

CEHTP Framework and Guiding Principles

Introduction

This document is intended to guide the development of the California Environmental Health Tracking Program. The Senate Bill 702 Expert Working Group recommended the development of a strategic plan as part the development of the proposed Office of Environmental Health Tracking. The Strategic Plan includes the Tracking Program's mission statement, the ethical principals that guide program activities, bylaws for program governance and work plan for program development. The program bylaws include uniform cluster response guidelines, the program's data-sharing agreements, responsible research guidelines and funding and collaboration guidelines. The strategic plan is being developed in conjunction with the California's Environmental Health Tracking Program's Planning Consortium which is advising program implementation. The primary audiences for this document are the Tracking Program, program advisory groups and potential collaborators.

Mission Statement & Organizational Design

The Tracking Program is committed to assembling, appraising and communicating information about health and the environment to protect and promote the health of all Californians (population health).

Our Mandate & Objectives

Our mandate is to develop a tracking network that delivers scientifically valid and personally relevant information on environmental exposures and disease trends and makes this information available so it can be used to protect and promote the health of Californians. The following five public health objectives guide the development of the tracking network:

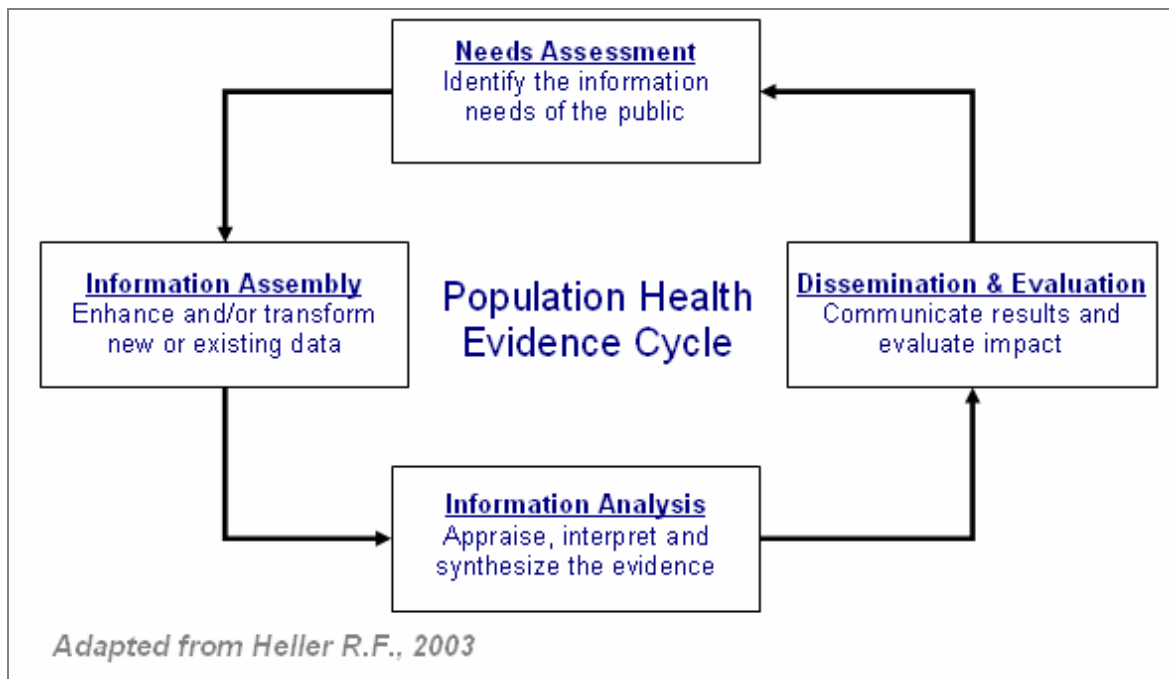
1. Evaluating and tracking environmental hazards and environmental exposures to guide prevention efforts
2. Tracking health outcomes (disease) to identify changes over time in residents statewide, in specific populations, or in certain geographic areas
3. Developing the capacity to link tracking information to generate hypotheses about possible relationships between the environment and disease to support environmental health research
4. Informing the development and evaluating the effectiveness of disease-prevention and environmental-protection policies
5. Providing access to information on environmental health issues

Our Organizational Capacities and Methods

The Tracking Program brings together a diverse staff to put our mandate into action. Delivering scientifically valid and personally relevant information requires the expertise of from various disciplines. Four organizational “core capacities” have been created to guide tracking network development. These core capacities are:

- Health Education, Communication and Evaluation (Health Education)
- Information Technology (Computer Sciences)
- Information Analysis and Interpretation (Epidemiology)
- Policy Analysis

We are in an era of rapid innovation in population health technologies. A core principal in public health is that improvements in science and technology should inform health policy and practice in a way that meets the needs of the community (the public). Given rapid innovation in health technologies and continually evolving needs of multiple stakeholders (publics), it is essential that we continuously evaluate our program activities. We have adopted ‘the population health evidence cycle’ as a framework to describe how our core capacities function to generate new information and promote communication and accountability.¹



¹ Heller, R. F., T. D. Heller, et al. (2003). "Putting the public back into public health. Part II. How can public health be accountable to the public?" *Public Health* 117(1): 66-71.

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Needs Assessment

California is the most geographically, ethnically and economically diverse state in the nation and the public's needs vary accordingly. Our health education, communication and evaluation team has developed multiple approaches to identifying the information needs of the public. These approaches include:

- Implementing needs assessments to identify, characterize, and prioritize the information needs of government, researchers and the public.
- Convening stakeholders to advise on the development of the tracking program and the implementation of demonstration and/or research projects.

Information Assembly

Emerging technologies present opportunities for improving disease surveillance, exposure assessment, and pollution and disease prevention. Our information technology and analytical teams work to apply emerging technologies to compile, enhance and transform data to produce scientifically valid and personally relevant information on environmental exposures and disease trends. This work includes:

- Working in collaboration with environmental protection and other public agencies to track geographically-related hazards (Objective 1: hazard tracking).
- Working in collaboration with public and private sector health organizations to document geographically-specific disease trends (Objective 2: health outcome tracking).
- Creating the infrastructure where environmental exposure information can be linked to disease information to support population health research.

Information Analysis

Epidemiologic methods continue to be developed enhancing our understanding of the association between environmental exposures and disease. Our analytic staff; with backgrounds in medicine, toxicology, and epidemiology; apply such methods to appraise, interpret and synthesize evidence related to exposure and disease. This work includes:

- Developing analytical tools to predict cumulative exposure to geographically-related hazards.
- Identifying hypotheses about relationships between environmental exposures and disease trends (Objective 3).
- Developing techniques for making health outcome tracking information available in a manner that supports the program evaluation and the public's right to know while protecting confidentially (Objectives 4 & 5).

Dissemination and Evaluation

There is an increasing need to communicate timely, accessible, and useful health and environmental information to support research, policy evaluation and the public's right to know. Our staffs work includes:

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- Identifying appropriate methods for making information useful for diverse audiences.
- Initiating collaborations with multiple organizations to support active dissemination of environmental health information.
- Supporting evidenced-based policies by using tracking information to evaluate the impact of laws, regulations and other initiatives.

Ethical Principles

The main duty of the staff of CEHTP is to protect and promote the health of Californians. In pursuing this mandate we recognize as public health professionals that we must respect the rights of, the public in general, stakeholders groups, research participants, co-investigators, funding agencies, political representatives and our coworkers and management.

The Tracking Program is committed to balancing four over-arching principles as we protect the public's health. We actively seek to: (1) help others and, (2) avoid doing them harm, (3) enhance the right of individuals and communities to make their own informed choices, and (4) identify solutions that are fair and efficacious.

We are committed to interpreting evidence and providing information in an ethical, impartial and trustworthy manner. We provide information to stakeholders with different informational needs that arise from different interests, cultural values and ethical viewpoints. Within the resources available to us, we strive to pursue the following strategies, aiming to meet the informational needs of all stakeholders in an impartial and trustworthy manner:

Democratic Process

Create mechanisms for stakeholder involvement in program governance and advocate for the budget and staffing required to support such participation.

Transparency

Make the rationales supporting program activities available in a manner that is transparent and intelligible. Document how we have generated conclusions from surveys, evaluations and research studies.

Truthfulness

Tell the unadorned, impartial truth, and indicate our degree of certainty to accommodate stakeholders who might take action even when we are not virtually certain.

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Policy Relevance

Ascertain information needs ahead of time and produce policy relevant findings including but not limited to facts about who is exposed and who is vulnerable, both of which are relevant to fairness.

Application of Foresight

Helping stakeholders to explore and evaluate alternative strategies for minimizing risk, even before we have virtual scientific certainty about the relevant facts.

