

## **STUDY DESIGN CONSIDERATIONS FOR EVALUATING COMMUNITY HEALTH EFFECTS OF HAZARDOUS WASTE INCINERATORS**

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### **ABSTRACT**

Incineration is an increasingly employed option for treating hazardous waste, but possible health effects of hazardous waste incinerator emissions in surrounding communities have received only cursory investigation. Two approaches for assessing such effects, risk assessment and environmental epidemiology, are described and compared. Risk associated with hazardous waste incineration has been assessed previously based on generic emission data. Little is known regarding emissions from specific incinerators and their temporal variations. Thus, an epidemiologic approach was chosen here, partially because it is robust with respect to uncertainties in exposure estimates. Study design concepts and their application to an existing hazardous waste incinerator are discussed.

### **INTRODUCTION**

In 1981, an EPA survey found that of the 282 million metric tons of hazardous waste produced in the United States, 5.5 million metric tons, or 2 percent, were subjected to thermal treatment (incineration or burning in industrial boilers and furnaces) [1]. In one state nine years later, about 17 percent of all hazardous waste treated, stored, disposed of, or reclaimed was burned in commercial incinerators [2]. Efforts by incinerator operators to site new facilities and expand existing ones

suggest that incineration may become a more widely used method of treating hazardous waste. Although hazardous waste prevention and minimization are the most desirable approaches, hazardous waste generation will not be eliminated in the foreseeable future. Accordingly, the safety of disposal methods must be evaluated.

Incineration has several advantages as an option for treating hazardous waste [3]. Generally speaking, it yields the greatest degree of waste destruction and volume reduction in the shortest processing time of the available technologies for organic wastes. In addition, alternative disposal methods, such as landfills, increasingly are viewed as undesirable.

Nevertheless, numerous questions remain regarding the health effects of hazardous waste incinerator emissions in the surrounding communities. In many cases, concerns about an incinerator's health impacts, as well as its economic consequences, have resulted in adversarial relationships among the incinerator operators, the community, and the regulatory agencies; the public's perception of these issues makes it difficult to find acceptable sites for new incineration facilities.

Here the design of studies for assessing the community health effects of hazardous waste incinerators is investigated and appropriate methods for conducting such studies are described. In particular, two commonly used, broadly applicable approaches, risk assessment and environmental epidemiology, are considered.

## BACKGROUND

### Emissions

Hazardous waste incinerators emit a wide variety of compounds, most at very low concentrations. Several classes of these emissions are controlled explicitly under the Resource Conservation and Recovery Act of 1986 (RCRA). According to the RCRA, hazardous waste incinerators are required to have a destruction and removal efficiency (DRE) of 99.99 percent for each principal organic hazardous constituent (POHC). DRE is operationally defined as:

$$DRE = (W_{in} - W_{out})100/W_{in} \quad (1)$$

where  $W_{in}$  is the mass flowrate of a POHC into the incinerator and  $W_{out}$  is the mass emission of that POHC.

As concentration in the feed stream decreases, stack emissions decrease. However, an EPA study found that the DRE decreases with decreasing input concentration [4]. Consequently, none of the POHCs below 200 ppm in the feed stream were treated with a DRE of 99.99 percent or higher. EPA suggests that the input constituents most appropriately used as POHCs are those present in higher concentrations which are difficult to incinerate [5].

The emission of HCl and particulate matter are also controlled under RCRA. Hazardous waste incinerators must have an air pollution control device capable of

removing at least 99 percent of the HCl generated unless the uncontrolled emissions are less than 1.8 Kg/h. Particulate emissions must be no greater than 180 mg/std.m<sup>3</sup> (corrected to 7% O<sub>2</sub> on a dry basis). Only one of the twenty-two incinerators tested by EPA failed to meet the HCl emission limit while six exceeded the particulate limit [5].

RCRA also has special requirements for incineration of materials containing PCBs and dioxins. Compliance with all RCRA requirements are determined by monitoring emissions during periodic trial burns. The feed composition during a trial burns is specified by the incinerator operator and approved by regulatory agencies. In addition to RCRA regulations, state air pollution control agencies may impose other limitations on emissions, feed rate and feed composition; require certain operating practices and conditions (e.g., combustion chamber temperature); and require continuous monitoring of stack gases.

