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Moving from Intersection to Integration: Public Health Law Research and Public Health Systems and Services Research

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Context: For three decades, experts have been stressing the importance of law to the effective operation of public health systems. Most recently, in a 2011 report, the Institute of Medicine recommended a review of state and local public health laws to ensure appropriate authority for public health agencies; adequate access to legal counsel for public health agencies; evaluations of the health effects and costs associated with legislation, regulations, and policies; and enhancement of research methods to assess the strength of evidence regarding the health effects of public policies. These recommendations, and the continued interest in law as a determinant of health system performance, speak to the need for integrating the emerging fields of Public Health Law Research (PHLR) and Public Health Systems and Services Research (PHSSR).

Methods: Expert commentary.

Findings: This article sets out a unified framework for the two fields and a shared research agenda built around three broad inquiries: (1) the structural role of law in shaping the organization, powers, prerogatives, duties, and limitations of public health agencies and thereby their functioning and ultimately their impact on public health ("infrastructure"); (2) the mechanisms through which public health system characteristics influence the implementation of interventional public health laws ("implementation"); and (3) the individual and system characteristics that influence the ability of public health systems and their community partners to develop and secure enactment of legal initiatives

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to advance public health ("innovation"). Research to date has laid a foundation of evidence, but progress requires better and more accessible data, a new generation of researchers comfortable in both law and health research, and more rigorous methods.

Conclusions: The routine integration of law as a salient factor in broader PHSSR studies of public health system functioning and health outcomes will enhance the usefulness of research in supporting practice and the long-term improvement of system performance.

Keywords: Public health law research, health promotion/legislation and jurisprudence, public health systems and services research, models, theoretical, public health practice, public health administration.

THE ROLE OF LAW IN ESTABLISHING, EMPOWERING, AND constraining public health agencies has long been a matter of interest to both legal scholars and health practitioners (Gostin 2008; Gostin, Burris, and Lazzarini 1999; Tobey 1939). The importance of "legal infrastructure" to public health and the need to review and possibly update the statutes that define the authority of health agencies at the federal, state, and local levels have now been emphasized in three major Institute of Medicine reports since 1988 (IOM 1988, 2002, 2011). Other commentaries have stressed the importance of the public health work force exhibiting competency in the use of legal authority and the appreciation of its boundaries (Center for Law and the Public's Health 2001; Gebbie, Rosenstock, and Hernandez 2003; Moulton et al. 2003). The chapter "Public Health Infrastructure" in *Healthy People 2010* includes as an objective "increas[ing] the proportion of Federal, Tribal, State, and local jurisdictions that review and evaluate the extent to which their statutes, ordinances, and bylaws ensure the delivery of essential public health services" (Office of Disease Prevention and Health Promotion and U.S. Department of Health and Human Services 2010). Likewise, *Healthy People 2020* encourages the use of public health law research and public health systems and services research to measure and understand improvements in public health system outcomes (Office of Disease Prevention and Health Promotion and U.S. Department of Health and Human Services 2011).

The importance of law to the effective operation of public health agencies and systems, often and plausibly asserted, has rarely been the

subject of academic research. Only a handful of researchers have empirically examined the relationship between law and public health system performance, and the work to date has not been informed by an explicit, shared conceptual framework or research agenda. The recent emergence of Public Health Law Research (PHLR) and Public Health Systems and Services Research (PHSSR) makes it possible to fill the void in theory and research. The framework we offer here identifies three broad areas of inquiry that deserve closer attention:

1. The structural role of law in shaping the organization, powers, prerogatives, duties, and limitations of public health agencies and thereby their functioning and ultimately their impact on public health ("infrastructure").
2. The way that public health system characteristics influence the implementation of interventional public health laws ("implementation").
3. The individual and system characteristics that influence the ability of public health systems and their community partners to develop and secure the enactment of legal initiatives to advance public health ("innovation").

We begin this article by defining PHLR and PHSSR and their relationship. We then present a causal diagram setting out the main domains of interest, which we use to frame a critical discussion of the research to date. Our review demonstrates the opportunities for integrating PHLR and PHSSR through common methods drawing on both the health services and empirical legal research traditions, and it points the way to a common research agenda. The results of a common agenda and research at the intersection provide an additional powerful tool for public health's efforts to improve public health practice and ultimately the health status of communities.

What Is Public Health Law Research?

Public Health Law Research (PHLR) is defined as "the scientific study of the relation of law and legal practices to population health" (Burris et al. 2010, 171). *Law* here has the broad definition used in modern sociolegal

research. It embraces not just the "laws on the books"—the constitutions, statutes, regulations, and other texts that formally state the law—but also the attitudes and practices of those who enforce the law or are subject to its enforcement (Ewick and Silbey 1998; Silbey 2005). PHLR is also concerned with the process of lawmaking and the determinants of public health policy. The field is inevitably multidisciplinary, informed by scholarship in law, economics, epidemiology, behavioral health, social work, sociology, anthropology, history, psychology, and political science.

PHLR draws on a rich and diverse set of theories and tools to investigate how law is made and works. For example, why people obey the law has been explained in terms of deterrence (i.e., the fear of sanctions), legitimacy (i.e., a normative belief in the lawmaker's authority to set rules), and, more recently, the degree to which individuals regard encounters with law as procedurally fair (Tyler 1990). Research in the "law and society" tradition treats law less as a set of rules that we consciously follow and more as a set of cultural beliefs and practices that shape how we see the world and that influence our behavior in ways of which we may not even be aware (Silbey 2005).

