

Mini-Module: What is an Exposure Investigation?



What is an Exposure Investigation?

- An exposure investigation, or EI, is a biological (blood, urine) or environmental (air, water, dust, soil, biota) sampling effort that is designed to fill a data gap in order to make public health decisions.
- A data gap is missing information that is needed to help understand what contaminants and at what concentrations people could be exposed.
- During the EI, the team attempts to sample individuals expected to be the most highly exposed (through biological monitoring) or locations expected to be the most contaminated (through environmental sampling).



Options to Fill Data Gaps

An EI is one alternative to consider to fill a data gap at a site. ATSDR performs EIs when other methods of filling data gaps are not possible. Other alternatives include

- Recommending that other agencies or organizations, such as EPA, tribal groups, state agencies, or site owners, conduct future or additional sampling methods; and
- Modeling exposure to contamination.

This presentation will discuss when it is appropriate to conduct an EI, and the steps to conduct this type of investigation.

1. Can an exposed population be identified?

To see if there is a potentially exposed population, ask the following:

- Is there any indication of a completed exposure pathway? This means that a contaminant is in a medium (for example, soil, water, air, plants, or animals) that a person contacts. Remember, in a completed exposure pathway, all five elements (contaminant source, environmental fate and transport, exposure point, exposure route, and exposed or potentially exposed population) are present.
- Are people coming in contact with the suspected contamination?
- Are activities, like playing, gardening, and using private well water, resulting in exposure to the contamination?
- Are contaminants of interest still found at the site?
- Are potential exposures recent enough to show up in biological samples?

2. Does a data gap exist that affects the ability to determine if there is a health hazard?

- Determine if the data gap is critical, and whether an EI is the only option to fill this gap. In other words, determine if a public health call can't be made without obtaining and analyzing the missing environmental or biological monitoring data specifically with an EI.
- For example, if a spill of a harmful contaminant occurred on the soil of a site, but no one has access to the area where the spill took place, then sampling of the soil is unnecessary to determine if people are exposed.
- Make sure to explain in the proposal how the EI will fill the identified data gap(s).

3. Can an EI be designed to address this data gap?

Think about whether having ATSDR conduct an EI is the best way to gather the missing environmental or biological monitoring data.

Or would another option such as recommending environmental data collection by another agency, conducting modeling, or reviewing available biological monitoring data (for example, blood lead data) address the data gap?

4. Will the EI results impact the public health decision for the site?

Determine if the data collected would allow ATSDR to make better public health decisions, such as

- Making recommendations to regulatory agencies on how to reduce environmental contamination;
- Conducting additional environmental contaminant investigations;
- Recommending a health study; and
- Improving or expanding health education to reduce exposure.

If the data collected through the EI will not have an impact on public health decision-making, follow a different approach to fill the data gap(s).

Requesting an EI

If the answers to each of the four questions is “Yes” you can submit a request for ATSDR’s EI group to conduct an EI at your site. Your proposal should address each of the four questions and include information that

- Describes the exposed population(s);
- Identifies the data gap(s);
- Explains how the EI will address the data gap(s); and
- States how the EI results will affect public health decision making.

The EI group will evaluate your proposal and make a decision about whether to conduct an EI at your site. Note that not all sites with “Yes” answers for each question will be selected for an EI.

El Process (continued)

Protocol – a protocol must be completed and go through ATSDR review and approval process to allow ATSDR to conduct biological and environmental sampling. It includes

- Recruitment materials (e.g., fact sheets, posters);
- Methods for sampling and analysis of data;
- Consent forms for participants;
- Questionnaire for participants; and
- Samples of letters that will be used to provide participants with their results.

EIs are not studies, so Institutional Review Board (IRB) approval is NOT required.

El Process (continued)

OMB package

- The Paperwork Reduction Act (PRA) indicates that federal agencies should not overly burden the public's time in conducting public health investigations.
- The intention of the OMB package is to ensure that the questionnaire asks questions that are appropriate and take a reasonable amount of time to administer.
- After the protocol has been reviewed and approved, the package is submitted to OMB for approval.

