Investigating Potential Health Effects of Environmental Toxic Exposures Standard Operating Procedure

Oregon Public Health Division – March 2018

Response Overview

Purpose and scope

This document outlines the Oregon Public Health Division's (PHD) procedures for investigating concerns about the health effects of exposure to potential toxic agents in residential or community environmental settings; it does not apply to investigations of occupational or medical treatment-related exposures. This is a companion document to the Public Health Division's Investigative Guidelines for responding to cancer cluster inquiries.

Response objectives

The assessment and response to community concerns about community environmental toxic exposures involve one or more of the following objectives:

To determine whether

1) the agent of concern is known or suspected to cause adverse health effects;
2) the agent is present in the environment in amounts that could harm health;
3) a route of exposure exists;
4) people have been exposed to the agent at levels that could harm health; and
5) the adverse effect is clinically apparent in people known to be exposed.

The figure below illustrates these objectives in terms of questions that need to be answered, and the type of public health investigation conducted, to determine whether an environmental agent could produce an adverse health effect. Ideally, the five objectives are addressed sequentially in order to determine whether a specific health outcome is linked to a specific exposure. However, questions or concerns might be raised at any point in the continuum. For example, a community may be concerned about a point source for emission of a known toxic chemical (1) and whether that has caused health effects (5), or concerned about an apparent cluster of illness (5) and whether or not it is caused by a toxic agent in the environment (2). Regardless of the initial question of concern, all five objectives must be met to establish a definitive link between an environmental toxic agent and an adverse health outcome.

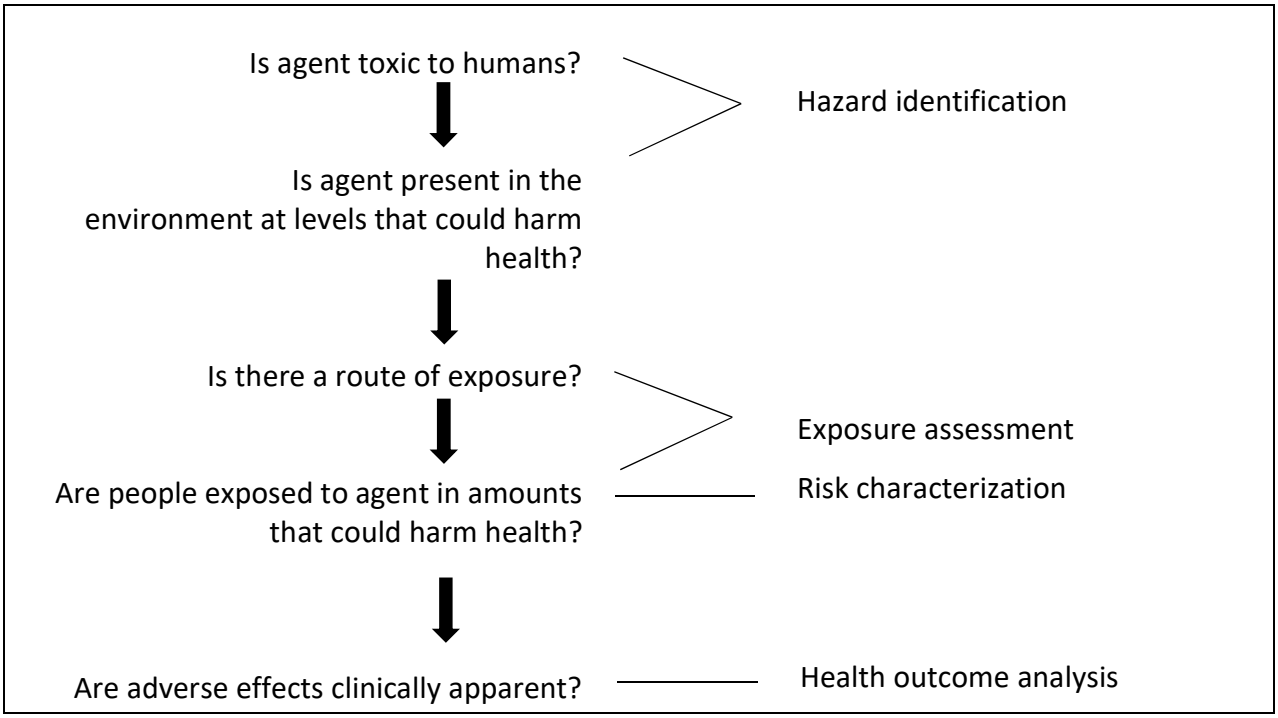

Figure. The questions that need to be answered and type of investigation needed to determine whether an environmental agent could produce an adverse health effect. In order to establish a causal link, all five questions must be evaluated, regardless of the initial question of concern, and all five must be found to be true. Adapted from Thacker SB, Stroup DF, Parrish RG, Anderson HA. Surveillance in environmental public health: Issues,

Hazard identification

Addresses Response Objectives 1 and 2:

1) Is the agent of concern known or suspected to cause adverse health effects?