PHLR distinguishes among three forms of public health law (Burris et al. 2010; Moulton et al. 2003). "Interventional public health laws" are enacted with the explicit aim of protecting and improving public health. When they are used intentionally as a tool for promoting healthier environments or behaviors, such laws can and should be evaluated for effectiveness, in the same manner as any other form of public health intervention. "Incidental public health laws" are enacted primarily for purposes other than promoting public health but nonetheless have positive or negative consequences for health. Studies examining the effect of criminal laws and the practice of criminal justice agencies on the spread of communicable disease (Burris et al. 2004) exemplify incidental public health law research. We can study laws that have important unintended effects on population health, and if necessary, they can be altered. Finally, "infrastructural law" establishes the powers, duties, and features of public health agencies (Moulton et al. 2009). Infrastructural law is the domain in which PHLR and PHSSR most clearly overlap and is the main focus of this article. We also consider how the characteristics of a health department influence the enforcement of interventional public health laws and the department's capacity to develop and advance interventional policy initiatives.

What Is Public Health Systems and Services Research?

Public Health Systems and Services Research (PHSSR) is a "field of study that examines the organization, financing, and delivery of public health services within communities and the impact of those services on public health" (Mays, Halverson, and Scutchfield 2004; Scutchfield and Patrick 2007, 173). Growing out of the field of Health Services Research, which focuses on the delivery and financing of medical care, PHSSR concentrates on parallel concerns within the realm of public health service delivery (Scutchfield et al. 2007). The 1988 Institute of Medicine report calls for research on the solution of "real world problems," including research questions derived from public health practice (IOM 1988). Both the 2002 Institute of Medicine report and *Healthy People 2010* note the need for more research to inform policymaking, with a focus on workforce, infrastructure, and financial investments (IOM 2002), as well as better information about the character, performance, and nature of local health departments (Office of Disease Prevention and Health Promotion and U.S. Department of Health and Human Services 2010). Most recently, the federal Patient Protection and Affordable Care Act of 2010 called attention to the need for PHSSR by authorizing an ongoing, federally funded program of research for "optimizing the delivery of public health services" (ACA Section 4301).

The field of PHSSR focuses on six categories of investigation: (1) organization and structure of public health agencies, (2) finance, (3) access to services for defined populations, (4) infrastructure and workforce, (5) quality and performance improvement, and (6) evaluation (Scutchfield, Mays, and Lurie 2009). The causal model for research in each domain takes into account the context in which a local public health department functions; its resources, processes, and services; and the outcomes—specifically a community's health status—achieved by the use of resources in providing public health services. PHSSR recognizes that a health department operates within a larger system of agencies and organizations in communities that contribute to the mission of public health, "assuring conditions in which people can be healthy" (IOM 1988, 53).

Each of these areas has a range of legal considerations, including the authority to act or create policies, regulations on routine functions, and even agency composition. Other issues are related to the perception of

law and its utility among individuals within a health agency, the other members of the public health system, as well as the overall organization and how law is used as a tool to advance population health. While such legal factors have been assumed or implicitly included in previous research, more research is needed to carefully examine these factors' role in public health systems and the delivery of public health services.

Integrating PHLR and PHSSR

Although both PHSSR and PHLR had early support from the Centers for Disease Control and Prevention (CDC) (Horton et al. 2002; Scutchfield et al. 2007) and have been nurtured by the Robert Wood Johnson Foundation (Larkin and McGowan 2008; Pérez and Larkin 2009; Scutchfield, Mays, and Lurie 2009), the two fields have developed independently. Meeting at the intersection of law and public health services, they draw on different research traditions, theories, and perspectives that have not been sufficiently integrated. PHSSR is building an increasingly empirical approach to classifying public health systems, their characteristics, their resource utilization, their performance, and their impact on population health outcomes. PHLR is working to better theorize and measure how law is understood and used by health agents and also the effects of laws and legal practices on public health agency and public health system outcomes. The goal of an integrated approach is to understand how law relates to other inputs and resources that determine how, and how effectively, public health systems operate. The current challenge is moving from the intersection of the fields to the integration of theoretical frameworks, research methods, and research agendas.

To address this challenge, we offer a causal diagram (Swanson and Ibrahim 2011) of the relationship among public health law, public health system characteristics, system outputs, and public health outcomes. We start with the input of law and move to the factors that mediate the performance of public health agencies: legal culture and legal capacity, authority to act, structural capacity, and implementation of the law. Important outputs include a variety of regulatory and health activities and the development of new health policy tools (see figure 1). The main focus of the causal diagram is on the mechanism by which law and legal authority affects public health agency and system performance. We also

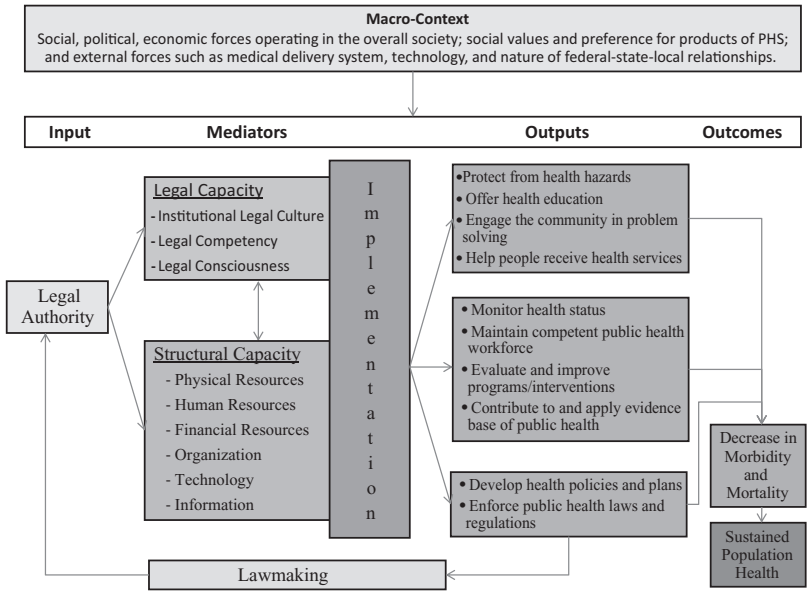

FIGURE 1. A causal diagram of the impact of law and legal practices on public health system performance.

recognize that the public health agency or system operates within a larger context that contains social, political, and economic forces, as well as the system of medical care delivery. In the following sections, we describe each component of the model.

