

Educated Guessing: Getting Researchers and Research Knowledge into Policy Innovation

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Educated Guessing: Getting Researchers and Research Knowledge into Policy Innovation

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Introduction

Law has played an indispensable role in public health's successes over the last hundred years, and remains one of the most potent and popular levers for increasing the quality and length of life (Burriss and Anderson 2013; Morain and Mello 2013). When deployed effectively, law promotes healthy behavior and reduces exposure to harmful products and environments. Like other health interventions, however, promising public health laws can turn out to be ineffective or even harmful. In the long run, research names the winners and losers, so a preference for “evidence based” interventions makes as much sense in law as it does in other domains of public health (Brownson, Colditz, and Proctor 2012). Research synthesis, research translation and a vigorous practice of public health law research are all crucial to inform the refinement (and, sometimes, the retirement) of policy (Burriss et al. 2010).

In this paper we explore the earliest stage of public health law development. Our target is ambitious — to improve public health law experimentation — but our aims are modest, and center around two contributions. The first is a three-step process for developing legal interventions. While scientific and critical in spirit, the reasoning process we describe is substantially intuitive and heuristic in practice, and reflects what law makers and advocates do every day. Our prescription consists in making the tacit explicit, and the spontaneous systematic.

Our second contribution consists of a handful of observations and suggestions for how to think about legal innovation within the broader campaign for evidenced-based policy. This paper is intended to offer researchers another way to contribute their expertise to the policy-making process, but we hope that other policy participants may find some of the tools we describe useful in the effort to respond effectively to new health threats.

In Part I we describe the primary contemporary strategies researchers and research institutions use for inserting evidence into policy: 1) developing tools for credibly synthesizing evidence as it accumulates, and 2) adopting the individual and institutional practices (e.g., relationship building between researchers and policy-makers, funding for translation work, cooperative learning initiatives) that best promote the timely translation of research evidence into actionable, salient and available knowledge for policy actors. Both strategies seem to be effective at increasing the uptake of evidence in areas where the evidence base is reasonably thick. Recently we have also seen progress in developing evidence synthesis and impact assessment strategies designed for emerging policies not yet assessed by a body of strong evidence.

While this work is essential to disseminating interventions of established effectiveness (or at least promise and feasibility), policy-makers and public health advocates facing new problems with new legal

interventions are, by definition, working without directly evidence-tested options. This early stage of the policy cycle is too often neglected in the conversation about evidence-based policy.

In Part II, we discuss how evidence about the problem lawmakers are addressing, combined with widely-used analytic tools and an understanding of the generic mechanisms through which law influences behavior and outcomes, can bring existing research knowledge into the crafting of even very innovative legal interventions for newly perceived problems. By participating in policy innovation, researchers have an opportunity to help advocates devise better asks and lawmakers identify more and better options for action.

Part I: Policy Learning, Evidence Tools and Translation in Public Health Policy

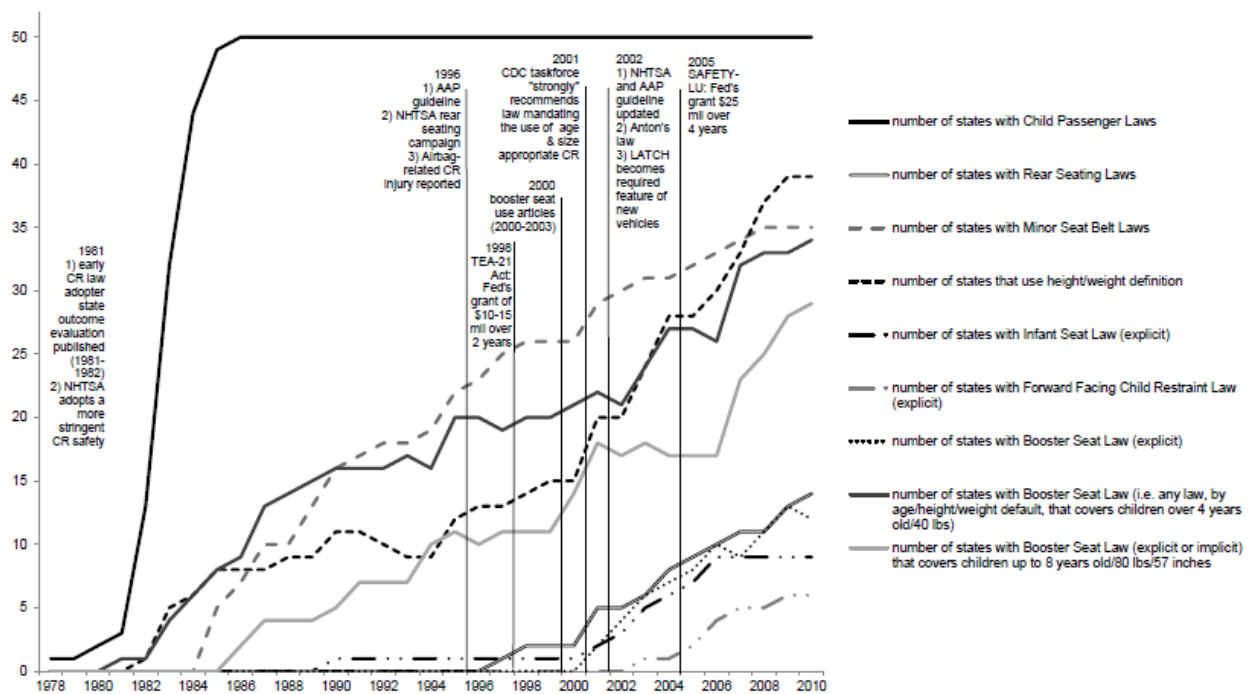
In response to growing awareness of the toll of motor vehicle crashes on children, every state in the U.S. adopted a law between 1978 and 1986 requiring at least some child passengers to be restrained in safety devices (Bae et al. 2013). There was wide political and social recognition of a problem, but no widely shared sense of exactly which children needed to be protected, how to protect them, or how stringent the rules should be. The first generation of laws varied considerably across a number of dimensions including the age, height and weight of children subject to the law, whether the law was enforceable as a primary or secondary offense, and the amount and type of penalty for violations (Bae et al. 2013). It was clear almost immediately that many of these laws had struck a less-than-optimal balance (Teret et al. 1986).

Variation like this is common in the formative stages of policy. The meaning and intensity of concern about emerging problems often differ across jurisdictions. These and other factors (different leaders, different levels of industry influence, different legislative processes (Shipan and Volden 2012)) influence how great an intrusion into current practice is politically feasible. The fact that an intervention is labeled “public health” does not mean that it poses no trade-offs or value-judgments upon which people may reasonably differ. Variation in policy can be frustrating and confusing for public health practitioners, but it has benefits for policy learning: variants represent natural experiments, allowing researchers to identify the effects of different policy choices. The work of states as fertile “laborator[ies]” for “try[ing] novel social and economic experiments” (New State Ice Co. v. Liebmann 1932) remains indispensable to an “experimenting society” (Campbell and Ross 1968) capable of dealing with complex emerging problems.

Evidence helped move states to act on child motor vehicle injury, even if imperfectly. A longer view observes evidence guiding initially diverse policies toward a more effective form. Evaluations of child restraint laws began immediately after their adoption in the early 1980s. The first results were single-state pre-post evaluations (Williams and Wells 1981, 1981; Sewell et al. 1986), showing that legal action was saving

lives. Following quickly thereafter, evaluators designed more sophisticated studies incorporating comparisons not only over time, but across states with and without similar laws (Guerin and MacKinnon 1985; Wagenaar, Webster, and Maybee 1987), a technique capable of providing much stronger inferences about the true effect of the laws (Wagenaar and Komro 2013). By the end of the 1980s, the evidence supporting the general effectiveness of child restraint laws was clear and the impetus in policymaking and research shifted toward identifying the most effective variations. In ensuing decades, researchers explored the effectiveness of requiring the use of different safety devices, the placement and location of children, and enforcement procedures (e.g., primary versus secondary). As the evidence base evolved, so too did state policies; since their initial adoption, U.S. states have amended their child restraint laws an average of six times to bring them into line with current evidence (Bae et al. 2013)(Figure 1).

Figure 1. Evolution of U.S. State Child Restraint Laws



SOURCE: JEAN BAE, EVAN ANDERSON, DIANA SILVER, JAMES MACINKO, 2014. CHILD PASSENGER SAFETY LAWS IN THE UNITED STATES, 1978-2010: POLICY DIFFUSION IN THE ABSENCE OF STRONG FEDERAL INTERVENTION, SOCIAL SCIENCE & MEDICINE100: 30-37

In reasonably effective regulatory systems, this policy learning process occurs constantly. Evidence informs the dissemination and refinement of effective policies and the repeal of unsuccessful ones. While a particular

study rarely produces immediate policy results, accumulating evidence seeps into the policy process through a number of information channels, including advocacy, legislative staff work, expert testimony, and the media – all providing a backdrop of information that influences policy (Weiss 1977; Brownson, Chriqui, and Stamatakis 2009). One need only consider the dramatic increases in the safety of motor vehicles, consumer products, workplaces and other frequent targets of regulation to understand the value of the policy learning dynamic (MMWR 1999; Burris and Anderson 2013). Of course, the process does not always work perfectly and seldom works quickly. Most importantly, it does not work automatically. Success stories like that of child restraint laws are the products of hard political work and the social investment in research and advocacy.