Metals, such as arsenic, barium, beryllium, chromium, cadmium, lead, mercury, nickel, and zinc, which are present in incinerated waste, are not destroyed by incineration although their chemical and physical form may be altered. These materials must leave the incinerator in one of three effluent streams: bottom ash, air pollution control device residue, or stack gases. Of these three effluents, stack emissions of metals are the most likely to have an impact on the health of communities near incinerators.

The risk from inhalation of airborne metals is not only related to the levels of exposure but also to their chemical form, physical state, and particle size. In several assessments of cancer risks from hazardous waste incinerators, metals were the greatest contributor to excess lifetime risk of cancer mortality. Nevertheless, total excess risks of cancer death were estimated to be quite low: from 1 in 100,000 to 1 in 100,000,000 [4].

All combustion sources emit a variety of organic compounds at low concentrations. The EPA survey gave average total hydrocarbon concentrations in stack gas ranging from 0.5 ppm to 61.7 ppm with a median of 1.8 ppm for eleven incinerators [5]. One class of compounds emitted are known as products of incomplete combustion (PICs). A PIC is any compound present in the stack effluent which was not present in the feed or air streams entering the incinerator. Studies have shown that emission rates of specific volatile and semi-volatile organic compounds from single hazardous waste incinerators covered a range of several orders of magnitude and that there was no noticeable difference between the emissions of these compounds from hazardous waste incinerators and their emissions from other combustion sources such as municipal waste incinerators, coal fired power plants, boilers, and kilns [5]. Thus, it is difficult to estimate emissions of specific organic compounds given the complex nature of the processes forming PICs and the highly variable feed composition.

Many risk assessments of municipal waste incinerators have focused on the hazards posed by emissions of two highly toxic classes of chemicals, polychlorinated dibenzodioxins (PCDDs) and polychlorinated dibenzofurans

(PCDFs) [6]. Hazardous waste incinerators tested by EPA emitted far less PCDDs and PCDFs than municipal incinerators. Furthermore, most facilities did not have detectable amounts in stack effluent [5]. Even a plant with dioxins present in the feed stream had stack gas concentrations nearly three orders of magnitude lower than typical municipal incinerators.

The classes of contaminant discussed above are emitted to the environment in stack gas from incinerators. Other releases to the air, called fugitive emissions, come from sources which are difficult to identify. Fugitive emissions of hazardous substances can occur while handling incoming wastes or effluents materials, or may emanate from leaks in the process equipment [7]. The most likely candidates for fugitive emissions are liquids with a high vapor pressure or fine particles. A risk assessment study of hazardous waste incineration found that fugitive emissions can be significant contributors to community health risks [8].

Ash and air pollution control device residues also contain hazardous substances and may represent a public health concern near the site of disposal. However, they are unlikely to have any health impact on the community near an incinerator unless, coincidentally, the disposal site is close to the incinerator. Thus, the potential health effects of exposure to ash and residues are primarily in areas near disposal sites and therefore are outside the scope of this discussion.

One method for determining the health impact of environmental contamination is risk assessment. Quantitative estimates of all the factors relevant to risk are integrated to estimate the excess risk to a defined population resulting from exposure. Environmental epidemiology is another approach to relating risk to exposure. In this approach, the relationship between the observed incidence rates of various health outcomes and "exposures" to hazardous agents is tested. Although the emphasis here will be on contrasting these approaches, they are generally complementary and in actual application there may be considerable overlap. For instance, exposure assessment techniques employed in the risk assessment method may be used in epidemiological studies.