Freedom from Conflicting Interests

Making sure that our personal finances or the way our projects are funded and managed, do not pose a real or apparent conflict of interest.

Data Sharing Guidelines

Scientifically Valid and Personally Relevant Information:

The Tracking Program is committed to identifying problems and interpreting evidence and providing information in an ethical, impartial and trustworthy manner. Towards this ends, the Tracking Program should develop and disseminate scientifically valid and personally relevant environmental health information.

- Add point on scientific validity?
- Add point on personal relevance?

Timely Dissemination

The Tracking Program should disseminate information in a timely manner for use by communities, researchers and the general public.

- Tracking program relies on data from other organizations need to make a point about “timely”?
- To support this principal, the Tracking Program should partner with other organizations to support information dissemination.

Privacy Protections

Dissemination should be limited to the extent necessary to protect the privacy and confidentiality of individuals and communities.

- The Tracking Program will not release “limited” or “confidential” data sets as described in the HIPAA Privacy Rule regulations (45 CFR, Parts 160, 162 and 164).

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- The Tracking Program will not release “raw” or “native” data from a third-party (e.g. health departments, environmental agencies or health care providers) unless such release is approved in writing by the original provider.
- The Tracking Program will work with partners from within the communities’ environmental health information concerns with the express purpose of ensuring that information release does not cause community harm.

Information is Usable and Understandable

Information should be disseminated in a manner that makes is useful and understandable to all audiences.

Responsible Research Guidelines

The Tracking Program is involved in a variety of environmental health research activities. Responsible research guidelines have been developed to ensure research activities are conducted in an ethical manner. For the purpose of establishing program research it is important to distinguish between (1) research involving human subjects and (2) other research.

Since the 1970s, all federally-funded research involving human subjects has been subject to ethical review through Institutional Review Boards (IRBs). Such review is designed to protect the rights and interests of research participants. Research conducted by public health agencies is also subject to such review, governed by the Common Rule (45 CFR 46)². The California Environmental Health Tracking Program (Tracking Program) may be involved in research involving subjects. These research activities are governed by the Common Rule. The tracking program may be involved in research activities that do not involve human subjects. One example involves the use of environmental monitoring data to predict pollution levels in certain geographic areas. Research involving secondary data sources may not be subject to for IRB approval.

Regardless of the specific review requirement the Tracking Program strives to conduct research in an ethical and socially responsible manner. This document enumerates responsible research criteria that should be adhered to in any proposed research project recognizing that not all criteria will be applicable to all research. Many of these criteria are consistent with requirements under the Common Rule. This document is not intended to be exhaustive, and in the context of a specific project, additional steps may be necessary. Rather this document is designed to identify basic criteria that should be addressed in any proposed project by the Tracking Program and any

² The Common Rule is the Federal policy for the protection of human subjects. The rule applies to all research involving human subjects conducted, supported or otherwise subject to regulation by any Federal Department or Agency.

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collaborators. Addressing the criteria below is intended to facilitate proposal development (e.g. minimum criteria to be addressed in proposals) and stakeholder review.

Recruitment

- During recruitment, the nature of the research and participation is explained to the potential study participant.
- Appropriate educational and background materials are provided to the potential study participant at the time of recruitment.
- Investigators explain to the potential study participant that refusal to participate in the study would not jeopardize access to health care services.

Use of Specimens

- Informed consent for future use of specimen(s) for specified and/or unspecified research purposes is obtained at the time of collection and the use of such specimen(s) is governed by the group collecting them.
- There is a mechanism for the participant to ask for withdrawal of his/ her specimen(s) from the research at any time.
- For banked specimens, if no informed consent for future use was obtained at the time of collection, investigators will request individual consent before use.

Results Communication

- Disclosure of individual lab results, with acknowledgement of scientific validity and limitations, is offered to all participants.
- If individual lab results have clinical implications, the participant will be informed and referrals will be provided.
- When applicable, individual results will be disclosed through a face-to-face encounter that is both culturally-sensitive and allows for counseling or debriefing, if needed.
- Results will be disclosed to participants to ensure understanding of the significance and limitations of the findings through the use of language and literacy-appropriate materials and resources.

Community Participation

- Mechanisms exist for community input in the planning, implementation and results communication stages of the study.

Study Implications

- Knowledge and experience gained from this study can inform policy and/ or public health actions.
- Knowledge and experience gained from this study can inform the community to take action.

Cluster Response Guidelines

In development.

Funding and Collaboration Guidelines

In development.