Speeding the adoption of the most effective policy models is a high stakes game for public health, in which the costs of delay can be measured in preventable death, injury and expenditure. The reasons for the lag between evidence and action have been explored in a rich and still-growing literature. Policy-makers face a “glut” of information (Colby et al. 2008) and almost always lack the time, resources, and expertise to make sense of it (Brownson et al. 2006; Jewell and Bero 2008). It is not just the daunting amount of information, but also how it is produced and received that matter. Significant differences in culture, training and experience between researchers and policy-makers often hinder the effective creation and exchange of information (Brownson, Chriqui, and Stamatakis 2009). Researchers, in a scientific culture, and policy-makers in a political one, think differently on different timelines that are shaped by different constituencies and priorities (Brownson et al. 2006). The size of the gap is reflected in the fact that those who specialize in bridging it no longer speak of “communication,” but of “translation.”

The effort in public health to speed the uptake of evidence in policy has followed two main strategies. The first is the development of tools (and sponsoring institutions) for credibly synthesizing evidence as it accumulates. The second is the study and adoption of individual and institutional practices aimed at strengthening the relationship between researchers and policy-makers.

Synthesis Tools

For a given intervention (e.g., child restraint laws), there are often many evaluations differing in design, analytic techniques, sample sizes, and, not infrequently, findings and interpretations. A systematic review is a study that reviews such a collection of evidence according to an explicit, rigorous, and transparent methodology (Greenhalgh et al. 2004). In the past three decades there has been an enormous acceleration in the production of systematic reviews (Moher et al. 2007). By collecting, filtering and appraising studies through robust and transparent methods, systematic reviews assess the effectiveness of an intervention based on the overall weight of the evidence available, taking into account not just study results but also the methods

that yielded them. Although they are too dense and complicated to be an ideal communications tool in the era of the one-pager (or the tweet), systematic reviews serve the goal of translation by distilling evidence from many sources into one.

In recent decades, important institutions have emerged to foster the systematic review of evidence in health and related fields. The Cochrane Collaborative grew out of Archibald Cochrane's observations in the early 1970s about the fragmented and often misleading state of knowledge on the effectiveness of maternal health interventions (Cochrane 1972). The Collaborative quickly became an international force in the promotion of rigorous and methodologically consistent reviews. There are currently more than 5,000 systematic reviews covering a wide range of health interventions in the Cochrane collection, each following a standard protocol detailing how the research question was defined, the relevant studies were identified and the overall body of evidence was characterized (Cochrane Collaborative 2013). The Campbell Collaboration, founded in 2000, provides a similar service with an equally robust collection of systematic reviews covering a broad range of social science subjects including, among others, education and criminology (Campbell Collaboration 2013). The Community Guide for Preventive Services publishes the findings from the U.S. Preventive Services Task Force, which was created by the U.S. government in 1996 to systematically identify effective and economically efficient public health interventions (Carande-Kulis et al. 2000; Zaza et al. 2000). Like Cochrane and Campbell, the Community Guide follows well-defined and transparent processes for conducting and reporting reviews (Briss et al. 2000).

In 2009, Moulton and colleagues identified more than 60 systematic reviews of the effectiveness of public health laws (Moulton et al. 2009). At least ten additional systematic reviews on interventional public health laws have been conducted since. These reviews produce policy-relevant guidance that is important to disseminate, and policy-makers regard them as a valuable resource (Lavis et al. 2003; Fielding and Briss 2006; Sweet and Moynihan 2007), but even a quick scan of the topics (see for example PHLR Evidence Briefs, PHLR 2013) reveals that in most cases, the production of a quantity of evidence sufficient to ground confident conclusions about the effectiveness of an intervention usually only happens after wide adoption. The reviews can help push late adopters, promote fine-tuning, or support repeal of ineffective policies (Sweet and Moynihan 2007), but they are of no use earlier in the process, when many durable policy decisions are made. Recently, we have seen action in recognition of this problem that adopts criteria and evidence standards more suitable for the intermediate stage of policy development. Brennan and colleagues devised a four-tier hierarchy of evidence for obesity policies. Their scheme gives greatest weight to systematic reviews and high quality empirical studies, but also includes evidence that would not qualify for a systematic review but that nonetheless can shed light on “promising” policies (i.e., tested by relatively less rigorous and preliminary research) and even “emerging” strategies (i.e., newly implemented and with high face validity, but

not yet subject to evaluation research)(Brennan et al. 2011). This is hugely important, but it still does not address the very earliest stages of innovation, the challenge we take up in Part II.

Dissemination and Implementation Science as Practice

Systematic reviews (and other less formal syntheses of established evidence of the “policy brief” type) are only part of a broader movement to narrow the “chasm between science and policy” (Brownson et al. 2006). To add value to policy, researchers must also explore policy-relevant issues in ways that yield policy-relevant information. And policy-makers must want, value, and believe in the information being produced, and have access to it when it matters. That sort of correspondence requires overcoming cultural and institutional differences between policy-makers and researchers, long recognized as primary impediments to evidence-based policy (Weiss 1989; Kingdon 2003).

In the last two decades, researchers from multiple areas of health practice have been working to understand and ameliorate these impediments (Brownson, Colditz, and Proctor 2012). This work began with a focus on knowledge transfer — getting evidence from researchers to practitioners — as exemplified in the work of Archibald Cochrane in 1970s and more system-oriented work in the evidence-based medicine movement of the 1990s (Green et al. 2009). Gradually however, and particularly in research on policy-making, there has been a move away from thinking about evidence problems exclusively or even primarily in terms of moving evidence from one group (researchers) to another (policy-makers), to an emphasis on relationships that foster the bi-directional understanding and exchange of information (Lavis et al. 2003; Mitton et al. 2007). In a systematic review of 24 studies including more than 2,000 interviews with health policy-makers, personal contact with researchers was identified as the most important facilitator of the use of research in policy-making (Innvaer et al. 2002). Trust and ready access to researchers turn out to be very important for policy-makers and tend to influence their view and use of evidence (Lavis et al. 2003; Jewell and Bero 2008).

Policy-makers will rely on researchers, when they are available, for “outside the box” thinking and fresh ideas (Haynes et al. 2011). Researchers, in turn, benefit from learning from policy-makers about the problems and the sort of evidence most likely to resonate in current policy debate. To increase researcher interest in such strategies and reduce obstacles tied to professional advancement (e.g., tenure systems that privilege publications over practical influence), there is increasing funding for translational research. Programs like the Robert Wood Johnson Foundation’s Clinical Scholars Program and CDC Research Fellows require participation in community-based participatory research emphasizing the importance of contact with evidence-consumers (Brownson, Colditz, and Proctor 2012). At the institutional level, the literature

recommends creating points or modes of connection at which members of each group can learn about and from each other (Lavis 2006). Examples include practice-based research networks (Mold and Peterson 2005), partnership initiatives that systematize collaboration between researchers and policy-makers like Canadian Metropolis Project (Shield and Evans 2012), provincial knowledge exchange health initiatives (Murnaghan 2013) and a wide range of variously named arrangements between academic centers and communities (Johnston, Robinson, and Lockett 2010).

For all the value of these efforts, a practical paradox confronts exponents of evidence-based public health law: if a legal intervention is truly innovative, there will not yet be direct evidence of its impact. There will be no studies for systematic reviews and syntheses to digest. Researchers who have established relationships with policy players will be in a good position to find out what to study next – the innovation – but they will not have evaluated the policy options under consideration, and so will have no directly applicable study results to share. It is plain to see why this phase of the policy-making cycle gets relatively less attention in discussions of evidence-based policy. Yet direct evidence from policy evaluations hardly exhausts the supply of researcher knowledge relevant to a policy decision, even under conditions of novelty and uncertainty.

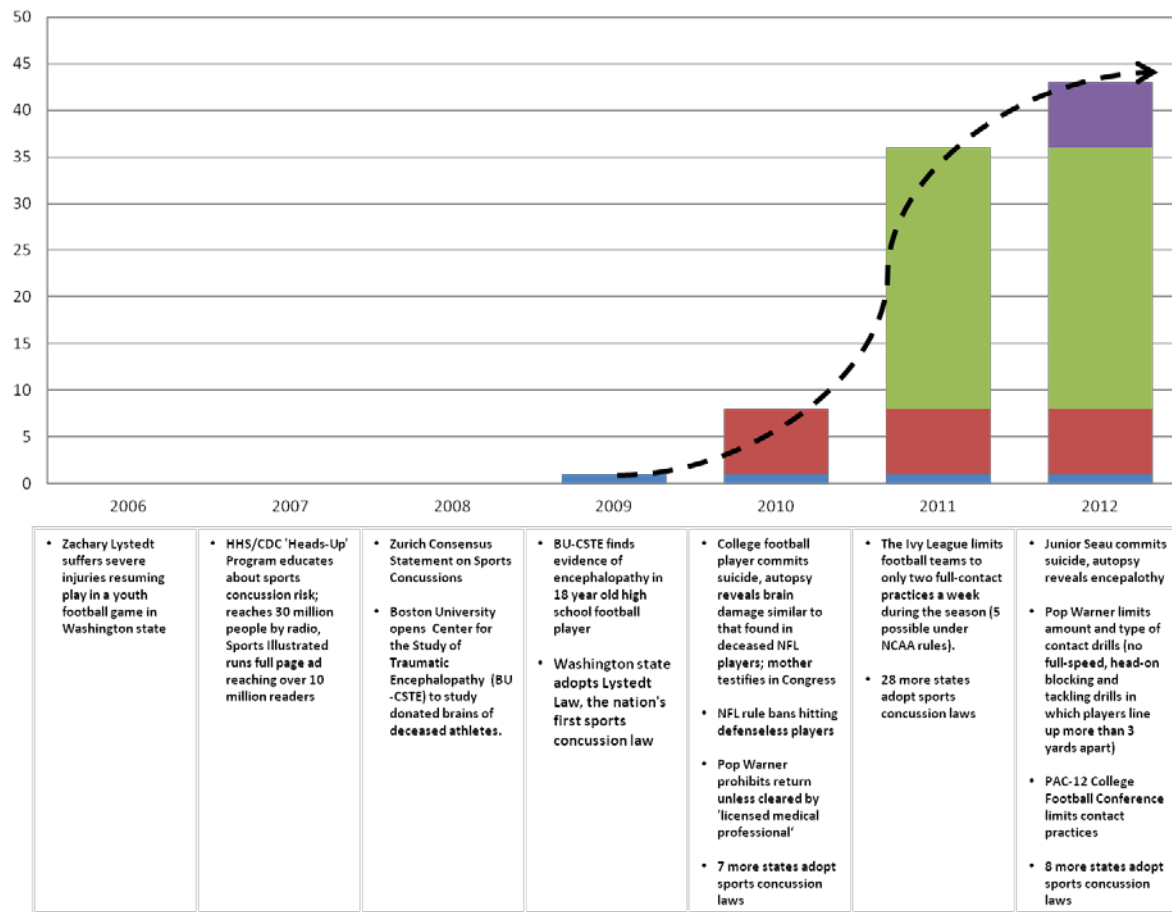
When a new threat to health emerges on to the legislative agenda as a “problem,” lawmakers and advocates who are sincerely looking for a promising intervention face several common challenges. First, they have to get a good grip on the problem for both political and practical reasons. Problems, after all, define solutions. It is not uncommon for an inaccurate characterization of a problem to lead to ineffective legislation. Second, they have to choose a legal approach to address the problem. The set of intervention options is likely to emerge quickly, and reflect a variety of interests, and ideological and psychological factors. As a result, even policy actors starting with a reasonably accurate framing of the problem may fail to identify promising options for action. Finally, crafting a new legal intervention entails many choices of regulatory strategy, each of which has the potential to enhance or diminish its impact.