## Risk Assessment

Figure 1 shows the risk assessment paradigm adapted from the National Academy of Sciences [9]. The first step is the identification of hazards which may result from exposures to pollutants emitted from an incinerator. A weight-of-evidence approach is employed because more rigid protocols cannot adequately deal with the complex data and "fuzzy" decisions which frequently are encountered [10]. Available human and animal data, supplemented with *in vitro* assays and metabolic and pharmacokinetic studies, are analyzed and synthesized qualitatively. The use of animal data to identify human carcinogens is problematic. For 479 chemicals tested for carcinogenicity in rats and mice, a chemical causing cancer at a given site in one species has only about a 50 percent chance of causing cancer at the same site in the other species [11]. Certainly, the positive

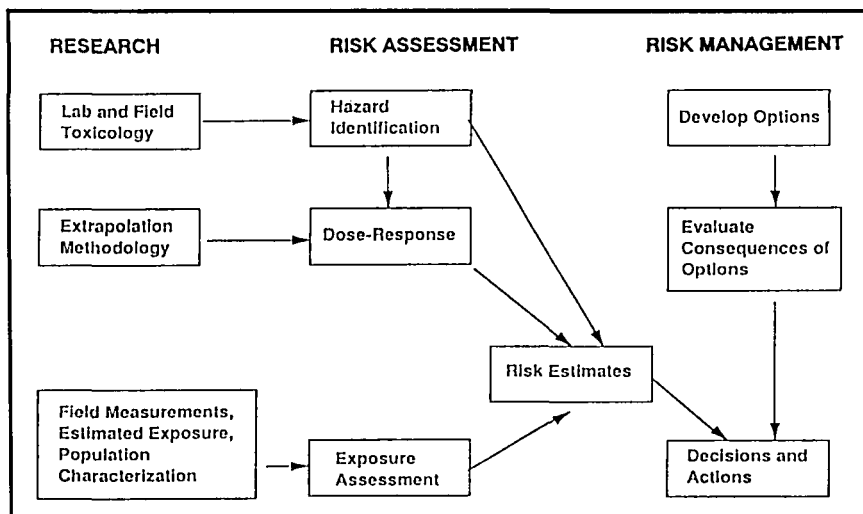


Figure 1. The risk assessment paradigm (adapted from the National Academy of Sciences, 1983).

predictive power from rodents to human is not likely to be higher than between two rodent species [11]. Nevertheless, EPA lists five characteristics of animal assays which increase the weight of evidence of an agent's human carcinogenicity [10]. Such refinements may increase interspecies predictive capabilities.

It is a fundamental concept in toxicology that the severity of a response of an individual and the proportion of the population exhibiting the response is directly related to the dose of the causative agent. The next step in the assessment of risk is relating response to dose or exposure quantitatively. Numerous sources of uncertainty complicate the definition of a dose-response relationship.

For carcinogens, mathematical models are used to extrapolate from the risk observed for high-level laboratory exposures to the long-term, low-level, ambient exposures. Whether these modeling protocols over or underestimate response, and therefore risk, is a subject of debate [10-14]. EPA [10] recommends use of the linearized multistage model [12] unless evidence regarding the mechanism of action suggests an alternative approach. This model yields an upper confidence limit of excess risk rather than the "most likely" risk level [10]. A positive excess risk may be obtained, even when the true excess risk is zero. Also, low-dose risk estimates may be exaggerated because mitogenesis rates are lower than at high-dose laboratory exposures [11]. However, others have suggested that risk often is underestimated by extrapolation with dose-response models [13-14]. Some biologically plausible mechanisms give supralinear dose-response curves at low-dose levels [13]. Also, the use of the lifetime average daily dose in multistage

models when the true exposure is intermittent can lead to a twofold to fivefold underestimate of risk [14].

Extrapolating animal dose-response data to humans also results in uncertainty. Interspecies comparisons commonly scale dose by body weight, body surface area, or lifetime. For carcinogens, EPA recommends adjustment by surface area unless evidence supporting another scaling procedure is available [10].

Toxic effects other than cancer generally are thought to occur when the dose exceeds the tolerance range of an organism. For these effects, the upper bound of the tolerance range, called the reference dose (RfD), is estimated. This level is used to provide protection for sensitive individuals in the exposed population [15]. As with cancer, uncertainties are nearly always present in dose-response characterization of non-cancer endpoints. Sources of these uncertainties include: 1) extrapolation from the general population to a sensitive subpopulation; 2) extrapolation from animals to humans; 3) the use of subchronic data to estimate a chronic RfD; and 4) extrapolation from a Lowest-Observed-Adverse-Effect-Level (LOAEL) to a No-Observed-Adverse-Effect-Level (NOAEL). Conservative uncertainty factors (UFs) of 10 may be applied for each of the sources listed above which are relevant [15]. In addition, a modifying factor between  $>0$  and 10 may be applied to adjust RfD estimates for factors not listed above [15].

