

## Chapter 1

# A Framework for Public Health Law Research

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### Learning Objectives

- Describe the field of public health law research.
- Differentiate three types of public health law.
- Identify principle types of public health law research.

Law is an important discipline within public health (Gostin, Burris, & Lazzarini, 1999). Legal “powers, duties and restraints” structure the mission of public health agencies and shape how it is carried out (Gostin, 2008). Law is a prominent intervention tool to achieve particular public health goals. Laws and their implementation also have important unintended effects, both positive and negative, on population health. Although public health law has a long pedigree in the United States (Tobey, 1939), it was one of the fields of public health that fell into neglect during the time that public health was thought to have conquered infectious disease. Over the past two decades, though, the reemergence of infectious disease as a major public health concern and a growing awareness of the complexity of health regulation at the local, national, and global levels have restored law to an important place within public health and academic law. No longer confined to end-of-the-day conference panels on “legal and ethical issues,” public health law now has its own office at the Centers for Disease Control and Prevention, academic centers, journals, national and international professional societies, and a shelf of important treatises (Larkin & McGowan, 2008).

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Notwithstanding these developments, there has been little discussion of empirical public health law *research* and its place within the fields of law and public health. Evidence produced by empirical research has an important role in public health law practice and scholarship. It constitutes the “facts” justifying regulatory action and supporting normative arguments about which policies are most desirable, most effective, or most consistent with human rights or other legal standards. To be sure, law legitimately serves as a site for the articulation and clash of values, and lawmaking often necessitates decisions that cannot await full information. Not all law is or can be “evidence-based,” even in public health. At the same time, empirical research is not just an ammunition dump for adversarial legal battle. The responsible use of law as a tool for improving public health requires a commitment to the pursuit and consideration of scientific evidence when possible. In public health, just as in health care (Sox & Greenfield, 2009), evidence should inform the investment in and implementation of policy, and a consciousness of data and the scientific method can improve the decisions of policy makers and practitioners even in the absence of data. This is the promise of public health law research.

### **Defining Public Health Law Research**

We define public health law research (PHLR) as *the scientific study of the relation of law and legal practices to population health*. This includes direct relationships between law and health and relationships mediated through effects of law on health behaviors and other processes and structures that affect population health. In this section, we elaborate on this definition to distinguish PHLR from other fields and forms of public health law knowledge.

### ***Distinguishing PHLR from Public Health Law***

Lawrence Gostin’s widely cited definition of public health law is “the study of the legal powers and duties of the state to ensure the conditions for people to be healthy (for example, to identify, prevent, and ameliorate risks to health and safety in the population), and the limitations on the power of the state to constrain the autonomy, privacy, liberty, proprietary, or other legally protected interests of individuals for protection or promotion of community health” (Gostin, 2000). Using this power-duty-restraint formula, Gostin succeeds in focusing the field on the state’s role in managing collective action to protect population health, while still encompassing a diverse range of cooperating actors and related functions, including private actors and the health care system. Some scholars have argued from diverse standpoints that Gostin and his colleagues in public health are expanding the jurisdiction of public health beyond its legitimate mission and into a realm of wrongful—and counterproductive—meddling

in the autonomy of citizens (Epstein, 2003; Hall, 2003; Rothstein, 2002). Yet for others this definition may be too narrow. Regulatory researchers, for example, question the importance of the distinction between public and private actors in health governance (Black, 2008; Lobel, 2004; Trubek, 2006). Other commentators insist that public health law should be treated as one of the social determinants of health (Burris, Kawachi, & Sarat, 2002; Magnusson, 2007; Mariner, 2009).

Debate over the boundaries of public health law plays out differently in the realm of public health law *research*. In defining PHLR, we are concerned not with what is right, proper, or legitimate to include within the jurisdiction of public health law, but with whether law can empirically be shown to affect the health of the population. Commentators might disagree upon whether equality, for example, ought to be considered a public health issue, but that is a different question from whether it is possible to empirically identify ways in which law affects health inequalities. Empirical data can be highly salient to disputes about normative concepts and positions, but do not in and of themselves resolve disputes about the legitimate scope of public health or public health law or the extent to which health promotion should be traded off against other social goods, such as civil liberties. PHLR, then, is distinguished from public health law by its focus on description, explanation, and prediction—that is, its focus on empirical investigation.

### ***Research Versus Scholarship***

When we refer to “research,” we intend a particular meaning: the use of systematic methods within an explicit theoretical framework to collect and analyze data. PHLR includes both qualitative and quantitative studies using experimental, quasi-experimental, observational, and participatory designs. It ranges from health impact assessments gathering limited data on legal effects in order to inform policy making in real time, on the one hand, to complex experiments and quasi-experiments studying the effects of law on health over extended periods of time, on the other. Formal decision analyses; simulations; econometric analyses; laboratory and field experiments; survey, interview, and focus group studies; systematic reviews; and meta-analyses are included, as is legal research to systematically and reproducibly collect, classify, and quantify laws and judicial decisions for analytic purposes (Hall & Wright, 2008; Tremper, Thomas, & Wagenaar, 2010).

