

Legislating for Health: Locating the Evidence

(Running Title: Legislating for Health)

Abstract:

The paper examines the timorous courtship between public health law and evidence based policy. Legislation, in the form of direct prescriptions or proscriptions on behaviour, is perhaps the most powerful tool available to the public health policy maker. Increasingly, the same policy makers have striven to ensure that interventions are based soundly on a secure evidence base. The modern mantra is that the policies to follow are the ones that have been demonstrated to work. Legislative interventions, involving as they do the trade off between public benefit and private interests, present formidable challenges for the evaluator. Accordingly, systematic reviews of their overall efficacy, the main tool of evidence based policy, are in their infancy. The paper presents a design for such reviews using the example of a forthcoming synthesis on the effectiveness of banning smoking in cars carrying children.

Key words:

Evidence-based policy, public health law, smoking bans, realist synthesis.

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Introduction

The apparatus of evidence-based policy, systematic review, meta-analysis, and so on is now quite considerable.¹ Legislative interventions, both in general and in public health policy, have remained somewhat distanced from such scrutiny. The more's the pity because usage of the law provides a seemingly powerful tool for affecting change. In the case of public health, a domain where progress is often slow and piecemeal, the argument has become compelling.² With the national coffers dwindling, sentiments are growing suggesting that it is time to introduce more immediate curbs on people's behaviour.³ A handful of examples of the varied public health domains in which such legislation already operates are given in Box 1. The big issue is whether we have evidence to show that they work and the data to decide whether they should be extended.

Box 1: Required and prohibited behaviour in public health legislation

Compulsory seat belts, corporal punishment bans, smoking-free bars, workplaces and public places, fines for under-age tobacco/alcohol sales, banning hand-held phones in cars, prohibiting driving whilst intoxicated, compulsory motor/cycle helmets, compulsory nutrition labelling, compulsory vaccination / screening, limiting sales of non-prescription medications, firearms control and amnesties.

First principles

This paper attempts to answer this grand challenge with a research design. It considers how one might go about collecting and synthesising evidence to help judge the efficacy of public health law. There is a keen debate underway about the best strategy

for conducting such reviews.⁴⁻⁶ We make no attempt to rehearse it here other than to mention that the methods associated with the Cochrane Collaboration, which have proved so valuable in the clinical domain, are often found to be unworkable in other fields of public policy.⁷⁻⁹ And so it is with public health legislation.

- The first stumbling block is the ‘gold-standard’ aspiration that the evidence base should be founded upon studies employing randomised controlled trials. Randomisation is impossible in the case of legislative interventions. The law is the law. We cannot, for example, contrive experiments in which the experimental group is compelled legally to drive around wearing seat belts whilst a control group is absolved of the requirement.
- Another difficulty is the requirement that synthesis should focus on precise outcome indicators, which can be aggregated across primary studies in order to produce authoritative ‘net effect’ calculations of programme efficacy. The measurement of health behaviour ‘in the field’ is infinitely more demanding than in the laboratory test. Consider in this respect, monitoring a ban on smoking in cars carrying children and the mighty surveillance operation that would be needed to discern every furtive puff and cocooned child.
- A third and major conundrum concerns the paramount need for communal endorsement in legislation. This is highlighted in the thoughts of the suffragette Carrie Chapman, ‘No written law has ever been more binding than unwritten custom supported by popular opinion’. Adherence to a law (unlike responses to medication) is strongly conditioned by levels of public support, which are often variable and fickle.
- A fourth limitation is set by the incremental nature of legislation. In mature jurisdictions, all new laws are basically extensions and amendments to

existing law. What is most often needed by way of evidential support is research on the augmentation rather than the core. In the case of evaluations of smoking bans, we find that studies are legion – except where they might now be needed, as in the recently muted extension to cars carrying children.

What then might be a more appropriate method for synthesising evidence on interventions, which are hard to manipulate and control, difficult to observe and measure, sensitive to context and culture, and which mutate under amendments and increments? There is a growing number of alternatives¹, the one pursued here being known as realist synthesis.⁵ Again, we refrain from technical details, concentrating instead on its organising principles.