Policy-makers face and overcome these challenges every day. Active involvement of researchers, and the use of simple tools to support systematic use of relevant knowledge, could help them do better at avoiding the pitfalls of problem path dependency, missed options, and errors of regulatory design. In the next section, we sketch out an approach for enhancing the translation of research knowledge at the policy innovation stage. We will illustrate the approach with a case study of one policy cascade, the U.S. legislative response to a rising concern about concussion in youth sports.

Part II: Linking Tacit and Explicit Knowledge in Policy Innovation

For decades epidemiologists and medical researchers knew that head injuries were a common risk in contact sports like football, that these injuries could be serious, and that they required care. Doctors and epidemiologists understood that traumatic brain injuries (TBIs) could have long-term impact on cognitive ability. Players, parents, coaches and fans, too, were all more or less aware that concussions occurred among young athletes. Most treated it, however, as a normal, if unfortunate, part of the game. As late as 2006, a systematic review carried the title “Pediatric Sport-Related Concussion: A Review of the Clinical Management of an Oft-Neglected Population” (Kirkwood, Yeates, and Wilson 2006). Then, suddenly, “youth sports concussions” took shape as a policy problem. Between 2009 and 2012 44 states adopted youth “sports concussion laws.” Many of these laws follow the “Lystedt Law” model mandating education about sports concussion risks and treatment, removal from competition for youth athletes with suspected concussions, and/or clearance by a health professional before an athlete could return to competition (Harvey 2013)(Figure 2).

Figure 2. Adoption of State “Sports Concussion Laws” and Timeline of Related Events



The drivers of this change were a familiar mix of evidence, anecdote and advocacy. Annual incidence estimates for high school athletes grew from 63,000 (Powell and Barber-Foss 1999) to 136,000 (Gessel et al. 2007) in less than a decade as diagnostic understanding of head trauma sharpened and surveillance improved. Current estimates of sports concussions across all youth ages run as high as 3 million or more (Langlois, Rutland-Brown, and Wald 2006). Anecdote and evidence combined in the cases of National Football League (NFL) alums suffering dementia, cognitive problems, and depression, some of whom contributed their remains to brain researchers at Boston University. Their symptoms, and the physiological damage observed post-mortem, were indistinguishable from *dementia pugilistica*, the longstanding clinical description of neuropsychological degeneration among boxers (DeKosky, Ikonomic, and Gandy 2010). A public discussion began about the possibility that repeated head injuries in football could cause serious, even life-threatening brain damage later in life. Players, parents, fans, and coaches began to wonder whether the hits

kids were taking in Pop Warner or high school could be enough to produce the terrible damage seen in retired pros or boxers like Muhammad Ali. The question spread to other contact sports including soccer, where the effect of repeated heading of the ball has long been a concern. The tipping point into advocacy came after a junior high football player in Washington State named Zachary Lystedt suffered multiple concussions in a single game, with catastrophic results. His parents took up a campaign for legislation, and in fairly short order the NFL and a variety of public health and social organizations were supporting them. In 2009, Washington became the first state to enact youth sports concussion regulations, in the aptly named Zachary Lystedt Law.

Political scientist John Kingdon's familiar model of legislation posits that a bill will pass with the merging of three distinct streams representing how a problem is defined, the availability of a policy response, and the politics of action (Kingdon 2003). It is evident from the rapid spread of the law that the politics were right, and why not? This was a bill to protect kids from readily imagined harm, supported by parents, health experts and the major industry involved. Countervailing ideological concerns about the “nanny state” did not take hold and the budget implications of the proposed law were slight.

The policy problem was very well constructed for avoiding trouble in the politics stream: as defined on the USA Football website, the official youth football partner of the NFL, “Zackery’s 2006 injury stemmed from returning to a game too soon after suffering a concussion” (Thu 2012). As this campaign moved toward legislation, it did not define the problem in terms of the rules of the game, the age of the participants, the equipment, or the field conditions, but the fact that after his first concussion Zachary did not stop playing. With Zachary, the impact of head injury he suffered was immediate and acute; his version of the problem did not evoke images of long-term chronic exposure that might have come up if the emblem of harm had been a middle-aged NFL vet with depression and early-stage dementia. This meant that the hardest issues, and greatest potential opposition, were defined out of the problem – and the solution. If premature return to play was the problem, the policy stream had a perfectly matched answer: increase awareness and promote proper medical management and time for recovery. There was no need to vote on the rules of popular sports. The policy is only triggered once a concussion has occurred, and its focus is on proper care of the injured child.

Though some commentators have criticized the Lystedt Law approach as more the result of NFL lobbying than serious attention to youth sports concussions (Harvey 2013), we don’t take that view. Without any existing policy models for dealing with concussions, let alone evidence of policy impact, advocates and legislators addressed a real problem with a plausible legal intervention. Whether it works or not, or how to refine the regulatory strategy for greatest impact, is now in the realm of evaluation research, research synthesis and evidence translation.

That is the end of the story; here we go back to the beginning, using concussion policy as an example of policy innovation under uncertainty. There was no direct evidence of the effectiveness of the Lystedt Law approach, but we will show how three straightforward tools could have been used by researchers, on their own or in collaboration with evidence brokers or policy actors, to add valuable research knowledge to the policy-making process.

Step 1: Bringing Evidence to the Problem

Scholars from all over the disciplinary map agree that the single most powerful factor in policy making is how the problem is defined (Kuran and Sunstein 1999; Kingdon 2003; Baicchi 2010; Rose 1992; Foucault 1991). Problems define solutions, and can be framed to flow with, rather than against, the political stream. Some staffer or lobbyist did a good day's work for football by describing the concussion problem as premature return to play and taking the game itself off the table. But that move may also have made rapid action across the country possible. Defining solvable problems is part of the politician's job description, and an art in itself.

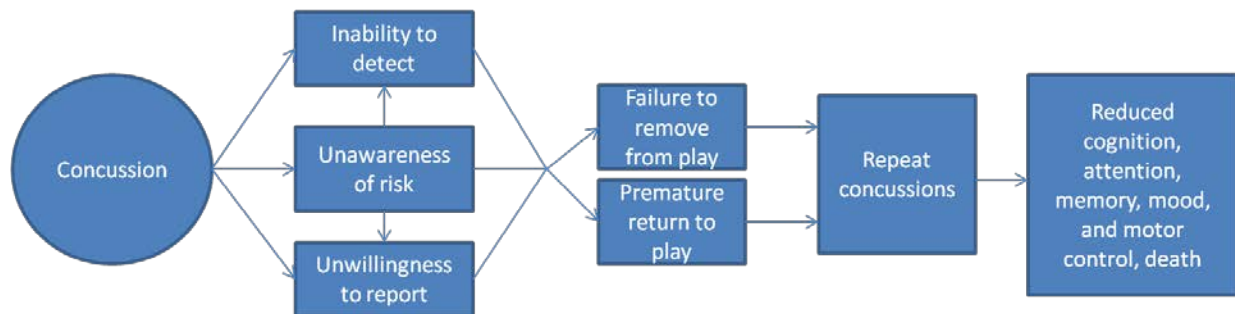
Researchers also define problems, but they do so by methods and for reasons that are usefully different than those of policy professionals. Epidemiological statistics and clinical knowledge are often eagerly collected by policy entrepreneurs as they define problems for action, but researchers can do more than supply raw statistical and anecdotal material for the constructions of others. Researchers can promote the framing of problems in a manner that is consistent with the available direct evidence and applicable theoretical models. This includes making implicit understanding about the causes of a health problem explicit in clear models, and then identifying the areas of those models that are complex and uncertain. It means linking proximate and more distal causes, and characterizing to what degree those links may be addressed as modifiable risk behavior or contingencies in the social and physical environment. Not all of these contributions will be salient or acceptable or effective in the policy world, but all will tend to promote more robust problem description to the extent they are influential in any given case.

