

Linking Environmental Laboratory Science with Epidemiologic Investigations

A Systems Approach



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Introduction

Environmental health comprises a complex system with multiple stakeholders. This document focuses on two parts of the system — epidemiology and laboratory science — and provides ways to create better linkages between the two, in an effort to improve the overall system.

Environmental epidemiology assesses the impact of multiple external factors (including physical, chemical, biologic, social and economic) on human health by studying specific populations.^{i,ii} Data used to support such investigations can originate from public health or environmental laboratories. For decades, these laboratories have collected, analyzed, and monitored air, water and soil in order to protect public health and the environment. More recently, laboratories have increased their ability to assess individual or population exposures to harmful environmental contaminants through biomonitoring — measuring the concentration of chemicals, or their metabolites, in blood or urine.

The Association of Public Health Laboratories (APHL) often hears about successful collaborations between members and epidemiologists. Yet, there are other instances when a laboratorian or an epidemiologist will say they did not participate when their respective expertise could have been helpful.

Environmental epidemiologists can help laboratorians by providing advice on study design and implementation, including: data analysis and reporting; monitoring environmental hazards; exposures and health outcomes over the course of a response; and during follow-up investigations. They also can provide recommendations to develop, implement and evaluate targeted interventions.

Similarly, laboratorians can help epidemiologists by supplying data for their studies, including: providing sampling recommendations and training, appropriate processing and shipping schema; identifying the appropriate analyte to test; and monitoring quality indicators to verify the integrity of test results. Integration of expertise from these two fields can provide a more comprehensive picture of a public health problem to answer community questions, offer solutions and even influence policy decisions.

Through funding from the Division of Environmental Hazards and Health Effects at Centers for Disease Control and Prevention's (CDC) National Center for Environmental Health, this guidance illustrates the benefits of collaboration between environmental laboratorians and epidemiologists, in order to better unite and integrate the two fields.¹ The document outlines strategies for state and local health agencies to incorporate from the beginning stages of an investigation. Key audiences include environmental laboratorians and epidemiologists, as well as Public Health Laboratory Directors, Environmental Health Directors and Health Officials.

APHL is confident that the strategies, suggestions and resources discussed in this document will ultimately improve the public health response to environmental events or issues.

¹ APHL worked in consultation with the Environmental Public Health Tracking Network's Biomonitoring Taskforce, previously convened by CDC. Other partners include the Council of State and Territory Epidemiologists and the Association of State and Territorial Health Officials.

Planning

Knowing Your Partners

Partners share long-term goals and overcome challenges together. A partnership between an environmental laboratorian and an environmental epidemiologist begins with the understanding of where each party resides in their respective agencies and their capabilities and limitations.

There are two generalizable categories of public health laboratories² that address environmental health issues. Environmental laboratories assure the safety of water, soil and air through testing for chemical, biological or radiological agents and other contaminants. Environmental *health* laboratories measure levels of chemicals in human tissues and fluids to assess potential environmental exposure (otherwise known as biomonitoring).ⁱⁱⁱ



Video 1: Click on the image to watch a video on 'What is a public health laboratory?'



Video 2: What is Epidemiology? Credit: CDC, National Center on Birth Defects and Developmental Disabilities

Most US states and territories and the District of Columbia have a central public health laboratory that resides within or serves as a part of the state's public health agency. Many states also have local public health laboratories to serve a metropolitan city or a region.^{iv} Environmental laboratories may or may not reside in the public health agency. When laboratories are not located within the public health agency or in close proximity, distance may act as a barrier for collaboration.

Epidemiologists serving in public health agencies investigate the cause, frequency and control of a disease in a given human population over a period of time. Epidemiologists also monitor the efficacy of prevention programs.^v US state and territorial health agencies have teams of epidemiologists who work on a range of issues, including chronic diseases, environmental health, infectious diseases, maternal and child health, occupational health and more.^{vi}

Environmental epidemiologists (hereinafter epidemiologists) study the environmental factors affecting the health of a particular population by using environmental exposure data to identify exposure-response relationships.^{vii} For example, epidemiologists assess the risk factors of a disease or illness by monitoring air and drinking water quality.^{viii} This type of assessment provides information to develop prevention strategies and other public health actions.