The core idea is to treat the review of evidence as a form of ‘programme-theory’ evaluation. Public health interventions are brought to life on the basis of considerable forethought. A set of preliminary ideas, ambitions, expectations, hypotheses or ‘programme theories’ is marshalled postulating that *if* certain resources (sometimes material, sometimes educational, sometimes environmental, and sometimes legislative) are provided *then* they will insinuate peoples’ reasoning to a sufficient extent that a change to healthier behaviour will follow. Before they are implemented (and especially when they impact on constitutional matters), new policies are given a ‘plausibility check’ – sometimes under formal consultation and sometimes under informal debate. The programme theory that emerges thus includes ideas about what is going wrong, ideas about how to remedy the deficiency, ideas about how the remedy itself may be undermined and, most importantly, ideas about how to counter these counter threats. The success of a programme is thus a matter of the credibility of its component conjectures.

Realist synthesis can capitalise on this scenario, deepening and formalising the plausibly check by putting the constituent ideas to empirical scrutiny. It begins by eliciting the key theories assumed in the construction of the intervention and then goes on to test their accuracy and scope – the programme is supposed to work like this but what has happened in practice? Empirical evidence is examined with the task of discovering where the policy architects’ assumptions have proved justified and where have they been dashed.

Legislative interventions – a basic programme theory

To many ears talk of the ‘theory’ behind legislative interventions is fanciful. The very idea is to stop pussyfooting around with advice, education and sloganeering and to compel people to behave. In practice, however, law making is less muscular and more nuanced. It is a considered process (Figure 1), inching its way though three broad stages:

- Identification and precise codification of behaviours deemed responsible for poor health
- Drafting regulations under the law to prescribe healthy /proscribe unhealthy activities
- Organising enforcement to mop up recalcitrant behaviour and reinforce compliance