Causal mapping is a practical way for researchers to enrich the problem with or for non-scientists. We use the term "mapping" here to embrace any visual tool that purports to depict how one variable influences another or changes over time. In health policy making, causal diagrams "can help to describe ("how things are now..."), classify ("why things go together..."), explain ("how things really work..."), predict ("what will happen if..."), and decide ("what you should do now...")" (Swanson and Ibrahim 2011). Pictures are a well-established tool for simplifying the complicated (Bartholomew, Parcel, and Kok 1998; Kellogg Foundation 1998), and the *exercise* of trying to do so is itself a useful intervention for making the

implicit explicit. Here we will demonstrate how causal mapping can first explain, and then raise some questions about, the Lystedt Law model.

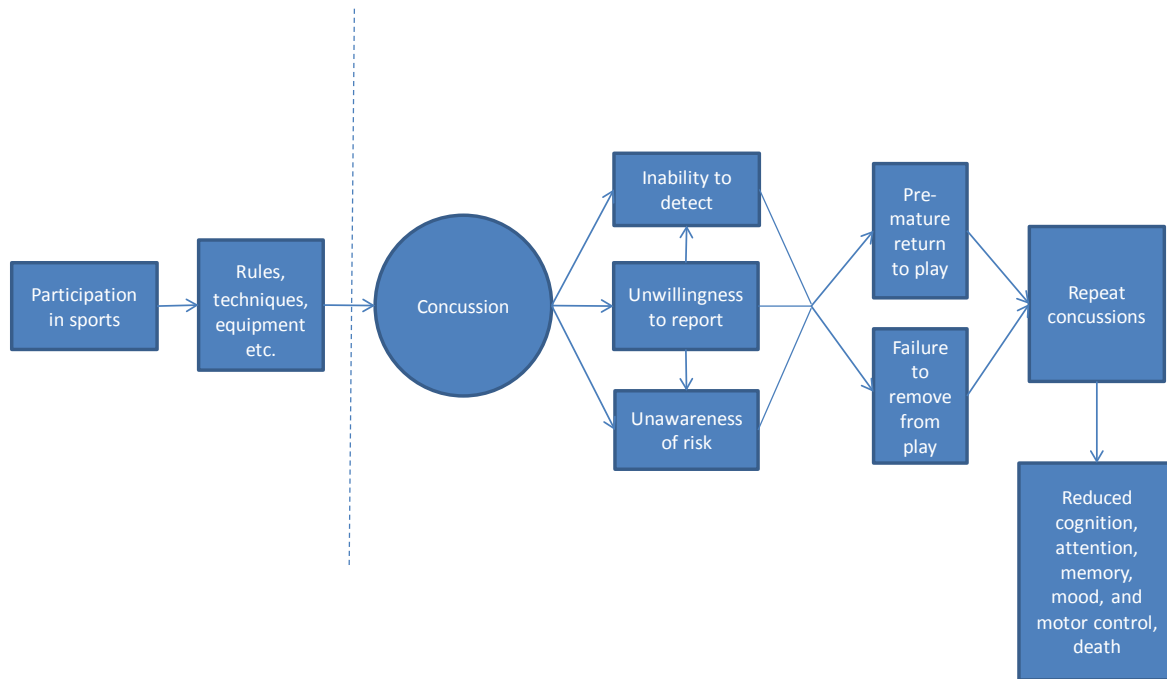
One can easily draw the causal diagram of youth sport concussions as explained by USA Football:

Figure 3. "The Problem" According to USA Football



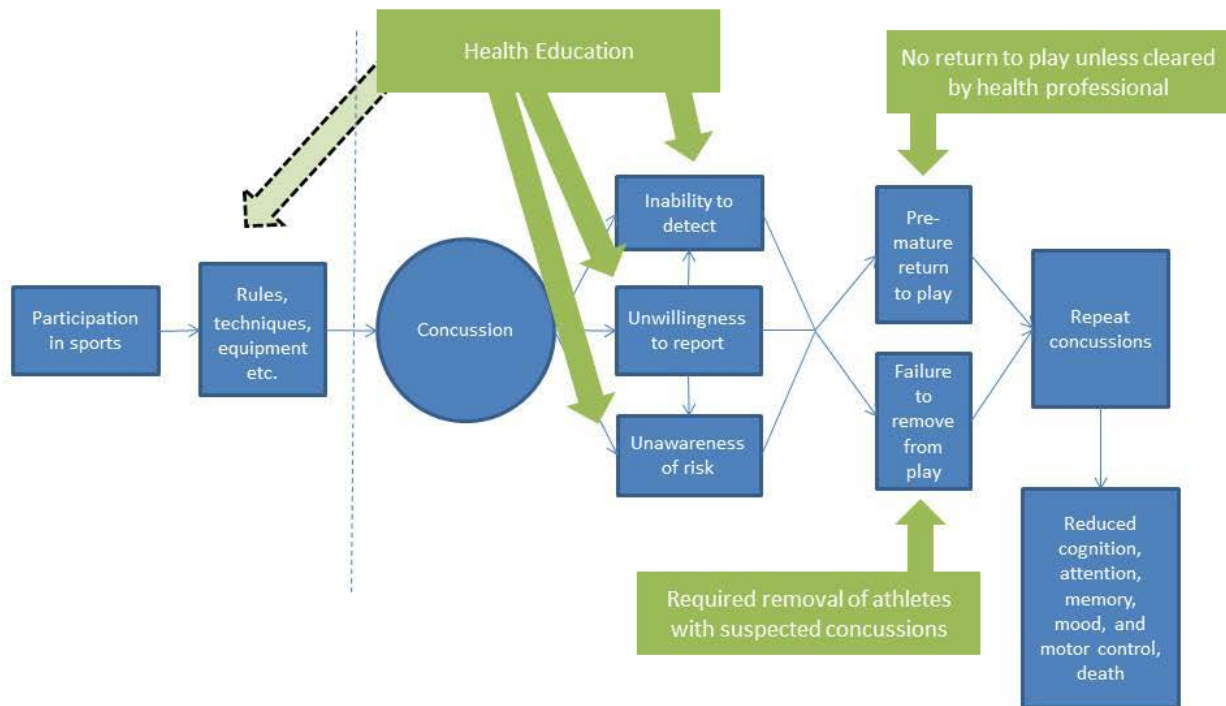
Here the problems to be solved lie between initial and repeat concussion, and consist in improving the detection of concussions and ensuring that kids who suffer them are removed from play and given adequate time to recover. A researcher in public health would see this as secondary prevention, and might add a bit more on the left:

Figure 4. Expanding the “Problem”



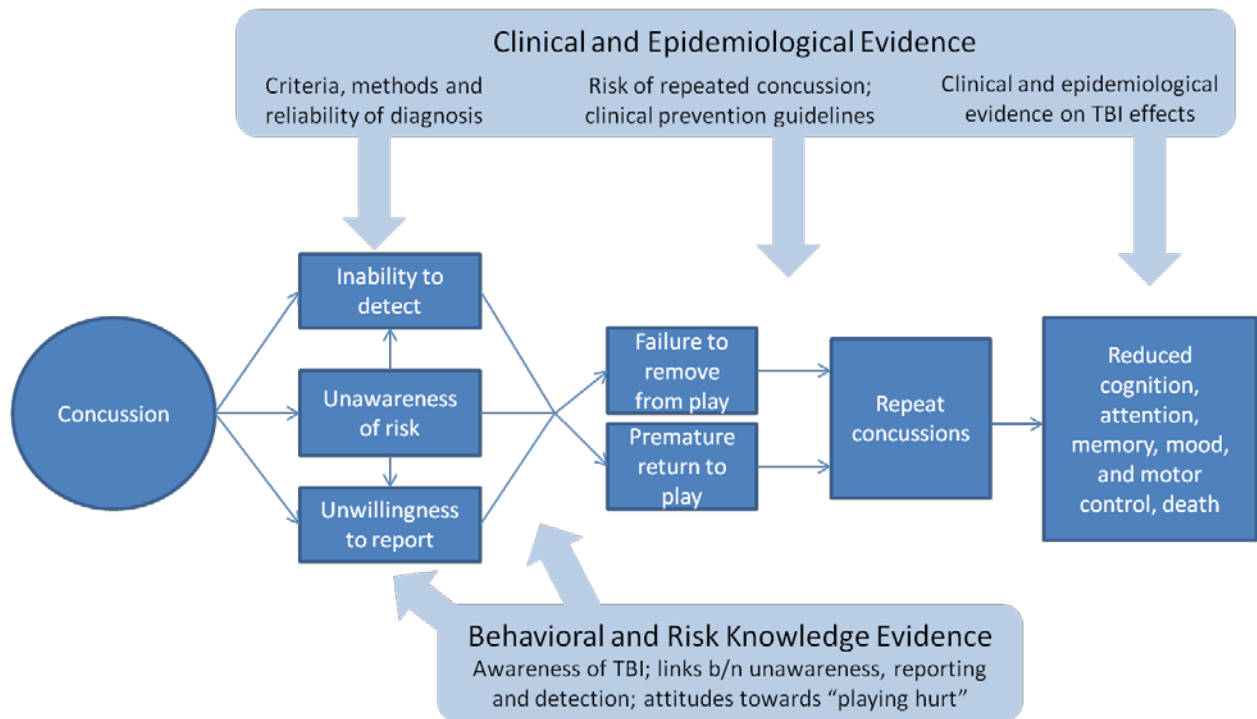
The dotted line here represents what may have been perceived by many participants as the border of political reality. Research knowledge may be able to change the definition of the problem in real time, expanding the range of conceivable interventions. Even if it can't, problem-definition, practiced well, is not simply about finding an actionable solution under present political circumstances, but also about building a foundation for future action. With the initial concussion as a given, the logic of the Lystedt approach becomes apparent (Figure 5): education addresses the factors that lead to non-detection and continued play, while new rules define the required response. If the education part succeeds (and research continues to expand understanding of the drivers of concussion risk), the dotted line of political reality could move. (Thus, Figure 2 notes that in 2012, the youth Pop Warner football program instituted rule changes aimed at reducing youth TBI.)