² **Public health laboratories** are governmental reference laboratories that protect the public against diseases and other health hazards.

Partnerships between laboratorians and epidemiologists may begin by either party reaching out to the other for assistance. The most successful partnerships occur when (1) both parties collaborate from the onset of an investigation, (2) are transparent about goals, limitations and outcomes, and (3) set up regular meetings to keep the lines of communication open.

For Example. . . . In Washington State, epidemiologists and toxicologists create a list of priority issues to work on, then engage their partners in the public health laboratory who provide input on the feasibility of each study from the analytical perspective. Limitations may include funding, staffing, technology and time. Next, the adjusted priority list then goes to the external Scientific Review Committee for review.

A partnership between laboratorians and epidemiologists is critical to attaining a comprehensive understanding of an exposure, disease or illness. Before an investigation is carried out, epidemiologists should:

- consider steps for submission of a review by an Institutional Review Board (IRB), if needed,
- identify a target population,
- work with the laboratory to determine appropriate methods for sample collection and storage for both clinical and environmental samples,
- prepare for risk communications to other state agencies and the public, and more.

Laboratorians can prepare a quality assurance plan, assist with an evaluation plan, interpret laboratory test results and advise on further analyses and next steps for the investigation.

Knowing Your Local Statutory Limitations

Although environmental laboratorians and epidemiologists work to protect the public from disease, their roles and authority may be limited by state law, general authority or funding source. See Table 1 below for some examples.

Table 1. Examples of Limitations in Authorities

Environmental or Clinical Laboratory	Environmental Epidemiology
Laboratory Policies: State laws or statutes often mandate what samples get sent to a laboratory. What is considered an appropriate sample specimen is driven in part by state law, the public health policy of the jurisdiction and programmatic needs.	Source of Study: If an inquiry is designated as research and not public health practice, some epidemiologists working for a state health agency may be precluded from participating since they are not allowed to conduct research.*

* Public health practice, defined by the application of established methods to monitor and investigate disease in a population, differs from research, which involves testing new interventions or strategies with unproven outcomes. Epidemiologists are often precluded from engaging in practices that involve potentially adverse or unexpected consequences to human individuals or populations.^{ix}

<p>Study Design: If clinical samples are collected and analyzed for an investigation, informed consent and an Institutional Review Board** may be involved.</p>	<p>Funding Source: The source of the funding may be heavily tied to the epidemiologist's ability to look into an environmental issue. Funding from federal, state and local governments are usually permissible; however, funding from universities and private entities may not be.</p>
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** Collecting informed consent and requesting a review by an IRB may not be a limitation, rather, it may act as a bottleneck especially if it involves multiple IRBs.

Identifying Goals

The identification of goals involves many steps and multiple parties. The first, and most critical, step to classifying the problem is to establish the goals and objectives. Formulating goals and objectives early in the process allows for planners to start thinking about which experts need to be consulted, the types of considerations to think about (such as an Institutional Review Board review, see below for more detail on IRBs), and establishing the target population.

For a clinical investigation involving biomonitoring, goals (CSTE, 2012) may include:

- **Targeted Investigations** — measuring population exposures in response to a community health concern or chemical contamination.
- **Population Surveillance** — monitoring population exposures over a period of time, identifying disparities in at-risk populations exposed to harmful chemicals and evaluating efficacy of public health interventions.
- **Rapid Response** — identifying or confirming acute chemical exposures after an uncontrolled chemical release or other type of incident.

The Investigation

Building a Study Team

A study team comprising scientific experts, stakeholders, and community or advocacy groups can help achieve predetermined goals and objectives. The study team provides a list of considerations from the beginning stages of the planning process that could otherwise delay or impede the final goals. Their varied expertise can lend direction during the planning, study design and results reporting phases of the investigation, and their experience can provide important considerations through all phases. This team should meet regularly to check-in about the investigation and at pre-determined milestones.

