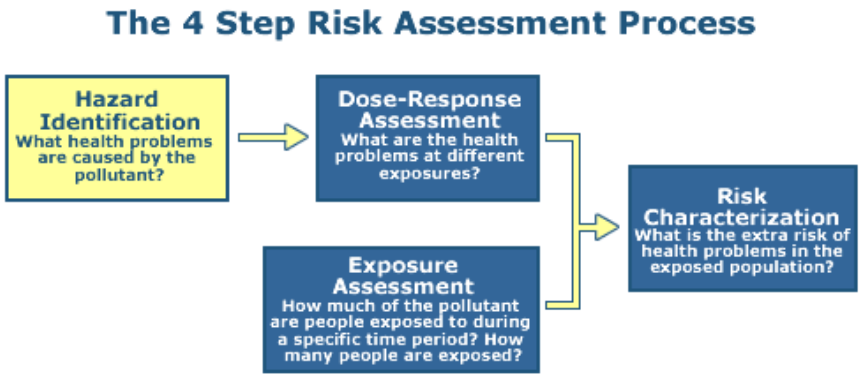


Figure 2-2. Overview of the Public Health Assessment Process

USEPA



USEPA includes a planning Process before conducting the Risk Assessment. This is used to Determine the purpose and scope of a risk assessment.

ATSDR Health Assessment vs. EPA Risk Assessment

- Risk Assessment used by EPA in the remedial investigation/feasibility study (RI/FS) to select remedial actions at a site
- Risk Assessment used by EPA to establish regulatory exposure limits
- Public Health Assessment used by ATSDR or States with cooperative agreements to provide information on health implications of a specific site
  - Legally required for every site that has chemical hazards that are on the USEPA National Priorities List
  - May also be petitioned by individuals
- ATSDR'S role is advisory only outcomes of Public Health Assessment are recommendations
  - Recommend Education
  - Recommend Health Action Plan
  - Recommend studies

Risk Assessment vs. Public Health Assessment

- Main difference between Public Health Assessment and Risk Assessment is how the information is used
- In Public Health assessment community concerns and health outcomes are considered
  - perceived outcome vs. actual outcome
  - PHA more qualitative in approach

Risk Assessment vs. Public Health Assessment

- In Risk Assessment we answer the question
  - what is the potential risk for adverse outcome
- Public Health Assessment addresses
  - what is the potential risk for adverse outcome to the public and
  - have adverse effects been observed in similar situations
  - are there data to indicate adverse effects in the potentially exposed population

Risk Assessment vs. Health Assessment

- The reason for the difference in Risk Assessment and Public Health Assessment is the different roles of EPA and ATSDR
- The processes are similar, but ATSDR focuses the public health perspective

Risk Assessment - Process

- Hazard identification
  - data collection and evaluation
- Exposure assessment
- Dose-response assessment
  - toxicity assessment
- Risk Characterization

Public Health Assessment Process

1. **Exposure** is determined using environmental data
2. **Health Effects** if exposures can or have occurred, the occurrence or potential occurrence of adverse health effects is determined.
    1. **Focuses on the community not the individual**
3. **Conclusions**
    1. **Level of the health threat**
    2. **Recommends methods to stop or reduce the exposure**
    3. **May issue public health advisory warning**
    4. **May authorize health education**
    5. **May authorize pilot studies of health effects**
    6. **May authorize epidemiological studies**
    7. **May authorize surveillance studies**
    8. **May authorize research on specific hazardous substances**

