Approaches for Exposure Characterization and Data Needs for Hazardous Waste Site Assessment

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This article provides an understanding of the approaches for determining exposure and dose to populations in the vicinity of hazardous waste sites. A review of the federal legislation and jurisdiction for assessments is provided, and the approaches of the U.S. Environmental Protection Agency and the Agency for Toxic Substances and Disease Registry are compared. These methods strive to aid in the evaluation of public health impacts of contaminants that were, are, or may be released to the community, and they are concerned with various aspects of the contaminant fate, human contact, and toxic response for chemicals of concern. Such approaches have been designed for generic contamination scenarios, but they aim to be applicable to a wide range of chemicals and sites in the real world. Along with any modeling framework for exposure and dose characterization, detailed information or real data are requisite for the completion of any site-specific assessment. What kinds of data are needed and where they may be found are also discussed. A comprehensive framework for exposure characterization, recently proposed by Georgopoulos and Lioy, is outlined. The framework is one employing the following elements: chemodynamic analyses of sources and receptors; characterization of the target population; toxicokinetic/toxicodynamic analyses; uncertainty/error analyses; and evaluation of the characterization performance. — Environ Health Perspect 103(Suppl 1):99–104 (1995)

Key words: exposure assessment, hazardous waste sites, superfund, public health

Introduction

Hazardous waste sites remain a prominent environmental issue, in large part because of the many unknowns about their impact on public health and the environment. The U.S. Environmental Protection Agency (U.S. EPA) currently lists close to 35,000 uncontrolled hazardous waste sites. The U.S. EPA's National Priority List has been developed to identify the sites posing the greatest threat; 1,232 sites are currently listed (1). Hazardous waste sites are frequently the result of viable industrial activities of the past conducted in ways acceptable to the standards of the times. Particularly, waste disposal practices of earlier years have contributed to a large fraction of the NPL sites. Facilities that are presently of concern were enterprises for municipal landfilling, liquid and solid waste disposal, chemical manufacturing, mines and processing, and farming. In addition to industrial sites, federally owned facilities make up approximately 10% of NPL sites. These include military installations of the Department of Defense and the weapons complex of laboratories and production operations of the Department of Energy (2). In many cases, groundwater contamination—current or potential—is chief among the hazards identified to motivate the initial investigation and the NPL listing.

The purpose of this article is to provide an understanding of the approaches for determining exposure and dose to populations in the vicinity of hazardous waste sites. A review of the federal legislation and jurisdiction for assessments is provided, and the U.S. EPA and Agency for Toxic Substances and Disease Registry (ASTDR) approaches are compared. Along with any modeling framework for exposure and dose characterization, detailed information or real data are requisite for the completion of any site-specific assessment. The kinds of data needed and where they may be found are also discussed.

Jurisdiction for Protection of Public Health

Starting in the 1970s, Congress began enactment of a series of legislative statutes to address the protection of the environment, focusing on the various media, e.g., air and water. In the late 1970s, a second set of acts was passed to begin remediation of past environmental problems, notably hazardous waste sites (Table 1). Amendment and reauthorization of the legislative statutes have continued into the 1990s.

The Resource Conservation and Recovery Act of 1976 (RCRA) and its amendments (the Hazardous and Solid Waste Act of 1984) gave the U.S. EPA authority to manage hazardous waste from its generation to its disposal and to require cleanup or "corrective action" at active hazardous waste facilities. RCRA requires a sequence of U.S. EPA processes: facility assessment, facility investigation, the