Based on the scope of the project, the following experts may be approached to participate in a working group that oversees the investigation from start to finish:³

- Analytical Chemists
- Epidemiologists
- Toxicologists
- Physicians and Nurses
- Industrial Hygienists
- Statisticians
- Communications Experts and Health Educators
- Community Groups

Asking other partners to join the discussion is also critical to achieving the end goals:

- Federal partners (including CDC, ATSDR, and EPA and their regional offices)
- Local health agencies
- Departments of environmental protection
- Hospitals
- Universities
- Elected officials
- Boards of health

Community and public engagement remains a critical component to a successful investigation. Health communicators⁴ and public affairs staff should be engaged early to craft messaging throughout every phase of an investigation.^x Proper messaging at the beginning of an investigation will ensure transparency and trust, leading to ease in communication and information.

For Example. . . In New York State, Department of Health epidemiologists and laboratory scientists worked together to respond to community concerns about exposure to depleted Uranium. During the course of project planning, community members addressed specific concerns such as the difference between spot urine samples and 24-hour urine samples. Laboratory scientists were needed at the planning meetings to explain and justify specific technical aspects of the sampling and analyses plans to keep the project moving toward its goal. (More information at http://www.health.ny.gov/environmental/investigations/national_lead/info_sheet.htm)

Study Design Considerations

An effective study design identifies responsibilities, goals and timeliness for sample collection and storage, testing, analysis, data interpretation, communicating results and more.^{xi} Three types of epidemiological study designs^{xii} exist: surveillance,⁵ targeted investigation⁶ and hypothesis-testing research.⁷

During an investigation, the selection of an appropriate study design is crucial for making

³ The California Department of Public Health's Environmental Public Health Tracking group serves as a model for this.

⁴ Often epidemiology staff take on the communications role because resources for specialized communications experts are rare. Still it remains important to access the expertise of a risk communications or public affairs expert if possible.

⁵ **Surveillance** is the ongoing systematic collection of data of interest to detect changes over time.

⁶ **Targeted investigation** is used to observe the course or the interaction (if there is one) between chemicals or interventions and health outcomes.

⁷ **Hypothesis-testing research** is used to test a proposed hypothesis related to sources of exposure or health outcomes.

comparisons among populations of interest. One study design consideration is whether the biomonitoring or environmental sampling component is just one element of a multi-faceted investigation, or whether this type of laboratory measurement tool is the central focus of the project. Making this distinction early on in the process may help with assigning roles and responsibilities, determining sample population, size and other design aspects.

Identifying IRB Considerations — if any

An Institutional Review Board (IRB) protects the rights and welfare of human subjects⁸ in a research⁹ project.¹⁰ The IRB possesses the ability to approve, require modifications or disapprove a research plan that falls within its authority.^{xiii} If a research project includes human sampling, one or more IRBs may become involved, potentially adding a considerable amount of time to the process.

Another delay may occur when a state views the IRB as an expansion of statutory authority of the state health agency. In this instance, the health agency's legal offices are required to review any materials related to human subjects in a research project.

State IRBs, statutes or other governing body may require additional steps. For instance, the New York State Department of Health required federal Office of Management and Budget¹¹ approval for an environmental health project. This step delayed their timeline by several months.

For example: In states like North Carolina, if a project falls outside of the scope of the Department of Health and Human Services' routine responsibilities, approval from the state's IRB is required. In addition, if data are to be provided by the state's public health laboratory to another state agency, a data-use agreement or a memorandum of understanding may be required. Becoming familiar with the guidelines to successfully proceed with an investigation remains critical to meeting project deadlines.

Selecting a Target Population and Sample Size

Considerations for selecting an appropriate target population¹² and determining the sample size¹³ depend on the goals and objectives of the study. In order for epidemiological study results to be generalized to a larger population, the sample size must allow for adequate statistical power. For a biomonitoring study, consider selecting a target population whose results can be generalized and applied to the broader population.

⁸ **Human subjects** are defined as "living individual(s) about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information."

⁹ **Research** is defined as "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge."

¹⁰ Research involving human subjects may be exempt from IRB review when they include educational testing and survey procedures using de-identified information to ensure that the subjects are not at risk of civil or criminal liability or be damaging to the subjects' financial standing, employability, or reputation. Similarly, research involving existing data, documents, or specimens, where no identifying information is recorded and linked to human subjects remains exempt from IRB review.

¹¹ The Office of Management and Budget resides under the White House, and is authorized to administer the data collection requirements under the [Paperwork Reduction Act](#).

¹² **Target Population** provides a frame of reference for the population of concern.

