Chapter 6: Data Governance

As emphasized throughout this orientation manual, two major points of focus for you as the lead chronic disease epidemiologist are data and partnerships—the vital means for achieving efficient and effective chronic disease surveillance and program evaluation to undergird efforts to improve population health. Data—especially personally identifiable data—is subject to a number of legal strictures governing its collection, availability and usage, referred to as “data governance”. To navigate this state and federal terrain, you as the lead chronic disease epidemiologist must be familiar with state statutes and public health reportable conditions, data user agreements, institutional review boards (IRB), and the like. These data governance topics are the subject of this chapter. The aspect of data governance not covered in this chapter is the decision making about what data to collect for what purpose. To address this gap and to bring this chapter alive, ask to observe an IRB meeting and a Board of Health meeting where the board is considering a new reportable condition or change in an existing reportable condition.

For the senior epidemiologist or professional who supervises or mentors the lead epidemiologist, you can use this chapter to highlight which topics are most relevant to your department or state, to illuminate nuanced differences, to share additional topics not covered, and decide how best for the lead epidemiologist to learn about the Board of Health and its rulemaking, especially related to reportable conditions. (For example, in Colorado, cancer is required to be reported by hospitals, diagnostic and/or treatment clinics, and pathology laboratories.) Show the lead epidemiologist where to access state statutes and Board of Health rules related to any and all chronic diseases, the cancer registry, and/or disability. Ensure that the lead epidemiologist knows the chain of command and approval process related to contact with a state legislator or with the governor’s office. For the entry-level epidemiologist assess whether or not the surveillance system that you use or know best covers all aspects of the framework for public health surveillance. Read the documentation that forms the basis of the authority to conduct the surveillance system, whether it is a Board of Health rule or an IRB-determined ruling that this surveillance is deemed public health practice.

As a simple reminder of the comprehensive data collected in chronic disease surveillance and the public health actions that data inform, the following framework is presented. The legal requirement to protect privacy, the detailed and personal nature of these data and the potential for harmful use drives the protections and security that governs them. It is these very protections, how they are determined, and how they can be changed that you as the lead chronic disease epidemiologist must understand.
Understanding the Basics: A Framework for Visualizing Public Health Surveillance

Surveillance is one of three critical functions of a lead chronic disease epidemiologist. You as the lead chronic disease epidemiologist must provide critical leadership to assure adequate capacity to survey chronic diseases and associated risk factors and to assure the relevance, quality and appropriateness of the collection, analysis, and interpretation of the data. Advances in information technology have created expectations for surveillance that is real-time, accurate, and automated.

Brookmeyer and Stroup define public health surveillance broadly to include “all types of data collected from populations that could be useful in guiding public health activities.”¹ They propose a framework (Figure 6-1) depicting the relationship among a variety of data types, levels of intervention and prevention opportunities. Inclusion of “social determinants” in this framework—encompassing everything from health care access to community safety—is a poignant reminder of the broad context of chronic disease epidemiology and the need to forge a variety of partnerships to assure access to data and to populations to carry out core public health activities.

**Figure 6-1. A Framework for Understanding Public Health Surveillance Data.**²

As mentioned in Chapter 2, surveillance is a vital function of a lead chronic disease epidemiologist, such that CSTE ranked it as one of the top three functions for this position.³ Though evaluation of health services was deemed a supportive function of a lead chronic disease epidemiologist, evaluation—like surveillance—requires data. Therefore, it is useful to repeat the evaluation role of a lead chronic disease epidemiologist to:

- Further the design and implementation of scientifically sound evaluations of the outcomes of health services and health promotion/disease prevention programs, assessing effectiveness, accessibility, and quality.
- Assist program managers and decision-makers in using evaluation results to enhance effectiveness of existing programs and to design new programs addressing identified needs.
- Perform evaluation activities, such as analysis and interpretation of data to discern program impacts using both qualitative and quantitative methods.

---

³ CSTE. Essential Functions of Chronic Disease Epidemiology in State Health Departments. 2004.
In addition to performing these essential functions, you as the lead chronic disease epidemiologist will assist in building and evaluating long-term surveillance capacity, by assuring access to data and data consultants, maintaining capabilities for data analysis/interpretation, and maintaining partnerships with a long list of chronic disease stakeholders from community leaders to academicians.