Summary

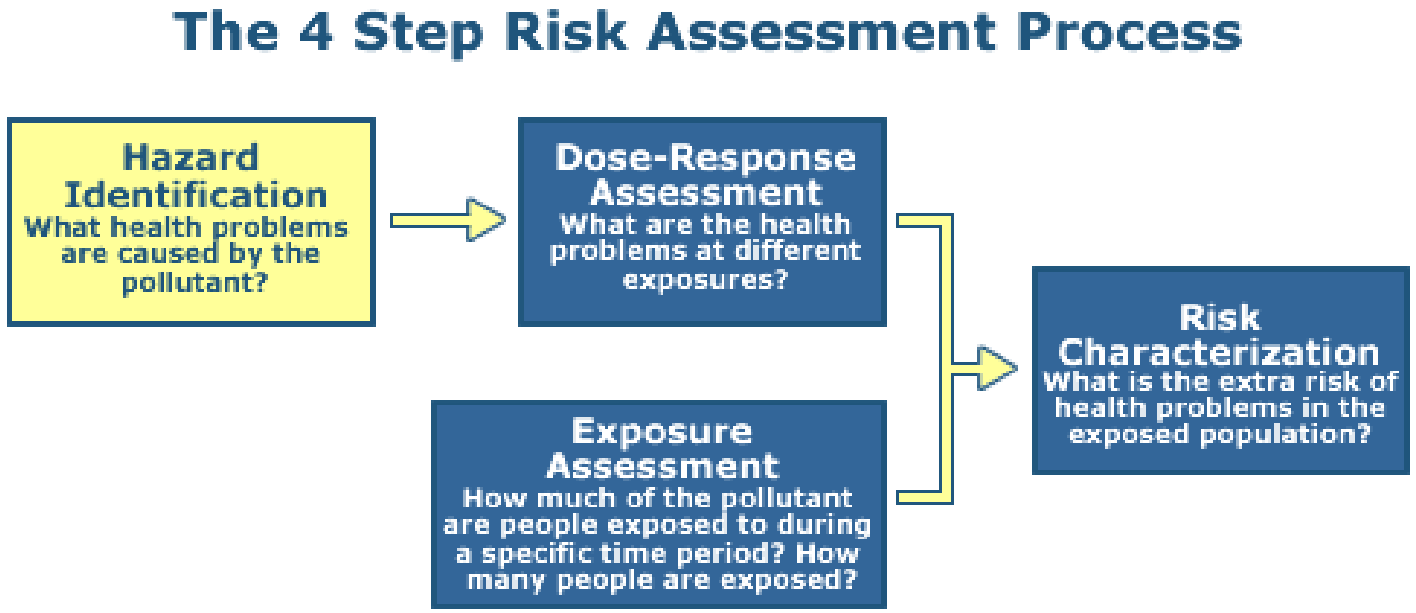
- The Risk Assessment Framework was developed by the National Research Council of the National Academy of Sciences to improve and standardize decision making in government policies
- The primary difference between the process as conducted by ATSDR vs USEPA is the role and goals of the agencies
- Data are used differently to satisfy those differences

USEPA Risk Assessment Process

Agenda

- Describe the process and uses of the USEPA risk assessment framework

Risk Assessment Process



Source: [USEPA Conducting a Human Health Risk Assessment]

Hazard Identification

The initial step in risk assessment, hazard identification, involves identifying chemicals that present a risk to human health.

This step entails performing a qualitative assessment of a chemical's potential for negative health impacts on humans.

Dose-Response Assessment

Dose-response evaluation, provides a quantitative view of the risk.

Involves a review of scientific studies and data.

The magnitude of response is correlated with the dose.

Exposure Assessment

The purpose of the exposure assessment is to measure or estimate a person's level of exposure.

Exposure is different from dose in that exposure refers to the amount of a substance in the environment, while dose is the level of a substance actually taken in by an organism.

Exposure Assessment

Dose can be influenced by many factors, such as how the substance enters the body, whether absorbed through the skin, ingested with food, or inhaled.

Risk Characterization

Risk characterization provides a description of the risk that addresses its severity, likelihood, and consequences.

The risk characterization includes an estimate of the negative effects to exposed individuals, such as the number of cases of cancer or deaths per 100,000 people.

Common Risk Characterizations

Deaths per million people in a selected population (nation).

Deaths per million people within a certain radius of the released pollutant.

Deaths per weight (tons or pounds) of the toxic substance(s) released.

Loss of life expectancy associated witrrh exposure to the toxic material(s).

Limitations of Risk Analysis

Limitations of risk analysis include uncertainty, variability, and effect of multiple exposures.

Despite these limitations, risk assessment is still a valuable tool for exploring and understanding the risks of the modern world.

Summary

- USEPA uses risk assessment to establish regulatory standards (i.e., primary drinking water standards)
- USEPA uses risk assessment to select and prioritize hazardous waste sites for remediation
- There are limitations to risk analysis that must be considered in the subsequent risk management and risk communication steps.

ATSDR Public Health Assessments

Agenda

- Review the process used by ATSDR and States with cooperative agreements to conduct public health assessments.

Public Health Assessment Process

1. **Exposure** is determined using environmental data
2. **Health Effects** if exposures can or have occurred, the occurrence or potential occurrence of adverse health effects is determined.
    1. **Focuses on the community not the individual**
3. **Conclusions**
    1. **Level of the health threat**
    2. **Recommends methods to stop or reduce the exposure**
    3. **May issue public health advisory warning**
    4. **May authorize health education**
    5. **May authorize pilot studies of health effects**
    6. **May authorize epidemiological studies**
    7. **May authorize surveillance studies**
    8. **May authorize research on specific hazardous substances**

Factors Considered in a Public Health Assessment

- Nature and Extent of contamination
  - Spatial extent
  - Temporal extent
  - What are the contaminants
  - Where are the contaminants (e.g., soil, water, air, biota).
- Demographics of affected populations
- Exposure Pathways to affected people
- Health Effects and disease-related data
- Child Health Considerations are a required component of a PHA

Community role in Public Health Assessment

- Community members are important resources for PHA
- Community members are the primary audience for PHA
- The relationship of the assessment team with the community is key to the value and success of the PHA

Six steps in every public health assessment

1. Evaluating site information – Site Scoping
2. Identify community concerns
3. Identifying contaminants
4. Identifying and evaluating exposure pathways
5. Determining public health implications
6. Conclusions and recommendations