¹³ **Sample size**, closely tied to statistical power, or the sensitivity of a diagnostic test, estimates the probability of a study to yield a significant difference when there truly is one.

Biomarker Selection — if applicable

Biomarkers¹⁴ may offer a better understanding of the linkage between environmental exposures and health outcomes.^{xiv} To effectively use biomarkers, the study design must include exposure and effect.^{xv} It remains critical to identify early in the study design stage which biomarkers will be investigated, as this greatly influences the selection of the specimen type to be collected. Selecting a biomarker requires several considerations, including:^{xvi}

- Accuracy
- Reproducibility
- Sensitivity
- Specificity
- Biologic relevance
- Practicality
- Temporal characteristics

It remains critical to consider whether the biomarker has been measured at the appropriate time, the critical life stage of interest and the disease's induction and latency characteristics. Some chemicals also have biological half-lives measured in years, which makes it feasible to detect exposures long after they occurred.^{xvii}

For more information on biomarker selection, see the APHL Guidance for Laboratory Biomonitoring Programs.

(http://www.aphl.org/AboutAPHL/publications/Documents/EH_2012_Guidance-for-Laboratory-Biomonitoring-Programs.pdf)

Data Collection and Interpretation

Before collecting biospecimens, epidemiological data or environmental data, establish standard methods for collecting, storing and transporting data or samples, particularly when working with third parties. Environmental sample collection and subsequent analyses of these samples may require the assistance of the Environmental Laboratory.¹⁵ Samples can also be obtained from other sources including, but not limited to, newborn screening, blood alcohol testing and blood lead levels. Using specimens for purposes other than what they were intended will likely require IRB approval and regulatory oversight.

CDC's National Environmental Public Health Tracking Network may provide data (e.g., surveys, demographical or geographical information, diet and governmental records). Obtaining access to a secure tracking portal may involve entering into a data use agreement with the owner of the data.

In addition to devising a method for data collection, consider procedures for submitting data from the laboratory to the epidemiologist and other scientific staff to analyze and interpret. A few points to consider:

- Before a data request is made, what are the relevant variables to describe the population affected, hazard data, exposure levels and health information?
- Is the designated individual appropriately trained to gather data from the laboratory's

¹⁴ A **Biomarker** is a biochemical, histological or physiological measure that relates in a dose or time dependent manner.

¹⁵ Not all Environmental Laboratories reside with the public health agency. Many states have separate agencies that represent environmental testing.

information management system and place it in a suitable format for the epidemiologist to use?

- Can the data be transferred electronically to reduce error and increase efficiency?^{xviii}

Such questions remain critical as navigating complex data may introduce error at times, such as when extracting data from a laboratory system and placing it in a format that can be viewed and used by the epidemiologist. An on-site observation session of the laboratory's data storage system by the epidemiologist may provide perspective.

Data Interpretation

By consulting with a laboratorian or medical consultant concerning laboratory data, epidemiologists can leverage the expertise of data generators to make more robust use of the data. The laboratorian can explain the sensitivity of detecting a particular biomarker or contaminant and the respective level of detection that can be performed by the laboratory, while the medical consultant can explain the clinical significance of the laboratory data.

Often, investigations conducted by state agencies answer descriptive questions such as who is affected in an incident (or exposure), when an incident takes place and where it takes place; consequently, this information aids in making hypotheses about potential linkages between hazard data, biomarker exposure levels and the occurrence of potential health effects. Data provided by other state agencies, such as the laboratory, assist the epidemiologist with describing patterns and frequencies of disease and illness in the affected population and making comparisons among groups, such as between males and females.

Finding potentially-harmful chemicals in bodily tissues, drinking water, the air or other media raises the possibility of adverse health effects. Interpreting data on such potential exposures includes the following considerations:^{xix}

- Is the biomonitoring result in a range that is typical of the general population?¹⁶
- Is this a vulnerable population?
- Do the results indicate a health risk?
- How did the exposure(s) occur?
- Are there means to decrease the exposure(s)?

The determination of the following is an essential step in interpreting and communicating results:^{xx}

1. Reference Range refers to the concentrations of analytes expected to be found in a population to which the results are compared (i.e. the general population). Interpretation of results improves by the ability to compare results to a reference range. This should be considered early on in the study design stage.
2. Critical Values are those which may indicate higher than average levels and need further attention or action.

