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Principles and methods of global legal epidemiology

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ABSTRACT

Although the theory and methods of 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—have been well developed in the context of domestic law, the challenges posed by shifting the frame of analysis to the global legal space have not yet been fully explored. While legal epidemiology rests on the foundational principles that law acts as an intervention, that law can be an object of scientific study and that law has impacts that should be evaluated, its application to the global level requires the recognition that international laws, policies and norms can cause effects independently from their legal implementation within countries. The global legal space blurs distinctions between ‘hard’ and ‘soft’ law, often operating through pathways of global agenda setting, legal language, political pressures, social mobilisation and trade pressures to have direct impacts on people, places and products. Despite these complexities, international law has been overwhelmingly studied as operating solely through national policy change, with only one global quasi-experimental evaluation of an international law’s impact on health published to date. To promote greater adoption of global legal epidemiology, we expand on an existing typology of public health law studies with examples of policymaking, mapping, implementation, intervention and mechanism studies. Global legal epidemiology holds great promise as a way to produce rigorous and impactful research on the international laws, policies and norms that shape our collective health, equity and well-being.

INTRODUCTION

Our era of pandemics and globalisation has underscored the importance of the global dimensions of the legal, political and social determinants of health in an increasingly interconnected world. Here, we present a description of the theory and methods of global legal epidemiology, which builds on the existing practice of legal epidemiology to study international laws, policies and norms. Drawing on foundational legal epidemiology texts, we highlight the diverse pathways through which international laws, policies and norms operate, as well as a typology of methods that can be leveraged to better understand this complex, multilevel legal space.

Legal epidemiology has been defined as ‘the scientific study and deployment of law as a factor in the cause, distribution and prevention of disease and injury in a population’.¹ This field has applied epidemiologic methods to evaluate and enhance

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Legal epidemiology scholars have developed robust methods and theoretical approaches to the study of law as a factor in the cause, distribution and prevention of disease and injury in a population.

WHAT THIS STUDY ADDS

⇒ We describe the pathways through which international laws, policies and norms can have impacts independently from their legal implementation within countries and detail key differences between the study of international and domestic law from a population health perspective.
⇒ A typology of major methodological approaches and illustrative global research questions is described to promote the adoption of global legal epidemiology.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE AND/OR POLICY

⇒ Global legal epidemiology holds great promise as a way to produce rigorous and impactful research on the international laws, policies and norms that shape our collective health, equity and well-being.

the implementation of law to improve population health, with recent expansion into machine learning, cumulative legal exposure and treatment heterogeneity.^{2–4} While the bulk of legal epidemiology has focused on the evaluation of domestic law, the context of globalisation and the recentring of global health equity as a core mission of public health have encouraged legal epidemiology scholars to translate this growing suite of approaches to the global level.^{5,6}

The development of legal epidemiology as a practice is based on three foundational principles: that law acts as an intervention, that law can be an object of scientific study and that law has impacts that should be evaluated. The first principle positions law as a tool intended to have population-level impacts, which can broadly be separated into categories of interventional law operating directly through legal injunctions, infrastructural law through the provision of authority to institutions to design and implement laws or incidental law through the intended or unintended interaction between law and its effects on people, places or products.⁷ The second principle extends core



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public health functions to the systematic monitoring of laws of public health significance, which has led to the more regular and widespread practice of legal surveillance.^{6 8} The final principle proposes that because laws have significant and complex population-level impacts, they should be evaluated through rigorous analysis to ensure that their impacts are beneficial and equitable and to inform the design of future laws.^{1 4-6 9}

Although the foundational principle of legal epidemiology remains just as important at the global level, there are unique characteristics and challenges in studying international laws, policies and norms that must be considered. Law acts differently at the global level, complicating the mechanisms traditionally assumed to underly laws' impacts on health and people, with important implications for research in this space. First, while legal surveillance typically assumes governmental implementation after legal adoption, this assumption is far more tenuous at the global level.¹⁰ Second, the evaluation of international laws, policies and norms is challenging as we cannot use a comparative approach: there is no counterfactual Earth with which to compare impacts. Finally, research at the global level must recognise an additional principle: that international laws, policies and norms are global social-political phenomena that cause effects independently from their legal implementation within countries. Although legal epidemiology scholars have put forward nuanced explorations of the causal mechanisms that underlie legal impacts, such as mechanisms of meaning-making, legal consciousness and law as legality¹¹—in practice—international laws, policies and norms have overwhelmingly been studied through a positivist and narrow conception of law flowing directly from international to national law.

Here, we present the theoretical considerations for global legal epidemiology and a typology of methodological approaches. We hope this burgeoning field can continue to grow and produce rigorous and impactful research on the international laws, policies and norms that shape our collective health, equity and well-being.