Know the Statutory Authority to Conduct Public Health Action

Federal and state laws govern public health practice in the United States, including public health surveillance. They describe in broad terms the powers and duties of a public health entity and also its limitations. Key is the balance between the Constitutional rights of individuals and the public health needs of the community as well as the relationship of the federal government to state government (federalism) in the U.S. Constitution. The sources of law necessary for public health practice include: constitutions, statutes by legislatures, administrative law by executive branches of government, and common law (including case law) by judicial court systems. As the lead chronic disease epidemiologist, you will need to know about relevant state statutes and state administrative laws (disease reporting regulations, for example).

State constitution and state statutes: Because the U.S. Constitution does not mention “public health”, the primary responsibility for public health was left to states. States have their own state constitution as sources of legal authority. State laws must meet U.S. Constitutional protections (due to the 14th Amendment). The state’s own constitution provides for the establishment of state and local government branches and powers. It is your state statute that gives power to executive branch agencies, such as state public health departments. As the new lead chronic disease epidemiologist, read the portions of the state statutes that apply to public health, the Board of Health, and chronic diseases. Look for how it defines public health duties and chronic diseases, including the public health use of data. Understand how it protects confidential data when your public health department gathers, accesses, stores, and uses them. Usually, it limits data access to public health professionals involved in the disease control efforts (though for communicable diseases often persons at risk can be notified), and the data cannot be released to prosecutors and tort lawyers. In addition to the protections in state statute, there is the federal privacy law, the Health Insurance Portability & Accountability Act (HIPAA), which is discussed later in this chapter. Federal regulation regarding research and human subjects protection is also discussed later. Finally, related to state statute, ask if there are public health exceptions in your state’s open records act.

Regulation: Legislatures through state statute can give state agencies the power to make administrative regulations that have the same force as statutes. Examples include the state board of health designating notifiable diseases or reportable conditions or setting enforceable environmental measures. Promulgating and amending regulation can be quicker than passing statutes, allowing states to address new challenges quickly. So as the statute describes and limits the general authority for public health, the regulation can address highly technical details in how that authority is carried out. For example, many state public health departments designate
reportable diseases and specify the manner of reporting in an administrative rule by the Board of Health, rather than in a statute. This administrative rule power gives the department the flexibility to add diseases or change reporting standards without new legislation. The administrative rule gives clear guidance to the persons with a duty to report. Both federal and state laws require agencies to allow for public participation in this rule making. As the new lead chronic disease epidemiologist, review any Board of Health rules related to chronic diseases and related risk factors, such as tobacco and obesity. Also learn about state laws and local ordinances related to physical activity (such as physical activity requirements in schools), nutrition (menu labeling, for example), or environmental (secondhand smoke exposure). Ask about any excise taxes, such as on tobacco.

Under the U.S. Constitution, U.S. Congress has enacted statutes creating a federal public health infrastructure (for example, the U.S. Public Health Service) and federal agencies with public health powers (CDC, FDA, OSHA, EPA, NHTSA). The federal government can and does influence state public health through its regulatory duties (federal school lunch program, for example) and through its funding (and defunding) of public health, including chronic disease prevention funding and school health funding.

For more information than summarized here, such as due process, police powers, quarantine, the recent legal concept of personal privacy (1977), and emergencies, go to the source for this information: [http://www.cdc.gov/phlp/publications/phl_101.html](http://www.cdc.gov/phlp/publications/phl_101.html)

Cancer is a nationally notifiable condition. States must report cancer cases to CDC annually.  

Understand the Data Use Agreement

A data use agreement is a common means to gain data access or provide it to others. It can reflect information from federal and state statutes as well as state regulation. This contractual document is used for the transfer of data that is nonpublic or subject to usage restrictions—the type of data often required for research. Standard terms of data use agreements protect confidentiality, while permitting appropriate publication or other sharing of research results in accordance with applicable laws, policies and regulations. Typically, a state health department will have a designated signatory authority. State health departments can use data use agreements within its department to administer a person's access to data based on their role related to a specific reportable condition. For example, the cancer registry program might have a data use agreement with the internal steward of the hospital discharge data owned by an external hospital trade association.