¹⁶ The **general population** excludes the occupationally-exposed members of a population.

3. Action Levels are those which greatly exceed the expected clinical concentration warranting immediate notification of findings by the laboratory.

NOTE: Before the data can be interpreted, there remains a great deal of preparation¹⁷ and editing to minimize issues around missing or questionable data.¹⁸ All data must be transferred to a computer system, and questionnaires need to be uniformly coded. Again, the data at this stage should be edited once again.^{xxi}

Results Reporting and Data Security

Results reporting informs participants, community, funders, policy or decision makers, and the general public about results from the study that impacts the community's health. To effectively communicate results, consider using experts in risk communications to discuss results with individual participants or groups. The communications strategy should explicitly convey the investigation findings to the target and affected populations.^{xxii}

Data security is essential to a study that involves human samples. Individually identifiable health information is strictly regulated under the Health Insurance Portability and Accountability Act (HIPAA). When sharing and reporting data, follow protocols established under both HIPAA and IRB to ensure privacy of study participants. See Appendix A for information on Laboratory Considerations Under CLIA.¹⁹

Quality Assurance

Much of the discussion surrounding quality assurance stems from studies, including clinical trials. The focus remains on standardizing study design and staff training to ensure a level of quality for data produced and to help with its replication.^{xxiii}

The US Environmental Protection Agency describes seven principles of communication (National Research Council of the National Academies)

1. Accept and involve the public as a legitimate partner.
2. Plan carefully and evaluate efforts.
3. Listen to the public's specific concerns.
4. Be honest, frank and open.
5. Coordinate and collaborate with other credible sources.
6. Meet the needs of the media.
7. Speak clearly and with compassion

¹⁷ Data preparation is necessary to reduce the number of variables for analysis.

¹⁸ Questionable data could include invalid values, outliers, the reasonableness of joint distributions, etc.

¹⁹ **CLIA** is an acronym for the Clinical Laboratory Improvement Amendments, regulated by the Centers for Medicare and Medicaid Services.

<p>Laboratory quality assurance requires the following four activities prior to data collection to help laboratories maintain high accuracy²⁰ and proficiency²¹ across the board:^{xxiv}</p> <ol style="list-style-type: none"> 1. Establishes and assesses an SOP and the effectiveness of the laboratory's policies and procedures. 2. Identifies and corrects problems. 3. Assures accurate, reliable and prompt results reporting. 4. Assures high quality of staff competency. 	<p>Epidemiological considerations of quality assurance aim to standardize the path of the investigation. Some recommendations include:^{xxv}</p> <ol style="list-style-type: none"> 1. More sophisticated statistical methods. 2. Newer strategies in the observational studies of clinical care. 3. Fundamentals of clinical information systems and data handling. 4. Appropriate national and regional sources of comparative clinical data.
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As clinical laboratories become leaders in the field of healthcare quality management, there is a growing interest in quality improvement of the samples collected and tests completed. Accrediting bodies, such as the Centers for Medicare and Medicaid Services, require laboratories to improve analytical quality by focusing on pre-analytic, analytic and post-analytic processes.^{xxvi} There is some standardization in this area; however, concepts of quality control²² continue to improve.

Evaluation of the Study and Next Steps

Evaluating a study before, during and after its conduction remains a good practice to help identify any changes in the study design and to reflect on the final study, results reporting, risk communications and partnerships. The process of communicating next steps to the participants, the study team and funders is critical to maintain trust and credibility.^{xxvii} Oftentimes, community-based participatory research relies on presenting the findings, what they mean to the community or individual and any next steps as a course of action.^{xxviii} See Appendix B for Evaluating an Epidemiologic Investigation.

Leveraging Resources

Limited funding within the state health agency or laboratory may present challenges for public health projects. Therefore, leveraging resources is key. This includes leveraging human capacity through cross-training, internships and partnerships with academia, particularly when a team is understaffed due to budget constraints.

²⁰ **Accuracy** reflects the agreement between the measured value and the true value. (National Research Council of the National Academies. Human Biomonitoring for Environmental Chemicals. The National Academy Press. p. 117.)