A third step in the risk assessment methodology is the assessment of exposure. This procedure defines the magnitude and temporal dimensions of exposure and identifies the populations exposed. Figure 2 illustrates some of the transport and transformation pathways of environmental contaminants that must be considered. Transport routes include atmospheric dispersion, fallout and dry deposition, surface water runoff, percolation into ground water, volatilization from ground water, and biological uptake. After the exposure levels have been determined, human uptake by all significant routes of exposure (usually inhalation, ingestion, and dermal absorption) must be determined. Risk assessment studies of hazardous waste incineration have emphasized the inhalation and ingestion pathways [17, 18].

An examination of the uncertainties is an integral part of exposure assessment. Qualitative methods for characterizing uncertainty include analysis of the limitations and validity of survey designs, measurement techniques and exposure models [10]. EPA also recommends determination, if possible, of quantitative measures of uncertainty, such as confidence intervals on exposure statistics, goodness-of-fit measures for input distribution functions and comparison statistics for alternative model predictions.

Finally, the dose-response relationship and the exposure assessment information are synthesized to estimate the increased risk of possible outcomes. The treatment of the combined uncertainties is critically important to the utility and credibility of risk assessment. For example, the lifetime cancer risk of drinking water from a reservoir was estimated via Monte Carlo simulation with and without consideration of the uncertainty in the cancer potency of one toxic constituent,