Theory and methods may be drawn from a variety of disciplines in the social sciences, including epidemiology, biostatistics, law, sociology, history, political science, economics, anthropology, and psychology. From the natural sciences, PHLR imports the scientific method, approaching research questions with a hypothesis to be tested rather than a position to be defended; gathering

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data for the purpose of testing whether the world is actually consistent or inconsistent with the hypothesis; and reaching conclusions on the basis of a careful and restrained analysis and interpretation of all relevant data.

Public health law research as we define it is thus distinguishable from public health law scholarship. *Scholarship* embraces a range of non-empirical work about public health law, from work grounded in philosophy or ethics (Ruger, 2006) to doctrinal exegesis (Lazzarini & Rosales, 2002) to the crafting of model laws to legal analysis arguing how the law ought to be applied in various situations (Ruhl, Stephens, & Locke, 2003). What we call PHLR does not exhaust all forms of knowledge gathering or analysis concerning public health law. Public health law scholarship includes many outstanding and influential works that have shaped the field of public health law, but do not fall within our definition of PHLR.

### ***Law and Public Health***

A key challenge in defining PHLR arises from the potential breadth of the definitions of *law* and *public health* (Magnusson, 2007). In linking the two in PHLR, we take a broad sociological stance, encompassing not simply written laws on one side and morbidity and mortality on the other, but the whole range of institutions, practices, and beliefs through which laws influence health and the determinants of health. This is particularly important given that the timelines for law to influence health may be long and data on key outcome variables scarce; it may be important to examine effects of law on mediating factors such as organizational practices or health behaviors. The key aspect of such a study, from the perspective of whether it is properly classified as PHLR, is that it examines the relationship between a law variable and a public health variable.

Social epidemiology, the branch of epidemiology aimed at understanding social determinants of health (Berkman & Kawachi, 2000), provides a theoretical framework into which PHLR can readily fit (Burriss, Kawachi, & Sarat, 2002). Most things human beings do, and most characteristics of our environments, have some effect on the level and distribution of health in a population. Whether styled as health inequities or health disparities, differences in health among identifiable subpopulations have become a major concern in health and policy (Commission on Social Determinants of Health, 2008). Health law scholars, too, increasingly recognize the need to examine individual interests and choices through the lens of population health, recognizing that “the choices individuals exercise and the health risks they face are determined, to a large degree, by the environments they experience and the populations they comprise” (Parmet, 2009, p. 268; see also Sage, 2008).

Our conception of *law* is not confined to “law on the books”—constitutions, statutes, judicial opinions, and so on. The mainstream of empirical legal research over the past thirty years has acknowledged the salience of law as it is implemented in practice and experienced by those it targets. Studies of legality or legal consciousness (Ewick & Silbey, 1998), behavioral law and economics research (Jolls, 2006), scholarship on compliance theory (Tyler, 1990), scholarship on deterrence theory and tort law (Mello & Brennan, 2002), and regulation and governance studies (Braithwaite, Coglianese, & Levi-Faur, 2007) all explore this theme. PHLR is necessarily interested in the psychosocial mechanisms through which compliance is achieved (Tyler, 1990), the range of regulatory techniques that may be deployed (Braithwaite, Coglianese, & Levi-Faur, 2007), and how law “operates through social life as persons and groups deliberately interpret and invoke law’s language, authority and procedures to organize their lives and manage their relationships” (Ewick & Silbey, 1998, p. 20). Law is fundamentally a social practice embedded in institutions and implemented by agents. It is part of, not distinct from, the social environment whose influence on health is the focus of social epidemiology.

PHLR also properly encompasses laws that were intended to affect population health as well as laws that have unintended health effects. “Interventional public health law” is law or legal practices that are intended to influence health outcomes or health-related mediators directly. “Infrastructural public health law” establishes the powers, duties, and institutions of public health (Moulton, Mercer, Popovic, et al., 2009). But much of the law that influences population health was not adopted for that purpose, and may on its face seem to have no connection to health at all. For example, criminal laws aimed at controlling illicit drug use may increase the risk of users acquiring HIV (Friedman, Cooper, Tempalski, et al., 2006). Research that investigates the relationship of law and legal practices to population health falls within PHLR when it investigates health effects or otherwise deploys an explicit population health framework, whether or not the law itself is health-oriented on its face. We label this important category of PHLR “incidental public health law.”

Finally, PHLR is distinguishable from other kinds of public health research in that it evaluates not merely the effectiveness of a public health intervention but the effectiveness of *law* as the tool used to implement or facilitate the intervention. For example, research on whether abstinence-only education reduces teenage pregnancy is not PHLR merely because abstinence-only education happens to be required by law, but PHLR does encompass research on how abstinence-only education rules are implemented (Sonfield & Gold, 2001) and whether the existence of state-level, abstinence-only legal mandates is associated with differences in state reproductive health outcomes.

### ***Health Services Research and Public Health Systems and Services Research***

Access to health care is an important determinant of population health, and health care is widely acknowledged to be a key component of the public health system (Institute of Medicine, 2002). The study of how law affects population health through the mediating structure of the health care system falls squarely within the definition of PHLR. PHLR therefore overlaps with the field of health services research, “the multidisciplinary field of scientific investigation that studies how social factors, financing systems, organizational structures and processes, health technologies, and personal behaviors affect access to health care, the quality and cost of health care, and ultimately our health and well-being” (AcademyHealth, 2009). Effects of law on racial disparities in cardiac care outcomes, for example, is an important subject for both health services research and PHLR.