²¹ **Proficiency testing** (PT) is the testing of unknown samples sent to a laboratory by a third party. Laboratories test PT samples applying the same protocols as used for 'real' samples, and submit their results to the PT program to verify the accuracy and reliability of their testing.

²² **Quality control** involves operational activities aimed at systems and processes developed to ensure the quality of sample collection and testing.

Another potential opportunity to leverage resources is through billback.²³ Look into whether services at the health agency or laboratory can be charged. The Affordable Care Act, in particular, has opened the doors to exploring this idea.

Finally, epidemiologists and laboratory teams should be upfront with stakeholders about their funding situation. If permissible, consult with interested parties — potential funders, foundations, state legislatures, other state government agencies, advocacy groups, academia, community groups and the media. Help these groups understand the value of the work being done.

There are other resources to leverage besides money and personnel to consider. For example, there are existing databases and other public health information resources (CDC's Environmental Public Health Tracking Network, EPA's Toxic Releases Inventory and APHL's Biomonitoring Capabilities List). See Appendix C for a full list of resources.

In 2009, the Rocky Mountain Biomonitoring Consortium applied for a biomonitoring grant as a group of collaborative scientists from Arizona, Colorado, Montana, New Mexico, Utah and Wyoming. A primary study objective was to enhance the collaboration between laboratories, epidemiologists, local public health agencies and other regional partners. One success story that came out of the Consortium included evaluating exposure to heavy metals from drinking water. Based on environmental monitoring data, each of the states identified regions with high and low levels of metals in drinking water supplies. The states sought volunteers and collected water and urine samples from 2,000 participants. In addition, a standard epidemiologic questionnaire was developed to assess potential sources of exposure to the metals. Epidemiologists from New Mexico and Wyoming compiled and analyzed the data. The project established initial population baselines for heavy metals exposure in the six states. It also demonstrated that, while individuals' drinking water levels correlated with urinary arsenic levels, they only explained 7% of the variation in urine levels, indicating that there might be other exposure sources. In addition, the study identified a previously unknown public health issue regarding elevated urinary uranium in one of the states, which is now under further investigation.

Additionally, working within consortia allows for collaboration between multiple states that staff experts in various disciplines. Working across multiple states also requires more organization. Hosting routine calls and meetings remains necessary to keep all workgroup members up to speed and engaged throughout the project.

²³ **Billback** is an accounting concept used for cost recovery. With a billback system, the client is charged a percentage of the total cost of equipment, services, and venues of which are used.

Conclusion

The key message from this document is the need for constant, open communication between environmental epidemiologists and laboratorians – understanding one another’s jargon, capabilities and limitations. When an event or issue arises where the two groups can collaborate on an approach, including timeline and budget, it should fit the needs of all parties. During such an investigation, constant communication becomes even more important; otherwise, the potential to become disengaged from the process increases and the group working on the study may not know:

- What stage of the study is beginning/ending
- Who’s responsible for what

It is also important to keep the lines of communication open to study participants, as they want to know and understand the important work you do on their behalf and in which they are very personally involved. Although they may not understand the science, they want to be treated with respect and ultimately to understand the potential impact on their health. Similarly, open lines of communication with policymakers remain important, as they can add, change or continue funding a program or investigation.

Another key to a successful collaboration involves reviewing a project at the conclusion. A de-briefing²⁴ after each collaborative project helps workgroup members talk about lessons learned as a group and continue to bond with one another. In addition, such an exercise may help spell out future actions:

- What are the possibilities or next steps of the findings?
- What are some immediate and long-term next steps to:
 - o Reduce exposure?
 - o Address mental health concerns?
 - o Reduce community members’ concerns?
 - o Address individual health and well-being?

With the tools and examples illustrated in this document, we hope that you will develop improved relationship and have an easier, more successful time achieving your study goals. To share information from this paper with your partners see Appendix D for a visual aid of steps outlined.

²⁴ A **de-briefing** (sometimes called a ‘hot wash’) is an after action discussion on a project or event. For the purposes of this paper, a hot wash is the recommended practice of connecting with all participants after an investigation to discuss what went well and what did not. This is also an opportunity to foster relationships built along the way, and possibly work together on the next investigation.