Primary Sections of PHA

- Summary
- Purpose and Health Issues
- Background
- Discussion
- Community Health Concerns
- Conclusions
- Recommendations
- Public Health Action Plan

Additional Sections of PHA

- Preparers of the report
- References
- Tables
- Figures

Additional Sections of PHA

- Appendices
  - Additional background materials
  - More in-depth technical discussions
  - Glossary
  - Response to public comments

Summary

- ATSDR has an advisory role
- ATSDR public health assessment process can produce
  - Public education plans and options
  - Informational materials for the public
  - Recommend a public health action plan to address any adverse health risks
  - Recommend and authorize surveillance and epidemiological studies
  - Recommend and authorize research on specific hazardous substances or agent

Environmental Risk Assessment

Data, Calculations and Presentation

Agenda

- Data needs, collection and validation
- Exposure assessment and calculation
- Risk Characterization and calculation

Risk Assessment - Process

1. Hazard identification
2. Exposure assessment
3. Dose-response assessment
4. Risk Characterization

Hazard Identification

DATA
COLLECTION

DATA
EVALUATION

DATA
SELECTION

Data Evaluation

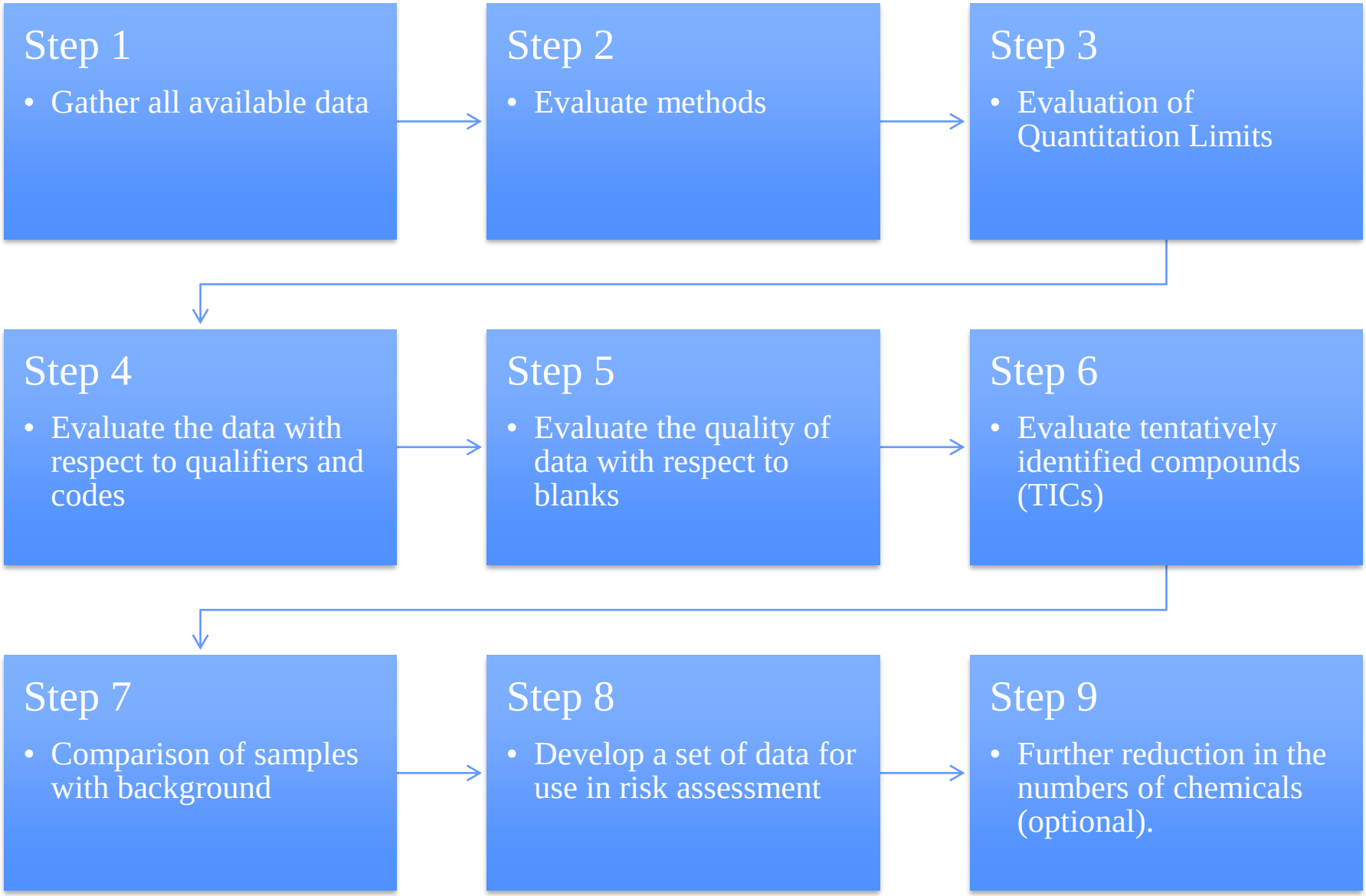
Nine steps are followed to organize the data for use in the risk assessment.