Law on the Books as a Structural Factor in Public Health System Performance

The hypothesis that the law that establishes the powers, duties, organization, and jurisdiction of public health agencies ("legal infrastructure") matters has been repeatedly stated (Gostin, Burris, and Lazzarini 1999) and put into intervention practice in the form of widely circulated and adopted "model law" provisions (Hartsfield, Moulton, and McKie 2007). The starting point in figure 1 is, therefore, legal authority. Public health agencies are established by constitutions and laws that determine their powers, geographic and topical jurisdiction, procedures, and management structures. Public health departments may be organized on state, county, or local levels or in a variety of combinations, and they may be

established as stand-alone entities or as units within larger health and human services agencies (Beitsch et al. 2006a, 2006b). There may or may not be a board of health, and the powers of boards of health vary from giving advice to formally making rules (National Association of Local Boards of Health 2011). Not all agencies that regulate important public health matters such as education, transportation, and land use planning have "public health"—or even "health"—in their name (IOM 2011).

Although the federal government's role in public health has been steadily increasing for more than a century, the legal infrastructure of state and local health agencies remains almost entirely a matter of state law (Grad 2004). The heterogeneous legal architecture of public health systems across the states amounts to a long-term experiment in public health management, albeit one that has not been extensively evaluated. Even in recent textbooks, the discussion of law in public health administration is limited to the agency's functions in the context of the larger governmental bureaucracy (Novick, Morrow, and Mays 2008), as opposed to a more thorough examination of the internal processes by which the law shapes public health agency performance.

Legal Implementation and Public Health System Performance

In figure 1, the exercise of legal authority—implementation—is mediated by two sets of variables: legal capacity and structural capacity. Decades of research in empirical legal studies and implementation have documented the decisive impact of implementation factors on how the law on the books is actually expressed in practice (Bardach 1977). This rich tradition in legal research has not been widely drawn upon in public health law. How actors in public health systems understand and apply the law, and the resources they use to do it, are likely to be powerful mediators of the effect of legal infrastructure on public health system outputs and outcomes.

Perhaps the largest deficit in the existing research on the role of law in public health agency performance is its thin conception of legal capacity. There is a small literature that defines "legal competencies" (Center for Law and the Public's Health 2001; Gebbie et al. 2008; Lichtveld et al. 2002), but the field has not yet drawn on the theoretically richer sociolegal literature on the "legal consciousness" and the "legality" of individuals and organizations (Cooper 1995; Ewick and Silbey 1998;

Silbey 2005; Stryker 2012). In this approach, law is not treated simply as a "tool" or "rule" that agents wield or obey but also as a set of individual beliefs and organizational norms regarding what the legal system is, how it actually works, and whether and why people should obey its commands. It encompasses what people consciously believe about law and also a range of unconsciously accepted norms and assumptions. Sociolegal theory moves beyond how people "use law," or their explicit legal knowledge, allowing researchers to bring critical empirical attention to bear on how the rule of law is socially constructed, contested, and perpetuated in social fields (Cooper 1995). It is just as important to study why some health officers or departments avoid law as a tool as it is to identify the determinants of creative and effective regulatory behavior. The sociolegal literature provides powerful theoretical and research methods for understanding how health system agents perceive their legal roles and authority to implement laws, their ability to act within a legal framework, and, indeed, the nature of that legal framework itself (Stryker 2012; Yngvesson 1988).

Figure 1 suggests that both objective legal competency—the explicit knowledge of the law and one's legal role—and the individual's ideas about law ("legal consciousness") are important determinants of an individual's and an agency's capacity to use legal authority effectively. The figure also posits that these can be understood as individual-level attributes and as characteristics of an agency or other organizational unit and that individual legal consciousness and competencies influence and are influenced by the institution's legal culture. The effect of law on organizations, particularly in regard to compliance, has traditionally been a core concern of empirical legal research and has produced a distinguished body of theory and evidence (Ayres and Braithwaite 1992; Braithwaite and Drahos 2000; Chriqui, O'Connor, and Chaloupka 2011; Gunningham 2009; Power 1997). Work on law in organizations has shown the value of understanding the construction of law at an organizational level and the processes through which legal decisions are made (Edelman and Suchman 1997). Organizations are not simply passive recipients of outside legal commands but are actively engaged in interpreting and reshaping law to make it consistent with organizational imperatives, norms, and beliefs (Edelman 2005; Teubner 1987). Strategies of law enforcement and regulation are shaped by politics and even a version of fashion, not just evidence and experience (Power 1997; Wood 2004). Understanding the institutional culture and its

determinants thus is essential to a proper assessment of a regulatory agency's work.

This recognition leads to the second set of mediating variables: the structural capacity of the health department and the public health system in which it operates. In the health services tradition, PHSSR posits that a set of basic structural capacities can be measured and assessed for their effect on the performance of public health systems (Bhandari et al. 2010). These capacities include human, physical, and financial resources; organization and relationships; and agency information and technology, all of which influence the implementation of the system's legally established mission. For example, environmental work such as inspection and citation is dependent on agency budgets, and as the budget drops, so does environmental work at the health department (Arnett 2011).

Structural capacity interacts with legal capacity and the larger social context. If there are constraints in human or financial resources, there may not be time to think about law or funds available for public health staff to collaborate with legal counsel. If the county executive is running for reelection at the same time the health department is citing influential local business owners for violating health department regulations, there may be more or less subtle pressure on the health department to ignore a major responsibility. If self-regulation and small government are the current fashion, advancing new command and control rules enforced by a bureaucracy will be difficult. Health departments *are* bureaucratic regulatory agencies. They operate within a larger administrative system and may be constrained by internal competition for rewards or resources or by jurisdictional confusion. Authority may be conferred to other departments or divisions within the bureaucracy (e.g., environmental, public safety, transportation), or the authority to act may be shared.

