Module Three

Risk Assessment

Module Three

Introduction to Risk Assessment

Time Allotted: 90 Minutes

Objectives:

Upon completion of this module, the learner will be able to

- Define and understand the concept of risk
- Identify and discuss the steps involved in performing a risk assessment
- Understand the roles of risk assessment and risk management
- Understand the role of ATSDR's public health assessment

Presentation Outline

I. What is Risk Assessment?

A. Hazard Identification
B. Hazard Evaluation or Dose-Response Assessment
C. Exposure Assessment
D. Definition of Each Component in an Exposure Assessment
E. Risk Characterization

II. Risk Management

III. Test Your Knowledge Quiz

IV. Activity Lab

V. Question and Answer Period

Lecture Notes

I. What is Risk Assessment (1)?

First, *risk* is defined as the probability that an event will occur. It can also be defined as the probability that a health effect will occur after an individual has been exposed to a specified amount of a hazard. Risk assessment is the process of gathering all available information on the toxic effects of a chemical and evaluating it to determine the possible risks associated with exposure. The process of gathering and evaluating the information can be divided into the following:

- Hazard Identification
- Hazard Evaluation or Dose-Response Assessment
- Exposure Assessment
- Risk Characterization

(A) Hazard Identification - this first step in risk assessment consists in collecting data from different sources to determine whether a substance is toxic. It involves gathering and examining data from toxicological and epidemiological studies.

- Epidemiology' is the study of the causative factors that are associated with the occurrence and number of cases of disease and illness in a specific population. Information from these studies should answer these questions:
  - Does exposure to the substance produce any adverse effects?
  - If yes, what are the circumstances associated with the exposure?

☛ *See Handout 3.1 – Types of information collected and considered when performing the risk assessment. (Obtained from the U.S. Environmental Protection Agency, Risk Assessment Guidelines and Information Directory, Government Institute, Rockville, MD, 1988.)*

Information collected and considered when performing a risk assessment are listed below.

- Substance Identification (name)
- Physical/chemical properties of the toxic substance (Does it dissolve? Is it reactive [explosive, flammable, etc.], What is its size?)
- Source of the toxicity information

  Epidemiological studies - The two major types of epidemiological studies are retrospective and prospective. Retrospective studies attempt to gather information from the past. Sometimes the information is incomplete because of the way the data was gathered. Because of that, it is sometimes difficult to determine if there is a relationship between the effect and a specific factor, such as exposure to a particular toxic substance. Prospective studies gather information from current, ongoing investigations. For that reason, the results are more complete and accurate than retrospective studies. Both methods are useful in identifying adverse health effects associated with a given toxic substance (1).

  Toxicological studies - Different types of studies fall under the category of toxicological studies, including acute toxicity studies, which look at short-term exposures, and chronic toxicity studies, which look at exposures over a long period of time.

- Other factors to consider include the species of test animal (was the study done in rats, mice, man, etc.), and other variables affecting toxicity (including age, sex, and health of the study population).

- Exposure to Toxic Substances

  Exposure to toxic substances depends on the

  - Route of exposure (skin contact, inhalation, ingestion, injection),
  - Duration of exposure (acute or chronic),
  - Frequency of exposure, and
  - Exposure to other toxic substances.
  - Other factors to consider when determining potential exposures to toxic substances include diet, lifestyle choices, and occupation.

B. Hazard Evaluation and Dose-Response Assessment

If the hazard identification process produces evidence of a hazard, then a hazard evaluation is performed. The purpose of this step is to calculate, if possible, the dose at which a harmful effect will occur. Since an effect in animals may not be the same in humans, at the same dose, "safety factors" are used. Safety factors account for the differences in response of test animals and differences in toxicity. The dose-response assessment tells the toxicologist what dose causes a response, usually illness or death, in the test animal.