Sample elements of a data use agreement include:

---

• Brief description of project(s) and intended use of the data, such as clinical research, health services research, or analyses to address public policy issues.
• Brief description of the subject area(s) to be investigated, such as health outcomes or service utilization.
• Brief description of the potential uses of the final products that may be created using the data, such as reports, quality measurements or performance measures.
• Assurances that the requester:
  o Will use only the dataset, or any part thereof, as permitted by the agreement.
  o Will prohibit others from using or disclosing the dataset, or any part thereof, except as permitted by the agreement; typically for research and aggregate statistical reporting.
  o Will keep data in a secure environment, with access limited to authorized users.
  o Will not release or disclose, and will prohibit others from releasing or disclosing, any information that identifies persons, directly or indirectly, except in cases explicitly permitted under the agreement.
  o Will comply with the privacy rule of the Health Insurance Portability and Accountable Act of 1996 (HIPAA).
  o Will not release or disclose information where the number of observations in any given cell of tabulated data is less than six.
  o Will not release or disclose information where the total population in any given subgroup of tabulated data is less than 50.
  o Will not release or disclose—and will prohibit others from releasing or disclosing—the dataset, or any part thereof, to any person who is not a member, agent, or contractor of the organization that is a signatory to the agreement.
  o Will require all those who will use or have access to the dataset (e.g., employees, agents or contractors of the signatory organization) to sign a copy of the agreement.
  o Will not attempt, and will prohibit others from attempting, to link the records of persons in the dataset with individually identifiable records from any other source.
  o Will not attempt to use, and will prohibit others from using, the dataset to learn the identity of any person included in the data set.
  o Will not contact or permit others to contact facilities or persons in the datasets.
  o Will not sell, market, or transfer the data, or cause or allow the transfer of the dataset or any part thereof.

Determine Whether Your Project is Research, Surveillance, or Evaluation

Research, surveillance, and evaluation share similar designs, data collection methodologies, analytical methods, and quality measures (e.g., statistical validity). However, there are also important differences among the three in terms of their purpose and guiding questions; their intended audience; and the means employed to interpret, report and use findings.
Lee, Teutsch and other authors of the text, Principles & Practices of Public Health Surveillance note several specific purposes of surveillance:\(^5\)

- Helping to assure accurate diagnosis and treatment.
- Enabling appropriate public health management of persons exposed to disease.
- Identifying disease outbreaks (or epidemics).
- Guiding population-based public health prevention programs.

Generally, surveillance required by federal or state law or by state or local public health mandate is not considered research. Voluntary reporting of risk behaviors, chronic disease knowledge, and chronic disease diagnoses might or might not be considered research. The purpose of research is to identify generalizable knowledge. “Generalizable knowledge means new information that has relevance beyond the population or program from which it was collected.”\(^6\) Research attempts to prove (or disprove) a hypothesis, to inform an audience external to the research organization, to ask “what is” and explain “how it works,” and to use findings to draw conclusions specific to the tested hypothesis that contribute to new, generalizable knowledge. Evaluation, on the other hand, aims to improve public health or public health surveillance, often informs an audience internal to the organization, asks “what has value” and “what is working,” and uses findings for decision-making about the specific program evaluated.

Importantly, research, surveillance, and evaluation each have their own standards and ethics for public health professionals. As the new lead chronic disease epidemiologist, follow your department’s established process to determine if a project or program is research, surveillance, and/or evaluation. However, a tipping point does exist: if any portion of a study or project qualifies as research, the entire enterprise is considered research.

Each governmental jurisdiction will have its own statues and administrative rules or procedures governing public health surveillance, evaluation, and research. For example, there may be differences across states in age to consent for research or ability to compensate state employees for participation in research. The lead chronic disease epidemiologist will need to learn the applicable policies in his or her state.

Use Institutional Review Boards (IRBs) When Necessary

The IRB is a federally mandated committee, established to assure that the rights and welfare of human research subjects or participants are protected. Human subjects/participants, in turn, are defined as living individual(s) about whom a research investigator obtains data through intervention or interaction (including online interaction) with the individual or through identifiable private information. The IRB has the authority to approve, disapprove, or require modifications to proposed or ongoing human subjects research.