THEORETICAL CONSIDERATIONS

Shifting the scope of analysis to the global level requires us to re-examine the fundamental question of how to define and understand law. The traditional dichotomisation between 'hard law' (eg, legislation, regulation, court cases) and 'soft law' (eg, policies, codes of practice, customs) becomes blurred in the context of international laws that can lack consensus of jurisdiction, clarity in interpretability, adjudicative courts for resolving disputes and forceful enforcement mechanisms. In this global context, even norms and customs are commonly considered to be equivalent to hard law.¹² This means that a doctrinal approach restricting investigations to the impacts of laws that are written down and legally binding on countries becomes much less policy-relevant than a practical approach to investigating how laws broadly defined are designed, interpreted, implemented, enforced and influential in practice.^{7 13}

In addition to revisiting the definition of law, global legal epidemiology requires us to understand the pathways through which international laws, policies and norms operate independently of national or subnational law to have direct impacts on people, places and products (figure 1). To date, most published research has focused on the impact of international law on national government actions.¹⁴ This narrow approach can largely be attributed to disciplinary interests and norms within political science and international law, which are largely focused on understanding or regulating the behaviour of governments.

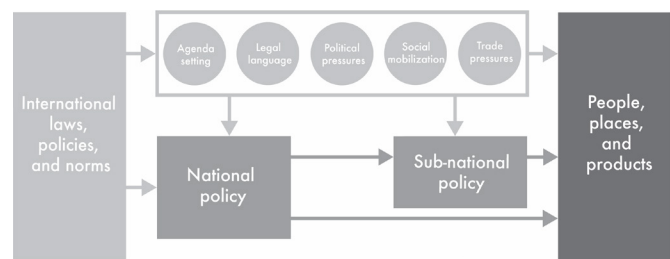


Figure 1 Simplified model of the ways through which international laws, policies and norms have impacts through global pathways and domestic legal pathways have impacts on people, places and products.

This leaves broader questions around the utility of these laws for solving global challenges unanswered. Some legal epidemiology studies have studied global issues, such as a systematic review of the utility of border closures to control influenza transmission within individual countries¹⁵ and a global mapping of states parties' compliance with the Convention on the Rights of the Child,¹⁶ but even these analyses are limited to domestic laws' impacts on global issues.

A less frequently studied pathway of impact flows directly from global law, policies and norms to subnational policy change, as exemplified by global alliances of cities, such as the C40 Cities Climate Leadership Group.¹⁷ Although this pathway opens up new mechanisms that circumvent national policy change, it omits studying the impacts of international laws, policies and norms through pathways that operate independently of domestic law. While this requires careful consideration of research design, it can yield important and novel insights. For example, the only quasi-experimental evaluation of the global impacts of an international law put forward a logic model of WHO Framework Convention on Tobacco Control (FCTC) impacts as operating through global political pressures, trade pressures, agenda-setting power, legal language, social mobilisation and public awareness.¹⁸ While traditional legal epidemiologic studies have rightly drawn attention to increased formal adoption of domestic tobacco control laws,^{19 20} this study's policy-relevant finding of stalled global progress in reducing tobacco consumption would not have been identified without changing the scale of analysis to evaluate mechanisms besides changes to domestic law.

METHODS OF GLOBAL LEGAL EPIDEMIOLOGY

Global legal epidemiology is a transdisciplinary practice with interventions, causal mechanisms and outcomes that span multiple jurisdictional levels. This requires a diverse set of approaches that can grapple with these complexities while upholding rigorous empirical research standards, which is a point of emphasis for both global and domestic legal epidemiology. Building on a typology of public health law studies put forward by Burrell *et al* (table 1),⁷ we present considerations for the application of these methods to the study of international laws, policies and norms as a starting point for the expanded practice of global legal epidemiology.

Designing more effective and equitable international laws, policies and norms requires a nuanced understanding of ways to mobilise evidence into action. Policymaking studies typically situate law as an outcome rather than as an intervention, in order to evaluate the conditions under which laws are developed, adopted, implemented and enforced. For example, the 2008 financial crisis led to significant changes in national laws governing domestic universal health coverage, demonstrating how global trade pressures can lead to powerful impacts on

Table 1 Definitions of major methodological approaches to legal epidemiology along with an illustrative global research question, based on the 'typology of public health law studies' put forward by Burris *et al*⁷

Major methodological approaches	Illustrative global research question
Policy-making studies: To 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.	What factors were associated with countries' decisions to close national borders in response to the COVID-19 pandemic?
Mapping studies: To analyse the state of the law or the legal terrain and the application of laws surrounding a particular public health topic.	What dietary guidelines are published by national governments and international agencies around the world, and how do they compare?
Implementation studies: To examine how and to what extent the 'law on the books' is implemented and enforced through legal practices.	How could an international treaty strengthen the implementation of existing national commitments to ban over-the-counter sales of antibiotics?
Intervention studies: To assess the effect of a legal intervention on health outcomes or mediating factors that influence health outcomes.	Did the Framework Convention on Tobacco Control decrease global cigarette consumption?
Mechanism studies: To examine the specific mechanisms through which the law affects environments, behaviours or health outcomes.	Do treaties have greater impacts through the incorporation of transparency, complaint, oversight or enforcement mechanisms?

