A conceptual modelling framework for developing the structure of Public Health economic models

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Abstract

**Background:** Public Health interventions tend to operate within dynamically complex systems and require consideration of a broader range of determinants of health than clinical interventions, including aspects of human behaviour and estimating impacts upon non-health costs and outcomes. The structural development of Public Health economic models is currently based upon *ad hoc* non-transparent methods. A conceptual modelling framework is a set of steps which can help to guide modellers through the development of a model structure. Key advantages of a conceptual modelling framework are to: aid the development of modelling objectives; provide tools for communication with stakeholders; guide model development and experimentation; improve model validation and verification; and allow model reuse. This paper describes a conceptual modelling framework for Public Health economic models.

**Methods:** The framework was informed by two literature reviews, qualitative research with modellers and a pilot study. The literature reviews aimed to: (1) describe the key challenges in Public Health economic modelling and (2) review existing conceptual modelling frameworks within the broader literature. The qualitative research aimed to understand the experiences of modellers when developing Public Health economic model structures and their views about the barriers and benefits of using a conceptual modelling framework. This involved; (i) following the development of a Public Health economic model including observing key meetings and undertaking in-depth interviews with the modellers involved; (ii) systematically analysing my own notes from a previous Public Health economic project; and (iii) holding a focus group meeting with modellers. A draft version of the conceptual modelling framework was piloted within a project assessing the cost-effectiveness of interventions for diabetes screening and prevention.

**Results:** Four key principles of good practice were identified; (1) that a systems approach to Public Health modelling is appropriate (feedback loops & unintended consequences are important); (2) developing a thorough documented understanding of the problem is valuable prior to and alongside developing and justifying the model structure; (3) that a systematic consideration of the determinants of health is central to identifying all key impacts of the interventions within Public Health economic modelling; and (4) that strong communication with stakeholders and members of the team throughout model development is essential. The conceptual modelling framework is described within the paper.

**Discussion:** A framework has been developed as a helpful tool for modellers of Public Health economic models. Initial evaluation will be via a focus group with modellers. It is offered for further testing within case studies.
1. Introduction
This paper describes a conceptual modelling framework for Public Health economic evaluation. A conceptual modelling framework is defined as: ‘A methodology that helps to guide modellers through the development of a model structure, from developing and describing an understanding of the decision problem to the abstraction and non-software specific description of the quantitative model, using a transparent approach which enables each stage to be shared and questioned.’

1.1 Aim of the conceptual modelling framework
The aim of this framework is to provide a methodology, which can be moulded according to different situations by different users, to help modellers develop structures for Public Health economic models. It acts as a tool to help modellers make decisions about the model structure, but it does not provide automated solutions to these choices. It is intended to be used by any modellers undertaking Public Health economic evaluations; for inexperienced modellers it provides a transparent process to follow; for experienced modellers it provides Public Health-specific considerations such as the broader determinants of health and understanding and describing dynamically complex systems, as well as a standardised approach which will help decision makers/clients to input into and use the model developed. Process suggestions and an example to illustrate the methods can be supplied upon request.

1.2 Benefits of the conceptual modelling framework
Conceptual modelling is the first part of a modelling project, which guides and impacts upon all other stages. This means that if this is done poorly, all subsequent analysis, no matter how mathematically sophisticated, is unlikely to be useful for decision makers. Key potential benefits of this conceptual modelling framework and what pitfalls these aim to avoid are shown within Table 1 below.

Table 1: Potential benefits of the conceptual modelling framework

<table>
<thead>
<tr>
<th>Potential benefit</th>
<th>What pitfalls can be avoided</th>
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<tbody>
<tr>
<td>To aid the development of modelling objectives</td>
<td>➢ Answering the wrong (or less useful) question with the model.</td>
</tr>
<tr>
<td>To provide tools for communication with stakeholders</td>
<td>➢ Representing a contextually naive and uninformed basis for decision-making, including misunderstandings about the problem, producing unhelpful model outcomes, and incorporating inappropriate and/or biased model assumptions. ➢ Ignoring important variations between stakeholders’ views. ➢ Producing model results which are not trusted by stakeholders.</td>
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<tr>
<td>To guide model development and experimentation</td>
<td>➢ Inefficient model implementation (i.e. repeatedly making structural changes to the implemented model) ➢ Inadequate analyses</td>
</tr>
<tr>
<td>To improve model validation</td>
<td>➢ Answering the wrong (or less useful) question with the model. ➢ Misunderstanding the key issues associated with the problem. ➢ Using the first theories identified from the evidence to develop the model. ➢ Not having a basis for justifying the model assumptions and simplifications.</td>
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<tr>
<td>To improve model verification</td>
<td>➢ Not having an intended model with which to compare the implemented model.</td>
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<tr>
<td>To allow model reuse</td>
<td>➢ Other experts not being able to identify or correctly interpret key model assumptions and simplifications and why these have been made.</td>
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2. Methods for developing the framework

The conceptual modelling framework was informed by two literature reviews, qualitative research with modellers and a pilot study. The literature reviews aimed to: (1) describe the key challenges in Public Health economic modelling and (2) review existing conceptual modelling frameworks within the broader literature. The qualitative research aimed to understand the experiences of modellers when developing Public Health economic model structures and their views about the barriers and benefits of using a conceptual modelling framework. This involved; (i) following the development of a Public Health economic model including observing key meetings and undertaking in-depth interviews with the modellers involved; (ii) systematically analysing my own notes from a previous Public Health economic project; and (iii) holding a focus group meeting with modellers. A draft version of the conceptual modelling framework was piloted within a project assessing the cost-effectiveness of interventions for diabetes screening and prevention. A more detailed description of the methods of development is available within the PhD thesis by Squires (in preparation). 3

3. The conceptual modelling framework

The conceptual modelling framework is made up of four key principles of good practice and a methodology consisting of four phases: (A) Aligning the framework with the decision making process; (B) Identifying relevant stakeholders; (C) Understanding the problem; and (D) Developing and justifying the model structure. Each of these will be described.