The toxicity of an agent of concern and relevant health effects can be assessed by reviewing the relevant scientific literature and consulting with the appropriate subject matter experts (i.e., toxicologists, environmental health specialists, the US Agency for Toxic Substances and Disease Registry [ATSDR], the US Environmental Protection Agency, etc.)

2) Is the agent of concern present in the environment at levels that could harm health?

We can only determine what is currently in the environment where it can be measured, or if it has been measured in the past during previous environmental studies.

The presence and amount of the agent of concern in the residential/community environment can be assessed by various types of monitoring equipment, and can include testing of air, water, or soil. The Oregon Department of Environmental Quality (DEQ) and/or the U.S. Environmental Protection Agency (EPA) are potential sources of data on the presence and amounts of agents in a setting (this is outside the scope of the Oregon Public Health Division). The presence of environmental toxic agents must include type, amount, and location of the toxic agent with as much specificity as possible.

Exposure assessment and risk characterization

Addresses Response Objectives 3 and 4:

3) Is there is a route of exposure?

The route(s) by which people may be exposed to a toxic agent of concern can usually be established by literature review or expert consultation. Most common routes of exposure to toxic agents include: cutaneous (through the skin), ingestion, and inhalation. Routes of exposure specific to a particular event or location can be informed by the findings of DEQ and/or EPA as to which environmental media (e.g. air, water, soil) are contaminated with the toxic agent and to what degree.

4) Are people exposed to the agent in amounts that could harm health?

To assess whether people in the community have been exposed to the toxic agent, we need to determine a) whether an actual exposure exists, and b) the dates and duration of any exposure(s). Even when a potentially toxic agent is present in the environment, not everyone is exposed equally. For example, a toxic agent in the soil may be more likely to expose children who are playing on the ground, or people eating vegetables grown in the soil, than people who work in an office setting in the area but live elsewhere. In some cases it is possible to measure the levels of contaminants in the blood or urine of potentially exposed people.

Health outcome analysis

Addresses Response Objective 5:

5) Are health effects that are potentially associated with the agent in question clinically observable?

Environmental toxic agents can produce a wide variety of health effects. The effects of highest concern tend to be longer-term, irreversible outcomes such as cancer or birth defects. However, when examining health outcomes, the analysis should focus on outcomes that are known to be associated with the agent of concern (published in the scientific literature). Investigating new disease outcomes related to a specific toxic exposure is beyond the scope of

a state public health agency, being generally accomplished through multi-site academic research studies.

It is important to keep in mind that many of the longer-term health outcomes are multifactorial. For example, well-known risk factors for cancer include increasing age, family history, and exposures to other known carcinogens such as tobacco smoke and radiation. These limitations make it hard to interpret results especially if Objectives 1–4 have not already been met. Therefore, the Environmental Health Assessment Program will not pursue these types of health outcomes analyses unless we have established that people are being exposed to a toxic agent in amounts that could harm health.

Oregon Public Health Division Assessment and Response

This section describes how the Oregon Public Health Division addresses the five objectives listed on page 1, and the criteria by which the Oregon Public Health Division decides whether or not to engage in these activities related to potential toxic exposures.

Response Objectives 1–4

The Oregon Public Health Division's Environmental Health Assessment Program (EHAP) has the tools to address Response Objectives 1–4. To do this work, EHAP uses funding and technical support from the US Agency for Toxic Substances and Disease Registry (ATSDR). The guidance that EHAP follows to address Objectives 1–4 can be found in ATSDR's Public Health Assessment Guidance Manual (https://www.atsdr.cdc.gov/hac/PHAManual/toc.html).

EHAP's process

EHAP's process (and ATSDR guidance) evaluates each of the objectives sequentially, regardless of the initial question of concern. This is important because it only makes sense to the next objective if the result of the previous step suggested that harm to health was possible. For example, it would not make sense to collect environmental samples (Response Objective 2) if it was determined that the chemical in question is not toxic (Response Objective 1). Similarly, it would not make sense to determine the degree to which people had been exposed (Response Objective 4) if it was determined that there was no route of exposure (Response Objective 3).