Laboratory Considerations under CLIA

For laboratories certified under the CLIA, individual laboratory reports must contain certain mandatory elements (APHL, 2012):

- name, address and telephone number of the laboratory
- two unique sample identifiers (typically these are name and date of birth but could also be any combination that includes those or the following: study identification number, medical record number)
- specimen type or source (urine, blood, serum etc.)
- date of specimen collection
- date of sample receipt
- date of sample analysis
- tests performed
- test results
- reference ranges
- if applicable, unit of measurement
- any additional testing used to normalize contaminant levels, including name of the reference laboratory as appropriate
- date final test results were generated

A full description of the CLIA requirements for laboratory reporting is available here: <http://www.cdc.gov/clia/regs/toc.aspx>.

Evaluating an Epidemiologic Investigation²⁵

1. **Research Objectives**
 - a. What was the primary outcome of the investigation? Was it achieved?
 - b. Were the right partners at the table and engaged appropriately?
2. **Study Population**
 - a. Was the right study population selected?
 - b. Was the 'case' defined accurately for this investigation?
 - c. Were the parameters for controls accurately placed?
3. **Exposure Assessment**
 - a. How accurate was the assessment of exposure?
 - b. Who constituted 'exposed' and 'unexposed' groups?
 - c. Were there outside variables or potential exposures that impacted outcome of the investigation?
4. **Sample Size and Analysis**
 - a. Was the sample size selected adequate to answer the question being investigated?
5. **Evaluation of Results**
 - a. Are the findings generalizable to other populations?
 - b. What are the strengths and limitations of the investigation? What could change to improve future investigations?
 - c. Is there a need for a follow-up investigation?
 - d. Were the results communicated in a way that the affected communities felt was appropriate?
6. **Additional Information on the Investigation**
 - a. Did the funding affect the investigation? If so, how?
 - b. Could additional funding support a follow-up investigation?

²⁵ Adopted from the [Systems Biology Center in New York](http://www.sbcny.org/Pdfs/Systems_Biomedicine_Course/cancer_module/class_10/Cancer_Epi_Guidlines.pdf). Systems Biomedicine Course, Cancer Module, Cancer Epidemiology. Last updated October 21, 2009. http://www.sbcny.org/Pdfs/Systems_Biomedicine_Course/cancer_module/class_10/Cancer_Epi_Guidlines.pdf. Viewed July 2014.

Resources

Noteworthy Publications

1. APHL's Guidance for Laboratory Biomonitoring Programs
2. CSTE's Biomonitoring In Public Health: Epidemiological Guidance for State, Local, and Tribal Public Health Agencies
3. Investigating Suspected Cancer Clusters and Responding to Community Concerns: Guidelines from CDC and the Council of State and Territorial Epidemiologists
4. HHS Institutional Review Board Guidebook
5. Eng, J. Sample Size Estimation: **How Many Individuals Should Be Studied?** *Radiological Society of North America*, 227, 309-313. Retrieved May 1, 2014, from <http://pubs.rsna.org/doi/pdf/10.1148/radiol.2272012051>

