Legal Epidemiology: The Science of Law

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Introduction

In Thomas R. Frieden's *A Framework for Public Health Action*,[1] law appears as a primary driver for "changing the context to make individuals' default decisions healthy." The notable public health interventions he mentions use law and policy to achieve this goal: fluoridating the public water supply, removing trans-unsaturated fatty acids in processed foods, and dis-incentivizing tobacco use through taxes and zoning. Laws also impact socioeconomic factors such as poverty, education, and housing, together responsible for creating the greatest impacts on public health.[2]

Despite numerous examples of the critical influence that law and policy have on public health outcomes, only systematic evaluations can show which laws facilitate, challenge, or harm health. To that end, legal epidemiology — the scientific study and deployment of law as a factor in the cause, distribution, and prevention of disease and injury in a population — has recently emerged as a unifying field for public health law research and practice.[3] The scientific study of law's impact on public health outcomes requires the use of rigorous methods to measure the characteristics and prevalence of laws of interest and assess their impact on health outcomes of interest.[4]

This work is inherently transdisciplinary,[5] requiring collaborations that foster innovative and insightful research, and can be challenging, particularly for government programs.[6] For example, tracking legal and policy provisions over time through policy surveillance[7] can be

labor-intensive, and policies are not often integrated into existing public health surveillance platforms. Legal evaluations that identify associations between legal levers and health outcomes or ask public health stakeholders about the effects of law on their activities[8] can require statistical software and support, federal approvals under the Paperwork Reduction Act of 1995, and other significant resources. The Centers for Disease Control and Prevention (CDC) explored ways to overcome these obstacles through four years of applying and supporting legal epidemiology in practice.

In this article, we describe a case study of one successful legal epidemiology initiative: the exploration of legal and policy approaches that might help increase the recommended practice of behavior therapy as first line treatment for young children with attention-deficit/ hyperactivity disorder (ADHD), rather than beginning treatment with medication. Behavior therapy, given by parents with the support of healthcare providers, uses positive communication, positive reinforcement, structure, and discipline to teach children to better control their own behavior at school, at home, and in relationships with others, leading to better outcomes.[9] This project exemplifies the purpose, process, and lessons learned that practitioners could adapt to their own legal epidemiology activities in the field.

The Public Health Problem

ADHD is the most common neurodevelopmental disorder of childhood, with approximately 6.4 million school-aged children diagnosed in the United States.[10] The percentage of U.S. children diagnosed with ADHD has increased by 3%–5% per year since the 1990s, and the percentage taking ADHD medication increased by about 7% per year from 2007 to 2011.[11] School-aged children with public insurance are 50% more likely to be diagnosed with ADHD than privately insured children,[12] and this disparity is even greater among 2- to 5-year-olds, a group for which treatment guidelines differ from those for older children.[13] Behavior therapy works for 2- to 5-year-olds, its benefits are known to persist and generalize, and it has no adverse events associated with its use.[14] For these reasons, the American Academy of Pediatrics recommends that healthcare providers first refer parents of young children with ADHD for training in providing behavior therapy to their children before trying medication.[15]

Approximately 40%–50% of young children with ADHD receive psychological services, which could include behavior therapy.[16] CDC recognized that addressing this discrepancy between recommended treatment and clinical practice could achieve measurable impact on public health quickly. With this support, researchers in the National Center on Birth Defects and Developmental Disabilities (NCBDDD) began to research strategies to increase the percentage of young children with ADHD who receive behavior therapy.

Transdisciplinary ADHD Research

To investigate the variety of tools states might use related to pediatric ADHD treatment, NCBDDD's research team conducted a 50-state policy review aiming to produce a dataset describing the applicable policies and an evaluation to study the effect of the policies on the use of medication and behavioral therapies. The team found some state Medicaid programs

that implemented policies intended to manage the use of ADHD medications and guide physicians toward best practices for treatment in children. These policies include medication prior-authorization requirements, which require Medicaid approval of medications for certain patients before reimbursement is granted. To apply current systematic methods, the team contacted CDC's Public Health Law Program to implement a comprehensive legal epidemiology project.