Public Health System Outputs and Outcomes

Figure 1 depicts the outputs of the public health system as the ten essential public health services. This typology is now at the center of efforts within PHSSR to develop robust measures of public health agency performance. Their origin is the 1988 Institute of Medicine report (IOM 1988), which defined public health governmental responsibility as assessment, policy development, and assurance. These were seen as specifically governmental activities, to be carried out by governmental

public health agencies in partnership with other organizations that contribute to public health. The IOM report calls attention to the unique roles played by governmental public health agencies in mobilizing, coordinating, and monitoring the contributions of other organizations that operate within the larger public health system. Later work divided those three governmental responsibilities into ten essential public health services, which are shown in figure 1. These services have become a touchstone for public health activities involving performance and drafting public health–related documents describing the role of local health departments and their system partners (Erwin 2008).

Work with the three core responsibilities and the ten essential public health services derived from them has led to new understanding of the mechanisms by which the public health infrastructure and inputs influence performance. For example, the services have been used recently to develop an evidence-based typology of local public health systems that allows systems to be classified and compared based on the scope of public health activities performed, the array of organizations performing these activities, and the distribution of effort between the governmental public health agency and other system partners (Mays et al. 2010). The instruments developed by the National Public Health Performance Standards Program have become vital to the establishment of the Public Health Accreditation Board (PHAB), which began its initial accreditation efforts in the fall of 2011 (Martin et al. 2010; Mays et al. 2007; Public Health Accreditation Board 2009).

Public Health Policy Innovation

Health policy can be an important *output* as well as an input for public health systems. The practice, experience, and knowledge acquired by actors within the public health system can drive the development of new public health laws, regulations, and enforcement strategies to improve system performance and public health outcomes. Health agencies often have substantial regulatory authority themselves and can join other stakeholders to advance legislative and regulatory initiatives before other policymaking bodies. In some instances, these agencies can even be involved in litigation. The extent to which individual staff and health agencies have an appetite for understanding and using the law and under what circumstances this occurs is a gap in the existing literature on policy innovation in health departments.

Existing Research

The PHLR literature has not yet been cataloged. Although the number of studies in incidental and interventional PHLR is predicted to be quite large, we have been able to identify only a handful of studies addressing infrastructural legal questions. A recent review of PHSSR found seventy-four papers on the organization and structure of public health in the published and gray literatures (Hyde 2011). Most studies looked at the relationship of organization, structure, and performance, but few engaged law in a significant way. While the connections between PHSSR and PHLR are apparent when one looks for them, the existing research does not sufficiently engage both disciplines.

The strength of evidence as a guide to practice is customarily assessed with reference to a hierarchy of research design. The criteria of the U.S. Preventive Services Task Force give greatest weight to the randomized controlled trial, followed by controlled observational or quasi-experimental studies, uncontrolled studies, qualitative case studies, and expert opinion (Harris et al. 2001). To date, research at the intersection of PHSSR and PHLR has clustered in the lower reaches of this hierarchy. In this respect, PHSSR/PHLR is consistent with other areas of empirical health law (Mello and Zeiler 2008). The limited literature offers instances of ambitious design and rigorous execution but also weaknesses. Law is generally insufficiently theorized or measured, or a thorough legal analysis is used in a study that does not adequately account for the influence of the public health department or system's organizational characteristics. Strong qualitative findings are not followed up with research that could yield generalizable results. We draw on examples from the existing literature addressing infrastructural law in PHSSR to illustrate these weaknesses and suggest topical and methodological directions for integrating the two fields.

Infrastructure

The important implications for rigorous infrastructural research at the borders of PHLR and PHSSR can be seen in studies that have examined one of the most widely held assumptions in public health law. For quite some time, influential scholars in public health law have pointed to antiquated or technologically superannuated statutes as a barrier to effective

public health agency performance (Gostin, Burris, and Lazzarini 1999). The work in PHSSR to develop measures of public health system performance makes it possible now to investigate that question empirically, and a few studies have attempted to do so. McCann, for example, looked at the core question of how the type and extent of discretion granted by a statute to a public health agency influenced the agency's success in implementing the statute (McCann 2009). Using a quasi-experimental, time-series design, the study defined three forms of discretion in setting standards for newborn screening: to decide which conditions to include in the screening panel, to set the charges assessed on hospitals, and to develop the criteria for including conditions in the panel. The study tested the hypothesis that each of these forms of discretion would be associated with fewer implementation problems. Fiscal discretion and the authority to choose what conditions to include were associated with successful implementation, while, interestingly, the discretion to set criteria slowed implementation. The study, as the author puts it, "only scratches the surface of public health law's importance for public health practice" (McCann 2009, 1906). Discretion is well theorized and has a robust impact, but the contradictory findings suggest that key mediating factors are missing from the theoretical framework.

One widely promoted cure for laws that are out of date or inconsistent with best practices is a "model law." Model laws are used to suggest clearer requirements more in keeping with current technologies, health practices, and legal norms (Erickson et al. 2002). Hartsfield and colleagues asked a deceptively simple question: To what extent did the sponsors of model laws provide information about the procedures—and the evidence—used to develop them? Such information, it turned out, was provided for only 7 of 107 model public health laws published between 1907 and 2004 (Hartsfield, Moulton, and McKie 2007). Model laws *may* embody evidence-based best practices, but there apparently is no evidence that they do. Simple in design and narrow in scope, the study illustrates the valuable insights that can be gleaned from systematic legal research and straightforward content analysis.