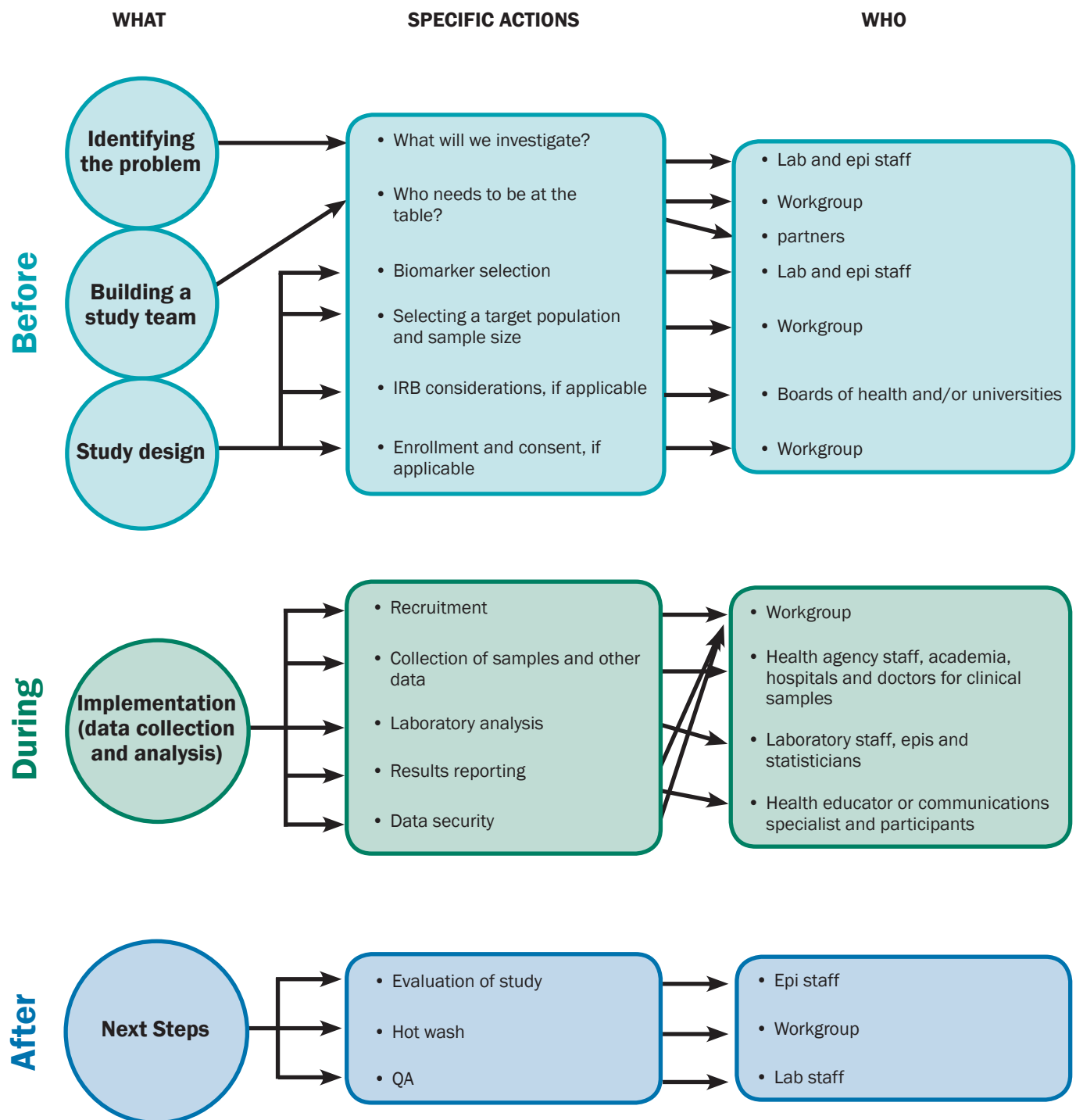
Databases and Toolkits

1. APHL's Biomonitoring Capabilities List
2. APHL's Biomonitoring Toolkit and Discussion Board
3. CDC's Environmental Public Health Tracking Network Reporting Tool
4. State- or regional-based databases:
 - a. Cancer databases
 - b. Birth defects registries
 - c. Environmental databases
 - d. Vital records data (for low birthrates)
 - e. Census data
 - f. Real property data
 - g. American Community Population data
 - h. Newborn screening results

Associations and Organizations

1. CSTE Environmental Epidemiologists: <http://www.cste.org/?page=EHPOC>
2. APHL Member Lab Listing: <http://www.aphl.org/aboutaphl/memberlabs/pages/default.aspx>
3. ASTHO State Environmental Health Directors: Contact ASTHO staff (EH@astho.org) for state-specific contact information.
4. Environmental Laboratories: contact APHL for more detail
5. [American College of Medical Toxicology](#)

Flow Chart



List of Acronyms

APHL	Association of Public Health Laboratories
ASTHO	Association of State and Territorial Health Officials
ATSDR	Agency for Toxic Substances and Disease Registry
CDC	Centers for Disease Control and Detection
CSTE	Council of State and Territorial Epidemiologists
HIPAA	Health Insurance Portability and Accountability Act
IRB	Institutional Review Board
PHL	Public Health Laboratory

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The Association of Public Health Laboratories (APHL) is a national nonprofit dedicated to working with members to strengthen laboratories with a public health mandate. By promoting effective programs and public policy, APHL strives to provide public health laboratories with the resources and infrastructure needed to protect the health of US residents and to prevent and control disease globally.



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