C. Exposure Assessment

An exposure assessment is performed to identify the affected population and, if possible, calculate the amount, frequency, length of time, and route of exposure. Exposure is "an event that occurs when there is contact at a boundary between a human and the environment at a specific (contaminant) for a specified period of time". Units to express exposure are "concentration times time"(1). Factors to consider when performing an exposure assessment include

- General information for each chemical
  - Identification of molecular formula and structure (how the chemical looks and is made) and other identifying characteristics
  - Chemical and physical properties
- Sources
  - Characterization of production and distribution
  - Uses
  - Disposal
  - Summary of environmental releases
- Exposure Pathways and Environmental Fate
  - Transport and transformation
  - Identification of principal pathways of exposure
  - Predicting environmental distribution
- Measured or Estimated Concentrations
  - Uses of measurements
  - Estimation of environmental concentrations

- Exposed Human Populations

  - Size and characteristics

  - Location

  - Habits

- Integrated Exposure Analysis

  - Calculation of exposure includes identification of the exposed population and identification of pathways of exposure.

D. Definition of Each Component in an Exposure Assessment

- General Information for Each Chemical - The physical/chemical properties of the toxic substance affects how it is transported, how it is accumulated in the environment and in tissues, and how it is transformed when it is released into the environment. Some examples of characteristics include:

  - vapor pressure (how easily can a chemical change from a solid or liquid to a gas?)

  - its ability to dissolve in water

  - its ability to stick to soil or sediments

Knowing these facts will help determine the dose and route of exposure.

- Sources of Exposure - Exposure to chemicals can occur anywhere, including the home (cleaning products, paints, pesticides, etc.). Outside the home, exposure to chemical pollutants in the air occurs through inhalation.
- Exposure Pathways and Environmental Fate - Once the source has been identified, the route and nature of the exposure must be determined. For exposure could occur through drinking water (the route could be ingestion of contaminated water).
- Measured or Estimated Concentrations - If possible, it is best to obtain actual samples from the source of exposure to calculate the amount of toxic substance present. However, samples are not always available and estimations of exposure can be calculated using a mathematical model. These models attempt to estimate the concentration of a substance at the point of exposure. Modeling is mostly used when determining concentrations of substances in air, but can be used to determine the amount in lakes or other bodies of water.
- Exposed Population - It is important to identify and characterize the exposed population in terms of sex; age; number of small children, pregnant women, and chronically ill individuals. Other information such as eating, work, exercise, and play habits is also necessary. Some populations are more at risk for illness than others, such as young children and older adults.
- Measuring Exposures - The effects from exposure to simple and complex mixtures are very important, as well as the health impact of these substances on susceptible populations (e.g., children, elderly, people of color). Exposure can

also vary greatly within geographic areas. Measurement of exposure is often determined through questionnaires or surveys, employment records, and evaluation of environmental contamination data for areas in which a study population lives (10). A problem seen in most communities is the absence of actual data, because no personal monitoring was conducted. This could lead to exposure calculations that could be too high or too low (10). How much exposure occurred and how much of a dose a person received is significant in documenting exposure.

Two major approaches for assessing total exposure include indirect methods and direct methods. Indirect methods include environmental monitoring; use of fate and transport (migration); computer models; (use of questionnaires, and/or surveys for residents). Direct methods, include the use of personal workplace monitoring equipment and biologic markers (2). The extent of exposure may depend on the size of the population, its proximity to the contamination source, a person's degree of personal contact with the site, and the extent of the release of hazardous substances. Children are one population particularly susceptible to the toxic effects of contaminants at hazardous waste sites. While playing outside, young children come into contact with environmental toxicants via dermal contact and subsequent hand-to-mouth activity. Therefore, children who play in areas where there is little to no vegetative cover, as in many urban areas, and pica

children (those who ingest greater than an average amount of non-food items [dirt] per day) are particularly sensitive to contaminants in soil.

- Calculation of Exposure (1) - Once the information is available, exposure can be estimated. Exposure can occur through more than one route, and when that is the case, the total exposure may be measured by adding the contributions of all routes. When data is not available, certain guesses are made, using standard reference values.

E. Risk Characterization

The last and final step in the risk assessment process is putting all of the information gathered from the other steps together to determine the actual risk of exposure to a specific toxic substance. This step relies on the expertise of the assessor in analyzing the information.

