**Title:** Developing logic models to inform public health policy outcome evaluation: An example from tobacco control

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**Abstract**

***Background*** The evaluation of large-scale public health policy interventions often relies on observational designs where attributing causality is challenging. Logic models – visual representations of an intervention’s anticipated causal pathway – facilitate the analysis of the most relevant outcomes. We aimed to develop a set of logic models that could be widely used in tobacco policy evaluation.

***Methods*** We developed an overarching logic model which reflected the broad categories of outcomes that would be expected following the implementation of tobacco control policies. We subsequently reviewed policy documents to identify the outcomes expected to result from the implementation of each policy, and conducted a literature review of existing evaluations to identify further outcomes. The models were revised according to feedback from a range of stakeholders.

***Results*** The final models represented expected causal pathways for each policy. The models included short term outcomes (such as policy awareness, compliance and social cognitive outcomes), intermediate outcomes (such as changes in smoking behaviour) and long-term outcomes (such as mortality, morbidity and health service usage).

***Conclusions*** The use of logic models enables transparent and theory-based planning of evaluation analyses and should be encouraged in the evaluation of tobacco control policy, as well as other areas of public health.

**Introduction**

Large-scale public policy interventions, such as tobacco tax increases and regulation of advertising for unhealthy commodities, are regularly implemented with a view to improving public health. The maintenance, improvement, and expansion of these policies depends on post-implementation evaluation of their effectiveness. This requires the identification of important outcome measures and appropriately designed analyses to measure policy impact.

A key challenge in this type of policy evaluation is the attribution of causality – does the policy cause a change in health outcomes, or is the change attributable to something else?(1) Population-level policy changes cannot usually be evaluated using randomised-controlled trials, because governments, rather than researchers, control their implementation.(2) Furthermore, researchers may not have the opportunity to design studies and collect relevant data prospectively. The evaluation of these ‘natural experiments’ therefore often involves observational designs, frequently relying on routinely collected data such as health service records or population surveys.(3) Some, such as cross-sectional designs, have particularly low internal validity.(2) Others, such as longitudinal studies, interrupted times series and difference-in-difference analysis, have greater internal validity but face challenges in disentangling policy effects from secular trends and other factors which contribute to changes in relevant outcomes.(2) This is a particular problem in settings where several policies are implemented in a short period of time. For example, in England, tobacco control policies have often been implemented close together, such as the smoking ban in public places and the increase in the minimum age of purchase for tobacco products in 2007, and standardised tobacco packaging and the European Union Tobacco Products Directive (which also made changes to the appearance of tobacco products) in 2016. Despite these challenges, studies which evaluate natural experiments can make a contribution to the evidence base for public health.(4-6)

One way of mitigating the above challenges is to articulate the programme theory, which describes how each policy is likely to work and in whom. The programme theory can be represented visually in a logic model, which shows the anticipated causal pathway of an intervention and the populations expected to be affected. Logic models are most frequently simple, linear models (Figure 1); others may seek to capture more complex pathways, such as non-linear pathways or multiple causal strands.(7, 8) Programme theory and logic models can be a valuable tool in intervention planning and implementation as well as in evaluation.(8, 9)

Ideally, programme theories should be articulated prior to the implementation of public health interventions, as part of the justification for their introduction, thus providing an a priori judgement, based on well-considered evidence, of how and in whom they will work. In the context of policy evaluation, a prespecified logic model allows researchers to test existing hypotheses about the effect of policy, in some cases using prospective data that is collected specifically for the purposes of evaluation. In the absence of existing logic models, it falls to researchers to generate hypotheses about the expected effect of the policy and provide a ‘plausible and sensible model of how a programme is supposed to work’.(10) In turn, this allows them to identify justifiable measures of intervention impact, and plan analyses of the most relevant outcomes, albeit often relying on existing data sources.

Many resources are available to public health practitioners and researchers who intend to develop logic models,(8, 11-15) and logic models have informed the planning and evaluation of a range of large-scale public health policies, including tobacco and alcohol policies.(16-21) However, they are not consistently presented in the peer-reviewed literature, and the development and application of these models is generally not described in detail.(16-20)

Some models are highly simplified (20), while others are extremely complex (19) which may limit their use. Sometimes existing logic models are adapted for policy evaluation, and it is often unclear how or why outcomes have been selected during adaption from existing models, creating uncertainty about the logic that underpins the attribution of causality.(17, 18, 21) Tobacco policy logic models often draw on the CDC models which, although evidence-based, are goal-focused rather than policy-specific and may overlook outcomes related to the implementation a particular policy. (17, 18, 21, 22) There is therefore a need for systematic and transparent approaches to disentangle the effects of large-scale public policies from each other, from secular trends and other factors.