IRBs operates under a federal wide assurance with the U.S. Department of Health and Human Services (HHS), assuring federal funders and the public that the research organization and researchers comply with Title 45 of the Code of Federal Regulations, Part 46 (45 CFR 46), and applicable state laws and institutional procedures concerning protection of human subjects in research. Three fundamental ethical principles underlie this code: (1) respect for personal rights of self-determination (including informed consent and surrogate consent/assent, as well as protection of individual autonomy, individuals with reduced autonomy, subjects and privacy/confidentiality), (2) beneficence to maximize subject benefits while minimizing harms (including the need for risk-benefit analysis, sound research design and appropriate researcher qualifications), and (3) justice or equitable distribution of research burden, costs, and benefits (including subject recruitment and selection protocols and inclusion/exclusion criteria).

Types of IRB Review

Depending on the risk level of research protocol and the participant population, an IRB may conduct either an expedited review or full board review.

An expedited review is carried out solely by the IRB chairperson or designee (rather than the full board) and is generally used for one of two purposes:

- To approve minor changes to a previously approved research project during the period for which approval is authorized (one year or less).
- To determine whether proposed research meets minimal risk standards and can therefore be exempted from further review.

Federal code defines minimal risk as “probability of risk or harm . . . no more than an individual subject would experience and/or ordinarily encounter in their daily life.” Exempted research—including activities such as anonymous medical record reviews—typically must involve no more than minimal risk, not involve intentional deception, not involve sensitive topics or populations, and include appropriate consent procedures.

The term expedited review, however, can be misleading; reviews of this type are not conducted faster or with less rigor. Researchers engaged in human subjects research qualifying for expedited review must still complete a full application form and prepare an informed consent statement. Moreover, investigators cannot assume that research poses minimal risk simply because it involves only interview or survey data. Sensitive questions may cause distress that exposes participants to greater than minimal risk. Loss of confidentiality can cause harm to participants, their relatives, and others. And non-invasive research that poses no physical risk, may nonetheless pose financial

---


risk, employment risk or risk of criminal or civil liability, stigmatization, loss of insurability, and/or embarrassment. It is important to consider a comprehensive view of risk.

The HHS Office for Human Research Protection has graphic decision-making tools available to determine whether a research activity is likely to qualify for expedited review or waiver of informed consent requirements. (See Resources at end of chapter.) All human subjects research that fails to meet requirements for exemption or expedited review must undergo a full IRB review.

Ongoing reporting to the IRB might include:
- Number of subjects accrued.
- Unanticipated problems or adverse events.
- Withdrawal of subjects.
- Complaints about the research.
- Summary of preliminary findings, recently published relevant research, or other relevant information, especially concerning research-related risks.
- Copy of the current informed consent document.
- Amendments or modifications to the research.

**Exempt Research**

Some types of research may not require IRB review. An example is research involving publicly available information. Research involving prisoners, fetuses, pregnant women, or newborns cannot be exempt from IRB review. However, the researcher does not make this determination of exempt research. Rather, researchers should check with their department’s guidelines or IRB policies to identify who will make the determination of whether or not a proposed study is exempt. Even when the IRB determines that the research is exempt from IRB involvement, researchers still have ethical responsibilities to protect participants’ rights.9

**Understand Your Obligations under the Health Insurance Portability & Accountability Act (HIPAA)**

HIPAA addresses three issues pertaining to personal health information: privacy, security, and electronic data exchange. Specifically, the act provides standards and requirements for electronic transmission of health information and a framework for the nationwide protection of client confidentiality and the security of electronic health information systems.10 Because HIPAA regulations are complex, they should be examined in the context of your own department. The state governmental organization with the mission to protect public health might be its own state department in your state or it might exist within the state human services department or the state

---


Medicaid department. Ask if your department is designated as solely a public health entity under HIPAA or as a “covered entity” which provide or pay for health care.

Protected Health Information

HIPAA standards for privacy of individually identifiable health information—commonly known as the Privacy Rule—define protected health information individual identifiers (including demographic information) and any personally identifiable information about an individual’s health/condition or payment for health care.\(^\text{11}\)

HIPAA regulations require the protection of protected health information, including, but not limited to, protected health information created, stored, or transmitted in/on the following media:

- Verbal discussions (i.e., in person, on the phone, via video chat);
- Paper (i.e., chart, progress note, encounter form, prescription, x-ray order, referral form, explanation of benefits, scratch paper, etc.);
- Computer applications/systems (i.e., electronic health record, laboratory information system, X-ray, etc.); and
- Computer hardware/equipment (PCs, laptops, pagers, fax machines, servers, cell/multifunctional phones, removable media, etc.).