II. Risk Management

Based on information obtained from the risk assessment, decisions are made about the best way to address environmental contamination and exposure. The risk manager also includes an evaluation of social, legal, economic, and policy issues to determine the best approach to address an exposure issue.

ATSDR's public health assessment is an evaluation of environmental data, health outcome data, and community concerns associated with a site where hazardous substances have been released. The health assessment identifies populations living or working on or near hazardous waste sites for which more actions or studies are needed.

III. Test Your Knowledge Quiz

1. Which of the following is **NOT** a step in the Risk Assessment Process?
   a. Hazard identification
   b. Hazard evaluation or dose-response assessment
   c. Exposure dose
   d. Risk characterization

2. Epidemiology is the study of causative factors associated with the occurrence and number of cases of disease and illness in a specific population.

   a. True b. False

3. Exposure tells the toxicologist what dose causes a "response" usually illness or death, in the test animal.

   a. True b. False

4. What activities should be conducted during the hazard identification step of the risk assessment?

   a. Identifying the substance name
   b. Describing the physical/chemical properties of the toxic substances
   c. Identifying the sources of toxicity information
   d. Identifying the exposure pathway
   e. All of the above

5. Prospective epidemiological studies gather information from the past.

   a. True b. False

6. The exposure assessment step in the risk assessment process identifies all **EXCEPT** which of the following?

   a. Frequency of exposure
   b. Type of chemical exposure
   c. Length of time of exposure
   d. Route of exposure

e. The amount of exposure

7. Susceptible populations that may be more at risk for illness than others includes the following **EXCEPT**:
    a. Young children
    b. Older adults
    c. Teenagers
    d. Women of Childbearing Age

IV. Activity Lab

Divide the participants into small groups. Have them perform a mock risk assessment on an environmental issue or contaminant of concern to them. To keep the process simple, inform the participants that they are to perform this activity in the manner described below.

The four steps in the Risk Assessment process are:

1) Hazard identification
2) Dose response evaluation
3) Exposure assessment
4) Risk characterization

The Risk Assessment asks five basic questions, which the participants must answer:

1) What is the hazard?
2) Are the people really exposed to the hazard?
3) If so, how long and how long will it take to determine the amount of exposure?
4) Is there evidence to prove that exposure occurred or is occurring?
5) Given the information collected, is there a risk of adverse health effects from an exposure?

V. Question and Answer Period

HANDOUTS and VISUAL AIDS

MODULE III

Handout 3.1 Types of Information Collected and Considered When Performing the Risk Assessment

A. Hazard Identification
- Collection of Data
  - a. Name of Substance
  - b. Physical/Chemical Properties
  - c. Source of Information
  - d. Exposure to Toxic Substances
    - Route of exposure
    - Duration of exposure
    - Frequency of exposure
    - Exposure to other toxic substances
  - e. Information on Other Factors

B. Hazard Evaluation or Dose-Response Assessment
1. Calculate Dose-effect
2. Incorporate Safety Factor
3. Determine Dose-response Relationship

C. Exposure Assessment
1. General Information for Each Chemical
   - a. Molecular Formula and Structure
   - b. Physical and Chemical Properties
2. Sources
   - a. Characterization of Production and Distribution
   - b. Uses
   - c. Disposal
   - d. Summary of Environmental Releases
3. Exposure Pathways and Environmental Fate
   - a. Transport and Transformation
   - b. Identification of Principal Pathways of Exposure
   - c. Prediction of Environmental Distribution
4. Measured or Estimated Concentrations
   - Estimation of Environmental Concentration
5. Exposed Human Populations
   - a. Effects from exposure to simple and complex mixtures
   - b. Geographic area
   - c. Health Impact on Susceptible Population
   - d. Population habits
6. Integrated Exposure Analysis (Measurement of Exposure)
   - Calculation of Exposure
     - a. Identification of the exposed population
     - b. Identification of pathways of exposure

D. Risk Characterization