3.1 Key principles of good practice

The four key principles of good practice are that; (1) a systems approach to Public Health modelling is appropriate; (2) developing a thorough documented understanding of the problem is valuable prior to and alongside developing and justifying the model structure; (3) strong communication with stakeholders and members of the team throughout model development is essential; and (4) a systematic consideration of the determinants of health is central to identifying all key impacts of the interventions within Public Health economic modelling.

(1) A systems approach to Public Health modelling is appropriate

Public Health economic modelling generally involves understanding dynamically complex systems. 4 This means that they are non-linear systems where the whole is not equal to the sum of the parts, they are history dependent, there is no clear boundary around the system being analysed, heterogeneity and self-organisation impact upon the outcomes, and people affected by Public Health interventions may learn over time and change their behaviour accordingly.5

Within complex systems there may be positive feedback loops, whereby if Factor A increases [decreases], the number of Factor B increases [decreases], which leads to Factor A increasing [decreasing] further, which would lead to exponential growth [decay] if no other factors were present. 5 For example, an increase in population obesity might lead to an increase in population mental illness which in turn leads to an increase in obesity, and so on. There may also be negative feedback loops, where an increase [decrease] in Factor A leads to an increase [decrease] in Factor B which in turn leads to a decrease [increase] in Factor A. 5 For example, an increase in eating will lead to an increase in weight gain (all other things being equal) which may lead to a decrease in eating. The dynamics of complex systems arise from the interaction between positive and negative feedback loops, and this may occur over a long period of time, often producing counter-intuitive behaviour. 5 The economy is an example of a complex system which displays such behaviour. Within these dynamically complex systems, factors are constantly changing over time, and a sudden change in
behaviour may arise as a result of a number of smaller heterogeneous changes, such as a stock market crash. Making assumptions of simple cause and effect may lead to inappropriate results. See the paper ‘Learning from Evidence in a Complex World’ by Sterman (2006) for a good discussion of dynamic complexity.5

A systems approach, or systems thinking, is a holistic way of thinking about the interactions between parts within a system and with its environment.6,7 Within systems thinking there are multiple system levels, whereby the system of interest is subjectively defined and there is always a higher level system within which it belongs and a lower level system which describes detailed aspects. The challenge within health economic modelling is to determine which level will be that of the system of interest (the model), by having sufficient knowledge about the higher level system (the broader understanding of the problem), and subsequently to be able to define an appropriate level of detail for the system of interest. Within systems thinking, the importance of not considering one aspect of a system in isolation is emphasised to avoid ignoring unintended consequences. Soft systems thinking also recognises the impact of culture and politics upon a situation,1 which is interlocked with Public Health policy evaluation. Culture and politics affect the process by which decisions are made, what is modelled (eg. the identification of the problem, stakeholder involvement, the interventions assessed and the perspectives and outcomes of the analysis) and the effectiveness of the interventions (eg. service provision and the behaviour of individuals and society). Thus, a systems approach is suited to modelling these dynamically complex public health systems. Figure 1 has been developed to depict key elements of a systems approach.

Figure 1: Systems thinking

(2) The modeller should develop a thorough documented understanding of the problem prior to and alongside developing and justifying the model structure in order to develop a valid, credible and feasible model

It is valuable to have an initial understanding of the problem and to document this understanding prior to making simplifications when developing the model structure because of both theoretical and practical reasons. Theoretically, it provides a basis for validation by facilitating the specification of an appropriate scope and structural assumptions, and for credibility by supporting stakeholder involvement and producing clear documentation when developing the model structure.8 We learn by building upon what we already
know, and how we see the world or a problem is constrained by our previous ‘knowledge’. As such, if a model is data-led and/or based only upon the analyst’s interpretation of the data, it may lead to a narrow view of what should be included within the model. Documenting an understanding of the problem prior to analysing available datasets allows that understanding to be reflected upon and shared. This reduces the risk of ignoring something which may be important to the model outcomes, which is particularly important given the potential dynamic complexity of the system. In terms of systems thinking (see key principle of good practice 1), documenting an understanding of the problem (the higher level system) allows the modeller to be able to define the boundary of the system of interest for modelling (see Figure 1). This description of the understanding of the problem should also help the modeller to understand the impact of potential simplifying assumptions they are making within the model.

Practically, if the problem is not sufficiently understood an inappropriate model structure may be developed which, if recognised at a later stage of model development, may take a long time to alter within the computer software. This is particularly true if an alternative model type needs to be developed (for example, a discrete event simulation rather than a Markov model). Thus taking the time at the beginning of the project to understand the problem could reduce overall time requirements. Documenting the understanding of the problem also enables communication with stakeholders and the project team (see key principle of good practice 3). An additional benefit is that the documentation of the understanding of the problem could be used (alongside any logic models developed) to help stakeholders understand all of the impacts of the interventions in order to inform the scoping and/or the interpretation of systematic reviews of intervention effectiveness. Finally, documenting the understanding of the project will enable researchers and policy makers who are not involved within the project to understand the problem and the basis for decisions about the model structure.