| Act                                      | Year enacted |
|------------------------------------------|--------------|
| National Environmental Policy Act (NEPA) | 1970         |
| Federal Water Pollution Control Act (FWPCA) | 1970         |
| (National Pollutant Discharge Elimination System) | 1970         |
| Clean Air Acts (CAA)                     | 1970         |
| Clean Air Act Amendments (CAA (National | 1990         |
| Emission Standards for Hazardous Air Pollutants) | 1990         |
| Resource Conservation & Recovery Act (RCRA) | 1976         |
| Hazardous and Solid Waste Act (HSWA)     | 1984         |
| Toxic Substances Control Act (TSCA)      | 1979         |
| Solid Waste Disposal Act (SWDA)          | 1980         |
| Comprehensive Environmental Response, Compensation and Liability Act (CERCLA) | 1980 |
| Superfund Amendments and Reauthorization Act (SARA) | 1986 |
corrective measures study and implementation. It also authorizes interim measures to protect human health or the environment. There have been 4300 facilities included under RCRA authority. The facilities are comprised of solid waste management units (SWMU), which consist of landfills, surface impoundments, waste piles, and incinerators. On average, each facility contains 15 to 20 SWMUs; the national total is over 60,000 SWMUs. Approximately 80% of the facilities are suspected to have releases requiring investigation.

The Comprehensive Environmental Response, Compensation and Liability Act (CERCLA) was conceived to supplement previous legislation focused on specific environment media and on waste handling and disposal. The Superfund legislation, as it is generally known, was borne out of two major hazardous waste catastrophes: the development of a community of homes on top of a waste site at Love Canal in upstate New York and an industrial fire that occurred at a chemical storage facility in densely populated northern New Jersey.

The U.S. EPA has the chief regulatory authority for hazardous waste sites, in terms of site investigation and remediation, although an array of federal and state agencies share jurisdiction. Those agencies include the Agency for Toxic Substances and Disease Registry, Centers for Disease Control, Occupational Safety and Health Administration, facility owner-operators, U.S. Department of Energy, U.S. Department of Defense, and state departments of health or environmental protection.

The Superfund legislation established and funded ATSDR as part of the U.S. Public Health Service to support the public health assessment needs. The act mandated ATSDR to establish a National Exposure and Disease Registry, to create an inventory of health information on hazardous substances, to create a listing of closed and restricted sites, to provide medical assistance in hazardous substance emergencies, and to determine the relationship between hazardous substance exposure and illness. The 1986 Superfund Amendments and Reauthorization Act (SARA) broadened the agency's responsibilities in areas of public health assessments, establishment and maintenance of toxicologic databases, information dissemination, and medical education (3).

The corrective action program under RCRA is different from Superfund's. RCRA aims to address contamination at active facilities, while CERCLA actions are used at inactive sites and to handle emergency response actions. At active sites, owners/operators are expected to pay for corrective action, ordered or advised under RCRA authority. Under Superfund, public funds are used to clean up facilities that are no longer active. The act calls for eventual recovery if viable “responsible” parties can be found. However, this places the investigation and remediation action under heavy scrutiny because litigation is a major concern of both the U.S. EPA and corporate owners.

RCRA aims to prevent the creation of future Superfund sites. This goal is to be accomplished by minimizing release of hazardous wastes to the environment by proper management of its generation, treatment, storage and disposal, and cleaning up of past releases of wastes and constituents by facility owners/operators while the facilities are still in existence and financially viable. RCRA gives U.S. EPA authority for permitting and enforcement to control hazardous waste activities and to require corrective action. It oversees four major types of facilities: treatment, storage, incinerator, and land disposal. Even as they terminate operations, land disposal facilities (i.e., landfills) are required to get a permit to close.

Required Assessments

In the course of site investigation for consideration of listing on the NPL and possible planning of site remediation, a number of assessments are conducted that evaluate public health impacts. The goals of the health assessments are compliant with regulatory requirements; public health (risk) assessment for current and future (potential) exposures; environmental restoration; and communication among the affected public, policy makers, and other interested parties. To evaluate the potential impact on public health and the environment and the need for corrective action (such as site remediation), various forms of assessments are required. Risk assessment methodology has been developed to characterize the potential health impacts due to contact with environment hazards (4). It is used by U.S. EPA in guiding the regulatory control of carcinogens and other chemicals under a number of Federal statutes. The format of the EPA Risk Assessment is shown in Table 2.