We aimed to develop a set of policy-specific logic models that could be widely used in tobacco policy evaluation. We aimed to do this using systematic methods that can be applied to other areas of public health where multiple large-scale policy interventions create complexities for evaluation. The purpose of this paper is to describe our novel systematic approach to the development of the models and present the resulting models.

**Methods**

*Context*

The logic models were developed in the context of a research project which aimed to evaluate a range of tobacco control policies implemented in England between 2007 and 2015 (Figure 2).

The project used a range of publicly available secondary data to assess the short and medium-term impact of these policies (for example, on smoking prevalence) using interrupted time series analysis (ITSA), and estimated the long-term effect of the policies on health care costs and population health outcomes by extrapolating the results of the ITSA using economic modelling. The purpose of the logic models was to identify hypothesised causal pathways and outcomes at the beginning of the project to guide the choice of outcomes in the subsequent analysis.

*Logic model development*

We used an iterative process to develop models for each policy on the timeline in Figure 2: 1) Development of an overarching logic model 2) Review of government documents and existing literature to populate individual policy models 3) Refinement of logic models through multiple rounds of stakeholder feedback.

*Stage 1:* Because the focus of our project was to assess the health-related effects of policies, we developed an initial overarching logic model drawing on Nutbeam’s three levels of outcomes for health promotion, including health promotion outcomes (such as knowledge), intermediate health outcomes (such as health behaviours) and health and social outcomes (such as mortality).(23) The Nutbeam model captures the overarching causal pathway for public health interventions and was therefore well-suited to our logic models. Our model was further informed by a logic model for tobacco control mass media campaigns that some members of the research team had previously worked on,(24) which drew on the work of Chen.(25) Chen distinguishes between the ‘action model’ and ‘change model’ within a programme theory. The action model describes what will be done and how, and is therefore most useful prior to and during implementation. The change model describes the causal process generated by an intervention. Because we were developing our logic models in the context of evaluation as opposed to planning and implementation, we developed change models to show the anticipated causal process. Our overarching model reflected the broad categories of tobacco use-related outcomes that would be expected in the short, medium and long-term following the implementation of tobacco control policies.

*Stage 2:* We subsequently developed policy-specific logic models by identifying the intended outcomes of each policy and outcomes on which an effect had been demonstrated in existing studies, using a combination of government policy documents and literature review. We conducted a search for policy and consultation documents related to the policies of interest on the UK government website, on the basis that they would describe the outcomes that were expected from implementing the policies, either in the document text or in logic models.(26) We reviewed these documents to identify the outcomes expected to result from the implementation of each policy, as well as the population (e.g. youth or adults) in whom the outcomes were expected, i.e. the target population. None of these documents contained logic models. The documents that we reviewed are listed in part A of the online supplementary material.

We conducted a literature review of existing policy evaluations to identify further relevant outcomes. We searched MEDLINE, Web of Science and EMBASE using a search strategy tailored to each policy group of interest to identify reviews and systematic reviews of evaluations of the relevant policies, both within and outside of England. Searches were limited to English language and restricted by date (January 2000 - April 2017). Where relevant reviews did not exist for a specific type of policy, we subsequently searched for primary studies and evaluation protocols. Where a relevant review existed but provided limited detail on relevant outcomes, we also accessed primary studies included in the review. From these publications we extracted outcomes that were reported to have been changed, or hypothesised by authors to have the potential to be changed, by the relevant policies as well as contextual factors which might have influenced the effect of the policy. To avoid researcher bias, we took an inclusive approach and included all outcomes that were reported to have changed in response to a policy, or for which such an effect was hypothesised. An example search strategy for one policy group, and an example of the outcomes extracted for one policy and the relevant reviews and studies are included in supplementary online material (parts B and C).

We combined the outcomes identified from government documents and the literature search to put together initial logic models for each policy, categorising outcomes according to the overarching logic model.

*Stage 3:* The initial models – both the policy-specific models and subsequently the overarching model - were refined through meetings of the research team, and meetings with a range of stakeholders. This included: a face-to-face meeting with a public involvement group of local smokers and ex-smokers, who were shown each model and provided feedback; a telephone conference with a project advisory group comprising national and international tobacco control researchers who provided feedback on the models which were sent to them prior to the meeting; and a face-to-face meeting with national tobacco control policymakers. This part of the process helped to ensure that potentially relevant outcomes and contextual factors which were not identified in Stage 2 were included in the models.