Thus, as also proposed by Kaltenthaler et al. (2011) within the context of clinical economic modelling, it is recommended that the model structure be developed in two phases. The first is to develop an understanding of the decision problem which is sufficiently formed to tackle the above theoretical and practical issues and should not be limited by what empirical evidence is available (see Section C). The second is to specify a model structure for the decision problem that is feasible within the constraints of the decision making process (see Section D). The understanding of the problem will inevitably continue to form during model development; however this initial documented understanding provides a basis for comparison and any major changes to this understanding can subsequently be documented.

(3) Strong communication with stakeholders and members of the team throughout model development is important for model transparency, validity and credibility

Literature suggests that stakeholders can encourage learning about the problem (including geographical variation of healthcare provision and stakeholders’ values and preferences), help to develop appropriate model objectives and requirements, facilitate model verification and validation, help to develop credibility and confidence in the model and its results, guide model development and experimentation, encourage creativity in finding a solution and facilitate model re-use. Additionally, stakeholders can help to define the meaning of subject-specific terminology which has a different lay meaning. Pidd has used the metaphor of taking a photograph of a scene, whereby each person involved might see different aspects of the scene and frame the photo differently. The more frames provided by people with different interests, the better our understanding of the scene, and differences between perspectives can be discussed explicitly. Section B of the framework describes the types of stakeholders which may be involved.
The modeller is encouraged to question the assumptions of the stakeholders and the project team throughout the model development process in order to uncover inconsistent, biased and invalid assumptions. Within topics where the project team have existing ‘knowledge’, it is important for them to be aware of the tendency to anchor to initial beliefs and be open to accepting new theories in order to develop valid models. Effective ways of communicating information such as using clear diagrams should be used in order to share information and describe assumptions.

(4) A systematic consideration of the determinants of health is central to identifying all key impacts of the interventions within Public Health economic modelling

The determinants of health which include the social, economic and physical environment, as well as the person’s individual characteristics, are central in the consideration of Public Health interventions. The determinants of health as described by Dahlgren and Whitehead are shown within Figure 2. Individual behaviours (or lifestyle factors) impact upon the broader determinants of health, which in turn impact upon individual behaviours. Thus, it is important to consider these broader determinants of health in order to be able to predict the full impact of the interventions upon health outcomes. In addition, the determinants of health could be used to think through all of the non-health costs and outcomes associated with the interventions that it might be useful to report, such as those within transport or employment. Consideration of the broader determinants of health also facilitates identification of potential intervention types to assess within the model including those which might impact upon individual health through making community and population-level changes, such as food production, as well as those which might impact upon health through changing individual lifestyle factors. Similarly, subpopulations that might benefit from the intervention could be identified. Finally, the consideration of social network effects could affect the analytical model type chosen, and subsequently the predicted impact of the interventions.

It would not be appropriate or feasible to include all of the determinants of health within the model; however, they should be systematically reflected upon during the understanding of the problem phase to consider which determinants it might be important to include within the model so that all important mechanisms and outcomes of the interventions can be captured.

Figure 2: Determinants of health
3.2 Overview of the phases within the conceptual modelling framework

Figure 3 describes an outline of the phases within the conceptual modelling framework.

Figure 3: Overview of conceptual modelling framework for Public Health economic modelling

<table>
<thead>
<tr>
<th>A) Aligning the framework with the decision making process</th>
<th>B) Identifying relevant stakeholders</th>
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C) Understanding the problem

i) Developing a conceptual model of the problem describing hypothesised causal relationships and modelling objectives

ii) Describing current resource pathways

D) Developing and justifying the model structure

i) Reviewing existing economic evaluations

ii) Choosing specific model interventions

iii) Determining the model boundary

iv) Determining the level of detail

v) Choosing the model type

vi) Developing a qualitative description of the quantitative model

An iterative approach

Choosing stakeholders and aligning the framework with the decision making process will generally need to be undertaken in parallel because the choice of stakeholders and their ideal level of involvement will depend upon the decision making process, but the availability of the stakeholders may have a substantial impact upon the process which is followed. It may be necessary to iterate between choosing relevant stakeholders and developing the understanding of the problem since the understanding of the problem phase may highlight the need to include stakeholders with specific expertise. Similarly, whilst it is important to develop an understanding of the problem prior to developing and justifying the model structure (see principle of good practice 2), in practice the understanding of the problem is never complete and it may be necessary to transparently revise this understanding at a later stage. These iterations are described by double headed arrows within Figure 3. The steps within the developing and justifying the model structure phase are also iterative as shown within Figure 3. Evidence identification is not described as a separate stage within Figure 3 (apart from reviewing existing models) since it is an activity required within the majority of the outlined stages. However, iterations are inevitable between appropriate conceptualisation and data collection because there is unlikely to be the exact evidence available that has been specified by the conceptual model.
3.3 Detailed methods of the framework

A) Aligning the framework with the decision making process

The conceptual modelling framework is intended to be flexible for different decision making arenas which means that decisions about how to employ the framework within the process are required. For example, the project team may need to operate differently according to the nature of the engagement with decision makers and clients within the project. If the client is the decision maker, then the scope of the model in terms of the interventions, comparators, populations, outcomes and perspectives may be better defined at the start of the project than if the client is not the decision maker (eg. a research funding body). This may influence the approach to evidence searching (in particular the search for intervention effectiveness evidence) and the time and resources required for model scoping. If the client is not the decision maker, the project team will need to identify the relevant decision makers and include them within the stakeholder group (see Section B).