Data Evaluation - Outcome

Identification of a set of chemicals that are likely to be site related

Measurements that are of sufficient quality to be used in the quantitative risk assessment

Nine Steps of Data Evaluation



Exposure Assessment

Exposure: The contact of an organism with a chemical, pathogen or physical agent

Exposure Assessment

Exposure Assessment:

Estimates the magnitude of actual or potential exposures for the pathways by which receptors are potentially exposed

Exposure Assessment

Outcome of exposure assessment:

Pathway specific intakes for current and future exposures to individual contaminants

Exposure Assessment Process

Three steps in exposure assessment:

1. Characterize Exposure Setting
2. Identify Exposure Pathways
3. Quantify Exposures

Exposure Assessment Process

- Characterization of Exposure Setting
  - Physical Environment
  - Potentially Exposed Populations

Exposure Assessment Process

- Identification of Exposure Pathways
  - Chemical Source
  - Fate & Transport
  - Exposure Point
  - Exposure Route

Exposure Assessment Process

- Quantification of Exposure
  - Exposure Concentration
  - Intake Variables
  - Pathway specific Exposure

Characterize Physical Setting

- Climate
- Meteorology
- Vegetation
- Soil Type
- Groundwater Hydrology
- Surface Water Bodies

C = Chemical Concentration

Because of uncertainty associated with any estimate of exposure concentration, the upper confidence limit (i.e., the 95% upper confidence limit) on the arithmetic mean is used for this variable

Calculate Exposure Concentration

Use the 95% upper confidence limit on the arithmetic mean as the exposure concentration

$$\overline{X} + t_{(0.95,n-1)}(S) / \sqrt{n}$$

Generalized Formula For Calculating Exposure

$$I = C \times \frac{CR \times EFD}{BW} \times \frac{1}{AT}$$

I = Intake

the amount of chemical at the exchange boundary (mg/kg body weight/day)

C = Chemical Concentration

the average concentration contacted over the exposure period (e.g., mg/liter water)

C = Chemical Concentration

because of uncertainty associated with any estimate of exposure concentration, the **upper confidence limit** (i.e., the 95% upper confidence limit) on the arithmetic mean **is used** for this variable

CR = Contact Rate

the amount of contaminated medium contacted per unit time or event (e.g. liters/day)

EFD = Exposure Frequency and Duration

describes how long and how often exposure occurs. Often calculated using two terms (EF and ED);

EF = exposure frequency (days/year)
ED = exposure duration (years)

BW = Body Weight

the average body weight over the exposure period (kg)

AT = Averaging Time

period over which exposure is averaged (days)

Ingestion of Chemicals in Drinking Water

$$I = \frac{CW \times IR \times EF \times ED}{BW \times AT}$$

Risk Characterization

- There are six steps used in Risk Characterization
    1. Review Outputs from toxicity exposure assessments
    2. Quantify risks from individual chemicals
    3. Quantify risks from multiple chemicals
    4. Combine risks across exposure pathways
    5. Assess and present uncertainty
    6. Consider site-specific human studies

Step 2. Quantify risks from individual chemicals

Risk from Carcinogenic Effects

Risk is calculated using either:

$$\text{Risk} = \text{CDI} \times \text{SF} \quad \text{(Low Risk)}$$

or

$$\text{Risk} = 1 - \exp(-\text{CDI} \times \text{SF}) \quad \text{(High Risk)}$$

SF – Slope Factor Calculated from the dose response curve for each carcinogen

Hazard Quotient (non-carcinogen)

The ratio of a single substance exposure level over a specified time period (e.g. subchronic) to a reference dose for that substance derived from a similar exposure period.

$$HQ=E/RfD$$

Hazard Index (non-carcinogen)

The sum of more than one hazard quotient for multiple substances and/or multiple exposure pathways. The HI is calculated separately for chronic subchronic, and shorter duration exposures

Hazard Index (non-carcinogen)

$$HI = \sum HQ$$

Pathway	Chemical	CDI (mg-kg-day)	SF (mg-kg-day)	Chemical Specific Risk	Total Pathway Risk	Total Exposure Risk
Well Water	Benzene	0.00025	0.029	7×10^{-6}		
	Chlordane	0.00015	1.3	2×10^{-4}		
					2×10^{-4}	
Fish	Chlordane	0.00008	1.3	1×10^{-4}		
					1×10^{-4}	
						3×10^{-4}

Pathway	Chemical	CDI	RfD	MF	HQ	PHI	THI
Well Water	Phenol	0.1	0.6	1	0.2		
	Nitrobenzene	0.0001	0.0005	1	0.2		
	Cyanide	0.0003	0.02	5	0.02		
						0.4	
Fish	Phenol	0.08	0.6	1	0.1		
	MBK	0.005	0.05	1	0.1		
						0.2	
							0.6