Figure 5. *The Lystedt Law: How It Works*



As Figure 6 indicates, research knowledge could have, and almost certainly did, influence the evolution of this problem and solution. Clinical and epidemiological evidence helped people see that Zachary Lystedt was not the only child suffering concussion injury, even if his was unusually severe. Clinical, if not epidemiological knowledge, supported concern about the risks of returning to play “too soon.” Studies confirmed the severe cumulative effects of repeat concussions in young athletes and identified a range of harms other than the acute trauma witnessed with Zachary (Collins et al. 2002). Observational and survey research found that many high school football players who suffer a concussion return to play the same day (Guskiewicz et al. 2000) and the reasons why (unaware of the seriousness of the injury or fearful of being removed from competition (McCrea et al. 2004)).

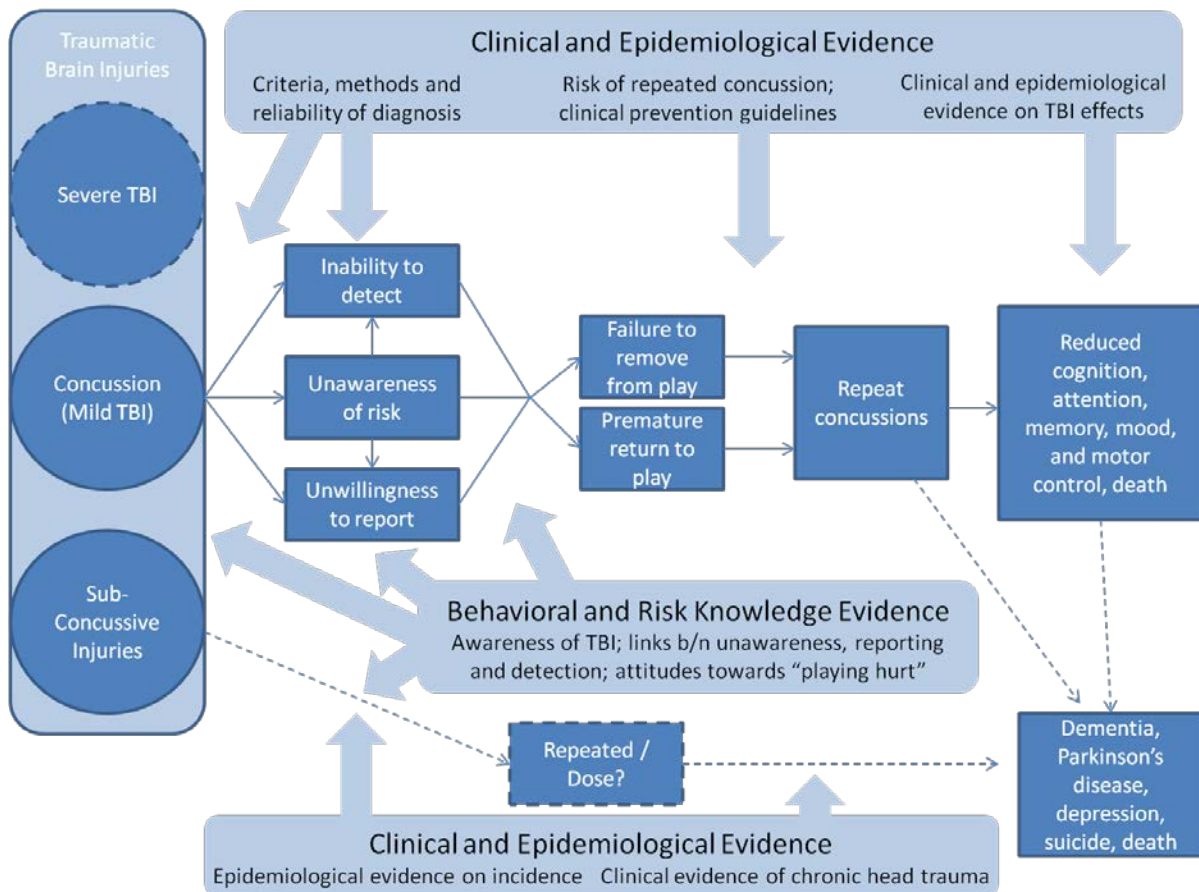
Figure 6. Bringing Evidence into the Picture



Even if we accept the line of political reality, there is research knowledge available to usefully complicate the problem. One place to start is with the term “concussion.” CDC defines it simply as a type of traumatic brain injury (TBI) caused by “a bump, blow, or jolt to the head that can change the way your brain normally works”(CDC 2013). For the purposes of health education, this teaches that any head injury is potentially important. As the cornerstone of health intervention or general policy planning in the area, however, it may be a little *too* simple. Concussion (from the Latin for “shaking”) often occurs without any external contact to head through inertial forces transmitted through the body that jostle the brain within the skull. This explains why, as a recent international consensus statement on sports concussion reminds, helmets are not proven to reduce incidence (McCrory et al. 2013). The focus on concussion, traditionally associated with rare severe hits, may obscure the potential harms of more frequent and slight head impacts as with soccer head-balls and routine contact between football linemen. Research about this chronic brain jostling – depicted in Figure 7 – is just emerging in the form of studies that track exposure to sub-concussive hits, explore risk relationships and detail potentially-related neurological harm (Gardner, Iverson, and McCrory 2013).

Available research also adds some complexity to the “rest and medical care” model for solving the problem. It is actually not clear from existing evidence that the legislatively prescribed recuperation periods, or clinical practices for determining adequate periods of recuperation, are appropriate (McCroory et al. 2013). One large study found that many concussed high school athletes did not wait for symptoms to resolve before resuming play and those that did were no less likely to suffer another concussion that year or to exhibit more lingering sequelae 45 and 90 days after their premature return (McCrea et al. 2009). How much do we know about the time period needed for recovery for various ages and genders? How reliable are clinical measures of recovery? The fact that we don’t have answers to these questions is an important kind of knowledge for policy-makers to consider. It does not make the Lystedt Law approach wrong, but it does make it fragile.

Figure 7. Considering Alternate Causal Mechanisms and More Distal Harms



There are good political reasons for staying away from the rules, the equipment, playing field design and other factors that implicate fundamental aspects of the game or the culture; nor is research yet pointing confidently to solutions in those realms. Premature return to play seems like a sensible pressure point for reducing harm to young people in sports. But perhaps we should be a bit worried about the gaps in our knowledge about what the right return to play practice should be, and also more open to options for primary prevention. In the next section we illustrate how established public health theories and strategies can be used to identify a broader range of legal interventions and consider the likely strengths and weakness of their respective designs. None of these can be sure to have replaced or modified the Lystedt model, but they might have, and they represent important options for the future.

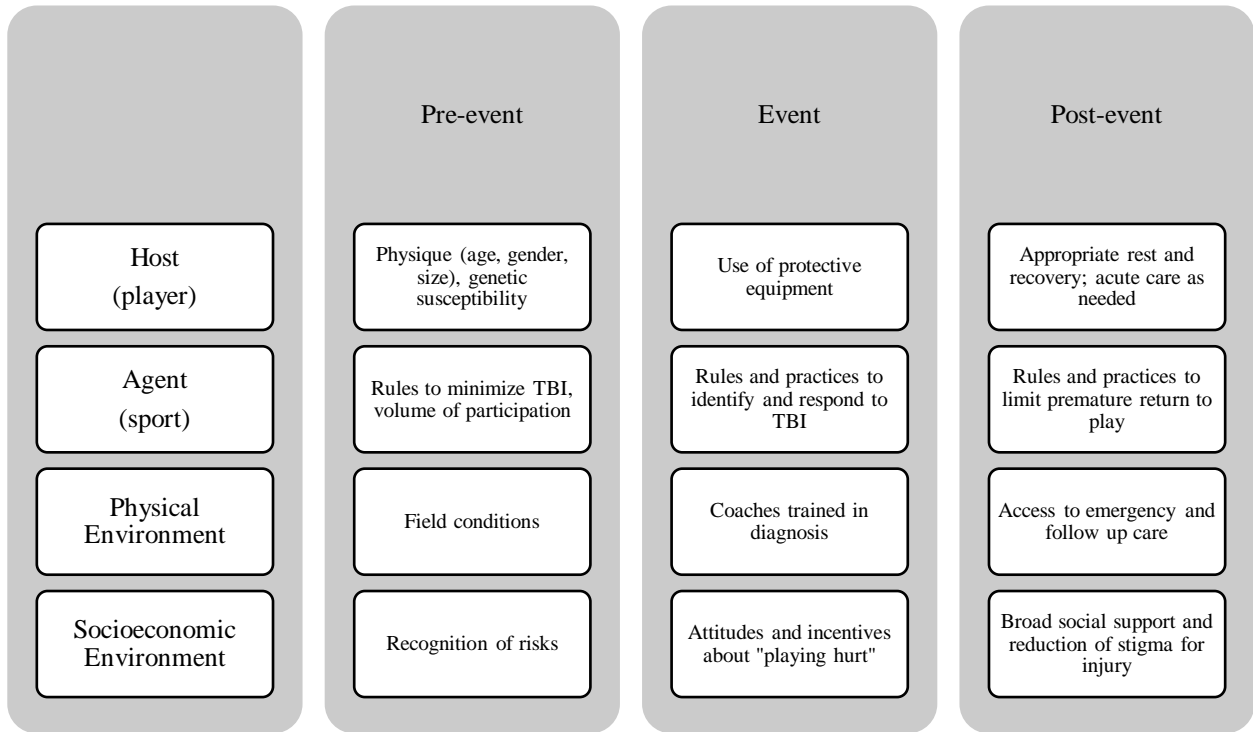
Step 2: Identifying Intervention Strategies

As in the process of defining the problem and its pathology, mapping is a valuable tool for organizing evidence and systematically thinking about plausible intervention strategies. Given the impetus of a politically effective problem definition, the stage of devising an intervention offers a second chance to understand the problem more capaciously. Researchers have at hand well-tested tools for these purposes. An excellent one was created by William Haddon, a pioneer in the science of injury prevention. Haddon recognized that all harms can be considered in terms of the interaction between a host, an agent and the social and physical environment over time. The resulting typology supports a matrix of approaches to addressing population harms (Haddon 1980). A completed matrix helps identify what to target (hosts, agents, and environments) and when (before, during, and after the event).