A protocol document outlining the project plan can be produced using the framework, as a basis for discussion between the project team and stakeholders. This helps the clients to understand whether the project is planned to run appropriately and the project team with project planning. Key process decisions to be made during this phase relate to the relevant modes of stakeholder engagement, the approach to evidence searching, and the time and resources available for the modelling project and each step of the framework.

B) Identifying relevant stakeholders

There are a number of different types of stakeholder within any Public Health project including clinical experts, decision makers and lay members. The choice of stakeholders involved with the development of the model will inevitably affect the model developed and the interventions assessed because modelling is subjective. For instance, stakeholders help define the model scope, make value judgements, use their expertise to recommend structural assumptions such as extrapolating short term trial data over the long term, and choose which interventions to assess within the model. Within some projects, the experts who inform the model development are chosen by the modelling team, whilst within others a group of experts are chosen by a decision making body, such as within the NICE process (see Section A). There is, however, usually the opportunity to involve additional experts chosen by the project team. A group of experts who will provide different expertise over a range of perspectives can be identified (see below). Practically, the approach to stakeholder communication needs to be flexible and some stakeholders will provide more input than others.

Customers, actors and system owners

Based upon Soft Systems Methodology (SSM)\(^1\) and a conceptual modelling paper by Roberts et al.\(^{10}\), the types of stakeholders to involve are:

1) Customers which might include patient representatives and lay members;
2) Actors which might include clinical experts and epidemiologic experts for all relevant diseases and methods experts;
3) System owners which might include policy experts (in addition to some of the people identified as actors).
C) **Understanding the problem**

One of the four principles of this framework is that developing and documenting an understanding of the problem is at the core of developing an appropriate model structure. This is about understanding what is relevant to the problem, and should not be limited by what empirical evidence is available.\(^8\) The understanding of the problem phase within Figure 3 includes (i) developing a conceptual model of the problem describing hypothesised causal relationships and (ii) describing current resource pathways.

i) **Developing a conceptual model of the problem describing hypothesised causal relationships**

This section outlines a methodology for developing a conceptual model of the problem by using the notation of causal diagrams, borrowing some of the methods from cognitive mapping,\(^{21}\) and ensuring that the worldview of each of the stakeholders is considered.\(^1\);\(^{21}\) This provides a systematic approach for developing an understanding of the problem at an appropriate and manageable level of relevance.

A causal diagram depicts the relationships between factors by arrows, using a + or – sign to indicate a positive or negative causal relationship. Causal diagrams allow feedback loops to be described which depict the dynamic complexity of the system. Each factor is a quantity such that one factor leads to an increase or decrease in another factor. For example,

\[
\text{CVD event} \xrightarrow{+} \text{Cost} \quad \text{and} \quad \text{CVD event} \xrightarrow{-} \text{Quality of life}
\]

mean an increase in CVD events leads to an increase in costs and a decrease in quality of life respectively. The hypothesised causal relationships associated with the problem can be depicted using this notation, bringing together the understanding of relevant diseases, human behaviour and societal influences. Drawing upon cognitive mapping, the ultimate aims can be stated at the top of the diagram (by asking ‘why is x a problem?’), with intermediate outcomes below and options for change underneath (by asking ‘how can the problem be avoided?’).\(^{21}\) Detailed steps to develop the diagram are described overleaf.

### Evidence for developing the conceptual model of the problem

Causal assumptions for policy prediction will be based upon experience and judgement since observational data can only be used to assess the statistical association between the specified causal relationships.\(^{22}\) The proposed diagram can provide an explicit description of our hypotheses about causal relationships and the challenge is to be able to justify the causal assumptions made. The causal hypotheses can be developed based upon a range of sources including the project scope, literature, stakeholder input, the team’s previous work in the area and any other diagrams which have been developed by the rest of the current project team or the decision makers to depict their understanding of the problem, as described within Figure 4 below. By developing the diagram with input from stakeholders, it allows their assumptions and beliefs to be made explicit so that they can be agreed upon or questioned. The iterative process using all of the evidence sources outlined within Figure 4 provides multiple opportunities to question and adapt the causal assumptions. Ultimately, the diagram will depict the modeller’s assumptions and beliefs about the causal relationships based upon all of these sources of evidence. In doing so, some forms of information may dominate over others according to the modeller’s views of the validity of the information.
Step 1: What is the problem?
The first step, based upon cognitive mapping, is to ask ‘what is the problem?’ This is the key problem from the decision makers’ perspective and could be based upon the project scope if available. The cause of the problem described should include a potentially modifiable component. The model objective is likely to be (although not necessarily) to assess the effectiveness and cost-effectiveness of interventions which might decrease this problem. Beginning the development of the diagram by identifying the key problem encourages a focused boundary around the understanding of the problem.

Step 2: Why is this a problem?
The modeller can then ask ‘why is this a problem?’, and continue to ask ‘why?’ or ‘what are the implications of this?’ until no more factors are identified, again based upon the methods of cognitive mapping. Within Public Health economic modelling the goal may be to maximise net benefit by maximising health and minimising costs, or equity may be considered of primary importance.

