USE OF MONITORING DATA IN HUMAN/ECOLOGICAL EXPOSURE ASSESSMENT

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Contents

1. Introduction
1.1. Research Data vs. Monitoring
1.2. Short-Term Monitoring
1.3. Compliance Monitoring
2. Types of Data Available
2.1 Sources of Monitoring Data
2.2. Continuous vs. Discrete Input Variables
2.3. Uncertainty in Monitoring Data
3. Weight of Evidence and the Precautionary Principle
3.1. Weight of Evidence
3.2. Precautionary Principle
3.3. Hypothesis Generation
4. Concept of Exposure Assessment (EA)
4.1. Who Performs an Exposure Assessment
4.2. Biological Markers in Exposure Assessment
4.3. Probabilistic vs. Deterministic Exposure Assessments
5. Structure of Exposure Assessment
5.1. Timing of Exposure
5.2. Environmental Transport and Transformation
5.3. Pathways of Exposure
5.4. Vulnerability and Susceptibility
5.5. Bioavailability and Absorption
5.6. Sources of Data in Exposure Assessment
6. Ecological Exposure Assessment (EEA)
6.1. Environmental Media and Pathways
6.2. Uses of Exposure Data
7. Human Health Exposure Assessment (HEA)
7.1. Human Health Monitoring Databases
7.1.1. The National Center for Health Statistics

7.1.2. National Human Exposure Assessment Survey
7.1.3. Environmental Quality Databases
7.1.4. Biomonitoring Databases
7.1.5. Industrial Ecology Monitoring and Exposure
7.1.6. Industrial Hygiene Monitoring
8. Case Study: Monitoring and Methylmercury Exposure
8.1. Methylmercury in Aquatic Food Chains
8.2. Methylmercury and Human Exposure
8.3. Using Biomonitoring Data on Fish for HEA
9. Conclusions
Acknowledgments
Glossary
Bibliography

1. Introduction

With increasing concern for ecological and human health, society seeks ways to assess the state of our environment, including the presence, impact, and implications of environmental contamination on a local, regional, and global scale. Decisions regarding the management of risks are often predicated on risk assessments, which in turn combine a toxicological (dose–response) assessment and an exposure assessment. While there are arguments about who should conduct such assessments, and at what scale, there is little disagreement that we need methods of assessing both the short-term and the long-term health of ecosystems and the organisms inhabiting them, including humans. These assessments require either sound data that are obtained either specifically for the risk assessment, or the use of data existing in the research literature or in a variety of monitoring databases. Monitoring programs can serve a valuable role in environmental and human health assessment, if the data are appropriately obtained in space and time and if the data are made available in a usable fashion. This chapter focuses on when and how monitoring data can be used in exposure assessment (EA) and risk assessment (RA).

1.1. Research Data vs. Monitoring

We distinguish between monitoring data and research data. For the purpose of this discussion, “monitoring” refers to data that are collected regularly and on a systematic basis, rather than data which are obtained specifically to address a risk assessment (RA) or exposure assessment (EA) need. Often, when monitoring data are inadequate in location, timing, quantity, or quality, it becomes necessary to obtain new data specifically for an exposure assessment. Monitoring data are often useful, however, in informing the RA and EA process, while an EA in turn can often define new monitoring needs.

1.2. Short-Term Monitoring

Ideally, monitoring programs are ongoing and are funded in perpetuity so that temporal trends can be documented. This allows for the identification of problems or for validation that an intervention has been effective in reducing exposure. However, some

research and planning projects develop short-term monitoring programs lasting weeks or months to address specific exposure questions. Only occasionally do such programs mature into ongoing monitoring, and we do not distinguish between these short-term projects and specific research measurements. In other words, just because an author reports that they "monitored" something does not mean that they established a monitoring program.

1.3. Compliance Monitoring

Although many monitoring programs are designed as early warning systems or to identify temporal or spatial trends, others are conducted routinely to ascertain compliance with certain laws, regulations, or permits. Compliance data usually are not assembled into useful databases until someone decides that it warrants study. Thereafter the data may become available for exposure assessment. Many local, state, and federal agencies routinely receive monitoring data that can be accessed.

2. Types of Data Available

The data used for an EA fall into three categories: (a) data obtained specifically for the EA, after the EA has defined its needs; (b) data obtained from the literature based on specific ecologic, toxicologic, or epidemiologic studies; and (c) data obtained routinely as part of a formal monitoring program. In principle, monitoring data ought to be useful for EA, while in actuality, EAs often identify the kind(s) of data that should be routinely monitored for.

2.1 Sources of Monitoring Data

Monitoring may provide information at the global, regional, landscape, ecosystem, or component level. Additionally, monitoring data sets differ in completeness, documentation, validation, and other quality features. Monitoring data can be obtained from many sources as described in previous chapters (see *Fundamentals of Monitoring Technology and Global Observation Systems*). Monitoring can involve many abiotic and biotic systems, at a variety of temporal scales. Ideally, an EA can make use of monitoring data that were tailored to meet the needs of the particular EA. Typically, however, one performs an EA using data that were not specifically designed for that EA.