ATSDR is mandated by Congress to conduct public health assessments for all sites on the NPL. From a description given in the Agency's guideline document:

A health assessment is the evaluation of data and information on the release of hazardous substances into the environment in order to assess any current or future impact on public health, develop health advisories or other recommendations, and identify studies or actions needed to evaluate and mitigate or prevent human health effects (3).

The ATSDR Health Assessment procedure is also given in Table 2 (5). These approaches are somewhat complementary in their utility. One chief difference between the two approaches is the emphasis by U.S. EPA on contaminant data and modeling versus ATSDR's employment of community health data. It is important to keep in mind that U.S. EPA's risk assessments are legal documents, which directly impact site permitting, remediation, and litigation, while the public health assessment is advisory in its scope and intent. The two assessment protocols are compared in Table 3.

### Need for Exposure Assessments

The two approaches to assessment both rely heavily on the determinations of human contact to evaluate the impact on public health or risk characterization. Pathways of exposure are shown schematically in Figure 1. Individuals at the site or in the neighboring communities are subject to contaminant exposure via contact with hazardous substances in the various media (Table 4).

Exposure is often described within a continuum that starts with the emission or release of a toxicant into the environment; incorporates its physical and chemical fate leading to the potential for human contact;

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**Table 2. U.S. EPA and ATSDR assessment methods.**

| EPA risk assessment | ATSDR health assessment |
|---------------------|-------------------------|
| Hazard identification | Evaluate site information |
| Toxicology (dose–response) assessment | Identify and respond to community health concerns |
| Exposure assessment | Determine contaminants of concern |
| Risk characterization | Evaluate transport and human exposure pathways |
|                       | Determine public health implications |
|                       | Determine conclusions and recommendations (including public health actions) |
includes its uptake, metabolism and elimination in the human biological system; and finally investigates the responses (systemic, organic, tissue and cellular, and biochemical) that are indicative of toxicologic effect. A graphic representation of this paradigm (Figure 2) has been aptly summarized by Lioy (7).

Often, an environmental regulator approaches human exposure as a mere component of a contaminant’s environmental fate. Calculations of potential human contact are called for, based chiefly on knowledge of the engineering and chemical systems. This is a mistake: the toxin should not be viewed as a conceptual projectile—from its source and through the environment—into the sphere of people. For one thing, there are many interactions between the contaminant and the human receptors. As in the case of any problem requiring multidisciplinary study, this approach should be considered too narrow for general use. Chemodynamic models are widely available; however, data are frequently lacking to support such a unidirectional concept. Hence, fate-derived estimates of exposures can be orders of magnitude off the mark.

Exposure measurement takes two essential approaches: direct and indirect. In all cases, the aim is to acquire information that is as specific to the target population as possible, affordable, and reliable. Indirect methods can include use of public records of surveillance data, environmental model calculations, using questionnaires and diaries of time use. The main advantage of indirect methods is the large reach that can be included in such surveys. The disadvantage, of course, is its greater uncertainty and inaccuracy. This is crucial to consider in the absence of direct method data to validate modeling of environmental data and categorical responses to questionnaires.

Direct approaches provide measurements are made on, around, or inside individual subjects (Table 5). For workers, monitoring their exposure follows industrial hygiene practice, since their location and activity can be well defined. For a population at risk in a residential community, this may be far more difficult, since their individual activities can vary as much as people do. However, it is possible to monitor a population as thoroughly as necessary given intent, resolve, and resources.