Step 3: Developing additional causal links
A set of questions have been constructed which may be useful to help develop the diagram further, as shown in Box 1. The development of the understanding of the problem is iterative, and hence it may be useful to continually revisit these questions.
Step 4: Incorporating types of intervention

Within dynamically complex systems like Public Health systems, the possible types of interventions may not be easily definable at the start of the project prior to developing a sufficient understanding of the problem. Thus, the modeller can ask how to avoid or reduce the impact of the described problem. It is useful to firstly know what is considered to be current practice. Potential types of interventions can then be added based upon the project scope, any effectiveness studies identified, and by considering within the diagram where interventions may be beneficial. Combinations of individual, community and population interventions may be considered. It is not expected that the final interventions being assessed within the model will have been chosen at this stage. However, it is important to define the types of interventions which might be assessed within the model so that their impact upon model factors, including those not already incorporated into the diagram, may be considered.

A set of questions have been constructed which may be useful for considering the impacts of the interventions, shown in Box 2. These should be considered in the context of each type of intervention potentially being assessed within the model.
Box 2: Questions about the interventions and their impacts

B1. Questions relating to the constraints of the decision making process are:
- Are there constraints on the project scope? (eg. are we constrained by the types of interventions we are assessing? What about the population?)

B2. Questions relating to the goals and mechanisms associated with the interventions are:
- What is considered to be a good outcome?
- What would happen in the absence of the interventions versus as a result of the interventions – would negative outcomes be prevented or delayed?
- What evidence exists to describe the outcomes of the intervention/ comparator over time? Are behavioural outcomes important? If so, do any relevant models of behaviour from psychology, sociology or behavioural economics exist to help describe the behaviour resulting from the intervention or the comparator? This will require additional targeted literature searches.
- Are there any determinants of health reported by the effectiveness studies which are not included within the causal diagram? Can such a relationship be described?

B3. Questions relating to the dynamic complexity of the system are:
- Might a third party act to reduce the impact of interventions?
- Are there any substantial impacts of social and/or community networks upon intervention effectiveness? Will these impacts be captured over the long term within the effectiveness evidence?
- Are there any substantial impacts of the interventions upon other lifestyle factors?
- Might the interventions have other impacts not already considered?

Modelling objectives
The modelling objective should be clearly defined and regularly referred to during the design-oriented conceptual modelling phase (see Section D) so that the model is built for purpose. This can be developed based upon the conceptual model of the problem, and may comprise the ultimate goals, the types of interventions being assessed and the population(s) of interest. As Roberts et al. suggest, the policy context of the modelling project needs to be clear, particularly in terms of the funder, the policy audience and whether the model is planned to be for single or multiple use.10

ii) Describing current resource pathways
The conceptual model of the problem can be used to inform what resources might need to be considered. This does not need to be a detailed description of resource use at this stage, since some factors within the conceptual model may be excluded from the quantitative model and hence it would be inefficient to collect detailed information. It also means that the general pathways can be validated with stakeholders prior to collecting detailed information. Flow diagrams, tables and/or a textual description of the resource pathways can be useful to inform consideration of the potential impact of the factors within the conceptual model of the problem upon the model results. This can be used to help choose which factors to include and exclude from the model as is discussed within the model boundary stage of the framework (see Section D(iii)).
D) Developing and justifying the model structure

This section aims to outline an approach for specifying an appropriate model structure that is feasible, valid and credible to develop into a quantitative model, which may be described as the design-oriented conceptual modelling phase. As outlined within Figure 3, this includes: (i) reviewing existing health economic models; (ii) choosing model interventions and comparators; (iii) determining the model boundary (deciding what factors are included within the model rather than being part of its external environment); (iv) determining the level of detail (the breakdown of what is included for each factor within the model boundary and how the relationships between factors are defined); (v) choosing the model type (the analytic modelling technique employed, for example a Markov model), and (vi) developing a qualitative description of the quantitative model.

i) Reviewing existing health economic models

It is standard practice within health economic evaluation to undertake a systematic review of existing health economic models in the same area. Some existing models may have been used to develop the understanding of the problem, but a systematic review of models at this stage can be used in a number of ways:

- To determine whether there is already a model which could be used, either in part or as a whole;
- To consider the strengths and limitations of existing economic evaluations, which can be used to inform the model development;
- To compare and contrast how other modellers have chosen to structure the model and estimate key variables, and how the model results differ based upon these choices. This may involve considering the use of mathematical relationships such as risk equations or parameters which have been included within previous models if their source and justification has been appropriately explained;
- To identify which variables are important in influencing model results (including any which have not been highlighted during the understanding of the problem phase) and which do not substantially affect the differences in outcomes between the interventions and comparators;
- To provide an insight into the types of data available which may inform the model level of detail.

ii) Choosing model interventions and comparators

Method for choosing model interventions to assess within the model

The decision makers (with consideration of the clients’ needs if they are not the decision makers) should define which specific interventions to model grounded within the results of an evidence review and according to expertise from other stakeholders. The decision makers may use the systematic review of effectiveness evidence to further limit interventions by discussing trial populations, outcomes and other potential biases. It is possible that one good study or a number of studies can be used to estimate the short term effectiveness. As far as possible, the comparator can be based upon the same studies as the interventions if this is representative in practice. If practice is substantially different, then an adjustment on the effectiveness estimate would be required. Given that economic evaluation is a comparative analysis, the model results are only meaningful in relation to the comparators chosen. Which outcomes the effectiveness studies report will guide the development of the model structure.