Using performance data from the National Public Health Performance Standards (CDC 2011), Merrill and colleagues examined the congruence among states' enabling statutes, the mission and essential services of public health as defined in "Public Health in America" (Public Health Functions Steering Committee Office of Disease Prevention and Health Promotion 1994), and the self-reported delivery of at least

some essential services in 207 localities (Merrill et al. 2009). The data in this cross-sectional, observational study were analyzed using binary logistic regression. In most local public health systems, the agency mission and essential services were rated congruent or highly congruent with the states' statutory language constituting the agencies' legal infrastructure. The association between congruence and agency performance varied from positive to negative across the ten essential services. As the authors themselves observed, the challenge for future research is to integrate legal variables with the wider range of structural capacity and other factors depicted in figure 1 in a design that will support causal inference.

Most recently, Jacobson and colleagues investigated how federal and state laws influence the preparedness of public health systems as reflected in the knowledge and attitudes of 144 agency staff, their legal counselors, and their legislative staffers in nine states (Jacobson et al. 2011). Explicit criteria were used to select sites that varied by key characteristics (per capita health expenditure, geographic region, organization of the public health system, and level of emergency preparedness), and semistructured interviews were used to elicit what laws the respondents thought were influencing preparedness and how. Although the study did not explicitly use sociolegal theories of individual or organizational legal consciousness, the researchers took it as given that there were "gaps between the objective and perceived legal environments" and that much of the explanation of how law influences preparedness would be found in them (Jacobson et al. 2011). The study found that local public health agency practitioners were ill informed and poorly advised about legal requirements influencing preparedness. Though not generalizable, the study is richly informative of the kinds of legal conundrums health officials worry about, the ways they try to resolve them, and the types of effects that law has on preparedness. The study exemplifies the potential for qualitative research to address important questions in rigorous ways—and the need for quantitative research to investigate hypotheses emerging from the study.

McCann's study included the collection of data on newborn screening statutes in all fifty states over a period of sixteen years. Merrill and colleagues collected the basic public health enabling statutes from all the states (Meier, Merrill, and Gebbie 2009). Neither study, however, offers a detailed description of the legal data set or how it was created or any indication that the data are available to other researchers. This is not

unusual and exemplifies an area where new standards could benefit the field. Excellent scientific data sets are available for a few topics, notably tobacco control and alcohol policy, and information about law is readily accessible to the public (Fishman et al. 1999; National Institute on Alcohol Abuse and Alcoholism 2011). All these data collections could be bricks in a building that the field needs to construct: a comprehensive, consistent data set of infrastructural public health law.

Implementation and Enforcement

McCann looked at the association between discretion and outcomes but did not study the process of implementation itself, work that might have helped explain why similar kinds of discretion had opposite effects on outputs. Merrill and colleagues found some associations between statutory language that matched public health's mission and service standards and the delivery of services, but they, too, did not examine the processes through which that occurred. Moreover, they used a design that could not illuminate whether more expansive statutes produce higher-functioning agencies or whether higher-functioning agencies earn more expansive powers. The study of how legal authority or other legal factors influence the day-to-day practices of health agencies is in its infancy. There are, as far as we know, no studies other than that by Jacobson and colleagues (Jacobson et al. 2011) that observe and assess the actual day-to-day exercise of general legal authority within health agencies, let alone any that draw on (and test) the elements that figure 1 posits as important.

The impact of interventional health laws is the most fully developed topic area of PHLR. The depth of the literature is captured in reviews of such important interventions as the safety belt law (Houston and Richardson 2005), taxes on alcohol (Wagenaar, Tobler, and Komro 2010), workplace smoking bans (Fichtenberg and Glantz 2002), and school vaccination requirements (Briss et al. 2000). Some evaluations of interventional health laws include data on implementation, but not all do, by any means. Few studies consider in depth the effect of health department activities or health system characteristics on implementation. An exception is the rich body of qualitative work that looks at how power, values, and politics have played out in the health and other agencies' enforcement of smoking restrictions (Ashley, Northrup, and Ferrence 1998; Howard et al. 2001; Montini and Bero 2008).

An excellent example is Jacobson and Wasserman's report of case studies in seven states and nineteen local jurisdictions (Jacobson and Wasserman 1999). They found a sharp divergence in enforcement practice between clean indoor air laws and youth access restrictions. The former were seen by health officials as largely self-enforcing, so most agencies took action only when there was a complaint. By contrast, most agencies deemed that laws restricting youth access to tobacco should require more active enforcement, although the strategies and intensity varied. The authors identified a number of legal and structural capacity issues retarding enforcement, including lack of resources, concerns by counsel that enforcement might not survive legal challenge, and fragmented enforcement authority. This work reveals the practical value of research that illuminates the determinants of effective enforcement. Like McCann's work, though, it also offers tantalizing glimpses of topics that could benefit from much greater attention, such as the nature and quality of the relationship between health officials and their legal advisers, or the gap between counsel's beliefs about litigation success and the actual outcomes (Nixon, Mahmoud, and Glantz 2004). Like Jacobson and colleagues' preparedness work, it invites confirmatory quantitative research.

Innovation in Policymaking

The role of state and local health agencies in developing and advocating new health laws is another area where there is a high level of interest and a low level of research. Again, the exception is antismoking policymaking, which has been the subject of many useful case studies that identify strategies and mediating factors that influence the success of health agencies in promoting new health laws (Dearlove and Glantz 2002; Givel 2005; Ibrahim, Tsoukalas, and Glantz 2004; Macdonald and Glantz 1997; Tsoukalas and Glantz 2003). The HIV epidemic has also produced some strong policymaking research, perhaps most notably the work of political scientist Ronald Bayer (Bayer 1989).