Figure 1: Legislative change – basic programme theory

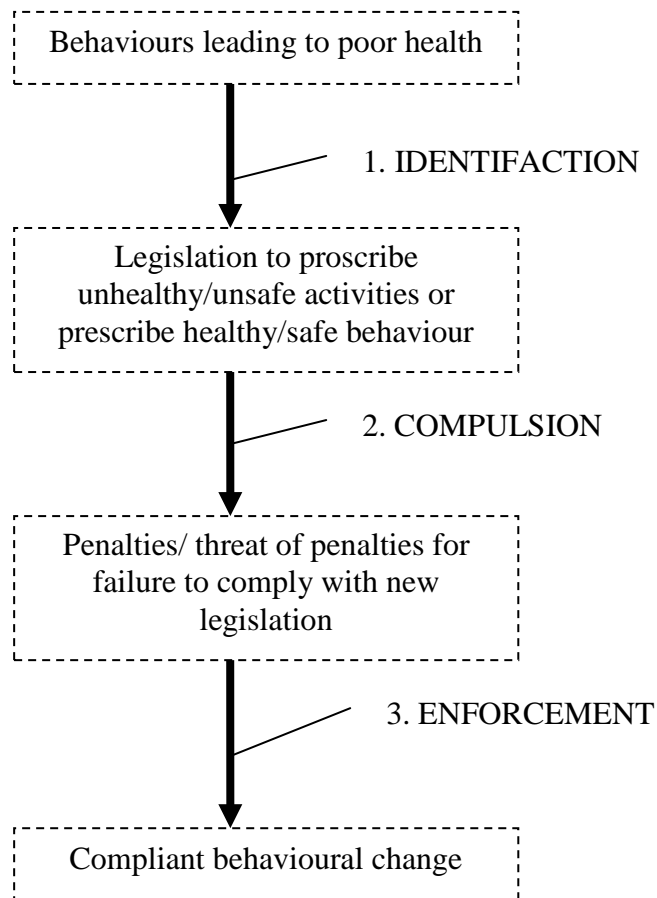
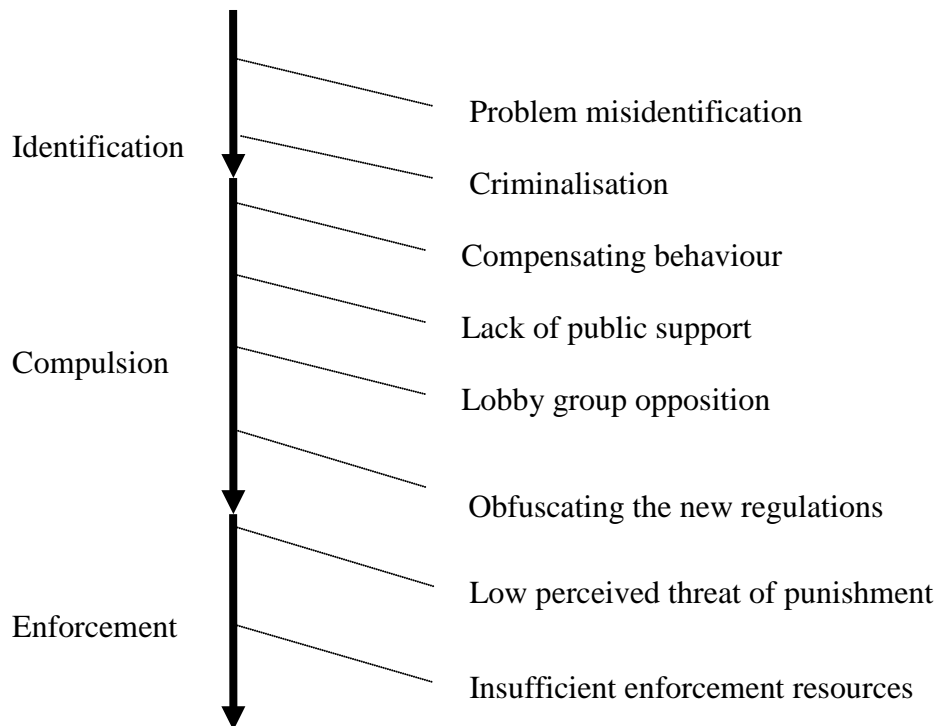


Figure 1 introduces some key analytic distinctions but is little more than a description of the legislative platform. The real ‘theory’ to legislative change lies with the ability to anticipate and deal with a series of stock problems running through this implementation chain. These ‘threats’ occur at each stage: i) failure to assess properly the health risks associated with a particular behaviour; ii) poor drafting of the legislation so that loopholes remain allowing the illicit behaviour to continue; iii) inability to marshal resources to adequately enforce compliance with the new laws. A schematic description of such constraints is catalogued in this section, together with illustrations of the unanticipated consequences that might flow from them. Figure 2 superimposes each threat onto the basic legislative platform. It represents the ‘programme theory’ which, we postulate, may be put to use in any review of any

application of public health legislation. The mechanics of such a review are described in the next section. First, the legislative minefield is described.

Figure 2: Threats to legislation



1. Problem misidentification. This refers to the failure of the initial theory – i.e. the basic diagnosis of the ‘problem’. Is the behaviour to be targeted in the legislation really the major contributor to the public health problem? For instance, in relation to corporal punishment bans to reduce child maltreatment, a case is made that a lesser symptom is being addressed and that mental health problems, marital conflict, ‘mercy killing’ and neglect are the major contributors to child homicide.¹⁰ Similarly, it may be that firearm amnesties harvest only defunct and defective weapons.¹¹

2. Criminalisation and blame: Subjects pursued and prosecuted under new legislation may become toughened in their attempts to pursue illegal behaviour. The classic example of this unintended effect lies in the area of substance abuse. Wolfson and

Hourigan, for example, argue for an ‘amplification of deviance’ hypotheses in the case of young adults (under 21s) prosecuted under the US liquor drinking ban and the tobacco purchase legislation.¹² They point to some evidence that arrest and violations continued to increase after legislation.