Use of the reviews to develop the model boundary, level of detail and model type

The review of existing economic evaluations and the review of intervention effectiveness can be used to facilitate decisions around the model boundary, level of detail and model type as shown within Figure 5 below.
Figure 5: Defining the model boundary, level of detail and model type

- Develop understanding of the problem
  - Review existing health economic models
  - Identify strengths & limitations of different model structures
  - Identify strengths & limitations of different model types
  - Identify the sort of data available
  - Assess whether there is an existing model which could be employed
  - Identify long term evidence & mechanisms

- Model boundary
  - Discuss potential model perspectives, outcomes, interventions & populations with stakeholders
  - Review evidence of relationships between factors
  - Identify key variables which generally affect model results (incl. any not already identified) & key variables included within the causal diagram which do not
  - Identify factors with not many causal links & assess whether they would have a substantial impact upon the difference between outcomes of interventions & comparators

- Model detail
  - Review effectiveness of relevant interventions
  - Identify effectiveness of interventions (to help choose which to model & for parameterisation)
  - Identify types of outcomes reported

- Model type
  - Review evidence of relationships between factors
  - Identify factors with not many causal links & assess whether they would have a substantial impact upon the difference between outcomes of interventions & comparators

iiii) Determining the model boundary
Determining the model boundary is about deciding, based upon the understanding of the problem, what factors should be judged as relevant for inclusion within the model and which can be excluded given the time and resource constraints of the decision making process. The boundary of the model structure must differ from the boundary of the understanding of the problem in order to be able to make informed judgements about what it is important to include within the model structure (see Figure 1). It is important to define the boundary of the model such that all important interactions between the elements of the system identified within the understanding of the problem are captured.\(^{17}\)

Model population and subgroups
The model populations can be discussed with the stakeholders, informed by the populations within the effectiveness studies. The modelling team and the stakeholders could consider whether there is a bigger problem in a particular subgroup or whether the intervention is likely to be more effective in a particular subgroup and if there is sufficient data to undertake any subgroup analysis. These subgroups might be based upon the determinants of health outlined within Figure 2 including age, sex and other inherent characteristics of the population of interest, individual lifestyle factors, living and working conditions and access to essential goods, and general socioeconomic, cultural and environmental conditions.

Model perspectives and outcomes
Often within health economic evaluation, the NHS and PSS perspective is employed.\(^{25}\) However, within Public Health economic modelling, other perspectives are likely to be relevant because substantial costs and benefits may extend beyond these sectors. Alternative perspectives include (but are not limited to) a societal perspective, a Public Sector perspective or the perspective of the particular agencies involved within the system. The perspectives of the system owners identified within Section B of the framework are likely to be appropriate. For example, if employers are considered to be system owners, then it is likely to be useful to consider an employer perspective. The choice of perspectives will also depend upon the modelling objectives. It should be noted that there are currently unresolved issues around using these alternative perspectives in terms of (i) whether it is possible or desirable to make social value judgements associated with the value of health relative to the value of other costs and benefits and (ii) the practicality of transferring costs and benefits between sectors.\(^{26}\) Nonetheless, if substantial costs and benefits are expected to fall outside of the NHS and PSS, presenting these alternative perspectives is likely to be informative for decision makers.

In order to be able to compare interventions across different populations in terms of health costs and outcomes, the incremental cost per QALY may be employed, based upon New Welfare Economics.\(^{27}\) Where the model boundary extends beyond health, it may be useful to understand the modelling requirements in other sectors so that relevant outcomes may be presented. One way of presenting multiple outcomes for different sectors is to present a cost-consequence analysis alongside the cost-effectiveness analysis.\(^{28-30}\) Decision makers can suggest which model outcomes it would be useful to report. For both model perspectives and outcomes, the modeller should follow any specific requirements of the decision makers such as the use of the NICE Public Health Methods Guide. A method for choosing model outcomes and perspectives has been outlined within Figure 6.
Figure 6: Method for choosing appropriate modelling perspectives and outcomes

1) Consider what is theoretically appropriate and what is required under a reference case if applicable for (a) perspectives and (b) outcomes. When considering (b) model outcomes, how do the model perspectives affect this?

2) Consider by whom the results of the research will be used to consider whether additional (a) perspectives and (b) outcomes may be useful.

3) Discuss with stakeholders those perspectives and outcomes identified within (1) and (2) and ask if there are any additional (a) perspectives and (b) outcomes that it might be useful to consider.

Other model boundary considerations

An algorithm to help define the model boundary is shown within Figure 7 and can be considered for each factor within the conceptual model of the problem. Within Figure 7, the question ‘does the factor have many causal links?’ aims to identify which factors are central and should be included within the model, even in the absence of data (lots of links), and which factors are less important (not many links to other factors). This can be done formally within computer software if preferred.21 The question around whether the impact of a factor is substantially captured by other factors attempts to exclude any double counting within the understanding of the problem phase (for example, including fatigue and diabetes) as far as possible from the quantitative model.

It is valuable to predict very approximately the results of the model to facilitate model verification. These predictions can also help with defining the model boundary. Figure 7 encourages the modeller to think about whether it is worthwhile including non-central factors given the expected results of the model and the anticipated direction of effect of the factor upon those results, as well as the differential impacts of the interventions upon that factor. If different interventions impact the factor by different mechanisms, then including or excluding the factor may lead to different conclusions based upon the incremental analysis.

