Chemical Risk Assessment in an Uncertain World

Satellite Conference
Tuesday, March 30, 2004
12:00-1:30 p.m. (Central Time)
1:00-2:30 p.m. (Eastern Time)
11:00 a.m.-12:30 p.m. (Mountain Time)
10:00-11:30 a.m. (Pacific Time)

Produced by the Alabama Department of Public Health
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Defining Our Terms

- Toxicity - an adverse effect that results from a chemical interaction of a substance on an organism.
- Hazard - potential to cause harm.
- Risk - The probability that a hazard will manifest itself as an adverse effect.

Defining Our Terms

- **Safety - The inverse of risk. This is often framed in the context of a circumstance with an acceptable level of risk.**
- **Risk assessment - the process of determining risk.**

Risk Assessment Can Be Classified As Either "Quantitative" Or "Qualitative".

- Quantitative risk assessment is a risk assessment, or a portion of an assessment, which generates a numerical value representing the safe level for chemical exposure. It may include a range of values dependent upon several different sets of assumptions.

Risk Assessment Can Be Classified As Either "Quantitative" Or "Qualitative".

- A qualitative risk assessment establishes the hazard of the chemical exposure in relative terms. In particular, it is used to determine whether hazards found in animal studies are relevant to people exposed at a defined level.

Risk Management

- The process of factoring the risk assessment against the possible alternative actions open to society, including cost/benefit considerations, consumer needs, or using alternative chemicals, etc., to determine how best to regulate or manage exposure to the chemical. When value judgments and society's preferential but subjective bias modify the risk assessment according to need, cost, or technical feasibility, this is risk management.

Predictions of human risks from chemical exposures are most accurate when based on past human exposure data. However, rarely are human studies available (i.e. quality human epidemiology studies).

Risk Assessment Limitations

Most of the time, predicting human risks from chemical exposures usually relies on animal toxicity testing data. This results in the limitations in the risk assessment process

- Uncertainty in the prediction due to extrapolation from animal models to the human model.

Risk Assessment Limitations (continued)

Uncertainty in the prediction due to extrapolation from the high doses used in the animal studies to the low levels of exposure that humans would be expected to experience.

What Is Chemical Risk Assessment (RA)?

Risk assessment is an interpretive process whereby all relevant toxicological information is assembled and evaluated in an attempt to determine a probable response in humans after chemical exposure.

How Can The Public Benefit From Chemical RA?

Risk assessment generally serves as a tool that can be used to organize, structure, and compile scientific information in order to help identify existing hazardous situations or problems, anticipate potential problems, establish priorities, and provide a basis for regulatory controls and/or corrective actions.

How Does RA Work?

The risk assessment process utilizes a mathematical model to estimate the probability, or risk, that a specific adverse human health effect may occur at a specific dose of a given agent.

Risk = Exposure x Toxicity

The Public Health Approach to RA

- Defining Problems and Putting Them in Context
- Analyzing Risks
- Examining Options
- Making a Decision
- Taking Action
- Evaluating Results

Adapted from: Framework for Environmental Health Risk Management; Presidential/Congressional Commission on Risk Assessment and Risk Management. 1997.

Defining Problems

- Identify and characterize the problem
  - There are two important steps:
    - 1. What is the problem (hazard)?
    - 2. Who is affected (exposed)?

Defining Problems (continued)

- Consider the context
  - There may be multiple contexts to consider:
    - 1. Multisource context
    - 2. Multimedia context
    - 3. Multichemical context
    - 4. Multirisk context

Defining Problems (continued)

- Identify Risk Management Goals
  - Goals may be risk related:
    - Reduce a risk of illness from exposure
  - Goals may be economic
    - Reduce risk without costing jobs or property value
  - Goals may involve public values
    - Reduce risk to protect people or wildlife

Defining Problems (continued)

- Identify Risk Managers
  - These are the people responsible for managing the problem

Defining Problems

- Establish a Process for Engaging Stakeholders
  - Stakeholders are all groups with a "stake" in the risk management
    - Those affected by the risk (Community/ethnic groups)
    - Risk managers (Local, State, and Federal agencies and governments, Public Health agencies)
    - Those affected by efforts to manage the risk (businesses, labor unions, environmental organizations, research institutions, etc.)