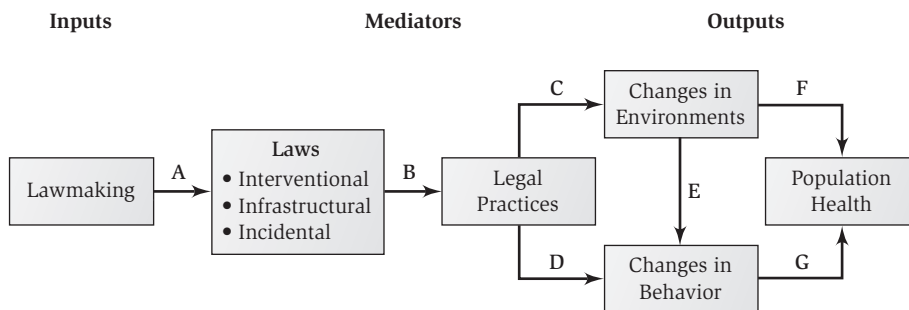
The area of overlap, however, is limited to research that focuses on *law* as an independent variable and population health (or an intermediate outcome with a well-demonstrated relationship to population health) as the outcome of interest. Research is not PHLR if it merely examines effects of some element of health care organization, financing, or delivery on health, without an important connection to law—for example, a study of the effect of capitated reimbursement in private managed care plans on utilization of branded drugs.

Public health systems and services research “examines the organization, financing, and delivery of public health services within communities and the impact of those services on public health” (Scutchfield, 2009). Its relationship with PHLR is discussed in Chapter 2.

### **A Causal Diagram for PHLR**

A wide range of laws and legal practices affects the health of the population in cities, counties, states, and nations. Cataloging all possible effects of law is impossible, and any schema for organizing such effects is characterized by tradeoffs and simplifications. Nevertheless, the field of PHLR is advanced by a shared understanding of the range of possible effects of laws, and potential mechanisms for such effects, encompassed within the field.

The way that law influences population health at the most general level is illustrated in Figure 1.1. In general, the independent variable in PHLR will be some aspect of lawmaking, laws, or the activities of legal agents. These will be studied in relation to dependent variables that can be arrayed along the presumed causal chain that includes key mediators as well as the distal or ultimate outcomes of interest—population morbidity and mortality.



**Figure 1.1.** Influence of Public Health Law.

First are studies of policy making—the factors that influence which laws are enacted and that shape the specific characteristics of the statutes and regulations adopted (path A in Figure 1.1). In these studies, public health laws (or judicial decisions) themselves are the outcome variable, and political and other jurisdictional characteristics are often the key explanatory variables tested.

Paths B and C examine key mediators in the causal chain linking laws and health outcomes. Studies of how law affects legal practices (path B) focus on the implementation or enforcement of the law on the books, including how the law affects the structure or operation of various regulatory systems. Laws may vary considerably in the degree to which they are effectively implemented; for example, whether a legal mandate for health education in schools translates into all pupils receiving the education that legislators envisioned may depend critically on the appropriation attached to the bill. There are opportunities and resources for litigation in some matters and not others. Unfunded mandates, unclear statutory provisions, failure to identify an administrative agency responsible for issuing implementing guidelines and overseeing rollout of the new legal provisions, lack of political commitment, and many other factors may undermine implementation. Similarly, laws may induce varying levels of compliance on the part of the regulated entities or population, depending on the degree of political resistance, the extent to which the administering agency is armed with effective enforcement mechanisms, the litigation environment, and many other factors. Completeness of implementation and effectiveness of mechanisms for ensuring compliance with the law are critical elements influencing the law's effect on health outcomes. Legal practices studies explore these influences as mediators of the statute or regulation's effect on health.

Paths C and D involve studying the effect of law (as implemented through legal practices) on environments and health behaviors. We use the term *environment* broadly to refer not only to the physical environment, but also to social structures and institutions. Even private institutions, such as corporations or the

family, are influenced by law. Laws and their implementation affect social institutions and environments by creating or reducing opportunities, increasing or decreasing available resources, expanding or reducing rights and obligations, and creating incentives and penalties. Research in this area examines these mechanisms of influence and how they shape the conditions for people to be healthy.

Law may affect health behaviors both directly (path D) and by shifting the environmental conditions that make particular behavioral choices more or less attractive (path C-E). For example, land use laws may influence where supermarkets and restaurants are located, affecting the availability of healthy food options and the healthfulness of the diet of local residents. Ultimately, changes in environments and behaviors lead to changes in population-level morbidity and mortality (paths F and G).

PHLR examines health outcomes directly or may use mediating environmental and behavioral changes as proxy outcome variables. While directly measuring health effects generally is desirable because it provides more information to policy makers about the public health returns to lawmaking, a focus on intermediate outcomes is often appropriate. For example, laws designed to improve rates of immunization with the human papillomavirus vaccine might best be evaluated in terms of their effects on the prevalence and burden of cervical cancer, but the time horizon for observing such effects is on the order of decades. Consequently, measuring rates of vaccinations is a reasonable intermediate measure.

## **PHLR in Practice**

The contours of PHLR as a distinct field are only beginning to emerge. Table 1.1, based on extant scholarship in the field and the conceptual model we have described, offers a typology of the principal forms of PHLR studies. In this section, we describe the primary methods for studying each of the paths described earlier.