Summary

- Nine steps in the data selection process
  - Goal of data selection is a data set usable in a quantitative risk characterization
- Three steps in the exposure assessment process
  - Goal of exposure assessment is to estimate the amount of exposure via various pathways
- Risk Characterization
  - Determine cancer hazard
  - Determine non-cancer hazard
- Sum risks across pathways and hazards

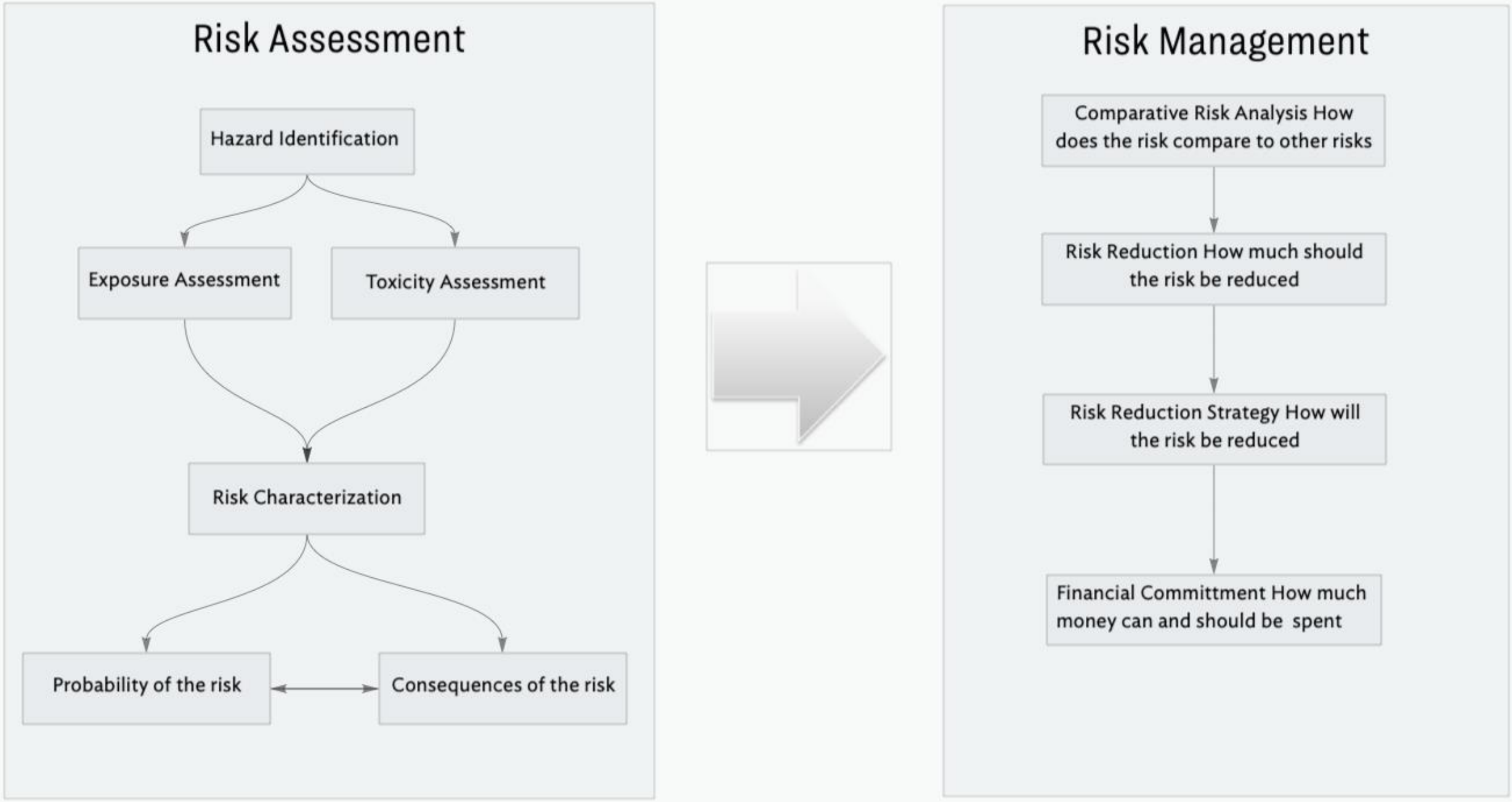
Risk Management/
Risk Communication

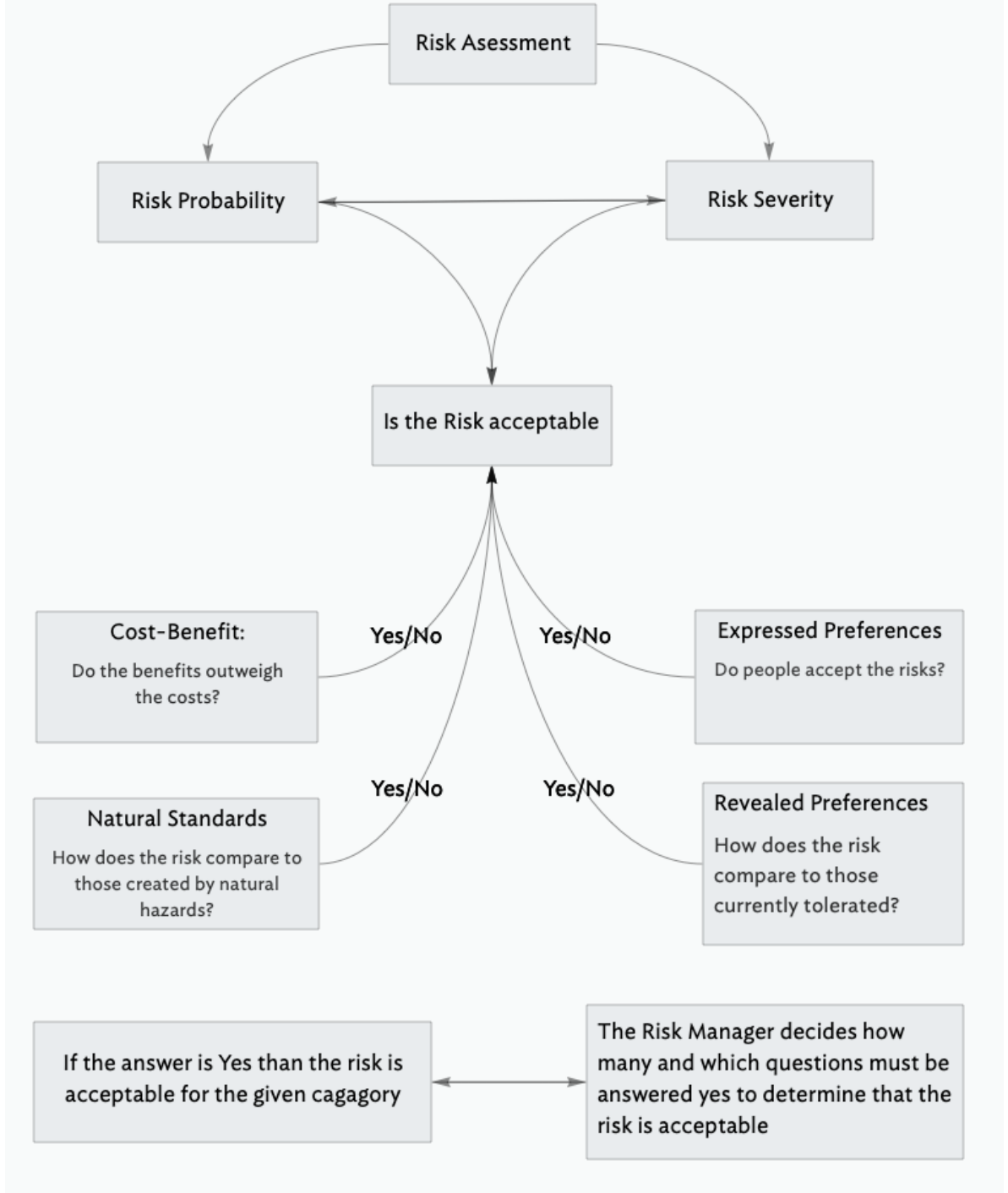
Agenda

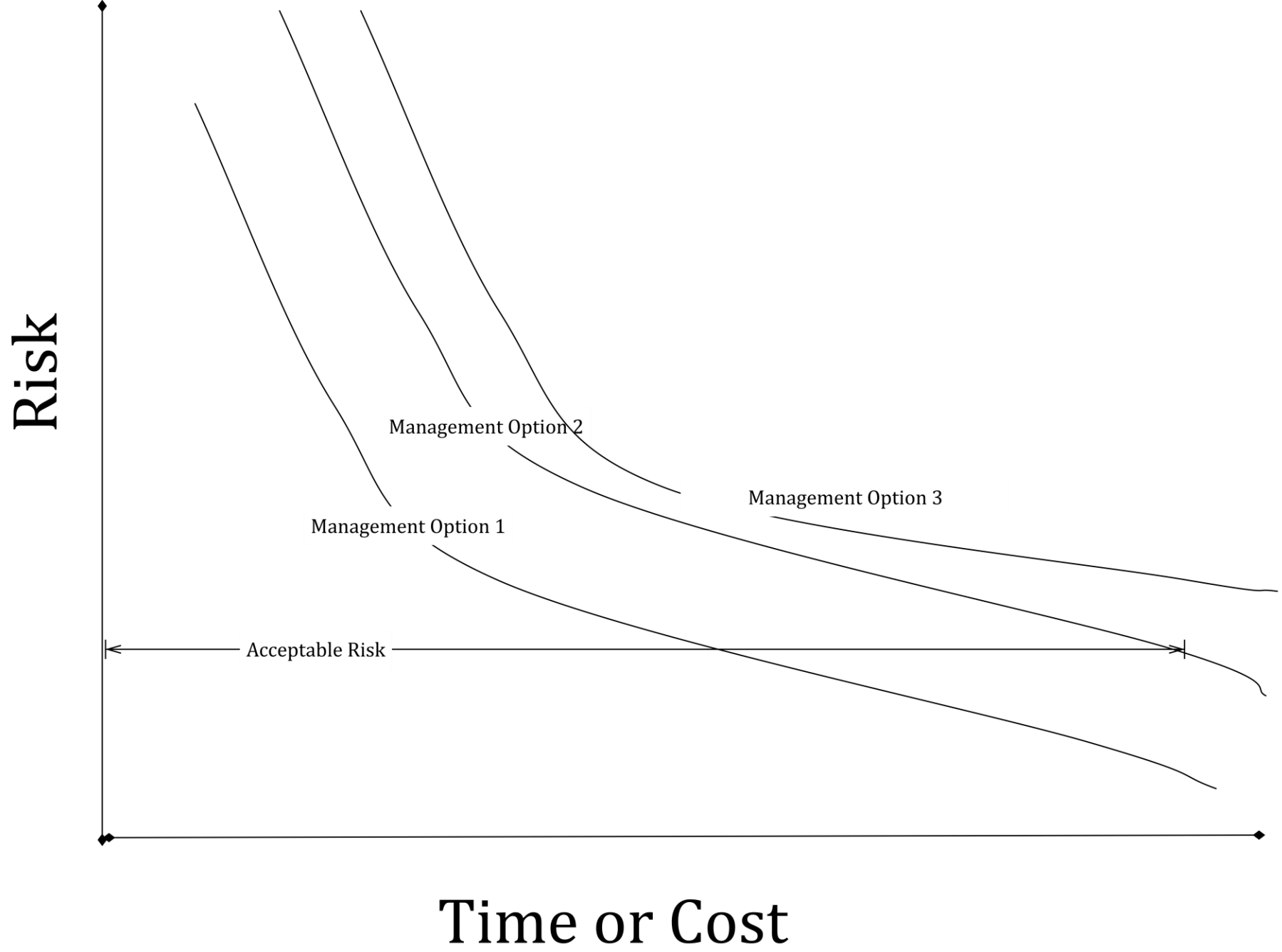
- Risk Management process
- Risk Management decisions
- Risk Communication
- Interaction of Risk Management and Risk Communication

Risk Management

Risk management involves merging the results of risk analysis with various social factors, such as socioeconomic conditions, political pressures, and economic concerns.


Risk Assessment
Hazard Identification
Exposure Assessment
Toxicity Assessment
Risk Characterization
Probability of the risk
Consequences of the risk
Risk Management