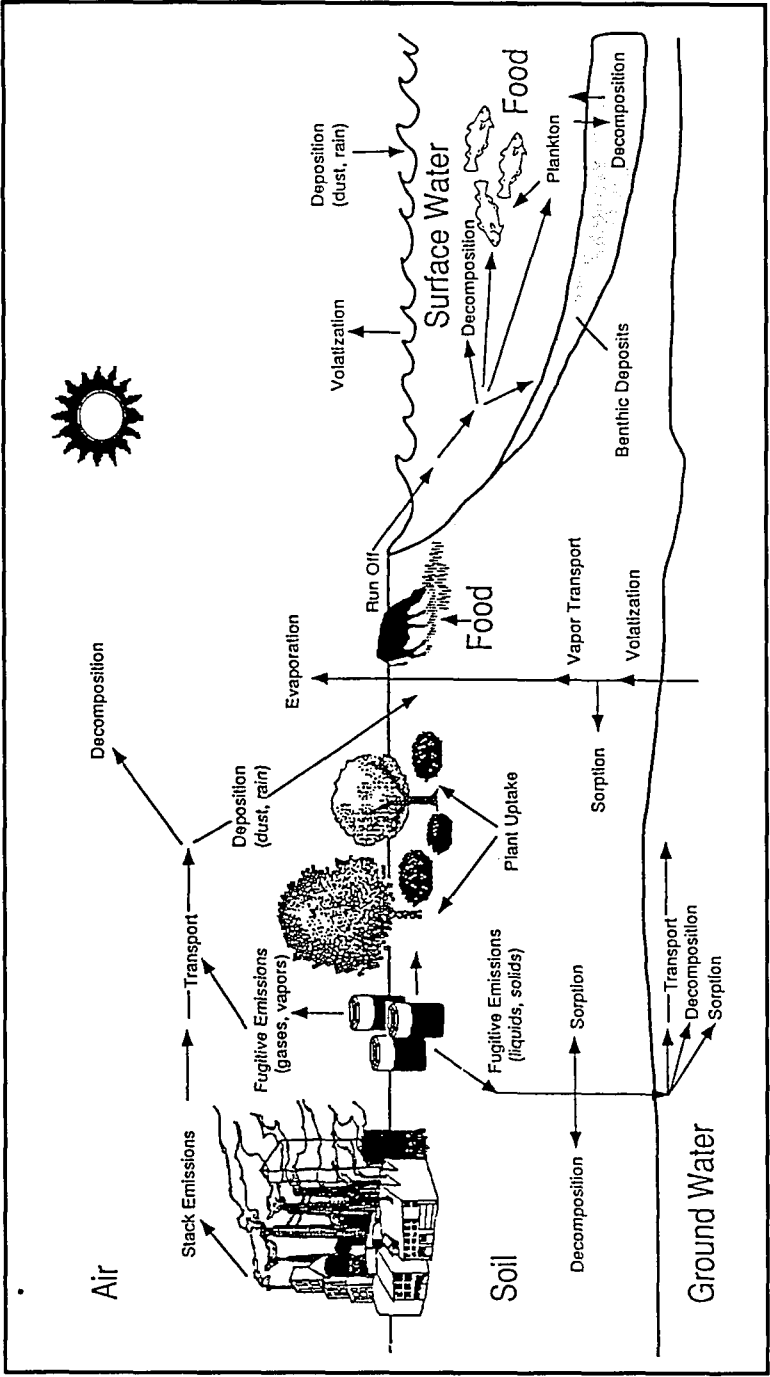


Figure 2. Possible pathways of environmental transport and transformation of pollutants emitted from a hazardous waste incinerator.

arsenic [19]. While the median excess risks of cancer were nearly identical for the two cases, the mean excess risk was nearly three times higher and the 95th percentile was an order of magnitude higher when uncertainty in arsenic potency was introduced [19].

Risk assessment procedures for inhaled pollutants transported directly to receptors are well established [10, 17, 19]. As noted, EPA has recently published a methodology for assessing the health impact of indirect exposure paths from combustion sources [1].

## **Environmental Epidemiology**

In general terms, epidemiology is the study of the distribution and determinants of health-related states or events in specified populations, and the application of this discipline to the control of health problems. To an epidemiologist, environment refers to all that is external to the individual human host that can influence the health status of populations [20]. One of the key terms in epidemiology, exposure, refers to a group whose members have been exposed to a presumed cause of a disease or health state of interest, or who possess a characteristic that is a determinant of the health outcome of interest [20]. Outcome, in epidemiology, refers to all the possible results that may stem from exposure to a causal factor. It can be defined as a health state, or as a change in a health state. From a general hypothesis of an exposure/outcome relationship, several study methodologies can be applied in a population-based setting to test the validity of the hypothesis. The application of this method requires an hypothesis of an exposure/outcome relationship and a large enough sample size to ensure statistical power.

Table 1 is a summary comparison of the risk assessment and epidemiological approaches. These two approaches have different strengths which determine their application. A critical difference between the two approaches for site specific evaluations of hazardous waste incinerators is the role of exposure estimates. In risk assessment, the calculated risk depends directly on the estimated exposure, while exposure estimates in epidemiological research are used simply to categorize the study participants according to their exposures. Thus, while absolute exposure estimates (i.e., estimates of the concentration and duration of exposure to causative agents) are desirable in epidemiologic studies, they are not essential; relative measures of exposure may be used to separate the participants into two or more groups with different exposure levels. In fact, the relative risk of health outcomes for persons exposed to incinerator emissions can be determined without knowledge of the actual etiologic pollutant or pollutants using the extent of contact with the incinerator plume as an index of exposure. For evaluating the health impact of specific incinerators, the method employed must be robust with respect to errors in exposure estimates because little is known regarding the day-to-day or hour-to-hour variation in emissions.



Table 1. Comparison of Risk Assessment and Epidemiological Approaches

Risk Assessment	Environmental Epidemiology
<ul style="list-style-type: none"> <li>• Existing and planned facilities</li> <li>• Depends directly on estimates of exposure and toxicity data to estimate risk</li> <li>• Insensitive to the size of exposed population</li> <li>• Multiple uncertainty factors or low dose extrapolation may drive estimate</li> <li>• "Paper exercise"</li> <li>• Can deal with low levels of excess risk</li> <li>• Yields hypothetical absolute estimate of excess risks</li> </ul>	<ul style="list-style-type: none"> <li>• Existing facilities only</li> <li>• Measures effects in actual exposed population</li> <li>• Often limited by size of population available for study</li> <li>• Assumptions have less effect on final result</li> <li>• Based on actual observation near the source</li> <li>• Limited to higher risk outcomes (<math>\geq 10^{-3}</math>)</li> <li>• Yields excess risk relative to a comparison group</li> </ul>