### ***Policy-Making Studies***

Studies of policy-making processes are a mainstay of political science and sociology. They explore issues such as the determinants of legislative, administrative, and judicial lawmaking (Law, 2005; McDougall, 1997; Waters & Moore, 1990); lawmaking processes (Rosenberg, 1991); and stakeholders' use of law to achieve their goals (McCann, 1994). Although in broad terms the policy process does not vary by topic area, health policy making has generated a substantial research literature focusing on how generic policy-making processes unfold in a health context. This literature treats policy-making processes as among the legal practices that affect the potential for law to promote health.



Table 1.1. Typology of Public Health Law Research Studies.

<i>Study Type</i>	<i>Purpose</i>	<i>Methods Examples</i>
Policy-making Studies	Identify factors influencing the likelihood that public health laws will be adopted, the nature of laws adopted, and the process through which they are adopted	Multivariate regression Key informant interviews Content analysis of transcripts, rulemaking notices, memos, and other policy materials Surveys of policy makers
Mapping Studies	Analyze the state of the law or the legal terrain currently or over time and the application of laws surrounding a particular public health topic	Content analysis of statutes, administrative regulations, and formal policy statements Key informant interviews Surveys of state and local policy makers
Implementation Studies	Examine how and to what extent the “law on the books” is implemented and enforced through legal practices	Content analysis of administrative agency documents, including public communications Key informant interviews Direct observation of enforcement actions Examination of business records of regulated entities Surveys of regulators, regulated entities, and the public
Intervention Studies	Assess the effect of a legal intervention on health outcomes or mediating factors that influence health outcomes	Descriptive analysis of outcomes data Multivariate regression Case-control designs Controlled experiments; natural experiments Simulations Surveys of persons targeted by the law
Mechanism Studies	Examine the specific mechanisms through which the law affects environments, behaviors, or health outcomes	Controlled experiments Surveys, focus groups, or interviews of persons targeted by the law

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Advocacy groups traditionally have been crucial instigators of health law, and researchers of “legal mobilization” have studied how advocates have integrated legislation and litigation into their strategies (Ashe, Jernigan, Kline, & Galaz, 2003; Mamudu & Glantz, 2009). The relative advantages of litigation versus legislative approaches have been investigated empirically and debated in public health law scholarship (Jacobson & Soliman, 2002; Jacobson & Warner, 1999; Parmet & Daynard, 2000; Wagenaar, 2007), as have the factors influencing legislative outcomes and the legislative process (Backstrom & Robins, 1995; Corrigan, Watson, Heyrman, et al., 2005). Of particular interest for PHLR are studies that examine how research evidence influences policy makers (Chalkidou, Tunis, Lopert, et al., 2009; Cochrane Collaboration, 2009; Innvaer, Vist, Trommald, & Oxman, 2002; Jewell & Bero, 2008; Lavis, Oxman, Moynihan, & Paulsen, 2008). Other work has examined the behavior and strategies of policy actors; for example, how they use devices such as preemption and litigation to shift policy battles into fora where they have a greater expectation of success (Jacobson & Wasserman, 1999), how community organizations may be brought more effectively into the lawmaking or law enforcement process (Tyler & Markell, 2008), or how consulting can be used to more effectively translate research knowledge for policy makers (Jacobson, Butterill, & Goering, 2005). There has been growing interest in the question of how model laws are developed for public health purposes, and whether and under what circumstances model legislation is more likely than other proposals to be enacted (Hartsfield, Moulton, & McKie, 2007).

Both quantitative and qualitative methods are appropriate for policy-making studies. Statistical analyses are useful for examining the extent to which various observable characteristics of a state or local government—such as the political party in control of the legislature and the health status of the population—predict the likelihood that a particular kind of law will pass. For example, researchers have used multivariate regression to examine predictors of state legislative action on childhood obesity (Boehmer, Luke, Haire-Joshu, Bates, & Brownson, 2008; Cawley & Liu, 2008). Such research may make important contributions by identifying “friendly” venues for experimentation with new public health law approaches and suggesting strategies for spreading successful strategies to other jurisdictions.

Qualitative methods are appropriate for obtaining a rich understanding of the policy-making process. (Chapter 15 in this volume describes qualitative methods.) Interviews are commonly and effectively used to understand the factors that lead policy makers to take or fail to take particular actions. Researchers have, for instance, conducted key informant interviews with state legislators and their staff to examine factors enabling and inhibiting the passage of obesity prevention laws (Dodson, Fleming, Boehmer, et al., 2009). Content analysis is another useful method of exploring political deliberations that occur

“on the record”—for example, legislative hearings and debate concerning particular public health issues or legislation, and the notice-and-comment process of administrative agency rulemaking. Researchers have used content analysis to explore, for example, the use of evidence and argumentation in debates over workplace smoking legislation (Apollonio & Bero, 2009; Bero, Montini, Bryan-Jones, & Mangurian, 2001). Although it may be difficult to generalize the results of qualitative studies across jurisdictions, the high-resolution picture of the policy-making environment that they provide can have great value in formulating strategies for advancing evidence-based public health law.