Monitoring data may reflect abiotic components (air, water, soil, and sediment), biological processes (e.g., numbers of organisms, mortality rates, and reproductive rates), biochemical markers (e.g., enzyme activity), or toxicological markers (e.g., blood lead and urinary metabolites). While biological processes usually involve individuals or populations, attention in the period leading up to the twenty-first century has focused on ecosystem structure and function, such as species diversity, productivity, nutrient cycles, and food-web relationships. Similarly, there are larger scale human processes (disease rates, migrations, demographic changes, and susceptibility) that may provide useful data. Data may relate to a very specific concern such as the levels or actions of a particular toxicant, or to more general concerns such as the impact of energy policies or suburban sprawl.

Sources of monitoring data may use low technology (field observations) or high technology (real-time data acquisition by satellites). Data sets may be sparse (one observation per year) or dense (updated several times a minute), and the scale of spatial resolution varies greatly as well. Both the vision of the monitoring agency and the budget available are important determinants. Because of political jurisdictions, data are often limited to counties, states, or countries, and rarely apply to entire continents or hemispheres. Monitoring on a global scale is more difficult, and is usually limited to considerations of global atmospheric conditions or ocean currents.

Monitoring may involve bioindicator populations or species that provide information on exposure or risk to ecosystems or human health. An indicator is particularly valuable and cost-effective when it provides both ecological and human health information.

2.2. Continuous vs. Discrete Input Variables

Monitoring data are typically quantitative in nature, and acquiring a set of monitoring data should allow identification of spatial or temporal trends and recognition of the underlying distribution of values from which parameters (at least mean and variance) can be extracted. Much environmental data proves, empirically, to have an underlying lognormal distribution. For some analytes in some media, many values may fall below the method's limit of quantification. Such distributions are referred to as censored. If many values are in the undetectable range, it is difficult to adequately characterize the distribution. This may be gratifying in a compliance monitoring program, but limits the data's applicability to an EA. However, where there are good distributional data in the monitoring data set, they lend themselves both to modeling (for example of dispersion in a medium or in the body), and they lend themselves to a probabilistic risk assessment.

2.3. Uncertainty in Monitoring Data

Monitoring data can be employed in an EA usually as a starting point in calculating exposure. The quality of the input data will have at least four sources of variability: intrinsic variation, sampling errors, analytic errors, and random errors. Some databases have built in quality assurance components that operate at the design and laboratory phase to minimize sampling and analytic errors. Analytic errors range from mix-up or mislabeling of samples to errors introduced during storage, preparation, compositing, extraction, analysis, calculation, and reporting. Chain-of-custody procedures can reduce some of the errors, but built in error-trapping algorithms should be used to reduce others. Quality control strategies including use of reference laboratories will further reduce errors, but are often not included in monitoring programs because of the added cost. In any case, the quality assurance procedures for any monitoring program should be reviewed before incorporating their data in an EA.

Users of monitoring data should have access to documentation of the Quality Assurance and Quality Control (QA/QC) procedures in order to be confident in the overall quality of the data. These procedures involve methods of assuring the accuracy and precision of the data, and vary depending upon how the data are generated or collected. Ultimately,

however, the user must decide whether monitoring data are sufficient in type, quantity, or quality to support an EA.

Almost invariably, cost considerations limit the amount of sampling data that can be obtained. Limits can be on the number of locations, the frequency of samples, the number of analytes or the range of indicators measured. When a monitoring system becomes particularly relevant to a policy problem, additional funding is likely to become available to expand the program—either increasing the number of sampling stations, the frequency of sampling, or the number of analytes.

3. Weight of Evidence and the Precautionary Principle

Traditionally, science has progressed by slow steps involving the accumulation of studies showing consistent associations that ultimately lead to acceptance or a consensus. Exposure assessments require sufficient data to allow for a minimum of extrapolations or assumptions. However, with increasing development and industrialization, environmental problems have escalated faster than the ability to collect sufficient data to form clear consensus among scientists. This is especially true for monitoring data where many years are required to generate sufficient data for trend analyses.

Since managers require scientific information to make decisions about ecological and human health risk management, regulation, and public policy, the gap has been filled by two approaches: weight of evidence and the precautionary principle. As with most public policy decisions, these involve an iterative process whereby scientific inquiry must continue to fill data gaps, and to determine if the decisions made by these processes are still appropriate and protective of human and ecological health.

3.1. Weight of Evidence

"Weight of evidence" refers to a quantitative ranking of evidence or the qualitative appraisal of many different sets of data to arrive at a conclusion. Sometimes much of the evidence is not suitable for mathematical treatment, but is qualitative. Much evidence derives from epidemiological and clinical studies, long-term laboratory assays, and predictive short-term tests, the latter two with animal models. Because of limitations of data and sample sizes, suggestive associations may not always reach statistical significance. Hence, meta-analyses are used to combine data from several studies in order to identify data consistencies.