In terms of the question within Figure 7 around whether the factor is likely to have a substantial impact upon the difference between costs and effects of the interventions, this entails having an understanding of the magnitude of the cost and outcomes associated with the factor and the extent to which the interventions might change these. These subjective judgements will inevitably be considered in the context of the time available for modelling and the potential future uses of the model. Whether or not the factor will impact substantially upon the model results is a subjective judgement which, practically, may be influenced by the time available to develop the model. However, the model boundary stage should not be overly dependent upon the evidence or time available as this can be accommodated for by the level of detail incorporated. It is likely to be more appropriate to crudely include a factor which is expected to substantially affect the model results than to exclude it from the model completely.

Finally, to maintain model credibility, stakeholders can be asked whether they are happy, given the above justifications, with the exclusion of factors. One way of reporting this stage is to produce a table stating whether each factor is included or excluded and the justification for exclusion as suggested by Robinson.31
Figure 7: Defining the model boundary

To be considered in the context of the time available for modelling & potential model reuse

Is the factor associated with the interventions, populations & outcomes being modelled?

Yes  No

Does the factor have many causal links?

Yes  No

EXCLUDE

INCLUDE

Is the impact of the factor predominantly captured by other included factors?

Yes  No

EXCLUDE

Yes

Are all interventions likely to be cost saving/ have a low ICER AND does the factor further increase benefits/ decrease costs AND do all interventions affect the factor in the same way?

No

Is the factor likely to have a substantial impact upon the difference between costs & effects of the interventions? This may be based upon (though not limited to):
(1) the review of economic evaluations;
(2) the description of resource pathways;
(3) clinical papers describing the causal links;
(4) existing models in similar areas which describe the impact of the factor;
(5) methodological choices eg. discounting;
(6) expert advice.

Yes  No

Would stakeholders prefer to include the factor for model credibility AND is it relatively easy to incorporate in terms of modelling skill & data availability?

Yes  No

INCLUDE

EXCLUDE
iv) Determining the level of detail

The level of detail is defined as the breakdown of what is included for each factor within the model boundary and how the relationships between factors are defined. A decision about which parts of the model are likely to benefit from a more detailed analysis can be made *a priori* in order to avoid situations in which the modeller focuses upon specific parts of the model because they are more easily dealt with and subsequently run out of time to develop other parts in detail. Essentially, determining the level of detail involves a mini cost-benefit analysis within which modellers can weigh up, based upon the documented understanding of the problem and the defined model boundary, whether the time required to do one analysis at a specific level of detail within the model is likely to have more of an impact upon the model results compared with the same time period spent upon other analysis, given the current evidence available and the overall time constraints. During model analysis, more detail can be incorporated if part of the model is shown to substantially affect the results. Box 3 summarises key questions for the modeller to help choose an appropriate level of detail.

Box 3: Questions to help in making judgements about the model level of detail

<table>
<thead>
<tr>
<th>General</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Is the time required to do the analysis at a specific level of detail likely to have more of an impact upon the model results than the same time period spent upon other analyses, given the evidence available and the overall time constraints?</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>To describe the relationship between the included factors over time</th>
</tr>
</thead>
<tbody>
<tr>
<td>• What outcomes are reported within the review of intervention effectiveness? (to help choose which causal links to include)</td>
</tr>
<tr>
<td>• What evidence is available to model the causal links and the outcomes of the factor? (to avoid relying on the first available evidence)</td>
</tr>
<tr>
<td>• What do other economic evaluations suggest are the strengths and limitations of different mathematical relationships between model factors?</td>
</tr>
<tr>
<td>• Which determinants of health are key drivers of the problem according to relevant theory?</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>To extrapolate study outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>• What outcomes are reported within the review of intervention effectiveness?</td>
</tr>
<tr>
<td>• What evidence is available for long term follow up?</td>
</tr>
<tr>
<td>• Is there sufficient evidence and time available to model social networks given the expected impact upon model results (based upon the understanding of the problem)?</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>The level of detail used to describe each included factor</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Which are the specific aspects of each factor that are likely to have a substantial impact upon the model results?</td>
</tr>
<tr>
<td>• Is all costly resource use captured?</td>
</tr>
<tr>
<td>• Are all substantial health benefits and disbenefits captured using measures acceptable to the decision maker given the available evidence?</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>How interventions will be implemented in practice</th>
</tr>
</thead>
<tbody>
<tr>
<td>• What do the effectiveness studies describe?</td>
</tr>
<tr>
<td>• What do stakeholders suggest would happen in practice and is this likely to lead to different estimates of effectiveness to those within the study?</td>
</tr>
</tbody>
</table>
**Searching for evidence**

Data for inclusion for specifying the model structure and for the parameters will need to be identified at this point if it has not been already. This could be based upon literature identified during the development of the conceptual model of the problem for which specific literature was noted as useful, although additional specific searches may also be required. Data collection and the development of a description of the level of detail for the model will be a highly iterative process. Sufficient evidence is required to be able to justify why the modelling choices have been made.\(^3\) It is important to note that elements for which there is a lack of empirical data which are considered to have key differential impacts upon the comparator(s) and the intervention(s) may be informed by expert elicitation. One consideration at this stage is likely to be the derivation of the disease natural history parameters which may be taken from existing studies or calibrated using statistical methods such as the Metropolis Hastings algorithm.\(^3\)

**Distinction between model assumptions and simplifications**

Robinson highlights the distinction between model assumptions and simplifications; model assumptions ‘are made either when there are uncertainties or beliefs about the real world being modelled’ and model simplifications ‘are incorporated in the model to enable more rapid model development and use, and to improve transparency’.\(^4\) Thus, model assumptions are uncertain and alternative plausible assumptions can be tested within the model, whilst model simplifications are chosen because they are likely to have limited impact upon the model results. It is important to be explicit about both of these when describing the level of detail and highlight model assumptions which could be tested within sensitivity analyses.