Considering the advantages of both risk assessment and epidemiology, we designed a study to investigate the community health effects of a hazardous waste incinerator in South Carolina. At the incinerator selected for study, two types of emission data are collected for regulatory compliance. Trial burn data gave emissions of an array of pollutants over a short time span for a limited range of feeds and operating conditions while continuous stack monitoring data was available for carbon monoxide, excess oxygen, and opacity. However, none of these measures has been shown to be an adequate surrogate for emissions of more toxic contaminants [5]. Thus, exposure estimates, and subsequent risk estimates based on these emissions data could be significantly in error, resulting in either declaring a hazardous air environment safe, or needlessly alarming residents with inflated risk estimates. Therefore, the study we proposed was fundamentally epidemiologic because that approach is more tolerant of uncertainties in emissions and employs the direct determination of health outcomes. The first phase of the proposed investigation is a cross-sectional survey comparing the prevalence rates of various respiratory symptoms and other outcomes in the community near a hazardous waste incinerator (study community) with those rates in a comparison community. The second phase is a longitudinal design in which health outcomes and an index of exposure are estimated over time. The major considerations in the design and planning of such a study is discussed below.

## METHODOLOGY

Among the considerations in planning an epidemiologic study of possible health effects of hazardous waste incineration are: selecting the study site, defining the study population, identifying health outcomes or endpoints, choosing an appropriate study design, assessing statistical power and other analytic issues, and disseminating results [21]. In this section, we will address each of these considerations as we conceptualize a health effects study. As an example of the application of these concepts, we will discuss how we handled each element in designing our on-going community study of health effects of a hazardous waste incinerator in South Carolina.

### Site Selection

Characteristics of an incinerator site that favor selection for health outcome studies include health effects expected or observed in the area and the uniqueness or prevalence of the exposure. In choosing a site, several issues regarding exposure must be considered. These include route of exposure, level and duration of exposure, and prevalence of exposure among the population. Exposures can be acute, that is intermittent or temporary, including accidental releases, as well as chronic or long-term. The level of exposure is important because the same contaminants can have different health effects at different doses and different outcomes at the same dose rate for different lengths of time. Ideally, we should have the ability to identify and measure exposures to specific contaminants and to estimate the prevalence of these exposures among the community population, but this is not an essential requirement to determine if a community near an incinerator has a higher prevalence of health outcomes or if these elevated rates result from exposure to incinerator emissions.

An important factor in the selection of a site for our project was the presence of other air pollutant sources near the community. Here our decision to employ an epidemiologic approach limited our choices to sites where exposures to pollutants from other sources do not coincide with exposure to the incinerator plume, confounding the effects of the exposure of interest. One hazardous waste incinerator in South Carolina was eliminated as a possible site because it is surrounded by a chemical manufacturing complex containing many potential air pollutant sources.

Health studies may be warranted at a specific site because of community concerns about public health. In this situation, the suspected adverse health effects and related exposures must be clearly defined by the study team.

### Study Population

There are several considerations with regard to the potentially exposed population. Primary among these are the size of the exposed group and its demographic

characteristics. Among the demographics, the age structure of the population may be the most important factor. Other exposures, either from occupational settings or through lifestyle choices, need to be considered. Finally, an appropriate comparison group (or an unexposed group) must be identified. The comparison group should be as similar as possible to the exposed group, except for the exposure. This may be achieved by: selecting a community with similar age distribution in another part of the state; using the same population after classifying the individuals by exposure status; or matching those with the health outcome to those without the health outcome and then ascertaining exposure (case-control design).

If an appropriate comparison group is not available, the rate of disease or mortality in the study population can be compared with state, regional, or national data.

Because the first phase of our study was designed to be comparable to a similar project in a neighboring state, an identical population size was selected. We used wind direction data to select a group of residents near the incinerator in the area of highest exposure. Here meteorological influences on the convective transport of incinerator emissions were used as a surrogate for more precise measures of exposure such as personal air monitoring or biological monitoring because the identities and emission rates of pollutants emitted from the incinerator were not known. We began surveying households nearest the incinerator site, moving outward in a roughly elliptical pattern, until our sample size objective was achieved.