3. *Compensating and displaced behaviour.* This refers to the problem that legislation may lower risks, only for the influence to be countermanded by the subject transferring to other risky behaviours. Low fat / low calorie labelling may lead to overeating of seemingly healthy foods – especially those products without a natural ‘serving’ control.¹³ Drivers who wear seat belts may feel safer and drive faster and more carelessly than they would otherwise do.¹⁴ Drivers may over-hasten when clear of enforcement cameras and road humps.¹⁵

4. *Lobby group opposition.* Vested interests do not lie down and die in the face of new legislation. Magzamen and Glantz report on tobacco industry tactics to repeal and undermine a Smoke-free Workplace Law.¹⁶ Attempts were made to obstruct its passage on grounds of: a) awaiting further evidence on the utility of a ‘ventilation solution’, and b) economic arguments about the need for delay to minimise implementation costs, to recruit new staff, and to offset the loss of business.

5. *State of public support / opinion.* An unpopular law will become embroiled in implementation discord. At the other extreme, a law that simply imitates popular opinion will make little difference. Alcohol restriction is generally unpopular and generates all manner of means to circumvent it.¹⁷ By contrast, a case is argued that the declining support for corporal punishment allowed Swedish legislators to ban it –

rather than the law promoting attitudinal changes.¹⁸ Somewhere in the middle is the case of smoking bans in, say, restaurants – these seem to be relatively easy to implement and work because they have often caught a growing wave of support.¹⁹

6. *Obfuscating new regulations*: Opponents may pick and choose in the face of complex legislation. ‘Fake compliance’ may be a problem in these circumstances. Wansink and Chandon discover that products required to carry fat *and* calorie *and* carbohydrate *and* sodium information are often promoted as ‘healthy’ in respect of their best performing characteristic (which is often the odd one out).¹³

7. *Low perceived threat of enforcement*. Laws may be ineffectual if miscreants believe they are unlikely to be caught or prosecuted. Drivers’ use of hand-held phones declined on the first months after a Washington DC ban but the decrease almost totally dissipated during the subsequent year.²⁰ The reasoning is perhaps that the offence is brief and, in the subject’s mind, unlikely to be witnessed. Turner and Gordon’s study of pupil’s perception of school smoking bans indicates that many youths regard enforcement regimes as tokenistic.²¹

8. *Insufficient enforcement resources.* Laws may be ineffectual if they are hard to police. Police routinely report that enforcement of seat belt and hand held-phone laws are wasteful of limited resources.²⁰ Jacobson and Wasserman compare differential rates of enforcement across tobacco control laws, with clean indoor air regulations being rarely policed, whilst teen access laws received a significant amount of vendor compliance checks.²²

Locating the right evidence: the stuff of systematic reviews

It is vital to our argument that the status of Figure 2 and the purpose of the accompanying illustrations are made clear. The examples, the vignettes provided above, are *not* forwarded as decisive nuggets of evidence; they are not deemed fatal flaws to the laws in question. The point is that they are potential and indeed well-known threats to the success of the legislation. Any legislator worth her salt will be aware of them and will try to countermand them, and the ensuing battle of wits and wills dictates the success or failure of any new law. Laws are not drafted overnight. A case is made for the legislation and cases (such as the above) are then made against them. Effective laws anticipate the objections and the ensuing regulations consist of a package of direct measures as well as countermeasures against the threats.

This brings us to our key point. If reviewers wish to gauge the likely success of a new application of a law, if they want to find out what works in legislation, they must follow the fortunes of the battle of ideas to date. Policy-makers frame laws knowing quite a bit about confounding effects and about how to circumvent them by anticipatory and supplementary legislation. The state of play of such moves and countermoves, minutely researched, is the stuff of public health systematic reviews. Evidence searches go beyond the identification of schemes and programmes and are

led by key-word searches framed in terms of the points of contention in the implementation chain – ‘criminalisation’, ‘displacement’, ‘enforcement’, ‘public support’ and so on. A review becomes systematic when it has harvested and scrutinised evidence in respect of each of the programme theories.