3.2. Precautionary Principle

In contrast, the precautionary principle states that where there are threats of serious or irreversible damage, lack of full scientific certainty or lack of adequate data shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation. This was affirmed by the Rio Declaration of the United Nations Conference on Environmental Development in 1992. Efforts to eliminate exposure should be made, unless there are adequate data for EA and RA to identify tolerable levels of exposure.

While many lines of evidence are used to make decisions that involve ecological and human exposure assessment, the precautionary principle may be applied when the data sets are less complete. This may occur where monitoring data are not sufficient for statistical analysis, but where enough information is available to identify a trend that should not be ignored, and where there are serious ecological or health consequences of waiting for more complete monitoring data for complete exposure assessment models.

3.3. Hypothesis Generation

Often the use of preliminary data (such as readily available monitoring data) can help an EA focus attention on the kinds and quantity of new data that are needed. Monitoring data may establish the boundaries of the data likely to be obtained, or identify the analytic specifications needed. Monitoring data, either of ecosystems or organisms, including humans, can often be used to generate hypotheses that can be tested in other systems or populations in the region, on other past data sets, or to predict future outcomes.

4. Concept of Exposure Assessment (EA)

4.1. Who Performs an Exposure Assessment

EA is not performed in a vacuum. Usually there is a specific risk assessment that must be accomplished to address a particular policy question or risk management need. Faced with a particular EA charge, a variety of specialists (environmental scientists, toxicologists, social scientists, modelers, epidemiologists, industrial hygienists, and medical personnel) may be involved in the selection and interpretation of data required for the toxicological assessment and the EA.

RAs require the coupling of toxicological dose–response information (how much causes how much effect) with exposure assessments (how much of a toxic agent reaches the target). A highly toxic substance such as lead may pose little risk if there is negligible exposure, while a substance with relatively low toxicity may engender risk if there is a large population with a high level of exposure. EA is therefore as important as toxicological studies in understanding the impact of hazardous materials on the environment and human health. EA is often depicted as a pathway from source to tissue, with different types of monitoring data available at most points in the pathway (Table 1).

Part of pathway	Monitoring
Source (smokestack)	Stack monitoring
Atmospheric transport and transformation	Atmospheric sampling
Deposition	Deposition network data
Inhalation	Not usually monitored
Contamination of secondary	

media (soil, water, food)	Monitoring concentrations in media
Ingestion or inhalation	Market basket surveys
Uptake into bloodstream (modified by bioavailability and absorption properties)	Biomonitoring (usually only in occupational settings)
Metabolism (excretion)	Urinary excretion
Distribution to other tissues	
Target tissues	Functional measurements
Biologically effective dose	
Storage sites	Monitoring of tissue levels
Subclinical condition	Biomonitoring
Clinical disease	Medical screening

Table 1. An exposure pathway for a hypothetical agent from its source (point of release into the environment) to the target tissue where a biological effect is engendered

EA as a discipline has grown greatly in scope and stature from 1980 to 2000. Several important review articles have appeared, and the dedicated *Journal of Exposure Assessment and Environmental Epidemiology* focuses on this area.

When exposure is expected for a human population, a typical approach is to conduct a cross-sectional screening that includes, wherever feasible, testing for a biomarker of exposure or effect. This is distinct from monitoring data. However, in some cases, routine monitoring data are available for comparison. For example, in the United States the National Health Nutrition Examination Survey (NHANES) measures blood lead or mercury levels in a random subset of the population, against which results from a putatively exposed population can be compared.

Overall exposure assessment includes defining populations or subgroups at risk; developing sampling strategies to determine concentrations in media and factors that control release, transport, and delivery; and identifying behavioral factors influencing contact.

Exposure (E) can be summarized as follows

$$E = (K_a \cdot I_a \cdot A_a) + (K_w \cdot I_w \cdot A_w) + (K_f \cdot I_f \cdot A_f) + (K_s \cdot I_s \cdot A_s) \quad (1)$$

taking into account the exposure pathways of air (a), water (w), food (f), and soil (s) and the relevant variables concentration (K), intake (I, amount ingested or inhaled), and absorption (A).

Each component defines a primary pathway. Table 2, the exposure matrix, illustrates secondary pathways as well.

Pathway	**Air**[a]	**Water**[b]	**Food**[c]	**Other pathways** (vaccines, drugs[d] and pesticides)
Inhalation	Small quantities in outdoor air; occasionally large concentrations in indoor air	Negligible amounts from showering		
Ingestion	In workplaces, mercurials can deposit on food	Usually low concentrations in drinking water	Fish are the main methylmercury pathway	Fungicide-treated grain has caused major epidemics
Skin contact		Slight absorption of organomercurials		Used as an antiseptic, formerly used as a topical anti-infectious agent Dimethylmercury killed one professor
Injection				Babies (especially premature)

[a]Air Deposition Network Data
[b]Some state monitoring of surface and ground water
[c]Old Food and Drug Administration (FDA) and National Oceanic and Atmospheric Administration databases, some state surveys; no current regular FDA monitoring
[d]Thimerosal; published concentrations of thimerosal in various vaccines

Table 2. An exposure matrix for mercury, a typical pollutant Available monitoring data are shown in boldface.

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