Putting aside their value as embodiments of best practices, model laws have received attention as a mechanism to "galvanize" lawmakers' interest in public health. To test this effect, Meier and colleagues undertook a comparative case study of the process and impact of the Turning Point Collaborative Model Public Health Act in four states (Meier, Hodge, and Gebbie 2009). The Turning Point Model Law embodied a comprehensive set of recommendations regarding agency

mission and function, infrastructure, collaborations and partnerships, and authorities and powers. The study conceptualized the use of the model law in three stages—use of the act to develop or focus support for reform, drafting of actual state legislation, and enactment—and identified barriers and facilitators at each stage. In two of the states, the model law process itself helped set the agenda for change; in a third, it failed to generate momentum to the second stage; while in the fourth, the model law added some impetus to reform efforts that were already under way. The study's careful, qualitative research gives us insight into questions that no one has tried to answer before. The next step is to build on the formative findings in more robust, generalizable studies. It is useful to take a broader view of health policymaking and its determinants, for example, looking for patterns in the breadth of health issues that states choose to regulate and the depth or intensity of their regulations on particular topics (Macinko and Silver in press).

Policy development outside legislatures—litigation, administrative rule making, executive orders, and enforcement strategies—has been almost entirely neglected. The public health work of attorneys general, which has led to such important results as the 1998 Master Settlement Agreement, has not been studied by PHSSR or PHLR researchers (Jacobson and Wasserman 1999; Rutkow and Teret 2010). What Kromm and colleagues call "public health advocacy in the courts" encompasses a wide range of "actions by public health professionals that inform and affect how courts approach matters that affect the public's health legislative modes of policy development" (Kromm et al. 2009, 889). These include not only filing suits but also providing expertise as witnesses, submitting amicus briefs, educating the judiciary, influencing judicial selection, and monitoring and evaluating court outcomes, all of which can powerfully shape public health policy and practice (Parmet 2009) but have rarely been empirically studied. The production of administrative law—arguably the most important vehicle for regulation under the control of public health agencies (Kinney 2002)—likewise has not been touched by empirical research in PHLR or PHSSR.

The Path Forward

The Institute of Medicine's 2011 report *For the Public's Health: Revitalizing Law and Policy to Meet New Challenges* devotes an entire chapter

to law and public health infrastructure (IOM 2011). The report recommends once again a review of state and local public health laws to ensure appropriate authority for public health agencies, and it adds some new, important, and practical suggestions: ensuring that health officials have adequate access to legal counsel; routinely evaluating the health effects and costs associated with legislation, regulations, and policies before and after implementation; and using better research methods to assess the strength of evidence regarding the health impacts of public policies (IOM 2011). All these recommendations speak to the need for an integrated approach between PHLR and PHSSR and point to three primary PHLR/PHSSR research questions.

Three Questions

The first question is, what is the relationship between statutory architecture and language and the outputs and outcomes of public health systems? Despite the IOM's repeated recommendations, some people doubt that the legal infrastructure is a significant factor in agency performance (Richards and Rathbun 2003), and although for thirty years this has been a talking point, most legislatures have declined to act. Answering the question is still important, though, because if legal infrastructure does matter, understanding *how* it matters will allow potentially inexpensive changes in law that can promote greater effectiveness in the delivery of health services. If there is a right way or a best practice in public health infrastructural law, we should know what it is. The IOM committee and many supporters have encouraged states to consider the Turning Point Model Act, but the fact remains that it is based on the wisdom of experience rather than empirical evidence of effectiveness. While innovation and improvement should not await definitive evidence, neither should it proceed in an evidence-free zone. We still do not know whether law works, which law(s) work, or even whether the exercise of law reform is good or bad for public health systems in gaining a place on the policy agenda (DeVille 2009).

The legal relationship of local health departments to one another is an urgent area for integrated PHLR–PHSSR work. Governments across the nation continue to restructure health departments in the face of massive budget cuts. New organizational structures vary from voluntary shared services among local health departments to regionalization and varying

levels of centralization in which multiple local health agencies are joined together under the leadership of the state health department (Libbey and Miyahara 2011). What is the best way to share services? Is it best to be voluntary and flexible, or should strict parameters be mandated by law? Should certain types of services be shared? Should particular responsibilities—for example, fiscal decisions—remain under the legal authority of individual local health agencies? How does preemption factor into the considerations? Economics must be balanced with legal requirements for the performance of health departments as outlined in state constitutions and statutory requirements for both state and local health departments (Baker and Koplan 2002; Baker et al. 2005; IOM 2002). As state and local agencies experiment with various models of shared governance, real-time evaluations of the performance of the health agencies and its impact on population health will be needed. The new structures also call for an ongoing assessment of the functions of the health departments and the quality of those public health services.

The second question is, what are the structural/operational determinants of implementation of law by health agencies? Few would disagree with the observation that some health agencies and leaders use legal authority more robustly and more effectively than others do. But why? Is it an accident of personality, background, geography, or local political culture? Does it reflect the way in which a public health agency is organized or its resources and capacities? Is there any sign that legal training for health officials, or health training for lawyers, plays a role? Research that documents how legal authority is used and identifies enabling and retarding factors can help us increase the effective use of legal authority. If we can figure out what the most effective users of legal power know, how they learned it, and how they put it into practice in the context of other governmental agencies and other levels of government, we will have something to offer to health agencies across the land.

The IOM acknowledges the importance of legal capacity and "recommends that every public health agency in the country have adequate access to dedicated governmental legal counsel with public health expertise"(IOM 2011, 7). It is a reasonable suggestion, but there are plenty of questions. Would this be a big change; that is, what is the current state of legal representation for health officials? How does the need for and provision of counsel in health agencies fit within the overall design of legal services in local and state governments? The current biennial health agency surveys by the Association of State and Territorial Health

Officials (ASTHO) and the National Association of County and City Health Officials (NACCHO) contain two questions addressing the legal counsel arrangement and legal services provided. The questions, however, are merely descriptive and do not explain the logic for the arrangement or the mechanism by which the provision of services occur; future research must address this gap. Jacobson and colleagues' work on preparedness makes a good start (Jacobson et al. 2011). The PHLR's National Program Office (NPO) has undertaken a formative study of legal representation available to health officials at the state and local level.