Some brief examples, again mere vignettes, follow in order to demonstrate the penetration to the next level of empirical evidence. What do studies reveal about ways of countermanding some of the most substantial threats to legislation? No attempt is made to cover the entire model here - only four of the above threats are examined. The point is to light the way into the deeper recesses of evidence.

A. Criminalisation and blame. There is some evidence to suggest that the ‘amplification of deviance’ can be avoided by careful specification of victims and beneficiaries in promoting the legislation. Positive strategies may be: a) Emphasising the ‘benefit to the blameless’ in rationalising a curb. Perdue et al. make the case that coercive measures aimed at the individual (this ban is in your benefit to prevent you stop smoking) might work less well than those aimed at protecting others (this ban will protect non-smokers from the dangers of second-hand smoke);²³ b) Pursuing the idea of ‘shared responsibility for misdeeds’. Grube and Nygaard report on how fines and threats of fines for retailers *as well as* underage customers seem to quell illegal purchases of alcohol.²⁴

B. State of public support. This may be harnessed by an incremental approach to legislation, by ‘catching the wave’ of public sentiment. An example is the claim that smoking bans are more effective if they proceed from transport to workplace to bars

to cars (i.e. from public to private spheres).¹⁶ A similar claim is made about public willingness to comply with enhanced enforcement regimes about seat-belt usage *after* the first wave of evidence (about injury and death reduction) had gained currency.²⁵

C. Lobby group opposition. The potential response here seems to be ‘point-by-point counter intelligence’. Magzamen and Glantz give examples of how tobacco company propaganda was *directly* countered during the passage of US smoke-free legislation (e.g. evidence-based counter-campaigns discrediting ideas about damage to turnover in small business).¹⁷ Tong and Glantz searched 50 million pages of tobacco industry documentation on second hand smoke, deconstructing the tobacco industry’s strategy of infiltrating the design and interpretation of cardiovascular studies.²⁶

D. Insufficient enforcement resources and low perceived threat. Possible strategies here, taken from criminology, to improve enforcement in a resource-neutral way include: i) The ‘benign big gun theory’: about conveying to the public the idea that direct enforcement is an available weapon, *even if* it is frequently holstered. There is some evidence in the area of drink-drive and seat belt legislation that primary enforcement (the capacity to stop potential offenders on suspicion) works better than secondary enforcement (checking alcohol/seat belt after some traffic offence);²⁵ ii) The ‘blitzes and crackdown theory’: this is about keeping the law in the public eye by periodic high-profile, high-yield but short-term enforcement. Smith et al report on the mixed success of such ‘clean-ups’.²⁷

Realist synthesis in practice

Having identified the appropriate raw materials for a programme-theory synthesis, we turn to a sketch of a strategy for an in-depth review, using the burgeoning example of

smoking bans in cars carrying children. As noted, such bans are in their earliest phases in only a small number of jurisdictions in North America and Australia and very few formal evaluations have been published. However, it is perfectly possible to 'review the evidence' on the ban by interrogating thoroughly all of its component theories. Here, we focus on just three elements from Figure 2, our analysis once again being illustrative rather than definitive.

I. What is the extent of the problem and has it been correctly identified? A review here would no doubt begin with two papers by Rees et al²⁸ and Edwards et al.²⁹ These studies use a portable measuring apparatus mounted in the rear seat of a car, measuring the toxicity of airborne particulates. A typical finding reports particulate levels of 272 ug/m³ (rather worse than those found in studies of smoky bars). This debate and the evidence does not end there, of course, a frequently put counter argument cites the idea that smokers generally increase ventilation when carrying non-smoking passengers. The Rees and Edwards papers begin to cover this angle with further data reporting 'open-window' toxicity levels down by three-quarters (but still dangerous). Another paper by Ott et al, using measures of 'air change' in a greater range of ventilation condition (windows / air-conditioning /speed / vehicle), emerges with rather different conclusions – citing a typical twelve fold increase in rate of air change with a single window open by 3 inches.³⁰ Another sub-theory to be explored here is the 'dose-response' counter argument about fleeting and therefore potentially insignificant exposure in short trips. A survey by Panagiotakos and colleagues reports that a significant proportion of the risks from tobacco toxins to peak at relatively low levels of exposure.³¹ A somewhat contrasting body of evidence is explored by Cook and Strachan, concluding there is a complex dose-response relationship, with second-

hand smoke being associated with different prevalence rates for different diseases at different stages of child development.³²