Obtaining a comparison community was more complicated. The primary criterion for selection was that the comparison community should not be significantly exposed to materials emitted from the incinerator. Thus, candidate areas were upwind or crosswind from the incinerator when the wind is blowing from the most frequent direction. In these areas, census data were examined to identify areas nearby with demographic characteristics similar to the study community. Major industrial operations, and thus potential point sources of pollutants, were identified by talking with the local fire department and driving through prospective areas. Two candidate comparison communities were eliminated because they were near possible sources of environmental pollutants. The final selection was a rural area with no industrial activity and no major traffic arteries.

## **Health Outcomes**

The anticipated health outcomes or endpoints from hazardous waste incineration studies can range from acute effects (such as eye or respiratory irritation) to chronic effects (such as cancer) to effects that vary with the time of exposure (such as certain reproductive effects). Some of these health effects, for example, respiratory irritation, may occur soon after exposure, while for other health effects, for example, cancer, there may be a long latency period.

Standard reporting systems (e.g., death certificates) may provide adequate data for some endpoints, but a survey of community residents will usually be required to study subtle endpoints such as syndromes of symptoms rather than clinically diagnosed diseases. To reduce the bias or misclassification associated with self-reported health information, all clinical diagnoses should be verified by physicians or from hospital records. Whenever possible, symptom reports should be supported by objective measurements such as spirometric measurements.

In addition to estimating the rates of health outcomes, one must be able to control for confounders and covariates. For example, lifestyle characteristics, such as smoking and diet, play a major role in determining health outcomes. Also, the interaction of multiple exposures and risk factors must be considered. Finally, a respondent's attitudes toward environmental pollution in general and specifically toward a nearby point source can be important components of overall health. In addition, psychological factors may play a role in the perception of risk and the reporting of individual health symptoms [22, 23].

We chose to investigate respiratory symptoms because: the incinerator had not operated long enough to impact the rates of diseases with long latency periods (e.g., cancer); we had no prior, objective data showing a particular health problem present in the area; and respiratory symptoms occur at relatively high rates in the general population so that alteration of these rates by contaminant exposure can be detected statistically.

Because we anticipated individual and household differences in factors affecting exposure to respiratory irritants other than what may have been due to the incinerator, we included a variety of questions on the indoor environment and personal lifestyle characteristics. Examples of information obtained include the fuel used to heat the home and cook, and whether a respondent or other household member smoked. We also included a series of questions designed to elicit personal feelings about outdoor exposures, exposures at work, and general psychological indicators of how the person felt their health was affected by environmental exposures. During the analysis phase, these perceptions of risk will be used to help interpret responses regarding respiratory symptoms. Statistical adjustment can be applied for other indoor or work-related exposures, as well as lifestyle factors. Using these techniques can help sort out the adverse health effects that cannot be explained by the other variables we have included in the models, and are presumably due to exposure to the hazardous waste incinerator. However, even if the cross-sectional study finds evidence of higher rates of respiratory symptoms in the study community than in the comparison community, we cannot ascribe these higher rates to incinerator emissions. This would, however, justify additional investigation, perhaps a more expensive study that includes a measure of personal exposure, to attempt to identify a specific source of the adverse respiratory health symptoms.

## Study Design

Study designs can vary from correlational analyses of aggregate data to complex randomly sampled survey and laboratory data on individuals. The major study designs, summarized in Table 2, provide many choices. From cross-sectional studies we can obtain data on the prevalence of both the exposure and health outcome at one point in time. While we cannot infer causality from cross-sectional studies, they are very useful in establishing baseline patterns and providing a starting point for follow-up studies. Cohort or follow-up studies, the "gold standard" in environmental epidemiology, can be used to infer causality, but require considerably more effort and are more expensive. These studies require measurement of specific individuals' exposure status at one point in time, monitoring both the exposed and unexposed groups over time for new cases of the health outcome of interest and then comparing the incidence between the exposed and the unexposed groups. An advantage of this type of study is that we can look for several health outcomes during the same study. The disadvantages include the expense of following a cohort and monitoring for health effects. It is better to use this approach when the prevalence of exposure in the population is high and the expected health effects will occur soon after exposure.