If the initial question of concern relates to an apparent cluster of illness (Objective 5), the program staff must first determine if environmental toxic agents are known causes of the apparent illness, and then proceed with the objectives sequentially based on the likely toxic agent. As noted above, identifying new environmental causes (i.e., toxic agents) for specific disease outcomes is beyond the scope of a state public health agency.

It is very rare for EHAP to pursue testing of blood or urine of exposed people to determine whether or not an exposure occurred. There are several reasons for this:

1. There is no way to interpret the results of this testing that is meaningful to health. Our understanding of toxicity and health risk is based on the amount of a toxic agent that is swallowed, inhaled, or absorbed through the skin—not on the amount that is in the body. The only exception to this is blood lead levels, which are correlated with specific health outcomes.
2. For most toxic agents, there are no standard clinical laboratory tests that can detect the agent at low enough concentrations to be helpful for this kind of public health assessment.
3. This type of testing does not tell investigators where the toxic agent came from. For example, arsenic that is measured in someone's urine could have come from eating seafood, cigarette smoke, drinking water from a domestic well, or other environmental exposure. The urine test does not differentiate between these, so additional information has to be collected to rule out common sources of exposure when interpreting the results.
4. EHAP does not have resources to do this kind of testing, and has to seek additional outside resources on each occasion.

Partnerships

EHAP's overall process requires close coordination with state and federal environmental agencies including the Oregon Department of Environmental Quality (DEQ) and the U.S. Environmental Protection Agency (EPA). The process requires environmental sampling data, and EHAP is dependent on DEQ or EPA to collect those data. EHAP does not have the resources or expertise to do environmental sample collection and analysis. Rather, EHAP plays the role of evaluating and interpreting the results of environmental sampling provided by DEQ or EPA. EHAP also advises DEQ and EPA on sampling plans to ensure that data are collected from the right locations and the right media (air, water, soil, etc.), and that samples are tested for the relevant contaminants for evaluating health.

How EHAP evaluates the extent to which it can meet Response Objectives 1–4

When asked to participate in a response to potential environmental toxic exposures, EHAP applies a set of criteria to decide to what extent the program can answer the questions associated with Response Objectives 1–4. These criteria are:

- *Are environmental sampling data available or is there a plan for them to be collected?* As mentioned above, EHAP cannot address Response Objectives 1–4 without environmental sampling data provided by DEQ or EPA.

- *Are environmental sampling data of adequate quality and appropriate for evaluating human exposure and health?* DEQ and EPA collect environmental sampling data for many purposes, many of which are not relevant to evaluation of human exposure. Examples include sampling designed to assess risk to wildlife and plants or to determine the source of pollution. Other examples of environmental sampling data that would not be appropriate for evaluation of human exposure are samples in moss or other media with which people do not interact in routine or predictable ways. Emissions inventory data from industrial facilities are also not sufficient to evaluate human exposure and health risks. Data that are not of adequate quality to evaluate human exposure but that indicate that public health could be at risk may prompt EHAP to ask DEQ or EPA to conduct follow-up sampling that EHAP could use. EHAP has a protocol for determining whether data are of adequate quality; criteria include accuracy, precision and applicability.
- *Are the questions being asked of EHAP questions that EHAP's process can answer (Response Objectives 1–4)?* Some requests that come to EHAP are questions that EHAP's process and tools are not able to answer. For example, EHAP's process cannot determine whether or not individual cases of disease are the result of specific toxic exposures, and EHAP's process cannot predict an individual's probability of developing illness. Rather, EHAP assesses health risks to communities and populations as a whole.

Data sources for addressing Objective 5

The two primary data sources for determining disease outcome such as cancer or birth defects are the Oregon State Cancer Registry and the Oregon Birth Anomalies Surveillance System.

The **Oregon State Cancer Registry (OSCaR)** has been conducting surveillance for cancer cases since 1996. Reportable cancers include invasive cancers (except most basal and squamous cell skin carcinomas) and selected pre-malignant conditions. While cancers are reportable, there is a lag period from diagnosis to reporting. Therefore, annual summaries are produced after a lag period of about 18 months.

The purpose of the Oregon State Cancer Registry is twofold: 1) to provide opportunities for Oregonians diagnosed with cancer to participate in scientific research projects aimed at treatment, and 2) to monitor overall rates and trends in cancer in the population in order to target and evaluate prevention efforts. When monitoring cancer in the population, we focus on known causes of common cancers and established risk factors and protective factors (e.g., smoking and lung cancer; colonoscopy and early detection of colon cancer).