The point we are making here is that whilst there is little clinical disagreement that second hand smoke causes diseases, the evidence is contested on the extent and immediacy of the relationship and the reviewer has to collate and transpose that evidence to the car's back seat.

II. Is the tobacco industry likely to oppose such legislation? This lobby group has managed to delay and dislodge many other restrictions on smoking. Have they and are they likely to act against smoking in cars? Unlike the risk question, this is a much easier programme theory to explore. Indeed the reviewer may be able to call immediately on previous research asking the same question. Freeman et al report on the Australian experience: "Unlike all other advocacy for smoke free areas, this debate was not contested by the tobacco industry or other groups motivated by the potential to see restrictions reduce sales and further denormalise use. Indeed, one tobacco company was supportive of the legislation".³³ A plausible theory for such muted opposition is that the smoking lobby prefers to declaim a 'freedom of choice' agenda, but are likely to demur in the face of the mighty pretext of 'protecting vulnerable children'. This further proposition is itself, of course, open to test and review.

III. Is enforcement feasible and effective? On this issue there is virtually no available data pertaining directly to the policing of smoking in cars. But, in a theory-based review, useful inferences may be drawn from evidence on other hard-to-enforce, in-

car bans such as for mobile phones and seat belts. Again, we confront a somewhat collateral and highly mixed evidence-base. Johal et al's UK observational study found that drivers hand held phone use fell by a half a few months after the law took effect.³⁴ As noted earlier, McCartt and Geary's research conducted in the US found a collapse in compliance in the longer term.²⁰ The ambiguities here would need to be further explored in a full review exploring such ancillary measures as: the efficacy of self-policing through the surveillance of fellow drivers, the utility of crackdowns and repeat publicity and so on.

We trust that these glimpses of the very different bodies of salient evidence demonstrate the potential of a theory-driven review – not to mention the considerable burden of having to traverse so many diverse studies!

References

1. Petticrew M. and Roberts R. (2006) *Systematic Reviews in the Social Sciences*. Blackwell, Oxford.
2. Gostin L. (2008) *Public Health Law*. University of California Press, Berkley.
3. Dobson R. (2008) Governments must get tough on alcohol misuse, public health experts warn. *BMJ* 336, 1266-1267.
4. Oakley A. (2000) *Experiments in Knowing*. Polity Press, Cambridge.
5. Pawson R. (2006) *Evidence-based Policy. A Realist Perspective*. Sage, London.
6. Petticrew M. (2003) Why certain systematic reviews reach uncertain conclusions. *BMJ* 326, 756-758.
7. Hammersley M. (2005) Is the evidence-based practice movement doing more good than harm? *Evidence and Policy* 1, 85-100.
8. Howe K. (2004) A critique of experimentalism. *Qualitative Inquiry* 10, 42-61.
9. MacLure M. (2004) Clarity bordering on stupidity: where's the quality in systematic reviews? *Journal of Educational Policy* 20, 393-419.
10. Beckett C. (2005) The Swedish myth: The corporal punishment ban and child death statistics. *British Journal of Social Work* 31, 125-138.
11. Kuhn E., Nie C., O'Brien C., Withers R., WIntermute E., and Hargarten S. (2002) Missing the target: a comparison of buyback and fatality related guns. *Injury Prevention* 8, 143-146.
12. Wolfson M. and Hourogan M. (1997) Unintended consequences and professional ethics: criminalization of alcohol and tobacco use by youths and young adults. *Addiction* 92, 1159-1164.
13. Wansink B. and Chandon P. (2006) Can "Low-Fat" nutrition labels lead to obesity? *Journal of Marketing Research* 43, 605-617.
14. Adams J. (2009) *Risk*. UCL Press, London.
15. Huang H. and Cynecki M. Effects of traffic calming measures on pedestrian and motorist behavior. 2001. McLean, VA, Federal Highway Administration.
Ref Type: Report