Gathering and analyzing state Medicaid policies is evidence-based work that is inherently transdisciplinary. NCBDDD's team of epidemiologists, biostatisticians, and psychologists joined with attorneys, health communicators, and data scientists to apply policy surveillance methods[17] to help better understand ADHD prior-authorization policies and produce two important resources. The research team hired an attorney to review law and policy language and conduct a legal mapping study with a dataset that compared Medicaid prior-authorization policies in 50 states and the District of Columbia.[18] The team culled secondary source research, federal reports, provider memoranda, and preferred drug lists, and spoke to Medicaid officials about their programs. CDC also engaged experts at Temple University's Policy Surveillance Program to design a legal evaluation comparing policy surveillance data to Medicaid claims data on rates of ADHD medication prescriptions and psychological services referrals.

These efforts produced impactful data. As of November 1, 2015, 27 states restricted ADHD medication payment approval for children served by Medicaid. The characteristics and criteria used to make authorization decisions varied significantly among states. Seven Medicaid programs asked a prescriber to indicate whether non-medication treatment, such as behavior therapy, was attempted before prescribing medication treatment. Sixteen Medicaid programs had policies applicable specifically to children younger than age 6 years, the target population for this CDC initiative.[19]

Significant progress has been made on this agency priority because it is now known which states have policies that (1) require prior-authorization for ADHD medications, (2) list specific medications for which this applies, and (3) provide criteria for approval. Legal epidemiology data and metrics of ADHD treatment patterns allow state Medicaid programs to compare their policies alongside other states and inform policy decisions. The findings could have broad implications across stakeholder groups, affecting the future use of law, policy, treatment, data, and public health interventions. Next, the team will evaluate whether the implementation of these prior-authorization policies influenced rates of psychological service and medication use for the relevant age group.

Lessons Learned

This study is an important example of how to effectively study the relationship of law and policy to public health goals and outcomes. Not only did the study produce actionable data, but the research process also required detailed documentation about purpose, roles, resources, and outcomes. These documents identified several key lessons for future legal epidemiology activities in governmental or other contexts.

First, discussion about public health and legal research processes and outcomes is essential. The type of data collected and analyzed should mirror evaluation goals, which in this case was to collect and analyze information that could inform Medicaid directors and decision-makers about policies that may support recommended treatment. Those who formulate coding questions must characterize policies in a way that is both legally and topically important. Scientific experts and lawyers alike might have to rethink the scope and phrasing of study questions in light of their differing areas of expertise. Communicating these goals to differing audiences similarly requires engagement from both sides, including deciding which audiences to inform.

Second, measuring the consequences of a law or policy requires time, resources, planning, and patience. In federal agencies, planning for legal evaluations can require months for application and approval from the Office of Management and Budget, validation by external experts, and significant financial resources. Although policy surveillance and quantitative evaluation studies are indispensable to understanding the landscape of public health interventions, such as policies governing ADHD treatment, they alone cannot reveal the effects of discretionary implementation and enforcement of prior-authorization policies. Qualitative studies could reveal other incentives that guide providers' decisions to use behavior therapy instead of medication, such as reimbursement for mental health services. These findings could alter the legal issues to be surveilled, the research priorities, and the resources dedicated to legal epidemiology.

Third, operationalizing legal epidemiology suffers from gaps that can be closed only by investing in systems to access data. For example, health data for evaluation purposes can be difficult to use because of the costs to access databases, the limitations in existing data sources, and the number of intervening factors that weaken a legal associational study. For the ADHD dataset, the evaluation of prior-authorization policies required a license to access Medicaid participant information and was limited by privacy requirements and reporting variability in each state's Medicaid payment structure. Tools to translate legal data into products for the client are also limited. For example, displaying state-based results on U.S. maps does not necessarily communicate all of the issues at play in comparative legal epidemiology studies.

Despite the energy and expertise researchers have brought to this important work, there are significant challenges in marshalling the diverse skillsets, quality controls, and funding to implement legal epidemiology activities. Public health law researchers are developing cross-cutting research and translation platforms to overcome many of those challenges. When applied to CDC's agency priority to promote behavior therapy first for young children with ADHD, the potential for legal epidemiology research is clearly evident and provides lessons learned for other research.

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