The exposure continuum shown previously might be conceptually convoluted into the concentric circles (Figure 3). The fate-derived estimates occur in the domain

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**Table 3.** Comparison of U.S. EPA and ATSDR assessment methods.

| U.S. EPA risk assessment | ATSDR public health assessment |
|--------------------------|--------------------------------|
| Bears regulatory weight of authority | Advisory                      |
| Quantitative, compound-oriented, site-specific; uses environmental contamination data | Qualitative, site-specific; uses environmental contamination, health outcomes, and community health concerns data |
| Statistical and/or biologic models used to calculate estimates of health risks | Medical and public health perspectives weighted to assess health hazards |
| Used to facilitate remediation or other risk management actions | Used to evaluate human health impacts and to identify public health interventions |
| May lead to selection of particular remediation measures at a site | May lead to pilot health effects studies, surveillance, epidemiologic studies, or exposure registry |

*Adapted from Johnson (6).*
Table 5. Exposure elements.

| Environmental quality | Microenvironmental | Personal | Biomarker |
|-----------------------|---------------------|----------|-----------|
| Concentrations in various media | Concentrations specific to location | Concentrations specific to person | Concentrations specific to bodily fluid or tissue |
| Ambient air, water supplies, soil, biota | Air (work, home, school, etc.), drinking water (at tap), house dust | Air, food and beverage, dermal contact | Exhaled breath, urine, cell tissue, serum, hair/nail |
| Internal dose/biologically effective dose | Exposure/Effect/Susceptibility | Health response specific to person | Early biological effect |

Figure 3. Paradigm for exposure measurements.

of environmental quality measurements. These are made largely irrespective of the experiences of the population at risk. In contrast, microenvironmental measurements are those targeted to the places the population spends its time. They can include measurements within a home, school or office, i.e., in places that typify the daily experiences of the people. In the case of exposure assessments for air contaminants, indoor air quality data are frequently absent, yet most individuals spend approximately 90% or more of their time indoors.

Personal sampling makes direct measurements within individuals' exposure domains. Industrial hygiene practices have been applied and modified to extend this practice to community exposure assessments. Time-weighted measurements of air contaminants in the breathing zone, prepared food samples, and dermal patches are examples. Personal sampling is intrinsically more accurate, but it demands dramatically more resources. In addition, it is not always required. For example, unless an individual in some way modifies breathing zone air quality (such as working with a combustion source), air inside a microenvironment has been shown to be homogeneous.

Human biomarkers are direct or indirect indicators of contaminant contact, uptake, metabolism, or elimination in the human biologic system. The National Academy of Science's Committee on Biomarkers divides them into three broad cases: markers for exposure, effect, and susceptibility. Taken on a continuum, these represent the gradient from mere internal presence of a chemical to changes in cellular or subcellular function to disorders of organs or organ groups to clinical disease. Biomarker studies have the potential to reduce much of the uncertainty about how and to what extent exposures are occurring. Most metals have the advantage that direct analysis of a variety of body tissue is possible. For many organic compounds, it is necessary to look for their metabolites as markers of exposure, since the chemicals themselves are rapidly modified or degraded. However, each step provides greater accuracy, frequently at substantially greater cost. Measurements of biomarkers are taxing and expensive because they are generally invasive and require sophisticated analytical methods.

Information Resources

There are currently 275 chemicals on the Priority List of Hazardous Substances. These are ranked using an algorithm that weights the toxicity, frequency of occurrence at Superfund sites, and the potential for human exposure. Metal contaminants are prominent, especially in soil, surface water, and sediment contamination. Solvents and pesticides are frequently found in groundwater contamination. The top ten chemicals on the 1992 priority list are lead, arsenic, metallic mercury, vinyl chloride, benzene, cadmium, polychlorinated biphenyl, chloroform, benzo[a]pyrene, trichlorethylene.

Information on the chemical and toxicological characteristics of the priority chemicals is compiled in the EPA Office of Toxic Substances in Hazardous Substance Fact Sheets. In addition, ATSDR was directed (under SARA) to prepare toxicologic profiles for the hazardous substances that are most commonly found at NPL facilities and that pose the most significant potential threat to human health. ATSDR has produced profiles for over 140 substances. The profiles give detailed information on health and toxicity data; chemical and physical properties; production, import, use and disposal; potential for human exposure; analytical methods; and regulations and advisories. Each profile begins with a public health statement, describing the substance's relevant toxicologic properties in nontechnical language.