Let's Practice

The following proposal has been submitted to the ATSDR EI Group to determine if an EI should be conducted.

"A community obtains water from private wells and residents have noticed changes in their water quality. A new factory has been built in the community that manufactures and packages various solvents and people are concerned that the operations may be impacting water quality in the area. Monitoring wells on the facility have shown that solvents and their byproducts have been found in the groundwater. The private wells have not been sampled since the factory started production. The state has requested that ATSDR perform an EI to sample the private wells and fill a data gap at the site."

Based on criteria needed for an EI, do you think that the ATSDR EI Group will accept the proposal? Let's go to the next slide to find out.

Let's Practice

Based on the EI criteria outlined below, ATSDR's EI Group will accept the proposal to conduct an EI. The following are the four EI questions and their respective answers:

1. Can an exposed population be identified?

Yes – the community served by the private wells.

2. Does a data gap exist that affects the ability to determine if there is a health hazard?

Yes – private well water quality data are not available since the factory began operations so it is not known whether contaminants may be in the private wells.

3. Can an EI be designed that will address this data gap?

Yes – the private wells in the area can be sampled.

4. Will the EI results impact the public health decisions for the site?

Yes – the results will allow ATSDR to determine whether there are contaminants in the private well water that may be a health hazard.

ET Team, Roles, and Responsibilities

If the ATSDR ET Group approves the ET proposal, they will start by organizing the ET Team, identifying an ET Lead, and determining the various roles and responsibilities. For instance, the ET Team will define and agree upon who will do the following tasks:

- Interact with the community
- Collect samples
- Fund sample analysis
- Interpret results
- Send individual results and data interpretation
- Write the ET report



Preparing the Protocol

Once the EI roles are designated, the team will start the EI process by preparing a protocol that includes the following information:

- Site background
- List of federal, state, and local partners
- Recruitment methods
- Questionnaire and consent forms
- Sampling and Analysis Plan (SAP)
- Data Management Plan (DMP)
- Template for sample results letters to participants

Approval of the EI Questionnaire and Consent Forms

The Paperwork Reduction Act (PRA) requires that federal agencies, including ATSDR, do not overly burden the public by taking up too much of their time when conducting EIs. ATSDR is required to submit forms that will be used to interact with the public to the Office of Management and Budget (OMB) for approval.

- The ATSDR EI group has a generic clearance package approved by OMB for conducting EIs. For each EI, a site-specific package is always required to be submitted that includes the questionnaire and consent forms to be used at the site. The site-specific package is submitted and approved by OMB.
- An Institutional Review Board (IRB) exemption is required for sites where biological samples are taken. IRB oversees research involving human subjects. EIs are exempted because EIs are not considered research.

Developing the Data Management Plan

- The EI Team will also prepare a Data Management Plan (DMP) that outlines how the data will be collected, handled, managed, and stored.
- The DMP describes the anticipated use and release by CDC/ATSDR of the dataset planned for collection.
- All DMPs need to be in compliance with CDC/ATSDR policy on releasing and sharing data.



Protecting the Confidentiality and Privacy of EI Participants

For more information about laws that protect the confidentiality and privacy of EI participants go to the following websites:

Freedom of Information Act of 1996: <http://www.foia.gov>

Privacy Act of 1974: <http://www.foia.gov>

Common Rule of 1991: <http://www.hhs.gov/ohrp/policy/ohrpreulations.pdf>

Public Health Service Act of 1944:
<http://www.cdc.gov/od/science/integrity/confidentiality/>

Conducting the EI

Once the EI Team has an approved protocol and OMB approval, they are ready to start the EI. They will complete the following steps:

- Use recruitment materials, questionnaires, and consent forms provided in the EI protocol.
- Collect and analyze data according to the EI Sampling and Analysis Plan.
- Send letters to notify participants of their results.
- Prepare the EI report using the data collected to share the EI findings with the participants and community.

In the next slides, we will further explain these EI steps.

Recruiting EI Participants

To achieve the sampling goals of the EI, the EI Team will recruit individuals expected to have the highest exposure to contaminants. This should be done with the help of local partners and community members.