Comparative Risk Analysis How does the risk compare to other risks
Risk Reduction How much should the risk be reduced
Risk Reduction Strategy How will the risk be reduced
Financial Committment How much money can and should be spent


Risk Asessment
Risk Probability
Risk Severity
Is the Risk acceptable
Cost-Benefit:
Do the benefits outweigh the costs?
Yes/No
Yes/No
Expressed Preferences
Do people accept the risks?
Natural Standards
How does the risk compare to those created by natural hazards?
Yes/No
Yes/No
Revealed Preferences
How does the risk compare to those currently tolerated?
If the answer is Yes than the risk is acceptable for the given cagagory
The Risk Manager decides how many and which questions must be answered yes to determine that the risk is acceptable


Risk
Management Option 2
Management Option 3
Management Option 1
Acceptable Risk
Time or Cost

What is Acceptable Risk

- EPA acceptable risks
  - cancer 10^{-4} to 10^{-6} excess lifetime cancer risk
  - non-carcinogens HI < 1.0
    - HI sum of HQ
    - HQ = exposure/safe dose

Risk Management

- Three avenues of risk management are:

- **Educational**
- **Economic**
- **Regulatory**

Risk Management

Risk management generally involves comparing the risk to some other factor such as the cost or reducing the risk or the benefit gained from the risk.

Risk Management

The “best” course of action is not always the one that reduces the most risk, but rather, is the most economically feasible option, reducing the greatest amount of risk per dollar spent.

Risk Communication

- The goal of risk communication is to effectively relay risk information developed through risk analysis to various interested groups.

Risk Communication

- Methods of risk communication include public hearings, emergency hotlines, information pamphlets.

Risk Communication

- Risk communication can be challenging, as it requires addressing people's different risk perceptions, biases, scientific knowledge, educational backgrounds, even race and gender.

Risk Communication

- Translating technical terminology into comprehensible terminology can increase risk communication.