Figure 8 is a representative Haddon Matrix for youth sports concussion. The “host” is the athlete who suffers the head injury and the “agent” of harm is participation in sport. Age, size, gender, and genetics are important attributes that are known to influence concussion risk for athletes. Rules and volume of play are obvious risk factors for sports as an agent of harm. The “physical environment” encompasses fields, equipment, size and speed of other players, and the nature of contact within the sport and the availability of coaches and others educated in concussion risk and diagnosis. The “socioeconomic environment” is shaped by a broader range of social norms including meaning of concussion risks, aggressive play, and “playing hurt.” Attention to social dynamics is particularly important in a case like this, where the risk arises within a culturally important activity: a young player’s dedication to his or her sport has traditionally been seen as both praiseworthy and healthy. Reducing risk may require a change in culture such that sporting performance weighs a little less and health a little more. The “event” phase is when head contact or another jarring force to the body occurs. The “pre-event” phase represents conditions that may be targeted for primary prevention;

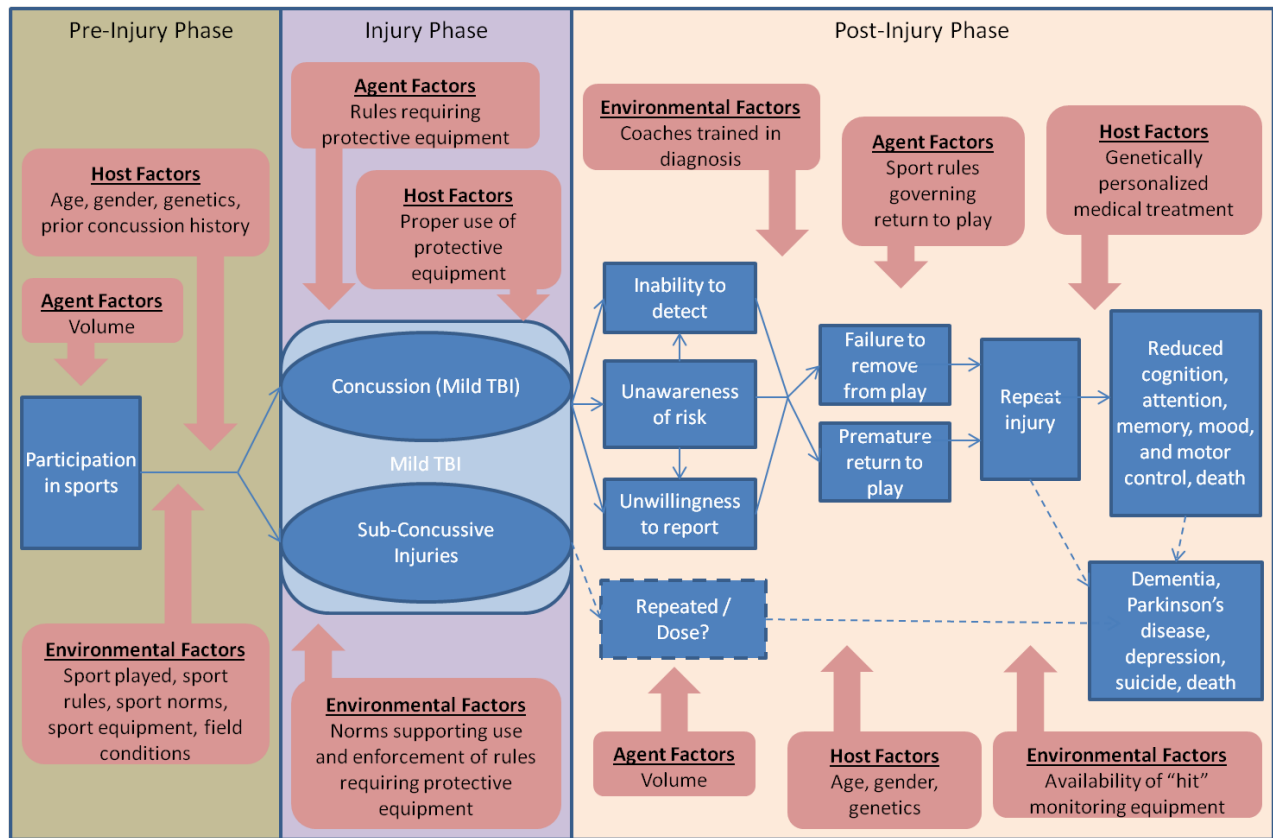
the “post-event” phase refers to possibility of reducing the harmfulness of inertial forces on the brain after impact occurs, and secondary prevention.

Figure 8. Haddon Matrix for Sports Concussions



The Haddon Matrix is a good tool for reexamining preconceived notions of a problem and looking for alternate intervention strategies. In Figure 9, the colored sections designate the three event phases. In each phase, important modifiable attributes of the agent, host and environment are noted.

Figure 9. Using the Haddon-Matrix to Revise a Sports Concussion Model



The Haddon Matrix helps bring attention to plausibly modifiable risk factors. Although not all actions targeting those risk factors are suitable to be done through law, a tool like Figure 9 can nevertheless be useful to a policy-maker or advocate as a guide for how to use available public health authority. The value of changing public perceptions of sports concussion cannot be overstated, and in legislating to address what happens after a concussion, policy-makers can reform environmental factors that influence the risk of primary concussion. Legislative signals, and changing public perceptions, probably had something to do with rule changes in youth and college sports (e.g., limiting the amount of full-contact practice), and with the decisions of the NFL and the National Institutes of Health (NIH) to invest more in concussion research. A broader cultural change towards health will begin to express itself in parents, coaches and even young athletes who find it unacceptable to place kids in a position where a significant risk of serious injury is “just part of the game.”

Step 3: Selecting Legal Interventions by Using Evidence of "How Law Works"

Once a consensus developed around the Lystedt approach, choices remained about how to implement each of its three primary elements. These choices raise questions about regulatory authority: Who will be required to do what? This is in one sense a technical legal matter, but in the case of youth sports and many other public health problems, sources of legal authority are typically available and apparent. Lawyers and policy-makers knew they could order state and local agencies to create and distribute information, require licensed coaches to receive information or demonstrate competencies, place conditions on sports participation, establish rules of behavior and set penalties for non-compliance. New legal interventions like the Lystedt law are, by definition, innovations not tried before with a particular problem. But the mechanisms through which they change behavior have almost always been deployed and evaluated in other contexts (Pawson 2002). Researchers can add value by bringing evidence to bear on how well these generic strategies generally work and under what conditions, knowledge that can illuminate decisions about how to design the regulatory system for sports concussion. Evidence about these *mechanisms of legal effect* therefore provides a helpful guide for the initial formulation, subsequent testing, and ongoing refinement of regulatory designs.

Mandated health education is a common legal intervention. There is no doubt that law can ensure that a sign is posted, a document transmitted and received, a training process completed. Regulatory designers in this instance could have chosen from a range of well-established models, ranging from simply requiring that information be posted in schools and locker rooms to requiring that the licensure requirements for coaches be changed to include training and demonstrated competency in concussion diagnosis and management. In the Lystedt Law, Washington's legislature barely pushed its available regulatory levers. It did not specify any route or amount of training for coaches, leaving the design and provision to individual school districts and the interscholastic athletics association. For parents and players, it required the annual receipt, signature and return of an information form. Most other states also used this informed consent model with parents, but twenty-nine states have explicitly required some kind of coach training. The laws vary, but generally delegate the task of creating and providing the training to a health department, school district or interscholastic athletic organization. Connecticut seems to push hardest, requiring completion of a training course in concussion management as a condition of licensure, with a refresher course every five years.

Posting health and safety information has long been used with good effect to transmit basic health and safety information and rules (Rousseau and Wogalter 2006), and sports concussion awareness mailings to pediatricians have been found to increase knowledge (Chrisman, Schiff, and Rivara 2011). However, regulations aimed at promoting complex competencies (like spotting and managing a concussion) typically

use more demanding mechanisms like certification or licensure based on specified curricula and/or passage of examinations. (Maisonneuve et al. 2009; Young and Willie 1984; Bloom 2005; Forsetlund et al. 2009).

Likewise, evidence from medicine and human research subject protection casts some doubt on the effectiveness of the sort of informed consent the law created for parents and students, especially when subjects are motivated to participate. From a researcher perspective, framers of most laws have done about as little as they could to ensure that the right information was received and understood by the right people.