Engaging the Community in the EI Process

The following are general tips to better engage and recruit community members for the EI:

- **Get to know the community.** Learn about their demographics, culture, social networks, norms, values, history, risk perceptions, strengths, and needs.
- **Communicate effectively.** Communicate openly and honestly with community members.
- **Tailor outreach and community activities.** Choose appropriate communication channels (for example, in-person meetings, written materials, social media activities, e-mails, and letters).
- **Work with informal and formal community leaders and organizations.** Choose those that are knowledgeable of the community and its health concerns.

Conducting the Sampling and Data Analysis

Once the EI Team has recruited community members expected to be the most highly exposed, environmental and/or biological samples are collected.

- All sampling will be conducted using methods outlined in the SAP.
- Participants will sign a consent form and be administered a questionnaire (some environmental EIs do not use questionnaires).
- Samples will be analyzed according to the SAP.
- Data will be verified and validated before use.

Biological Monitoring As Part of the EI

The EI Team uses biological monitoring to identify whether exposure has occurred in a given individual by measuring a biomarker (a chemical or its metabolite) in a sample such as blood or urine.

Biological monitoring has some disadvantages, like:

- Testing for chemicals with short biological half-lives is limited to people's recent exposures;
- Testing cannot identify the source of exposures; and
- The health significance of many biomarkers is uncertain.



Examples of Biological Monitoring

These are examples of biological monitoring that could be conducted if a data gap is present and exposure is suspected:

- Testing blood lead levels in children and pregnant women living in a community where lead was released to water and soil from industrial activities
- Testing urine for arsenic in community members living next to a hazardous waste site
- Testing blood and urine for per- or polyfluoroalkyl substances (PFAS) in areas where PFAS has been found in residents' drinking water

Environmental Sampling As Part of the EI

The EI team may sample environmental media, such as soil, water, air, or biota (plants and animals) to characterize contamination present in the environment where people live, spend time, or play.



Examples of Environmental Sampling

These are examples of environmental sampling that may occur if a data gap is present and exposure is suspected:

- Testing private well water in homes located downgradient of a former dry cleaner that used TCE
- Testing soil for contaminants associated with a fuel spill
- Testing sediment, surface water, and fish for contaminants associated with a PCB (polychlorinated biphenyl) spill
- Testing ambient air for hydrogen sulfide in a community adjacent to a construction and demolition debris landfill

Next Steps

Once the sampling and data analysis are completed, the EI Team will notify participants of their sampling results and prepare the EI report using the data obtained from the EI.

The contents of the EI report are discussed next.



El Report Information

The El report will typically include the following information:

- Executive Summary: a summary of the methods, results, and conclusions of the EI
- Background: information that outlines the suspected contaminants at the site and the data gap(s) that will be filled by the EI
- Methods: a discussion of participant recruitment, data collection methods, and laboratory data analysis for the EI
- Results: the results of the EI sampling
- Conclusions: the conclusions of the EI based on the sampling results and the impact on the community
- Recommendations and Public Health Action Plan: provides recommendations for the community and the Public Health Action Plan based on the results of the EI

Follow-up

Finally, the EI report and its findings will be shared with the participants and community. The findings may be shared by various means, such as conducting community meetings, posting the EI report in a repository (like a local library), and developing and distributing materials summarizing the EI findings (such as fact sheets). It is important to note that the EI findings and recommendations can lead to other public health actions like

- Health education for the community on how to prevent exposures to contaminants;
- Health education for health professionals about special diagnostic techniques to identify possible site-related illnesses;
- Community health interventions such as referrals to health care providers, including community health centers or local health departments; and
- Health studies if the EI Team identifies an exposed population for whom a site-specific epidemiologic health study should be considered.

If you need more information or have a question on how to request an EI,
please contact:

Peter J. Kowalski, MPH

Acting Branch Chief, Science Support Branch

Division of Community Health Investigations, ATSDR

Pek2@cdc.gov

770-488-0776

For more information, contact ATSDR

1-800-CDC-INFO (232-4636)

TTY: 1-888-232-6348 www.atsdr.cdc.gov

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