The empirical study of regulation and governance, which focuses on the effective use of regulatory authority, has largely neglected public health agencies (Braithwaite, Coglianese, and Levi-Faur 2007). The IOM report mentions two important implementation issues arising from our federal system: preemption and coenforcement. Preemption is a constraint: federal law can supersede state law, and state law can supersede local law. Preemption can bring uniformity, but it can also cut off policy innovation. It is, politically, a weapon of choice for any interest group that wants to set a broadly applicable standard, so it is a regular topic of health policymaking. Knowing more about how the risk or reality of preemption is managed by public health agencies can help us assess whether its overall impact on enforcement is positive or negative. By contrast, coenforcement—when state and federal agencies jointly enforce health and safety regulations—is a potential source of new practical authority and efficiency, but it has not yet been shown by evidence to be positive. The need for research on the relationship of federal, state, and local governments reinforces the need for more sophisticated analyses that can account for hierarchical relationships.

Accreditation, which the IOM recommends and which has had an enthusiastic reception in public health practice, is seen as a way of both improving agency performance and increasing agency credibility and influence (Bender and Halverson 2010). As a moving target, accreditation in recent years has presented a number of pressing legal issues relating to how current state law would influence the process. PHLR funded a legal mapping study and also case studies of pilot accreditation implementation. The legal mapping study found an unexpected synergy between the emerging accreditation movement and an interest in regionalization largely driven by increasingly severe budget pressures (Matthews and Markiewicz 2011). As accreditation settles in and

budgets stabilize, research at the intersection of PHLR and PHSSR will be needed to determine whether accreditation is bearing fruit. With time, we will be able to get a clearer picture of how legal infrastructure influences the choice to be accredited and the success of the process and how accreditation influences agency performance, including enforcement of law, achievement of basic outputs, and ability to devise and promote new uses of legal authority. The challenge is to ensure that research on accreditation examines the legal issues in a sophisticated and determined way.

Finally, the third question is, what individual and system characteristics influence the ability of public health systems and their community partners to develop and secure enactment of legal initiatives to advance public health? We have a toehold in the climb to understand the role of health agencies in promoting innovation in public health law. Case studies in areas like tobacco and HIV document the contest between those promoting health regulations and those who oppose them on ideological or economic grounds. There is no magic bullet to be discovered, no secret to winning in the political process. The importance of the research is in increasing the odds for healthy public policy by identifying the strategies and mind-sets of agencies and leaders that come up with and are able to advance laws and regulations that improve the public's health.

The IOM offers a ringing endorsement of a Health in All Policies approach (HIAP). HIAP advocates collaboration between government and the private sector to devise and implement coordinated strategies to promote health (Collins and Koplan 2009; IOM 2011). This entails creating coalitions or councils of the many public and private actors whose activities are important to health. Data on the known or potential effects of policies are seen as essential to moving diverse stakeholders to align their interests and agree on action. A health impact assessment (HIA) is "a combination of procedures, methods, and tools by which a policy, program, or project may be judged as to its potential effects on the health of a population, and the distribution of those effects within the population" (Dannenberg et al. 2008, 241). From a research perspective, the question is whether a HIA does in fact mobilize and inform stakeholders, put health on the agenda, and produce better policy outcomes for health. Although a new development in the United States, the HIA has been used for more than a decade in Europe, and some cautionary findings have emerged (Wright, Parry, and Mathers 2005).

Improving Research at the Intersection of PHLR and PHSSR

These primary questions are the nucleus of a research agenda that will continue to grow as more researchers, practitioners, and funders immerse themselves in the field. They implicate a number of challenges for the field in producing more and more rigorous research.

Data. Poor availability of legal data has been identified as a general challenge to empirical health law (Mello and Zeiler 2008). The lack of legal data sets that capture the features of public health law in a scientifically credible, and usable, way has been a chronic impediment to sophisticated research on the impact of law in public health systems (Chriqui, O'Connor, and Chaloupka 2011). Taking up a suggestion made by PHLR researchers (Burris et al. 2010), the IOM called for work to test the feasibility of systematic "policy surveillance" as part of a broader effort to give "evidence-based policy" the same sort of documentary resources as evidence-based medicine (IOM 2011). The IOM committee suggested that the CDC develop a policy surveillance pilot that would track a set of important laws across the states and over time. For its part, the PHLR's National Program Office (NPO) has begun building consensus on basic standards and methods for quantitative legal data sets (Tremper, Thomas, and Wagenaar 2010). These standards include a core set of elements such as date of passage, date of enactment, regulatory targets, and the regulatory elements themselves, all comprehensively and (for the most part) dichotomously coded. The NPO also suggests the use of Federal Information Processing Standard (FIPS) codes as unique identifiers for states, facilitating the integration of legal data with data on public health agency performance or population health outcomes. Studies that create such data sets—referred to as "mapping studies" (Burris et al. 2010)—should be recognized as an important contribution to public health research, even if they do not themselves correlate the legal data with outputs or outcomes (Ibrahim et al. 2011).

The routine inclusion of a protocol documenting the search methods to collect the laws, a codebook to document the variables and types of measures, and the data themselves in readily accessible forms, such as Excel, ASCII, or specific statistical analysis package formats, may allow many more health researchers to gain access to updatable, adaptable, and inexpensive legal data. The hope is that supply will stimulate demand as researchers realize that previous barriers to including legal variables

in research are falling. The value of this approach to collecting and coding laws goes beyond research, however. Many policymakers, advocates, health professionals, and nongovernmental organizations have an interest in knowing what the law is and how it is changing. Currently, they get this information from occasional "fifty-state surveys" published by researchers in legal or medical journals (Burris et al. 2011; Gostin et al. 1996; Houry et al. 2002) or from websites maintained by various interested parties, such as the Governors Highway Safety Association. But the fifty-state surveys rapidly go out of date, while websites rarely provide the documentation that would allow users to assess the validity or timeliness of the information, or the level of detail about the laws themselves that allow independent assessment of the law. Legal data that are not prepared quantitatively cannot readily be integrated with health data. Across the new landscape of health information data platforms like the County Health Rankings that organize health data by jurisdiction (Robert Wood Johnson Foundation and University of Wisconsin Population Health Institute 2011), law is almost entirely absent. Policy surveillance would serve these needs as well and provide a more comprehensive picture of the law.