Law is a reliable way to organize the provision of specified information to a specified class of recipients, but of course the real challenge is to change knowledge into behavior change (Fishbein and Ajzen 1975; Rosenstock 1966). Commonly, law's special advantage over other modes of behavior change is thought to be the power of punishment, which uses the mechanism of deterrence to secure compliance with a stated standard of behavior. If anything, however, the Lystedt Law in its original Washington version disclaimed deterrence, going so far as to create an immunity from tort liability for those who followed its minimal requirements. Pennsylvania law makers, by contrast, were willing to give deterrence a chance: coaches who fail to remove players from the game after a possible concussion can be punished by temporary (and in repeat cases, permanent) suspension (PA Statute 24-5323). Which legislature got it right? Deterrence as a mechanism for promoting compliance with legal standards has been studied extensively, and we know that it depends upon three key perceptions in the actor's mind: that non-compliance will be detected, that punishment will be quick, and that it will be more unpleasant than non-compliance is rewarding (Jennings and Mieczkowski 2013). From this perspective, we can see some problems in the Lystedt case. In most states, there are no penalties, nor is any agency given the job of watching over compliance. Even in Pennsylvania, no enforcement system beyond parental complaint was established. And in all states, deterrence runs into a problem that the rewards of non-compliance (winning for the coaches, staying in the game for the students and parents) may be perceived as more valuable than the sanctions are costly.

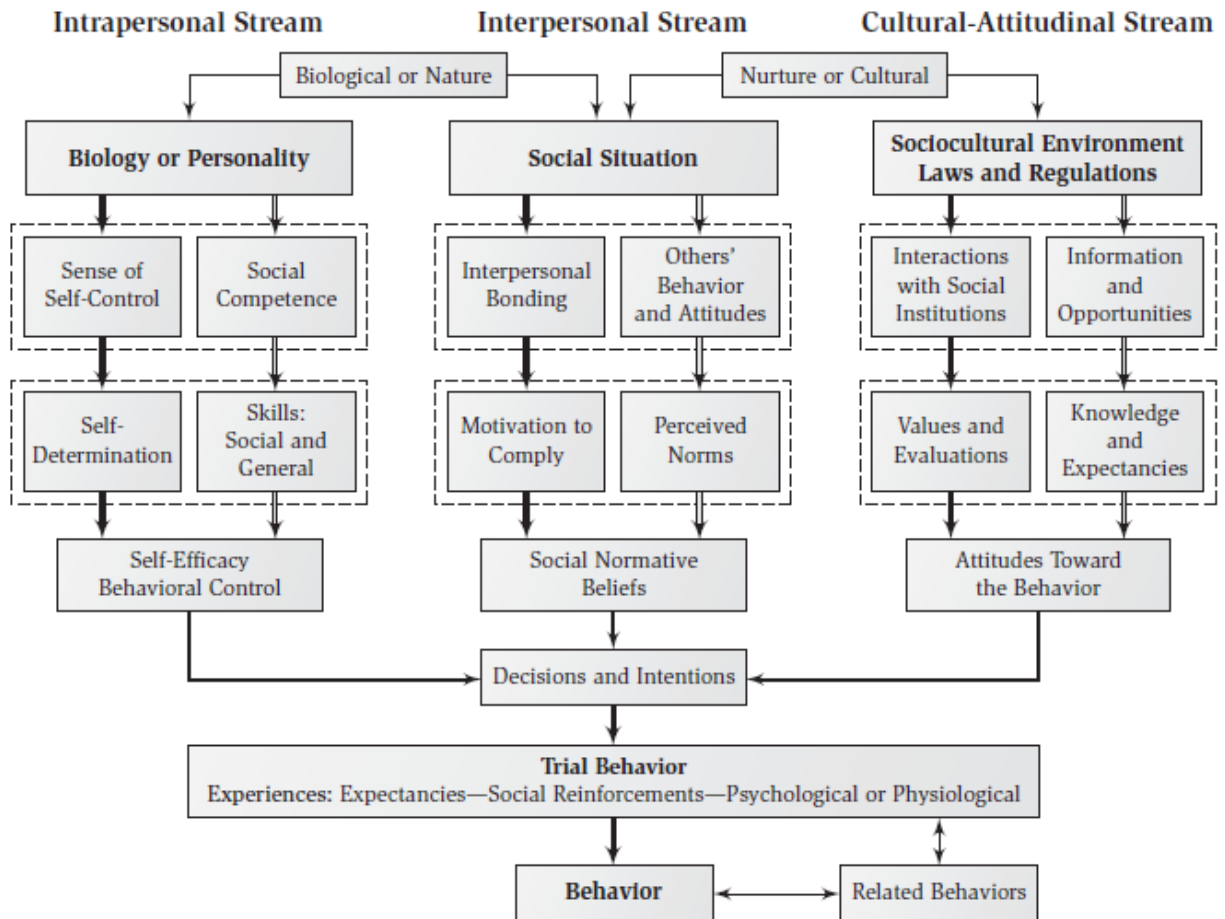
Do the modest education requirements, the lack of punishment, and the absence of an enforcement system mean the Lystedt model is toothless and not intended to work? Not necessarily. Deterrence is only one mechanism for getting people to obey the law, and one that is perhaps relied on more often than it deserves (Tyler 2006). In many if not most cases, law works best (and most efficiently) when people obey the law voluntarily, without state enforcement. Indeed, there is some evidence that deterrence, if mechanically applied, can actually decrease this sort of internal motivation to comply (Tyler and Mentovich 2013). The Lystedt law in Washington can also be understood, and consciously enhanced, as a psychosocial intervention, whose mechanism of effect is social normative change. Its best chance of working may be through a change in culture that brings different expectations of sports safety into homes and onto bleachers, such that coaches perceive a different set of risks and rewards, and the law is enforced by hundreds of onlookers and players at every game. Although the use of law in this role may be unfamiliar or underappreciated, psychosocial

interventions are ubiquitous in public health promotion, using strategies grounded in behavioral theory and research.

We will illustrate with the Theory of Triadic Influence, which integrates well-established theories of change along three “streams”: cultural, interpersonal and intrapersonal (Flay and Shure 2013). The Lystedt Law changes the sociocultural environment (depicted in Figure 9) by establishing a new behavioral standard for coaches. Coaches see the new rules being operationalized in institutions, changing their sense of what will happen to them if they don’t change their practices with respect to concussions, and of how likely they are to run into trouble. These experiences can change their attitudes towards their prior behavior and give them a more positive view of the behavior mandated by the law.

The influence of law is also felt in the interpersonal and intrapersonal streams. In the interpersonal stream, the law and its factual premises can become a feature of the individual’s community, peer and family relationships, manifested not just in attitudes but also the behavior of others. These change the individual’s perceptions of what is normative in the community, and triggers the desire to please others to whom the individual is bonded. The law thus changes interpersonal relations as norms begin to reshape the context and social negotiations of “playing hurt” and other risky behaviors. What was once accepted as good or normal (or even heroic) begins to be seen by some as deviant, and these changing group norms influence coaches’ understanding of how their decisions will be viewed by parents and professional peers. Intrapersonally, a clear rule of behavior, recognized as at least a possible social norm, can increase an individual’s ability to follow the rule, supporting self-control and/or giving the individual a pro-social justification for the new behavior. On this view, law works through social, institutional and individual affective processes to produce “voluntary” compliance without overt government oversight or threats of government sanctions. It is about a culture of health, not a culture of compliance.

Figure 9. The Theory of Triadic Influence



SOURCE: BRIAN R. FLAY & MARC B. SCHURE, THE THEORY OF TRIADIC INFLUENCE. IN: PUBLIC HEALTH LAW RESEARCH: THEORIES AND METHODS, 2013 (EDS. ALEXANDER C. WAGENAAR & SCOTT BURRIS), SAN FRANCISCO, CA: JOSSEY-BASS.

Deliberately or not, the drafters of the Lystedt Law chose to rely on a social normative mechanism to induce voluntary behavior change. In so doing, they were choosing a mechanism of legal effect that has a solid evidence base in experiences like drunk driving and limits on public smoking. A researcher drawing on knowledge of this mechanism could point to the importance of the social marketing component of the law (mandated information) and of a robust social marketing effort outside of and beyond the law. There is no formal government oversight of compliance in many instances for the removal and return to play components, but if parental education works, the stands will be full of “police.” Likewise, even if no actual legally-stipulated penalties exists, a social-normative model like the Theory of Triadic Influence ultimately

contemplates some “punishment”: under the Lystedt model, if it works, coaches who fail to identify potential injuries or enforce a waiting period can be subject to social disapproval, expressed in interpersonal situations or through secondary channels of state enforcement – i.e., complaints to the school administration. These kinds of social sanctions, for most people, are quite powerful.

An understanding of how legal rules actually produce changes in behavior can help reassure us that the Lystedt approach, which stipulates no enforcement or punishment, can actually have powerful behavioral effects – but only if community norms change. Attention to mechanisms of effect is also necessary to evaluation and ongoing refinement. Recent research in Washington State confirms that coaches and student-athletes are getting the health education on sport concussion risk required by law (Chrisman et al. 2014). But a large proportion of student-athletes in the state continue to hide concussion symptoms from coaches and parents, remaining in active participation (Rivara et al. 2014). Moreover, a large proportion of student-athletes in the state continue to hide concussion symptoms from coaches and parents, remaining in active participation (Rivara et al. 2014). If norms are changing, they are changing slowly. Rivara and colleagues suggest that more objective and accurate detection methods are needed; a social norm perspective suggests stronger reinforcement of the norm would be just as important.