Defining Problems (continued)

- Risk management decisions made in collaboration with stakeholders are more effective and durable
- Identify stakeholders early in the process

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Analyzing Risks

- Effective risk management involves knowledge of the potential harm a situation poses and the likelihood that people or the environment will be harmed
- The analysis of these factors is RA
- The nature, extent, and focus of RA should be guided by risk management goals

Analyzing Risks (continued)

- The goal of RA is to assist in the making of public policy that is the basis for regulations that aim to be protective of human or environmental health.
- RA can be controversial because it is not scientifically predictive of adverse outcomes.

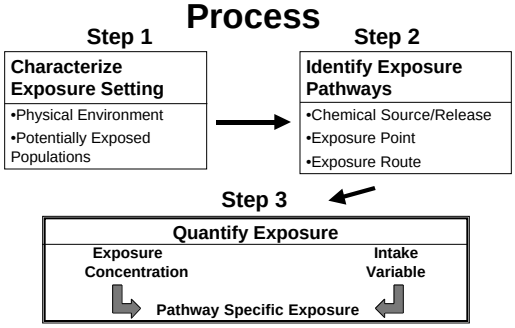
Analyzing Risks (continued)

- RA is performed by considering hazards, the extent of exposure to the hazards, and information about the relationship between exposures to hazards and responses.

Components of RAs

- Exposure assessment
- Toxicity assessment
  -Hazard identification
  -Dose-response
- Risk characterization

The Exposure Assessment Process



Exposure assumptions are used throughout this process to liken the RA to real-life situations. Assumption is a source of uncertainty in RA.

Toxicity Assessment

- **Hazard identification**
  - Determine the type of health effect(s) caused by a chemical
    - Noncancer effects (e.g. liver, kidney, CNS)
    - Cancer (USEPA ranking system as to whether chemical has caused cancer in human or animals)

Toxicity Assessment

- Extrapolation of animal data to human RA is a major source of uncertainty in chemical RA.

Toxicity Assessment

- **Dose-response assessment**
  - relationship between the amount of exposure to a chemical and the adverse health effect
    - Noncancer effects - USEPA develops a reference dose (RfD) that is used in calculating noncancer risk.
    - Cancer - USEPA develops a slope factor that is used in calculating cancer risk

Toxicity Assessment

- Different species often show varied responses to similar doses of a chemical, another source of uncertainty in chemical RA.

Calculating Lifetime Cancer Risk

- **Lifetime cancer risk**
  - **25%-33% of people will develop some form of cancer in their lifetime.**

Calculating Lifetime Cancer Risk

- **It is important to note that theoretical lifetime cancer risks do not predict the number of cancers that will occur in a population of people exposed to a chemical. For instance if a chemical exposure increases cancer risk by 1 in 10,000, this does not mean that a population of 100,000 people will see 10 more cancers.**

Calculating Lifetime Cancer Risk

- **Lifetime cancer risks are used to set exposure levels that are tailored to protect any one individual from experiencing an unacceptable increase in their personal cancer risk.**

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Examining Options

- This step involves identifying risk management options and evaluating their effectiveness, feasibility, costs, benefits, unintended consequences, and cultural or social impacts.
- Examining management options can be aided by a complete RA, but also can help refine the RA.
- Stakeholders may assist in this process by assisting in the development of methods to identify, analyze, and evaluate the effect of management options.

Examining Options

- The steps of examining management options include:
  - Identifying options: engineering controls, regulatory policies, risk reduction education, establishing incentives for risk reduction
  - Analyze options: What are the benefits? Costs? Who pays? What are the implications? Are options feasible? Will other risks be increased?

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Making a Decision

- Who decides?
  - Win-win decisions are possible when decision makers consider the inputs of stakeholders who have to live with the consequences of the decision.