**Results**

*Final logic models*

Figure 3 shows the overarching logic model that was used to develop individual policy models. Figure 4 shows an example of one of the individual policy models, and distinguishes between outcomes identified in stage 2 (literature and policy document review) and stage 3 (research team and stakeholder meetings). All final models are shown in supplementary online material. The final models represented the expected causal pathways for each policy and identified the target populations in which changes in outcomes were expected to occur. The models included proximal outcomes (such as policy awareness, compliance and social cognitive outcomes), intermediate outcomes (such as changes in smoking behaviour) and distal outcomes (such as mortality, morbidity and health service usage), which broadly overlap with the three levels of health promotion outcomes.(23) Stage 3 in the model development process suggested that the intermediate outcomes were better divided into two categories (labelled i and ii), to provide a more detailed representation of the causal pathway. The distinction between outcomes identified at different stages of the logic model development process highlights the importance of the multi-stage approach, which helps to ensure that no important outcomes are missed. The ‘population and contextual moderators box’ captures factors which may influence the effect of the policy. These include other tobacco control policies, the economic context and social norms. The latter may also be directly influenced by the policy - for example stigma associated with purchasing cigarettes after a point-of-sale tobacco display ban, as shown in Figure 4.

**Discussion**

***Main finding of this study***

We have demonstrated a staged approach to the development of logic models for the evaluation of tobacco control policies, and used this approach to identify logic models for several of the major new tobacco control policies in the UK in the last decade. Our logic models identify the short, medium and long-term outcomes expected to result from these policies. Our overarching logic model could serve as a starting point for tobacco control policy evaluation in other settings. Our policy-specific models can be used or adapted for evaluation of similar policies in other settings, and could be updated should evidence of effects of policies on other outcomes be identified. Each stage of our proposed process could be adapted for evaluation of policy in other areas. We have described our approach in the context of development of logic models following the implementation of policy; our approach could also be adopted for the prospective development of models, and we recommend that models are developed in advance of policy implementation where possible.

***What is already known on this topic***

The limited feasibility of randomised controlled trials for the evaluation of population-level public health policy means that natural experiments may often provide the best possible evidence.(5) Maximising their potential requires careful planning, especially as they often rely on routinely collected data over which researchers have limited control.(6) In particular, due to the challenges associated with demonstrating causal effects when evaluating natural experiments, it can be difficult to justify the selection of outcome measures. The long chains of outcomes between the intervention and the ultimate health outcome mean that thinking critically about the causal pathway is particularly important.(24)

The application of logic models to evaluation planning can enhance the transparency and the credibility of findings. However, while logic models are often presented as part of evaluation studies (16-18, 20), their development is often not clearly articulated, and it is therefore not always clear whether they are realistic representations of expected causal pathways. There are resources in the grey literature which can be used to guide the development of logic models.(8, 11-14) However, while these often describe the need for stakeholder engagement, these typically do not suggest a more structured approach incorporating evidence from the peer-reviewed literature and relevant government documentation. NHS Scotland has developed logic models for tobacco control and explicitly links to the literature that has contributed to their development; however, a detailed description of how the models were developed is not provided.(15)

***What this study adds***

In this paper we have described a structured approach to the development of the models, which makes use of a wide range of relevant government documents and existing literature, as well as including extensive stakeholder engagement. Using a multi-faceted approach such as this, and documenting the process, provides reassurance that the resulting models reflect existing evidence as well as expert opinion.

The development of logic models prior to the development of evaluation analysis plans enables a theory-based approach to analysis planning and ensures that analysis focusses on the outcomes and populations that are most pertinent to the policy in question. Our logic models provided a conceptual framework to guide hypothesis generation and subsequent analysis to evaluate tobacco control policies using interrupted time series analysis and economic modelling. The development of logic models is also an important step in the development of population models that extrapolate the long-term health and economic outcomes of policies, helping to ensure that the outcomes and subgroup analyses are aligned with the decision-making process.(27, 28)

After the development of logic models, the next stage is to consider the practicalities of available data and analysis methods. We linked outcomes from our logic models to available secondary data on smoking-related measures at the national level to identify which outcomes we would be able to analyse for each policy and in which population. Relevant data were identified in national surveys. From this we generated a series of hypotheses, which were published as part of an analysis plan placed on the project webpage prior to starting the analysis; the results of this analysis have yet to be published.(29) Where available, a comparable approach could also be applied using regional or local data. The pre-publication of study protocols or analysis plans is increasingly encouraged by funders (6) and journals (30) alike as a way of enhancing transparency. In the case of natural experiments, as well as with other interventions, the use of logic models can support the development of evidence- and theory-driven hypotheses and analyses. Such analyses will in most cases rely on observational data, and identifying effects and attributing causality is likely to be challenging. In addition to quantitative analysis there is a role for qualitative research to help to understand the reasons for apparent effect – or lack of effect – of policies.