Environmental exposure databases are essential to the conduct of risk assessments, risk management, analysis of status and trends, and epidemiologic studies (8). Information that is developed into such databases is varied in source and kind. It is routine for environmental monitoring to be tabulated and archived. This includes measurements in all media for regulatory, investigative, or operational purposes. These provide the largest resource of environmental quality information. Remote sensing data are also available from various sources to provide synoptic information on environmental quality. Site investigators frequently review facility operation and activity records. These are sometimes compiled and available for review but more frequently are proprietary data. Similarly, records of the medical surveillance of plant workers can be very relevant to site-specific assessments of exposure, but these are frequently difficult to acquire and interpret. Community health records, such as registries of exposure, tumors, birth outcomes, etc. can aid in site-specific investigations. Site visits are frequently required, and they can provide an updating of the information of record. These are the databases that can address the quantitation of human contact.

The strengths and weaknesses of these resources are that they

- provide baseline information on exposures;
- serve as vehicles for surveillance of emerging problems;
- assist modeling approaches for estimating exposures;
- enable evaluation of exposure trends.

Their primary weaknesses are that they

- do not characterize the full range of exposure or all routes of potential exposures;
- provide data that are not true measures of exposure;
- provide inadequate information on sensitive populations;
- measure only a limited number of pollutants;
- do not include pollutant mixtures;
- only consider limited health end points;
- offer data of inconsistent quality;
- are inaccessible to users;
• are expensive to use and maintain;
• provide information that is not current.

The ideal exposure database would be able to:
• provide exposures for individuals;
• delineate distribution of population;
• characterize most highly exposed sub-populations;
• measure total exposure;
• apportion information, by source;
• provide longitudinal data on exposure trends;
• incorporate a strong public health basis for measurements;
• measure cross-media transport;
• track environmental fate;
• allow archiving of biological and environmental samples;
• provide linkages to other databases;
• offer high accessibility;
• provide flexibility to increase the number of pollutants measured.

This critique was adapted from Burke et al. (9), whose report was produced by one of several working groups on the use of exposure databases. The need to link multimedia data, environmental chemodynamics, and exposure information for relevant human populations was identified. The recurrent hope is that data will be collected and archived with its utility for addressing public health concerns in mind. A further goal is to combine resources in ways that reduce uncertainties in the data used to estimate human exposures.

Framework for Exposure Characterization

In consideration of the regulatory and public health agencies' exposure assessment needs, Georgopoulos and Lioy (10) have proposed a framework for exposure characterization. A fundamental premise of the framework is that the process of data collection and analysis and mathematical modeling of toxicant dose resulting from exposures must employ the following elements: chemodynamic analysis; population characterization; toxicokinetic/toxidynamic analysis; uncertainty/error analysis; and evaluation of the characterization. Such a framework would include:

• preliminary source analysis source analysis;
• preliminary receptor analysis;
• detailed site and domain characterization;
• macro-chemodynamic modeling; environmental transport and fate assessment;
• micro-chemodynamic modeling: characterization of microenvironments;
• identification of target population(s);
• development of time/space activity patterns;
• exposure distribution modeling;
• toxicokinetic modeling for dose estimation;
• toxicokinetic modeling for exposure reconstruction;
• uncertainty analysis of exposure characterization; and
• performance evaluation of the exposure characterization.

Some of the elements are already present in the EPA and ATSDR exposure assessment guidance documents. However, the framework offers unique and needed formalization of approaches for data management and analysis; mechanistic mathematical modeling toxicant dose results from multimedia and multipathway exposures to toxic chemicals; and computational evaluation of an integrated system of exposure-related processes. Among the insights in the proposed paradigm are that exposure must be viewed as a sequence of coupled events and systems; phenomenological and mechanistic processes interplay; exposure probabilities differ for individuals than for populations; and the goals of the characterization are both prognostic and diagnostic. The coupling of PBPK modeling with environmental fate models, along with physiologic response models, can be used in predictive health studies and for dose reconstruction.