Individuals have the right to receive an accounting of disclosures of their protected health information, including any disclosures made to an inappropriate individual or entity in error and disclosures made to:

- Meet legal requirements.
- Support public health activities.
- Report abuse, neglect, violence.
- Support health oversight activities.
- Report to judicial/administrative bodies regarding official proceedings.
- Support law enforcement.
- Respond to threats to health or safety.
- Support specialized government functions.
- Report about decedents.
- Provide information for worker’s compensation claims.

The use or disclosure of protected health information must be limited to the minimum necessary to accomplish the intended purpose for which the request was made or limited to the information a client has given permission to disclose via a client authorization.

---

HIPAA defines following data elements as identifying information:

- Any geographic subdivision smaller than a state (except for the initial three digits of a zip code if current Census Bureau data indicate that the geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people).
- Any elements of dates (except year) directly related to an individual; all ages over 80; and all elements of dates, including year, for ages over 89, except that all such ages and elements may be aggregated into a single category for age 90 or older.
- Telephone number.
- Fax number.
- Electronic mail address.
- Social security number.
- Medical record number.
- Health plan beneficiary number.
- Account number.
- Certificate/license number.
- Vehicle identifier and serial number, including license plate number.
- Device identifier and serial number.
- Web universal resource locator (URLS).
- Internet protocol (IP) address number.
- Biometric identifiers, including finger and voice prints.
- Full face photographic images and any comparable images.
- Any unique identifying number, characteristic, or code not assigned by the investigator by which one could identify or could reasonable expect to identify the participant.
Resources


CDC Surveillance Practice: Legal, Ethics, Policy at [http://www.cdc.gov/surveillancepractice/policy.html](http://www.cdc.gov/surveillancepractice/policy.html)
Includes additional resources on data sharing agreements, ethics, HIPAA privacy rule, human subjections protection, legal and regulatory issues, and meaningful use of interoperable electronic health records.

Federal Policies on Human Subjects Research


Tools and Educational Materials on Human Subjects Research


Federal Privacy Policy


Federal Policy on Research Misconduct

Summary

This chapter provides you with a basic overview of statutes and regulations that govern data access and use.

- Surveillance: State and federal laws govern data access and use, especially state statutes, state Board of Health regulations, federal Health Insurance Portability and Accountability Act (HIPAA) and the federal protection of human subjects in research. Understand the statute and Board of Health regulations that authorize your department to collect and use data on chronic diseases, especially any limits on the type of data and their use. As a lead chronic disease epidemiologist, you might need to know more than one reportable condition or notifiable disease. Compare the characteristics of research and program evaluation to the uses of chronic disease data, especially for the diseases that are not a reportable condition. Ask if historically any of the chronic disease surveillance systems were used in research. In many states, the cancer registry is one of the oldest chronic disease data systems. Ask its manager about its state statutes, any regulation, and any research that used registry data. Ask to see the IRB forms for the research that used cancer registry data, if still available. Ask how the cancer registry is used to improve population health. Ask how they provide aggregated results and/or censor data to protect confidentiality. Learn the topics of all reportable conditions as one way to learn about unique data systems in your department. For example, maternal mortality, though rare, might be reportable and findings from the maternal mortality review might be of interest.

- Communication: Your role is to communicate scientific and technical information in a way that decision makers can use it. Practice and prepare by writing a brief justification for the BRFSS being a public health practice under state statute. Then compare your justification with any actual justification (such as in the funding announcement from CDC or in your state’s application to CDC for funding).

- Consultation: It is often through your consultation that you connect the science and data to the policy options and policy makers in your state. Ask if there are any proposed changes to the chronic disease statutes or related Board of Health regulations. Ask if you will need to provide a scientific justification for the changes. Ask about the process for making changes, identifying constituent support, and selecting persons to testify.

Having reviewed data governance, you are ready to dive into the details of the data sources and indicators used in chronic disease surveillance, oral health, and maternal and child health in Chapter 7.