16. Magzamen S. and Glantz S. (2001) The new battleground: California's experience with smoke-free bars. *American Journal of Public Health* 91, 245-252.
 - 17 World Health Organization. Seventh Futures Forum on Unpopular Decisions in Public Health. 2005. Copenhagen, WHO Europe.
- Ref Type: Report
18. Roberts J. (2000) Changing public attitudes towards corporal punishment: the effects of statutory reform in Sweden. *Child Abuse and Neglect* 24, 1027-1035.
 19. Sciacca J. (2005) A mandatory smoking ban in restaurants: concerns versus experience. *Journal of Community Health* 21, 133-150.
 20. McCart A., Helliga L., and Geary L. (2006) Effects of Washington, DC law on driver's hand-held cell phone use. *Traffic Injury Prevention* 7, 1-5.
 21. Turner K. and Gordon J. (2004) A fresh perspective on a rank issue: pupils' accounts of staff enforcement of smoking restrictions. *Health Education Research* 19, 148-158.
 22. Jacobson P. and Wasserman J. (1999) The implementation of tobacco control laws. *Journal of Health Politics, Policy and Law* 24, 567-595.
 23. Perdue W., Mehsah G., Goodman R., and Moulton A. (2005) A Legal Framework for Preventing Cardiovascular Diseases. *American Journal of Preventive Medicine* 29, 139-145.
 24. Grube J. and Nygaard P. (2001) Adolescent drinking and alcohol policy. *Contemporary Drug Problems* 28, 87.
 25. Dinh-Zarr T., Sleet D., Shults R., Zaza S., Elder R., Nichols J., Robert S., Thompson R., Daniel M., Sosin D. (2001) Reviews of evidence regarding interventions to increase the use of safety belts. *American Journal of Preventive Medicine* 21, 48-65.
 26. Tong L. and Glantz S. (2007) Tobacco industry efforts undermining evidence linking second-hand smoke with cardiovascular disease. *Circulation* 116, 1845-1854.
 27. Smith M., Clarke R., and Pease K. (2002) Anticipatory Benefits in Crime Prevention. In *Analysis for Crime Prevention* (ed. Tilley N.) Willan Publishing, Uffculme.
 28. Rees V. and Connolly G. (2006) Measuring Air Quality to Protect Children from Secondhand Smoke in Cars. *American Journal of Preventive Medicine* 31, 363-366.
 29. Edwards R., Wilson N., and Piers N. (2006) Highly hazardous air quality associated with smoking in cars: New Zealand pilot study. *The New Zealand Medical Journal* 119, 2294.

30. Ott W., Klepers N., and Switzer P. (2008) Air change rate of motor vehicles and in-vehicle pollutant concentrations from second-hand smoke. *Journal of Exposure Science and Environmental Epidemiology* 18, 312-325.
31. Panagiotakos D., Chrysohoou C., Pitsavos C., Papaioannou I., Skoumas J., Stefanadis C., and Toutouzas P. (2002) The association between secondhand smoke and the risk of developing acute coronary syndromes, among non-smokers. *BMC Public Health* 2, 9.
32. Cook D. and Strachan D. (1999) Summary of effects of parental smoking on the respiratory health of children and implications for research. *Thorax* 54, 357-366.
33. Freeman B., Chapman S., and Storey P. (2008) Banning smoking in cars carrying children: an analytical history of a public health advocacy campaign. *Aust. N. Z. J. Public Health* 32, 60-65.
34. Johal S., Napier F., Britt-Compton J., and Marshall T. (2005) Mobile phones and driving. *Journal of Public Health* 27, 112-113.