### ***Mapping Studies***

PHLR includes studies that gather purely legal data for empirical purposes: information about the prevalence and distribution of specific laws (Gostin, Lazzarini, Neslund, & Osterholm, 1996; Hodge, Pulver, Hogben, Bhattacharya, & Brown, 2008), what levels of government have relevant authority (Horlick, Beeler, & Linkins, 2001), and variation in characteristics of the law across jurisdictions and over time (Centers for Disease Control and Prevention, 1999f; Chriqui, Ribisl, Wallace, et al., 2008; Shaw, McKie, Liveoak, & Goodman, 2007; Wells, Williams, & Fields, 1989). Methods may include content analysis of legal texts (laws, regulations, court decisions, and so on), qualitative research designed to elicit information from officials and others who are knowledgeable about the state of the law, or a combination of the two approaches (Horlick, Beeler, & Linkins, 2001). Although no independent-dependent variable relationship is studied, these studies can be scientific—and therefore fall within the field of PHLR—if they involve the systematic collection and analysis of data using replicable methods. Methods for mapping law are the focus of two chapters in this volume (Chapters 11 and 12).

Mapping studies often contribute information that is useful in its own right—state and local policy makers are keen to know what other jurisdictions are doing and what they might consider borrowing or learning from policy experiments in other jurisdictions. Mapping studies facilitate “policy surveillance,” the “ongoing, systematic collection, analysis, interpretation, and dissemination of data” about law (Chriqui, O’Connor, & Chaloupka, 2011, p. 21). However, mapping studies are typically an early phase of larger projects designed to evaluate the magnitude and nature of effects of laws on health. Properly conducted, they provide reliable and valid measurement of the key explanatory variable(s) in such studies. Thus a rigorously conducted mapping study requires consistent implementation of a clearly defined protocol for identifying and classifying laws. It will specify a definition of the type of law being investigated, perhaps with explicit inclusion and exclusion criteria; search methods that acknowledge strengths and weaknesses of extant databases; and a

coding scheme identifying key features of the laws, such as population covered and enforcement mechanisms specified (Tremper, Thomas, & Wagenaar, 2010). They may also characterize laws according to some overall scale of stringency, scope, or strength through transparent and reproducible means. For example, a recent mapping study of state laws regulating sales of sugar-sweetened beverages in schools coded laws according to seven substantive features and eight process features and then grouped laws into “strong,” “moderate,” and “weak” categories (Mello, Pomeranz, & Moran, 2008).

### ***Implementation Studies***

For a law to be effective, its implementation must be such that it actually influences the behavior of its targets. The process of putting a law into practice can be understood in terms of a series of mediating factors, including attitudes, management methods, capacities, and resources of implementing agencies and their agents; methods and extent of enforcement; the relationship between legal rules and broader community norms; and attitudes and other relevant characteristics of the population whose behavior is targeted for influence. Text of the law and resources appropriated for its enforcement constrain, but do not eliminate, discretion of bureaucratic entities to reshape rules to fit their existing culture and mission (Deflem, 2004).

Implementation research classically starts with investigating the “transformation process” that occurs along path B in Figure 1.1, the differences between the goals and methods of the law as explicitly or implicitly contemplated in the “law on the books” and the “law on the streets” actually put into practice by legal agents charged with enforcing the law (Percy, 1989). Case studies or other analyses of how health agencies organize their mission or perform in a given mission are a common form of implementation research (Buehler, Whitney, & Berkelman, 2006) and often look at the question of what legal powers an agency has or how it uses them (Lawson & Xu, 2007). Creative compliance and outright resistance on the part of targets of regulation are also studied (Nakkash & Lee, 2009). Implementation research in PHLR includes studies of the relationship between “legal infrastructure,” legal or other competencies, and agency function (Kimball, Moore, French, et al., 2008). Such studies may examine effects of law on private agencies operating under a legal authorization, such as the effect of legal authorization on syringe exchange programs (Bluthenthal, Heinzerling, Anderson, Flynn, & Kral, 2007). Implementation researchers also measure proximate outcomes of new rules that may provide an early indication of health-relevant effects—for instance, the actual speeds observed on highways after a change in the nominal speed limit (Retting & Cheung, 2008).

Research on legal practices in PHLR may investigate the means through which systems can be better governed or regulation better designed in order to achieve their goals. Although it has as yet had little influence specifically on PHLR, the study of techniques of regulation and governance has become an important part of broader empirical legal research and scholarship (Ayres & Braithwaite, 1995; Croley, 2008; Moran, 2002; Rhodes, 1997). For nearly three decades, regulation in the United States and many other developed countries has exhibited an increasing pluralism, not just in spreading of regulatory functions beyond government to private parties and public-private hybrids (Burris, Kempa, & Shearing, 2008; Lobel, 2004; Osborne & Gaebler, 1993) but also in the use of a wide range of strategies beyond detailed rules backed by carrots and sticks (Parker & Braithwaite, 2003). Contemporary regulators use cooperation, deliberation, education, competition, and other “soft” strategies that can be more effective than traditional command-and-control bureaucracy (Lobel, 2004). Theory and research in governance have highlighted the importance of actors outside of government—such as advocacy groups, corporations, and gangs—in managing the course of events in social systems, and have investigated how these actors regulate governments and each other (Buse & Lee, 2005; Scott, 2002).