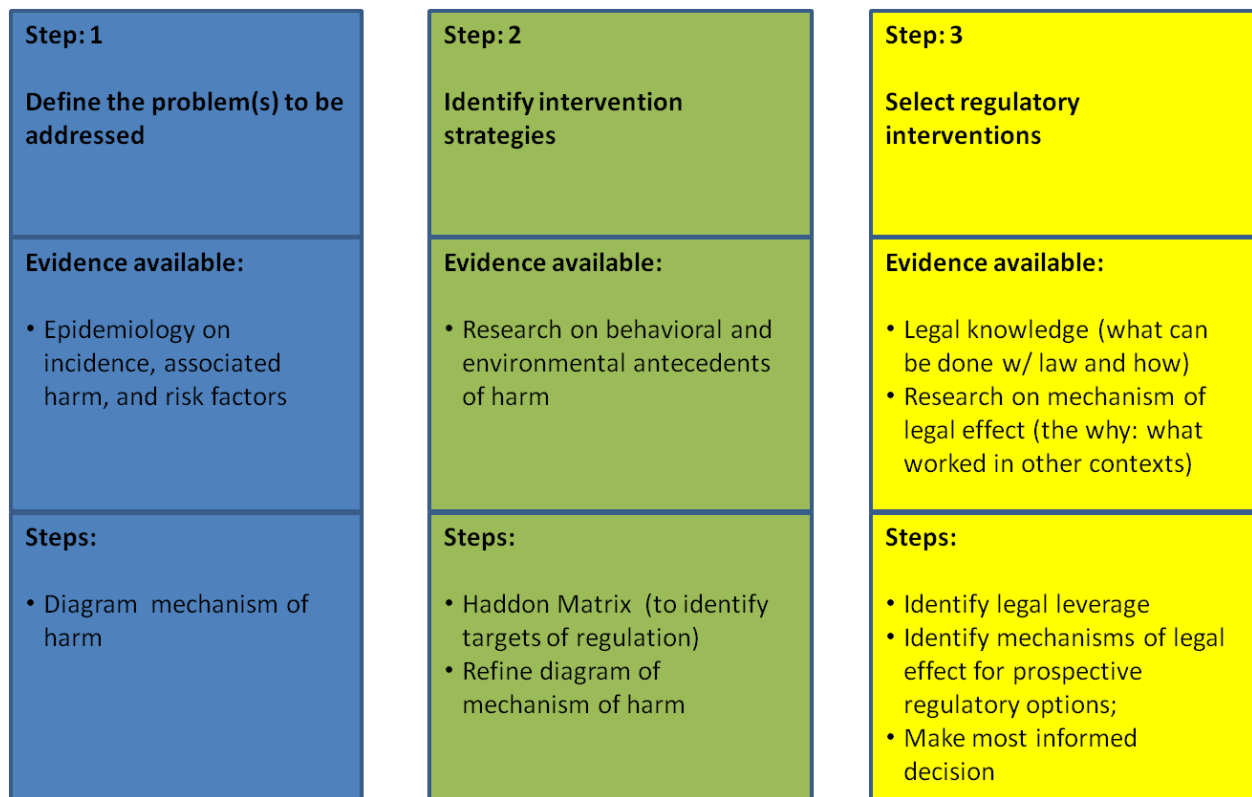
Part 3: Discussion and Conclusion: Three Actions in Search of a Practice

What we have just presented may strike even a charitable reader as an extended excursion through the obvious, with occasional detours to the well-known. Precisely. The steps we have described, and set out here in Figure 10, *must* be taken by anyone moving between the desire for a law and a bill. In that light, anyone who has watched or participated or studied the law-making process will be able to call to mind instances in which the various steps were taken mindfully with as much information as possible. And anyone can also call to mind instances in which the three steps were taken in a heedless sprint. Figure 10 also summarizes generic forms of research-based knowledge (aka “evidence”) that will often be available to inform the law-making process even when the particular intervention or target is novel. It is pretty obvious, for example, that epidemiological data have a big influence on defining a phenomenon as a health problem, and that regulatory expertise can help drafters design a rule that will work in practice. Here, too, what happens in practice does sometimes but not always match what is possible.

In this paper aimed primarily at researchers and brokers of evidence-informed policies, we have laid all this out explicitly to draw attention to the opportunity to bring research knowledge to bear in policy innovation – an opportunity that is not explicitly addressed, let alone thoroughly considered, in the current

literature on research translation. As the child restraint story suggests, the work is seldom done with the initial adoption of law. Legal interventions, like youth sports concussion laws, are constantly being refined, reflecting both the political constraints on early action and related evolution of understanding of problems and solutions. Especially at an early stage of understanding and action, a legislator might quite plausibly regard doing *something* the best way to proceed towards figuring out and building support for the *right thing* down the road. The policy learning process is capable of moving us towards the optimal laws. But how quickly we arrive there, and therefore how much harm we avoid along the way, depends on the quality of both the experimentation and the subsequent evaluation. The process we sketch serves both interests. On the experimentation side it helps bring evidence to bear on the specific regulatory choices associated with emerging solutions. Specifying these choices and their underlying logic in turn provides a map to guide evaluators in deciphering whether laws are working as expected.

Figure 10. A Simple Process



One goal of this paper is to make explicit certain actions that researchers can take to encourage evidence translation even in the crafting of new laws to address emerging problems. Our decentralized regulatory system relies on policy experimentation. There is imperative and perhaps an unrealized ethic to do it as well as possible using every opportunity for incremental improvement. This requires promoting and modeling a

culture of critical thinking that explicitly avoids the idea that innovation means or validates evidence-free decisions.

Conclusion

In the last few decades, there has been a broad effort to strengthen the use of law as a tool for the promotion of population health. There are two major fronts in the campaign, each essential, and both largely successful, though much work also remains. One aims to increase the quantity and quality of empirical research on the health effects of existing policy choices (Burris et al. 2010). The other focuses on how best to get such knowledge into action in the form of policy and practice (Brownson, Colditz, and Proctor 2012). In this paper, we draw attention to a third front: the formulation of new legal interventions. Though policy experimentation is necessary for evaluation research and translation and implementation, it has been the subject of relatively little systematic study. For proponents of evidence-based public health law, policy experimentation presents a paradox: if a legal intervention is truly innovative, there will not yet be direct evidence of its impact. Yet direct evidence from policy evaluations is never the only source of research knowledge relevant to a policy decision, even under conditions of novelty and uncertainty. And few interventions are truly new in a broad sense; in most instances, similarly designed laws have been deployed before, just not for the same specific purpose.

In Part 1, we presented the evolution of child restraint laws as an example of policy learning beginning with their appearance in the late 1970s. There is, of course, more to the story. By the early 1970s, the toll of child injury in motor vehicle crashes was clear, and research had identified technology that could provide significant protection to young bodies. But appropriate and consistent use of the devices was lacking. Compliance was especially low earliest in a child's life when parents felt most strongly about holding their children while riding as passengers. Clearly small children should not be entirely free in a moving motor vehicle – that much was obvious – but what was the harm of being restrained in the arms of a parent or sibling rather than a child seat? The answer from physicists (Mohan and Schneider 1979) helped the public health community refine its view of the problem:

Can a mother of a newborn baby lift 200 pounds? This is a question a physician might ask when discussing automobile restraints. For in a head-on accident during the infant's first ride home from the hospital, with an impact of only 10 mph, this is the restraining force the mother must exert to hold the infant. At 30 mph, the infant can easily reach a peak weight of almost 600 pounds within 3 milliseconds. . . the mother . . . does not realize that she needs help. (Scherz 1976)

We see a similar turn today in how the science of sports concussion is unsettling preconceived notions of the nature of that problem and pointing interventionists towards new and better levers for reducing incidence and associated harms.

Armed with a solid understanding of the problem of child injury in crashes, the motor safety community was confronted by the question: what next? In a process in which Haddon himself participated, researchers began exploring different strategies for increasing restraint use. Some, like television education campaigns, failed miserably (Robertson et al. 1974); other more targeted efforts fared slightly better but were expensive, inefficient, and/or difficult to scale (Allen and Bergman 1976). Striking at the heart of reliance on health education were findings that appropriate use had no relationship with parental knowledge about either the risks of child injury in motor vehicles or knowledge about prescribed recommendations for device use by safety experts (Neumann et al. 1974). Attention turned finally to mandates, with support coalescing into the requisite political will for the first time in Tennessee, the first state to require the use of restraint devices for child passengers. At the time, the idea of using legislation to regulate such behavior was politically and legally controversial (Wanebo 1980). However, recent experience with new state laws requiring helmets by motorcyclists provided evidence that a mandate could change behavior and save lives (Robertson 1976).

There are many important value questions about specific legal interventions, about which reasonable minds can often disagree. There are likewise a host of political and social influences on how government wields authority. But there is no reason that the creation of new policies should be any less systematic than the evaluation of existing ones or the dissemination of findings. In this paper we have set out a three step process for systematically considering legal intervention in the face of a new or entrenched public health problem. When a new threat to health emerges onto the legislative agenda as a “problem,” lawmakers and advocates face several common challenges. First, they have to get a good grip on the problem for both political and practical reasons. Problems, after all, define solutions. It is not uncommon for an inaccurate characterization of a problem to lead to ineffective legislation. Second, they must choose a legal approach. Many options for legal interventions are likely to emerge quickly, reflecting a variety of interests. Heuristics like Haddon's Matrix and the use of diagramming more generally are helpful for organizing evidence, identifying uncertainty and grappling with intervention approaches. Finally, crafting a new legal intervention entails many choices of regulatory strategy, each of which has the potential to enhance or diminish its impact. Deliberate consideration of past experiences with particular legal mechanisms is often a source of valuable insight and guidance.

The implications of our inquiry are modest but (we hope) useful. Our approach is a mix of the descriptive and the prescriptive, and seeks to make explicit the tacit reasoning that prevails in policymaking. At a minimum, our three steps highlight the fact that evidence can have a decisive impact in policy, even at the policy-experimentation stage. We hope others will follow, refining and elaborating on the role that researchers and research can play in policy innovation.

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