Making a Decision

- What is the best decision?
  - The best decisions:
    - Are based on the best available scientific, economic, and technical information
    - Account for a hazard's multirisk contexts
    - Choose management options that are feasible

Making a Decision

- What is the best decision?
  - The best decisions:
    - Give priority to preventing, not just controlling, risks
    - Use alternatives to command-and-control regulation
    - Are sensitive to political, social, legal, and cultural considerations
    - Include incentives for innovation, evaluation, and research

Decision Making in Chemical RA: Establishing Cleanup Levels

- Chemical cleanup levels for soil and groundwater should:
  - Be based on sound RA to protect human health and the environment
  - Account for site-specific characteristics (multirisk)

Decision Making in Chemical RA: Establishing Cleanup Levels

- Chemical cleanup levels for soil and groundwater should:
  - Be achievable according to currently available cleanup and sampling methods (feasibility)
  - Reduce or eliminate risk of recontamination (prevention)

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Taking Action

- Good risk management decisions can be implemented effectively, expeditiously, flexibly, and with stakeholder support
- All previously mentioned stakeholders may play a role in this step of the process, from implementation, to monitoring of results.

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Evaluating Results

- Review the actions implemented
- Evaluate the effectiveness of actions
  - Monitoring and measuring
  - Comparing costs to benefits
- Evaluate the effectiveness of the process leading to implementation of action.

Evaluating Results

- Evaluation provides information about:
  - The success of implemented actions
  - Whether the management process should be altered to improve success
  - Whether information gaps hindered success
  - Whether new information has emerged that some step of the management process should be revisited

Evaluating Results

- Evaluation provides information about:
  - Whether the management process was effective and if stakeholder input was helpful
  - What lessons can be learned to drive future risk management processes

Summary of Risk Management

- The risk management process and its proper application to public health is dependent upon sound judgments involving hazard identification, risk analysis, management options, decision making, actions taken, and evaluation of the effectiveness of the risk prevention activities.

The Fear of Risk

- We are bombarded by the media with warnings about risks to our well-being.
- True risks to our health must be well researched and documented.
- Too often, rumors or false information drive our society's perception of real risks.
- Examples:
  - "Cell phones cause brain tumors"
  - "Breast implants cause connective tissue disease"

The Fear of Risk

- Examples:
  - "Electromagnetic radiation from power lines causes disease"
  - Each of these perceived risks was debunked by epidemiological studies
- Despite solid evidence of safety, many consumers continue to be greatly influenced by false perceptions of risk due to the emotional impact.

Uncertainties in Risk Assessment

- RA is Ultra-Conservative
  - RA is Protective ***not*** Predictive
  - Based on animal data almost exclusively
  - Often data from the most ***sensitive*** species, rather than the most ***appropriate*** species, are used in calculating risk

Uncertainties in Risk Assessment

- Exaggeration of risk exists in regulations
  - Use of unwarranted assumptions rather than site-specific data
  - Use of theoretical "worst-case" scenarios in assumptions
  - These factors are compounded in calculating risk resulting in over-estimation of risk

Making Sense of Risk: Comparative Risk Values

- The International Toxicity Estimates for Risk (ITER) database is now part of NLM's TOXNET.
- ITER is a database of human health risk values from major organizations worldwide for over 600 chemicals of environmental concern.

Making Sense of Risk: Comparative Risk Values

- ITER is a product of Toxicology Excellence for Risk Assessment (TERA), a non-profit group whose mission is to protect public health by developing and communicating risk assessment values, improving risk methods through research, and educating the public on risk assessment issues.
- http://toxnet.nlm.nih.gov/cgi-bin/sis/htmlgen?iter

Making Sense of Risk: Comparative Risk Values

- ITER risk values are included from the USEPA, ATSDR, Health Canada; the IARC, the RIVM (the Netherlands); and various other groups.
- http://toxnet.nlm.nih.gov/cgi-bin/sis/htmlgen?iter

Making Sense of Risk: Comparative Risk Values

- ITER provides a comparison of international risk assessment information in a side-by-side format and explains differences in risk values derived by different organizations.
- http://toxnet.nlm.nih.gov/cgi-bin/sis/htmlgen?iter

Other Upcoming Programs:

Reproductive Health Issues for Women Over 40
Wednesday, April 14, 2004
2:00-4:00 p.m., Central Time

Obesity in Adolescents and Adults
Wednesday, April 21, 2004
2:00-4:00 p.m., Central Time

Other Upcoming Programs:

Hospitals Response to Emergency Events
Thursday, April 22, 2004
12:00-1:30 p.m., Central Time

For a complete listing of programs, visit our website: www.adph.org/alphtn