national policy around the world.^{21–23} More recently, the conditions and factors associated with countries' decisions to close national borders in response to the COVID-19 pandemic has emerged as an important research question.^{24 25}

Mapping studies, also referred to as policy surveillance, systematically track and compare policies to produce fundamental evidence to inform evaluative and normative research.^{8 26 27} Although international law is generally accessible,²⁸ systematically mapping domestic law across multiple countries brings challenges related to accessing, translating and differences in legal cultures.⁶ One such study used a systematic mapping approach to identify and harmonise current national and international food-based dietary guidelines.²⁹ In order to facilitate observational analysis and future evaluation, diverse dietary guidelines referring to key food groups for health and sustainability were standardised. This multilevel mapping process allowed for the quantitative analysis of alignment between food supply and dietary guidelines, uncovering decades-long misalignment which continue to undermine the efforts of the Food and Agriculture Organization and the WHO for a global transition toward healthy and sustainable food systems.

Implementation studies assess the legal process or the context in which changes occur, using methods from implementation science, complexity science, network theory and systems approaches developed in political science. These studies can identify strategies for maximising the impact of evidence on international law and policy.^{7 30–32} As one example, researchers and policymakers are collaboratively drawing on evidence to inform the design of a sustainable international agreement to address antimicrobial resistance.^{33–35} In this emerging policy space, the scale of the global threat posed by antimicrobial resistance is increasingly well-known and many domestic policy interventions have been demonstrated to be effective. However, critical questions of scalability remain, and navigating a global governance system that was not built to address global collective action problems is an ongoing implementation challenge.

Intervention studies detect and measure the effectiveness and equity impact of legal interventions using primarily quantitative approaches.^{36–38} The strongest study designs for impact evaluations are typically quasi-experimental, including interrupted time series analysis,^{18 39–41} difference in differences,^{42–45} event modelling,¹⁸ network models^{46–48} and meta-analysis,^{49–51} for descriptive analysis or hypothesis testing. Although examples of intervention studies abound at the domestic level, our systematic review of quantitative evaluations of international law revealed that only a handful of studies demonstrated the methodological rigour and specificity that guarantee useful insights for assessing the effects of international laws and policies in question.¹⁴ Even

high-quality studies are primarily focused on whether ratification of international laws have individual country-level effects (eg, on adoption of national policies) rather than whether international laws have independent population-level effects (eg, on health outcomes).

Appropriate model selection is crucial to accurately quantify impacts at the global level. This requires accounting for the countervailing or synergistic effects across the multiple levels in which domestic and international law interact. For example, a study using interrupted time-series methods did not find any effects in the rate of change of global cigarette consumption following the FCTC's adoption in 2003, yet uncovered multi-level impacts when stratifying by income and by region.¹⁸ This stratified result was hypothesised to be the result of 'equilibrium effects' across borders in which strict regulations imposed by one government encouraged companies to move to jurisdictions with fewer restrictions to maximise profits, ultimately leading to increased cigarette consumption in low-income and middle-income countries.

Mechanism studies use a separate but related set of methodologies to evaluate the mechanisms and barriers through which international law, policy and norms have effects, considering pathways within and outside the confines of domestic law. This means that the effects of international laws, policies and norms cannot only be examined within countries but can and must be examined on countries and among countries, including multi-level, interaction and equilibrium effects. Systematic review and policy surveillance methods are particularly well suited to synthesising and interpreting existing knowledge on global legal epidemiology questions, though there are still advances to be made in the measurement, interpretation and translation of law.⁵² As one example, research is beginning to investigate which of the most common accountability mechanisms in international law, such as transparency, complaint, oversight and enforcement, have the greatest impacts.¹⁴

No matter the study type, normative research methodologies can enrich global legal epidemiology by identifying axiological theories that can be used to comparatively evaluate on what basis particular legal instruments and their impact should be considered good, bad or better than alternatives—as well as deontic theories that can be used to analyse which legal instruments and their impacts are justified in terms of, for instance, their fairness.⁵¹ Every stage of research, from what evidence to use, to what metric to measure evidence of impact and to how evidence should be mobilised for impact, involves implicit or explicit value judgments. This fundamental connection between the normative and empirical requires engagement with ethics and the philosophy of science to acknowledge and critically engage

with the alignment between the existing practice of global legal epidemiology and principles such as well-being, social justice and equity.⁵³

CONCLUSION

Global legal epidemiology employs empirical methods rigorously to study the global impacts of international laws, policies and norms while making use of the findings derived from these methods to inform global policy. The methodological tools, data and theoretical foundations needed to conduct global legal epidemiology have never before been as well developed or widely accessible. As a shared understanding of the theoretical considerations and methodological approaches that underlie global legal epidemiology emerges, a community of practice can lay the groundwork for impactful research for years to come. By evaluating international law at the global scale, independently of the implementation of national law, global legal epidemiology is poised to emerge as a practice that brings scientific rigour to the design, implementation, enforcement and evaluation of international laws, policies and norms that impact health and health equity within and across countries across the globe.

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