Recommendations

A number of research areas are evident in which expanded study is needed, including:

• more measurements in microenvironments;
• greater application of population time-use data;
• conducting survey studies to provide reference levels for background exposures;
• investigation of toxicant bioavailability;
• integrating biomarkers and PBPK models;
• comparison of exposures from studies at different sites; and
• enhancement of database technology, and management.

These needs are inspired by the goals of the exposure characterization, as it fits the context of the hazardous waste site assessments discussed, herein, and public health and risk assessments, in general.

Since quantitation of human contact is the goal, measurements must be made where individuals spend their time (homes, schools, offices, commuter routes, etc.). Measurements also must be made of pathways that lead directly to exposure (dermal dose, foods, drinking water supplies, etc.). Also, there are still limited data on the time-use patterns in various populations, to guide microenvironmental measurements. It is like the old story of a man looking for his car keys under the street lamp—not because he dropped them there, but because that is where the light is. Instead, greater efforts must be directed to illuminate the areas where critical uncertainties remain. Large-scale surveys of the background exposure levels will give important information about the true nature of localized impacts of hazardous waste sites.

The available reportage of the environmental presence of toxicants does not directly address its likely impacts on public health. This is due in part to insufficient knowledge of factors affecting its bioavailability. Models of toxicant uptake and metabolism (e.g., physiologically based pharmacokinetic or PBPK models) are becoming increasingly powerful tools to guide investigations of the detailed mechanisms of likely human health impacts, especially at the subclinical levels. Targeted measurements of biomarkers need to be made to verify the results of PBPK models.

Finally, exposure studies for site-by-site cases are increasing; hence, there is a need for better coordination of the results from different sites where contaminant exposures can be compared. Linking raw data from multiple sites will give greater statistical power and uncover a wider range of meaningful exposure scenarios. There is a clear need for the development of relational and object-oriented databases, and implementation of distributed computing and high-speed national and international networking. These will be essential for managing and utilizing the amounts of information relevant to comprehensive exposure assessments. Furthermore, interactive simulation and scientific visualization applications for exposure assessment will be most valuable in understanding the dynamics of complex exposure systems.

REFERENCES

1. Federal Register. 59:27989 (May 31, 1994.)
2. Office of Technology Assessment. Complex Cleanup: The Environmental Legacy of Nuclear Weapons Production, U.S. Congress, OTA-O-484. Washington:U.S. Government Printing Office, 1991:212.
3. ATSDR. FY1992 Agency Profile and Annual Report. Atlanta:Agency for Toxic Substances and Disease
Registry, 1992;289.
4. NRC. Risk Assessment in the Federal Government: Managing the Process. National Research Council. Washington: National Academy Press, 1983;191.
5. Johnson BL, Jones DE. ATSDR's activities and view on exposure assessment. J Exposure Anal Environ Epidemiol 1 (Suppl 1):1-17 (1992).
6. Johnson BL. Principles of Chemical Risk Assessment: The ATSDR Perspective. Proceedings of the Conference on Chemical Risk Assessment in DoD: Science, Policy, and Practice (HJ Clewell, ed). Cincinnati, OH:American Conference of Governmental Industrial Hygienists, 1992;29-35.
7. Lioy PJ. Assessing total human exposure to contaminants. Environ Sci Technol 24:938-945 (1990).
8. Sexton K, Selevan SG, Wagener DK, Lybarger JA. Estimating human exposures to environmental pollutants: availability and utility of existing databases. Arch Environ Health 47:398-407 (1992).
9. Burke TD. Role of exposure databases in risk management. Arch Environ Health 47:421-429 (1992).
10. Georgopoulus PG, Lioy PJ. A comprehensive framework for exposure and dose assessment. Computational Chemodynamics Laboratory Technical Report CCL-TR93-02 (Review Draft). Piscataway, NJ:Environmental and Occupational Health Sciences Institute, 1993;49.