Cancer is common in the US and Oregon; 20,000 new reportable cancers diagnosed in Oregon residents each year. Nationally, 1 in 2 men will develop invasive cancer and 1 in 4 will die as a result; 1 in 3 women will develop invasive cancer and 1 in 5 will die as a result.

The **Oregon Birth Anomalies Surveillance System (BASS)** has been conducting surveillance for birth anomalies since 2013. It was set up to identify and collect information about all children ages 0–6, born with certain birth anomalies in Oregon. Initially, data on 12 birth anomalies were collected. In 2016, BASS expanded to collect data on 50 anomalies. The BASS receives administrative data regarding birth anomalies from Medicaid claims, hospital discharge data, birth and death certificates, and Early Hearing Detection and Intervention Program data. Annual summaries are produced after a lag period of 36 months from the most recent year of birth.

Birth anomalies are common in the US and Oregon. BASS data on 12 birth anomalies indicate that more than 1% of Oregon births are affected by a birth anomaly. Every 4 ½ minutes, a child in the US is born with a birth anomaly.

Analysis of human outcomes (Objective 5)

Although PHD has access to some health outcome data, many diseases are not tracked (e.g., chronic diseases such as ALS, or autoimmune diseases). For analyses of cancer or birth anomaly data in the geographic area of a potential environmental toxic exposure to be meaningful, only those specific cancers or birth anomalies known from the literature to be associated with a specific toxic exposure should be analyzed.

For longstanding community/environmental exposures to a known toxic agent, OSCaR and BASS staff will aggregate data from multiple years to increase the reliability of data. Reliable OSCaR data are available since 1999, and reliable BASS data are available since 2008. Where the source of an exposure is known to be a single point, outcome data will be investigated for the smallest practical area down to the census tract. Because of concerns about reliability of the data due to small cell sizes, the Public Health Division will only calculate rates when ≥ 5 cases occurred in a specific census tract for a particular time period.

Comparison of observed and expected rates (Objective 5)

If indicated, OSCaR and BASS staff will follow a standard procedure to undertake case finding using existing OSCaR/BASS database files. OSCaR data will be used to calculate incidence rates and standardized incidence ratios. BASS data will be used to calculate prevalence rates and standardized birth prevalence ratios. Worksheets should record assumptions used for the case definition, calculations and conclusions.

Limitations of health outcome analyses

When the public reports an apparent cluster of illness, analyzing rates of illness in a small area (e.g., a neighborhood) may tell us whether the rate is higher than expected, but it does not help to identify environmental contaminants that people are being exposed to. Thus, for any given analysis to be helpful, we must know that there are potential toxic causes of that illness.

The methods for small-area analyses was developed by CDC and the Council of State and Territorial Epidemiologists to address situations in which a group of people in a specific area were noted to have the same type of uncommon cancer. This would provide an initial indication about whether or not an assessment should be done to identify any potential environmental exposures.

Understanding the statistics involved in small-area analyses is important. Standard statistical methods using 95% confidence intervals will find randomly occurring significant results 5% of the time. That is, for every 20 analyses done, approximately one may have a statistically significant finding that is due to chance alone. A statistically higher (or lower) rate by itself doesn't help to provide meaningful data for action.

Moreover, the methods were not developed to determine which cancers might be occurring in an area of a known environmental exposure. When the environmental exposures of concern have been identified, neighborhood cancer rate analyses do not provide additional information that will protect public health.

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Resources/ References

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Table: Activities, roles, and responsibilities

Response Objectives	Activities	Responsible Party
Is the agent of concern known or suspected to cause adverse health effects?	Review research literature Consult with appropriate subject matter experts (i.e. ATSDR, EPA, Oregon Poison Center, etc.)	OHA Environmental Public Health
Is the agent of concern present in the environment in amounts that could harm health?	Environmental sampling	Oregon DEQ US EPA
	Comparison of environmental data to health-based screening levels	OHA Environmental Public Health
Is there a route of exposure?	Identify type of exposure(s): dermal, ingestion, inhalation, etc.	OHA Environmental Public Health
Are people exposed to the agent in amounts that could harm health?	Determine duration of exposure(s)	OHA Environmental Public Health
	Analyze measurements of contaminants in blood or urine of exposed communities*	OHA Environmental Public Health
Are adverse effects clinically apparent?	Analysis of health outcome data (e.g. cancer, birth anomalies) Case finding	OHA epidemiologists

OHA: Oregon Health Authority

DEQ: Oregon Department of Environmental Quality

ATSDR: Agency for Toxic Substances and Disease Registry

EPA: Environmental Protection Agency

*OHA rarely collects blood or urine samples. OHA may evaluate sample results generated by other parties.