Case-control studies represent an efficient use of resources when the health effect is known and past exposure history is available. These studies are also useful when the health outcome is rare and occurs after a long latency period. However, only one health outcome can be studied at a time and it may not be possible to obtain past exposure data. Ecological analyses are correlational studies that compare regions (or areas) rather than individuals. These studies are useful for generating hypotheses. In addition, complex study designs which combine the features of several of the fundamental designs above may be possible if appropriate historical data are available [24].

Table 2. Epidemiologic Study Designs

Type of Study	Study Features
Cross-sectional	Prevalence estimates of both exposure and outcome
Cohort or Prospective	Incidence rates; risk statements; causality
Case-Control or Retrospective	Estimates of relative risks; odds ratios
Ecological	Correlational analyses of aggregate data; hypothesis generating

The appropriateness of a study design depends on the resources available, the ability to measure exposures and outcomes, and the strength of the suspected relationship. Often, hypotheses are explored using ecological analyses and tested with a more rigorous approach.

The first phase of our study was a cross-sectional comparison of prevalence rates of reported symptoms among those living near a hazardous waste incinerator with those living in a similar community without a hazardous waste incinerator. The information we obtain from this type of study can lead to specific hypotheses for future studies. We may also be able to use the baseline data obtained in this study to select individuals for case-control studies when we have developed a better way of estimating exposure, or if we conduct a follow-up study to assess health changes in each community.

In phase two of our study, a random sample of residents near the incinerator will be asked to record in a diary for a thirty-day period respiratory symptom occurrence, self-administered peak flow meter measurements, and their daily activities. Data will be obtained daily by phone. On-site meteorological measurements will be used with an EPA air pollution dispersion model to obtain indices of exposure to the plumes of the incinerator and other nearby sources for each participant individually. Relative exposure levels may then be correlated with measurements and symptom occurrence. In addition, data may be analyzed as a case-control study with participants serving as their own control.

## **Statistical Issues**

The importance of statistical issues becomes evident during the analysis and interpretation of the data. Even if the suspected health effect is present, a study may not have sufficient power to show this relationship statistically. For this reason, during the planning stages of a study issues such as sample size, the prevalence of exposure in the population, and the expected strength of the association must be considered. In addition, the sample size must be large enough to sort out the effects of multiple exposures, or other covariates that must be controlled in the analysis. Once a site has been selected and the exposure-outcome hypothesis defined, the appropriate study design can be selected. The sample size needed will depend on the prevalence of the exposure in the population, the strength of the expected association of the exposure and the health effect, and some investigator-defined limits on acceptable power values. Sometimes preliminary or pilot data may be needed to obtain the estimates necessary for sample size calculations.

In our community health study, we are able to use estimates of prevalence of exposure and outcome from a similar study conducted in a neighboring state. In this way, we ensured that our sample size would be adequate to detect adverse health outcomes (in our case respiratory symptoms) if they were present in our communities.

## SUMMARY AND CONCLUSIONS

In reviewing the literature describing previous studies of the health effects of incineration, we have found some information on the nature of emissions from hazardous waste incineration [3-5], many studies on hazardous waste incineration risk assessment [6-8, 17-19], and articles that describe the many methodological problems associated with environmental health studies of this type [21-24].

While not minimizing these methodological problems, there are many well-tested scientific approaches for studying health problems in general, and these approaches can be adapted for use in community studies of hazardous waste incinerators. The study described here is an example of how these approaches can be adapted to study a specific problem. Many technological advances, even within the past few years, have given us the ability to capture massive amounts of data on exposure and health outcomes via computer technology and to use powerful statistical techniques to sort out the effect of competing factors.

In conclusion, by following a systematic approach and using clearly defined exposure-outcome objectives it is feasible to evaluate the community health effects of hazardous waste incinerators. Such studies are essential for developing public policy recommendations regarding hazardous waste incineration.

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