Module 11: Monte Carlo Risk Assessment

11.1 Introduction to Risk Assessment

Risk Assessment

- Risk assessment is a technique to estimate the chance of an adverse effect from exposure to a hazard
- A hazard is something that might be dangerous like riding in a car, playing a sport, or ingesting a chemical
- A risk includes a hazard, an exposure, and an effect
- It's impossible to determine exactly what effect will occur or to who, only probabilities can be estimated

Risk Assessment

- Risk Assessment has four component parts:
  - Hazard Identification
  - Exposure Assessment
  - Dose/Response Modeling
  - Risk Characterization

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Hazard Identification

- Begins with the suspicion that a substance causes harm to humans or the environment
- Generally involves looking at similar substances to estimate possible toxicity
- May involve a historical review of known exposures and effects
- If evidence exists of possible risk, the assessment continues

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Exposure Assessment

- Involves looking at
  - the possible routes of exposure
    - Ingestion
    - Inhalation
    - Dermal contact
  - organisms that may be exposed
  - current and future exposure scenarios
- The result is an estimate of the reasonable maximum exposure

Exposure Assessment

- Controversies include:
  - Use of single estimates for things that vary such as characteristics of the organism (body weight, age) and behavior
  - Uses conservative values to be protective of the entire population
  - Uses current and future scenarios that may not reasonably occur

Dose/Response Modeling

- Involves modeling the relationship between the dose of the hazard and the effect
- Often involves laboratory tests on animals since humans cannot be experimented on
- Sometimes includes known exposures to humans if they occurred in the past

Dose/Response Modeling

- Controversies include:
  - data on animals may or may not be meaningful for humans
  - high doses are used in the laboratory to ensure an effect
  - the shape of the true dose/response relationship is unknown
  - the existence of a threshold is debatable

Risk Characterization

- This step pulls together everything that has been determined in the other steps and attempts to synthesize an overall estimate of the risk
- Risks are expressed as a probability or a ratio

Risk Assessment

- Traditional risk assessments are deterministic. That means that they use single point estimates for each of the coefficients in the calculations.
- Using single point estimates gives a point estimate output
- However, many of the model coefficients are both variable and uncertain

Risk Assessment

- Examples of risk assessment coefficients:
  - Body weight
  - Quantity of food eaten at a meal
  - Skin surface area
  - Breathing rate
  - and so on
- Clearly these, and other coefficients, vary between situations and individuals

Risk Assessment

- In addition to coefficients that vary, many things are highly uncertain
- Examples
  - Uptake of a chemical into a human body
  - The amount of soil a child playing outside ingests in a day
  - The number of hours a person will spend in a contaminated area over their lifetime

Risk Assessment

- Reasons to treat risk assessment coefficients probabilistically:
  - Many things vary naturally between organisms and contexts
  - No matter how much we know, they will still vary
  - Other things may not vary but they are not well known.

Monte Carlo Simulation

- Monte Carlo methods are one way to do a simulation study to include estimates of both variability and uncertainty in the risk assessment
- These are called Probabilistic Risk Assessments (PRA)
- They result in a distribution of risk estimates rather than a single point

Monte Carlo Simulation

- The risk distribution reflects both the variability and uncertainty that exists in a situation
- Either the entire distribution or one of its percentiles may be used to make risk management decisions