New regulatory and governance approaches have raised a fascinating range of empirical questions, from the role of audit as a compliance tool (Power, 1997) to the design and effectiveness of public-private and self-governing regulatory structures (Gunningham, 2009a; Ostrom, 2005). This work resonates with research in behavioral law and economics, captured in Sunstein and Thaler’s book *Nudge*, which describes how regulators can creatively structure options to systematically influence behavior by means other than simple legal rules (Sunstein & Thaler, 2008).

Because so much regulation is now conducted outside of traditional bureaucratic frameworks (and indeed outside of the government), scholars working in this area begin with a generic definition of regulation and its constituent elements. *Regulation* is the “sustained and focused attempt to alter the behaviour of others according to defined standards or purposes in order to address a collective issue or resolve a collective problem” (Black, 2008, p. 139). It uses a combination of basic strategies of control, including standard setting, monitoring, and enforcement (Scott, 2001). The use of these strategies can be studied regardless of the particular mode through which the regulatory task is accomplished, and without regard to what sort of entity is performing it (Braithwaite & Drahos, 2000). This analytic approach allows researchers both to better capture the regulatory role of actors outside of traditional regulatory agencies—for example, the role of Mothers Against Drunk Driving in fostering stronger social norms condemning drunk driving—and to offer more creative

approaches to regulation, as exemplified by *Nudge* and other works in behavioral law and economics (Lobel & Amir, 2009).

Although research in regulation and governance has been limited in public health law (Biradavolu, Burris, George, Jena, & Blankenship, 2009; Burris, 2008; Trubek, 2006), its applicability is plain (Magnusson, 2009). Public health services are provided by a diversity of public and private actors (Institute of Medicine, 2002). It is widely recognized that complex systems such as health care cannot be managed solely or even primarily by top-down rules, but require use of a range of flexible tools, such as professional self-regulation, ethics, accreditation, collaborative and deliberative decision making, continuous quality improvement, and market incentives (Berwick & Brennan, 1995; Braithwaite, Healy, & Dwan, 2005; Lobel, 2004; Trubek, 2006). Internationally, health governance has been dramatically altered by the rise of new public-private hybrid institutions, such as the Global Fund to Fight AIDS, Tuberculosis, and Malaria; the enormous wealth of the Gates Foundation; and the consolidation of authority over national health, safety, and intellectual property law in the World Trade Organization (Hein, Burris, & Shearing, 2009; McCoy & Hilson, 2009). The Framework Convention on Tobacco Control is a typical instance of the “soft law” approach, setting broad goals for national action but minimizing binding rules in favor of deliberation and flexibility. Legal scholarship has begun to explore the “constitutional” implications of these structural changes (Fidler, 2004), but they have not been extensively investigated in PHLR.

### ***Intervention Studies***

Intervention studies evaluate the intended and incidental effects of legal interventions on health outcomes or key mediating factors that drive health outcomes. They may focus on “law on the books”—for example, examining the effect of states’ passage of graduated driver’s license statutes on rates of injury-causing crashes (Foss, Feaganes, & Rodgman, 2001)—or on legal practices, such as the effect of issuing restraining orders against perpetrators of domestic violence on future victimization (Harrell & Smith, 1996). Intervention studies can be deployed to evaluate interventional health law, but also to investigate the health effects of public health’s legal infrastructure and the unplanned effects of what we have called incidental public health law. Intervention studies lie at the heart of PHLR, as they most directly address the core question of the field: When it comes to using legal tools to promote health, what works?

Intervention studies can draw from an extensive methodological toolkit (Table 1.1). The strongest are experimental or quasi-experimental designs employing careful controls and comparisons. These designs are discussed in two chapters in this volume (Chapters 13 and 14). Variation in how and when

laws are implemented from jurisdiction to jurisdiction provide a rich set of opportunities for quasi-experimental studies, although sophisticated methods may be required to account for other ways in which jurisdictions differ from one another, and extensive longitudinal data are required. Useful study designs and analytical methods can be borrowed from the fields of econometrics and epidemiology (Ludwig & Cook, 2000). Real-world, randomized experiments are rare, but have been employed to study judicial-branch reforms such as specialized courts (Gottfredson, Najaka, & Kearley, 2003). Experimental studies can also be carried out using simulations, such as tabletop exercises (Dausey, Buehler, & Lurie, 2007; Hodge, Lant, Arias, & Jehn, 2011; Hupert, Mushlin, & Callahan, 2002; Lurie, Wasserman, Stoto, et al., 2004).

There is already a substantial evidence base on the effectiveness of interventional public health law, ranging from single studies through literature reviews to meta-analyses and systematic reviews conducted by entities such as the Campbell Collaboration (Campbell Collaboration, 2009) and the U.S. Task Force on Community Preventive Services (The Community Guide, 2009). There is also a rich, if less-well-organized, research literature on incidental public health law. For example, researchers have studied the unintended consequences of HIV reporting laws on attitudes toward testing, time of testing, and willingness to be tested (Hecht, Chesney, Lehman, et al., 2000; Tesoriero, Battles, Heavner, 2008). Research on the health effects of infra-structural health law has been more limited.