To our knowledge, this is the first time a wide range of logic models have been developed for the purposes of tobacco control policy evaluation using a consistent and replicable approach. Applying a consistent method of logic model development to a broad range of policies is particularly valuable when seeking to separate out the effects of multiple policies that are implemented at similar times. Specifying the causal pathway prior to developing analysis plans may subsequently help to increase confidence in attributing causal effects, and may help to identify policy effects more quickly, allowing faster policy expansion. Our approach to logic model development was systematic and used a wide range of available international evidence. Furthermore, we took a collaborative approach, ensuring that the views of a wide range of stakeholders were considered.

We acknowledge that our approach requires more resources – both in terms of time and skills - than that typically outlined in the grey literature, owing to the need for detailed literature reviews and meetings with multiple stakeholder groups, and may therefore not be feasible in all settings in which logic models are used. However, logic models can be valuable tools in both the planning and evaluation of public health policies. While our approach to logic model development has some limitations (described below), the stages that we have set out could help to increase the rigour and transparency of logic model development. Our staged approach could be combined with guides on logic model development from the grey literature, which provide detail on how to conduct stakeholder engagement and activities that can support the identification of outcomes.

***Limitations of this study***

Our logic models have some limitations. Although we adopted a rigorous search strategy to identify published evaluations and reviews of evaluations, our literature review methods were not systematic, and we may therefore have missed outcomes in the literature. Our method relied to a large extent on existing published evaluations, which risks placing more emphasis on outcomes on which an effect has previously been identified. However, incorporating information from policy documents and the views of a range of stakeholders helped to mitigate this. Our logic models did not capture potential differential effects by subgroups other than by age. This largely reflects that existing studies tended not to identify subgroup effects (for example by socioeconomic status and sex). However, it also reflects that the policies of interest did not target specific groups other than adults or young people. However, our subsequent statistical analyses did assess differential effects by subgroup. Furthermore, our logic models imply that the causal pathway for each policy is linear, which may not fully capture the complexity of the causal pathway. In particular, it seems likely that relationships between shorter term outcomes, such as attitudes and smoking behaviour among individuals may not be linear. For example, a change in attitudes towards smoking may lead to a reduction in smoking, which in turn may change attitudes to smoking. Furthermore, we have not explicitly considered interactions between different policies that are in place at the same time. Logic models such as that developed Funnell are better placed to captures these dynamic effects; however, logic models are generally understood as simplifications of reality, and are less likely to aid planning and communication if they are too complex.(31) In addition, designing evaluations to capture these dynamic effects is likely to be particularly difficult. Interactions between policies can nevertheless be considered in analyses of policy effects; when planning analyses based on logic models, researchers should consider the timing of different policies and potential confounding and interacting effects.

Our logic models were change models and were designed post-policy implementation, which has some disadvantages. It is preferable for logic models incorporating both action and change models to be developed a priori by intervention stakeholders. This ensures a shared understanding of an intervention between stakeholders, facilitates intervention monitoring and formative evaluation, and helps to guide plans for evaluation (such as data collection) prior to implementation. However, it is not uncommon for researchers and evaluators to have to develop logic models retrospectively, and our approach ensured that this was done in a reliable and transparent way.

***Conclusion***

The logic models guided the development of hypotheses and choice of outcome measures in subsequent evaluations of tobacco control policies. The use of logic models enables prospective and theory-based planning of evaluation analyses, which in turn enhances the transparency of policy evaluation. The use of logic models should be encouraged in the evaluation of tobacco control policy, as well as in other areas of public health. Logic models can be developed quickly by policy planners and evaluators with limited resources; however such models may not reflect the existing evidence base in relation to the policy, nor the expertise of a broad group of stakeholders. Where possible, such as in the context of evaluation research, the development of logic models should encompass: 1) Development of an initial logic model; 2) Revision of the initial model based on (systematic) review of the literature and other relevant documentation; 3) Revision of the model based on feedback from stakeholders such as policymakers, researchers and the general public; and 4) Documentation of each stage of logic model development.

**Acknowledgements**

This study is funded by NIHR PRP (PR-R14-1215-24001). The views expressed are those of the authors and not necessarily those of the NHS, the NIHR, the Department of Health and Social Care, arms length bodies or other government department.

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