Address Jargon and Unfamiliar Concepts

- Define terms that matches education level of the stakeholders
- Provide a frame of reference for the current situation
  - Provide examples with similar risks that the public is familiar with

Risk Communication

- Gain public trust
  - Show empathy and concern
  - Provide information about your qualifications
  - Listen carefully

Summary

- Risk Management addresses
  - Is the risk acceptable
  - If the risk is not acceptable what are the best management options
  - Not possible to reduce risk to zero risk
  - Does not necessarily minimize the risk, but lowers it to an acceptable level

Summary

- Risk Communication addresses
  - Management decisions
  - Considers and addresses public risk perception
  - Public must trust the messenger

Introduction Risk Assessments and Risk Communication

Agenda

- Define Risk
- Describe and discuss risk perception
- Define Risk Assessment and Risk Analysis
- Characteristics of Environmental Risk

What is Risk?

- Risk can be:
  - Financial
  - Personal
  - Social
  - Health
  - Environmental

What is Risk?

- Involves a range of activities, situations and concepts.
  - drinking a glass of red wine daily
  - skydiving
  - driving to work
  - chemical exposure
  - exposure to a pathogen

What is Risk?

- Quantified in:
  - Cost
    - Dollars lost
  - Adverse health outcomes
    - Lives lost
    - Disease rate
    - Probability of cancer
  - Quantity of assets lost or damaged

What is Risk?

- Risk is commonly used to describe types of people or situations.
  - Risk-taker
  - Risk-free
- These labels are situational

Risk Perception

- Perceptions vary
  - People accept certain risks because they enjoy the benefit they receive from the behavior or activity.
  - Some people seek out activities that appear to most of us to contain unacceptably high risk
    - Rock climbing
    - Skydiving
    - Bungee Jumping
    - Mountain climbing
    - Extreme sports

Risk Perception

- Influenced by the nature of the event
- Individual experience
  - Driving a car vs. flying.
  - Occupation

Risk Perception

- Risk perception is important because:
  - Influences public attitudes
    - Influences risk management decisions
    - Influences the risk communication message
      - Method of communication
      - Content of the communication


Risk Perceptions
Less Risky
Voluntary
Familiar
Controlled by Self
Chronic
Natural
Fair
Detectable
Not Memorable
More Risky
Involuntary
Unfamiliar
Controlled by Others
Acute
Artificial
Unfair
Undetectable
Memorable

What is Acceptable Risk

- EPA acceptable risks
  - cancer 10^{-4} to 10^{-6} excess lifetime cancer risk
  - non-carcinogens HI < 1.0
    - HI sum of HQ
    - HQ = exposure/safe dose

Risk Assessment

- The quantitative and qualitative estimation of risk of harmful outcomes
  - Business Loss
  - Equipment Failure
  - Adverse Health Outcome
  - Damage to assets
  - Likelihood of exposure to harmful chemicals or pathogens

Environmental Risk Assessment

- Effect of human activity
  - Damage to ecosystems (Ecological Risk Assessment)
  - Disease or death rates in:
    - Livestock
    - Wildlife
    - Humans (Human Health Risk Assessment)
- Feedback influence on human exposure and disease

Environmental Risk

- Environmental risk is usually **involuntary**.
- People do not choose to ingest chemical pollutants such as pesticides or industrial solvents in their food and water or undergo workplace exposures to dangerous chemicals.

Environmental Risk Assessment

- Primary “actors” in the United States
  - United States Environmental Protection Agency (USEPA)
  - Agency for Toxic Substances and Disease Registry (ATSDR)
  - National Research Council/National Academy of Sciences (NAS)
  - Occupational Health and Safety Administration (OSHA)
  - National Institute for Occupational Safety and Health (NIOSH)
  - National Institute for Environmental Health Sciences (NIEHS).
  - State Environmental Regulatory Agencies
    - In Tennessee – Tennessee Department of Environment and Conservation. (TDEC)
  - State Public Health Agencies
    - In Tennessee – Tennessee Department of Health (TDH)

Risk Characteristics

- Risk can be defined as the **likelihood** of an **unwanted** occurrence and **uncertainty** about when and where the risk might occur.

Risk Characteristics

- Many environmental risks involve **unknown exposures** with **unknown outcome** and **unknown time** until outcome occurs.

Development of Risk Analysis

- In risk analysis is the process of reviewing information on a hazard to characterize that hazard’s impact on human health.
- Risk analysis allows public groups to make informed decisions and weigh the risks and benefits in their community.

The Process of Risk Analysis

- A review of scientific studies
- An understanding of the properties of a risk,
- An assessment of levels of human exposure and dose
- A conclusion about the likelihood, impact and extent of a risk.
- See the two editions of the reports titled
  - Risk Assessment in the Federal Government- Managing the Process (1983)
  - Science and Decisions- Advancing Risk Assessment (2009)

Summary

- Risk for our purposes is the probability of an adverse health outcome
- Risk perception influences how the public views the risk of various exposures and activities
- Environmental Risk is involuntary
- Environmental Risk is the likelihood of an unwanted outcome
- Risk assessment uses scientific information and data to determine the likelihood of an unwanted outcome