Consistent with ecological models in public health, intervention studies may investigate how laws influence health by changing environments. For example, zoning rules, clean indoor air laws, and laws regulating the condition of rental properties can directly shape residents' exposures to noise, environmental toxins, and stress, as well as their activity patterns, social connections, collective efficacy, and many other factors that appear to influence population health outcomes (Browning & Cagney, 2002; Maantay, 2002; Schilling & Linton, 2005). Occupational health and safety laws affect workers' exposure to hazardous conditions on the job. Product regulations protect consumers from a range of hazards arising from the use of products, from herbal supplements to firearms (Larsen & Berry, 2003; Robson, 2007; Vernick & Teret, 2000).

Interventional research focuses not only on how the law changes physical environments, but also on how it may change social environments in ways that affect health or health behaviors. Law may shape people's health knowledge and attitudes, the way they perceive risks and benefits of different choices, frames through which they view particular choices, and social norms against which their health decisions are set. PHLR can measure any or all of these dependent variables, as well as changes in health behaviors. There are many examples: research on the effects of indoor smoking prohibitions on social

expectations about exposure to secondhand smoke in public (Kagan & Skolnick, 1993); the effect of laws requiring disclosure of calorie information on restaurant menus on consumers' awareness of calorie content and attitudes about the role of calorie information in food-purchasing decisions (Bassett, Dumanovsky, Huang, et al., 2008); and the effect of punitive laws concerning substance abuse during pregnancy on the prenatal-care-seeking behavior of pregnant women (Poland, Dombrowski, Ager, & Sokol, 1993), to name a few.

Finally, intervention research can illuminate policy choices under conditions of uncertainty. When problems or policy responses are new, there naturally will be little or no intervention research directly on point. Policy making can still be informed by established theory on mechanisms of legal effects, understandings of how law typically works to influence environments and behaviors, and evidence about analogous policies, although all analogies are, of course, imperfect proxies for the situation at hand. An example is the area of legal restrictions on cell phone use by drivers (Ibrahim, Anderson, Burris, & Wagenaar, 2011). Although public health research recently has provided good evidence of the injury risk associated with this behavior, evidence about the effectiveness of different legal and policy approaches to the problem is not yet available. Until it is, lawmakers seeking to respond to what is clearly a significant health risk might be guided by the lessons learned about the design and enforcement of laws requiring safety belt and helmet use and prohibiting driving under the influence of alcohol. Health impact assessment has also emerged as a useful way to use mixed methods to develop and inform policy decisions with reliable data on possible effects, intended and unintended (Collins & Koplan, 2009; Lee, Ingram, Lock, & McInnes, 2007; Mindell, Sheridan, Joffe, Samson-Barry, & Atkinson, 2004). Monte Carlo simulations, widely in use in the field of decision science but rarely used in PHLR (Studdert, Mello, Gawande, Brennan, & Wang, 2007), offer an intriguing method for accounting for uncertainty about multiple parameters of importance to evaluating the likely effect of law. Economic evaluation that systematically explores the costs and benefits of policy options (or enacted policies) can and generally should influence policy choices. Methods for cost-effectiveness and cost-benefit studies of public health law are described in Chapter 16.

### ***Mechanism Studies***

To advance the field, we need to have not only more evidence of law's health effects but a greater understanding of *how* law has the effects it has. There are a number of reasons this is important. Evidence of mechanisms strengthens specific causal claims. Understanding how a particular intervention influences environments and behavior facilitates identification of further interventions, or of alternatives to eliminate superfluous requirements or unintended side effects



and strengthen the mechanisms that are working. The better we understand how law works, the better we can deploy it, replicate its successes across jurisdictions, and extend its approach to other kinds of health risks. Informed by theories of health behavior, PHLR can develop and test models to explain the manner in which public health law effects change in health behaviors and ultimately health outcomes.

At a simple level, laws encourage healthy, safe, and socially beneficial behaviors and discourage unhealthy, dangerous, and socially deleterious ones by shaping incentives (rewards) and deterrents (punishments). Though the theory may be simple, the process is not. There are myriad levers and tactics that regulators can use to influence behavior directly or through manipulation of the environment, and each choice in a regulatory system can and should be studied for its effectiveness, both in absolute terms and relative to less burdensome alternatives. The many mechanisms through which law exerts its influence are the focus of Part II of this volume.

With respect to laws imposing outright prohibitions on particular behaviors, many of the key research questions relate to mechanisms of implementation and enforcement: What penalties are applied to violators of legal rules? What processes are used to detect violators? With what degree of certainty and swiftness will sanctions ensue from a violation? Sociolegal research drawing on disciplines such as psychology, criminology, and sociology has a great deal to contribute to mechanism studies in PHLR. The psychological literature has explored contingencies of reinforcement, criminologists have fleshed out the factors influencing deterrence, and sociological research has plumbed the normative effects of standard setting. Tom Tyler's influential work, for example, has shown the importance of experiences of procedural fairness to compliance with law (Tyler, 1990).

A classic example of compliance research in public health law is investigation of primary versus secondary enforcement of safety belt laws. Primary enforcement laws permit police to pull over motorists for not wearing a safety belt, while secondary enforcement laws permit police to issue a ticket for not wearing a belt only when the motorist has been pulled over for another reason. Because secondary enforcement relies primarily on social norms to enforce safety belt use, with the threat of a ticket serving a greatly subordinate role, studies comparing these approaches to enforcement are essentially a test of the relative effectiveness of punishment versus social norms as a means of encouraging compliance (Dinh-Zarr, Sleet, Shults, et al., 2001). Among the most interesting findings of this PHLR is that the relative benefits of primary enforcement laws varied across population subgroups, with the greatest marginal benefit observed for groups that tend to have lower rates of safety belt use, including males, young people, African Americans, and American Indians (Beck, Shults, Mack, & Ryan, 2007).