The development of PHSSR has faced comparable obstacles. Basic data on health systems have been unavailable. For example, between 1992 and 2008, no data on the current characteristics of state health departments were gathered. In other instances, data were available but not comparable. The NACCHO, ASTHO, and National Association of Local Boards of Health (NALBOH), working with the University of Kentucky's Center for Public Health Services and Research, have established a standardized database for state and local health departments and their governing entities. These data may be matched with legal data to answer questions posed by PHLR and PHSSR researchers (Scutchfield et al. 2009).

Researchers. A hallmark of PHSSR has been its organic connection as a research enterprise with public health practice. The ethic of research by practitioners on practice for practitioners remains strong and is also a value of PHLR. Partnerships with practitioners can drive the appetite for research among practitioners, both as consumers of research findings and as participants in research development and implementation. Practitioners can provide valuable insight into the development of research questions and guide the conduct of the research to ensure that the findings are relevant and useful. Public health practice–based

research networks (PBRNs) can facilitate and institutionalize this type of inquiry by bringing multiple public health practice settings together into an ongoing collaboration with academic partners to support the design, implementation, translation, and dissemination of new research (Mays 2011). The practice setting can provide a real-time "lab" in which to study the development, implementation, and effect of public health laws on public health systems performance and even encourage experimental study designs. Adding PHLR to the mix adds a new segment of practice: legal counsel. Unlike health practitioners, lawyers typically are not exposed to empirical research or methods during their professional training, so bringing lawyers into research and practice networks requires openness and willingness to learn on both professional sides. Mello and Zeiler have described the many challenges of recruiting and supporting researchers in empirical health law (Mello and Zeiler 2008).

Research Methods. The limited PHLR/PHSSR literature is composed primarily of qualitative and uncontrolled observational designs. Most existing PHSSR studies use cross-sectional designs that do not support robust causal inferences (Lenaway et al. 2006). This is to be expected in a new area of research, in which formative research helps create a foundation for hypotheses and the development of research tools. More sophisticated methods, including longitudinal analyses and multilevel modeling, can be used to examine change over time and the relationships among different levels of government agencies. Most changes in laws and regulations affecting population health are natural experiments, offering great scope for sophisticated quasi-experimental studies that can provide a strong basis for assessing the causal impact of law (Wagenaar and Komro 2011). Randomized controlled trials of law will always be the exception: the same diversity of lawmaking and executive authority that creates a favorable climate for quasi experiments makes true experiments difficult to arrange. Researchers are virtually never in a position vis-à-vis legislators or public health officials to randomly assign a set of local health departments to one legal intervention and another group to a control/placebo, although including practitioners in research teams could make it more feasible to implement new legal interventions in a manner that would allow experimental designs (Ayres, Listokin, and Abramowicz 2010). PHLR is developing a series of methods monographs describing the tools for studying how law influences health and health behavior, including guidance both on research design and on how to

theorize and measure legal effects (Public Health Law Research Program 2011). PHSSR's funding is being directed in particular to supporting quasi-experimental studies.

Care should be taken to ensure that classic epidemiologic methodology issues are addressed. Research in PHSSR and PHLR should be sensitive to issues of confounding, bias, and the inferential limits of cross-sectional regression analysis. Rigor in scientific method must apply to the research of PHSSR and PHLR if it is to be an accepted part of the community of science. That said, it is also important to affirm the value of qualitative and observational research, legal mapping studies, and health impact assessments to public health research and practice. Qualitative research can provide invaluable insights, rooted in the experience of their peers, to practitioners and policymakers. When longitudinal data or cross-jurisdictional variation are lacking, cross-sectional studies and regression analysis are indispensable to building a broad evidence base. HIA and other modes of systematic rapid assessment make up in timeliness what they lack in certainty. The field requires work at every level of the evidentiary hierarchy. Progress means that every study at every level is as well done, as well targeted, and as well timed as possible.

Conclusion

Historically and to the present day, law has been treated by empirical researchers as an afterthought to the organization and work of health agencies. Perhaps because of a lack of a clear conceptual framework and supporting research methodologies, researchers often leave law for discussion sections rather than truly engaging and measuring its effects. There can now be no disputing that law is an important force at work in public health systems and that it requires the same study and attention as other drivers of public health agency characteristics, performance, and outcomes. The integration of PHLR and PHSSR is essential because law, for all its importance, is a force that works in interaction with other factors—resources, training, community values—whose impact is likely to vary over time, topic, and place. Our vision is not one of a new crop of studies devoted solely to law (although some formative research is certainly needed) but the emergence of PHLR as an integral part of PHSSR, and vice versa.

More and better research is needed, but research remains a means, not an end. Law has enormous potential to improve the delivery of public health services, in both efficiency and effectiveness. In the face of demands for austerity, resistance to a "nanny state," and long-term ideological attacks on the effectiveness of government regulation of any kind, policymakers and public health practitioners must be able to demonstrate that what they are doing works and works cost-effectively. The reorganization of health departments, the redrafting of enabling statutes, accreditation, and the development of new legal health interventions have no inherent value; they are justified by results. And so it should be. PHSSR and PHLR must work in partnership with practice to wisely use, credibly justify, and, in so doing, properly increase public funding and political support for public health.

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