These and other studies make clear that deterrence is a complex phenomenon. The deterrent effect of law often seems to be assumed, without appreciation of the factors that will influence whether a person's behavior will be influenced by a fear of detection or punishment. Threat of fines may have a different effect than threat of jail (Wagenaar, Maldonado-Molina, Erickson, et al., 2007). Deterrence may be weak or incomplete because people are ill-informed about what the law requires, because they do not believe violation will result in a sanction, because they are insulated from the adverse effects of a sanction (for instance, by insurance coverage), or because the sanction is not strong enough to outweigh the perceived benefits of noncompliance with the law (Mello & Brennan, 2002). Uncertainty about legal standards can also have the opposite effect, fostering overcompliance in an attempt to avoid sanctions (Mello, Powlowski, Nañagas, & Bossert, 2006). Mechanism studies can examine all of these phenomena. Survey methods, interviews, focus groups, and formal decision analysis can be used to deconstruct how people think through the costs and benefits of different actions. Analysis of administrative data on enforcement actions can shed light on the degree to which popular perceptions reflect what actually happens when a law is transgressed.

Another variable of interest in mechanism studies that focus on compliance with legal rules is the perceived legitimacy of the body imposing the legal rule. Weber classically tied obedience to law to the acceptance of the legitimacy of the system. Even people who are aware of the law may not trust the system, or may see strategies other than compliance as more useful to them in achieving their goals (Burriss, 1998b). Studies of the perceived legitimacy of public health lawmakers and law enforcers may be particularly useful in understanding differences in compliance across population groups whose historical experience in the United States has led to different levels of trust in government.

Mechanism studies may also focus on understanding how law shapes behavior in ways more subtle than outright prohibitions. How do regulatory tools such as taxes and subsidies, mandated disclosure or receipt of information, default rules, accreditation and certification, and delegations of authority to private institutions shape how individuals and organizations behave? When are these alternatives more effective and desirable than traditional, command-and-control regulation utilizing rigid rules and penalties? For many of these forms of regulation, understanding the cognitive biases and heuristics that affect individual decision making about risk is critical (Kahnemann, Slovic, & Tversky, 1982) and empirical research can examine how these biases operate to influence health outcomes.

PHLR takes a number of forms, each utilizing diverse methods (Table 1.1). By illuminating the paths we have delineated in our causal model, these forms each play important roles in establishing how law is being deployed to promote population health, and how and to what extent it is achieving its intended purpose.

## Conclusion

Lawyers have long proclaimed the maxim that “the health of the people is the supreme law,” but in practice, making law work for public health is a constant challenge. The contribution of PHLR is to provide the evidentiary foundation for these efforts. Through policy-making studies, PHLR can identify forces that shape public health policy and strategies for effecting policy change. Through mapping studies, it can illuminate what has been done and thus what kind of action it is possible for various government units to take. Through implementation studies, it can provide information about how best to ensure that “law on the books” becomes effective “law on the streets.” Through intervention studies, it can determine which legal approaches are most efficacious in improving health environments, behaviors, and outcomes, and identify harmful side effects. Finally, through mechanism studies, it can tell us why laws have the effects they do, and what mechanisms are at our disposal for improving the effectiveness of legal interventions addressing the entire range of public health concerns.

Researchers carrying out this work and collectively advancing this vision face significant challenges. These include increasing methodological rigor, ensuring adequate research funding, identifying data sources, expanding the knowledge base about mediators of health outcomes, and ensuring the effect of PHLR on policy (Ibrahim, Anderson, Burris, & Wagenaar, 2011). Fortunately, a combination of forces has made the potential for overcoming these challenges greater than ever before. The interest of research sponsors, the broader trend toward interdisciplinary research, the increasing number of legal scholars trained in social science disciplines, and signals from Washington that policy will increasingly be driven by evidence and expertise are all cause for optimism (Obama, 2009).

We urge scholars of public health law to explore and recognize the value of empirical methods. We also hope that scholars and policy makers will adopt the philosophy that evidence derived from rigorous research ought to inform, if not drive, health policy decisions. Through the production of knowledge and conscientious efforts to translate research findings for decision makers, PHLR can make the case for laws that improve health.

## Summary

Public health law has received considerable attention in recent years and is assuming the role of an essential field within public health. Public health law *research* has received less attention. Public health law research may be defined as the scientific study of the relation of law and legal practices to population health. Its focus encompasses policy making, mapping patterns and distributions

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of law across jurisdictions and over time, implementation, and effects of all these on physical and social environments, behaviors, and, ultimately, population health. Research on the content and prevalence of public health laws; processes of adopting and implementing laws; and the extent to which and mechanisms through which law affects health outcomes can be pursued using methods drawn from epidemiology, economics, sociology, and other disciplines. Public health law research is a young field, but holds great promise for supporting evidence-based policy making that will improve population health.

### Further Reading

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*Note:* This chapter is an amended version of the article “Making the Case for Laws That Improve Health: A Framework for Public Health Law Research,” published in *The Milbank Quarterly*, 88(2), pp. 169–210. Used with permission.