**Reporting level of detail**

The simplifications and assumptions should be described and explained, initially for communication purposes with stakeholders and the project team to develop model validity and credibility, but also to facilitate future modelling projects in the same area. A document can be developed which specifies all of the key model simplifications and assumptions for discussion with stakeholders, ideally during a second workshop. This can help to identify the most appropriate evidence for the model and also improve model validity and credibility. Writing down all of the key simplifications and assumptions and their justification provides a mechanism for systematically questioning them within project team discussions and with the stakeholders; thus enhancing the appropriateness of the model simplifications and assumptions.

**Expressing structural uncertainty**

It may be that where there is more than one plausible assumption it is appropriate to develop model structures for each assumption in order to undertake posterior analysis of structural uncertainty, for example model averaging. This would be undertaken by creating a parameter to be included within the probabilistic sensitivity analysis to represent the probability of each structure being appropriate. This parameter and its distribution could then be estimated by elicitation with experts.\(^5\)

The level of detail will be affected by the model type chosen, and hence it will be an iterative process between identifying an appropriate level of detail and choosing the model type.
Choosing the model type

Most appropriate model type given the characteristics of the problem

It is important to understand the most appropriate method given the characteristics of the problem, even if it is not practical to develop this model type, so that the modeller can understand the simplifications they are making. A number of existing papers outline taxonomies for deciding upon appropriate model types given the characteristics of the problem for health economic modelling.\textsuperscript{36-38} The taxonomy developed by Brennan \textit{et al.} (2006) is used here.\textsuperscript{36} It can be summarised by asking whether interaction, timing and stochasticity are important, and whether there is sufficient data for an individual level model rather than a cohort model, each of which leads to a preferred model type. Whilst decision trees and Markov models are most often employed within Health Technology Assessment,\textsuperscript{37} because of the complexity associated with Public Health systems it is likely that alternative model types may be more appropriate. Agent-based simulation (ABS) is not included within the taxonomy by Brennan \textit{et al.}; however it may be useful for modelling dynamically complex Public Health systems. ABS is a bottom-up approach where the behaviour of the system is a result of the defined behaviour (based upon a set of rules) of individual agents and their interactions within the system.\textsuperscript{39} Thus, ABS may be preferable when the interactions between heterogeneous agents and their environment are important. ABS more easily allows the analyst to capture spatial aspects in order to model appropriate interactions (eg. family and friend networks for transmission of a contagious disease).\textsuperscript{39} Studies have shown social network impacts of behaviours such as dietary habits.\textsuperscript{40}

Most appropriate model type based upon broader considerations

It may not always be practical to employ the model type which is most appropriate for the characteristics of the problem. Figure 8 provides an outline of how the modeller might decide on the most appropriate model type according to broader practical issues.

Figure 8: Choosing the model structure

\begin{center}
\begin{tabular}{|c|c|c|}
\hline
Determine the most appropriate model type for the characteristics of the problem (see above). Is this feasible within the time and resource constraints of the decision making process given: (i) the data available? AND (ii) the accessibility of any existing relevant good quality economic evaluations for use as a starting point? AND (iii) the expertise of the modeller? & Yes & No \\
\hline
\end{tabular}
\end{center}

\begin{center}
\begin{tabular}{|c|c|c|}
\hline
Are you intending to use the model again for other projects? & Yes & No \\
\hline
\end{tabular}
\end{center}

\begin{center}
\begin{tabular}{|c|c|c|}
\hline
Develop the model & Yes & No \\
\hline
Do you think a simpler model type would lead to the same conclusions, given your understanding of the problem? & & \\
\hline
Develop the simpler model type, documenting the provisos, uncertainties & implications of the simplifications & & \\
\hline
Develop the more complex model & & \\
\hline
Can you answer the question with a few provisos with a simpler model type, given your understanding of the problem? & Yes & No \\
\hline
Explore with the decision maker the most useful purpose of the modelling given the project constraints & & \\
\hline
\end{tabular}
\end{center}
vi) Qualitative description of the quantitative model

A qualitative diagram of the quantitative model alongside the development of the model structure can facilitate clear communication of the final model structure to stakeholders, other members of the team and people who may want to understand the model in the future. This will depend upon the model type developed but may take the forms outlined in Table 2. Whilst the design-oriented conceptual modelling can be described prior to the quantitative model development, it may be iteratively revised according to data availability and/or inconsistencies identified during the development of the quantitative model. These modifications should be documented throughout so that there is transparent justification for the final model developed.

Table 2: Suggested diagrams to represent the implemented model

<table>
<thead>
<tr>
<th>Model type developed</th>
<th>Suggested diagram</th>
</tr>
</thead>
<tbody>
<tr>
<td>Decision tree</td>
<td>Decision tree diagram</td>
</tr>
<tr>
<td>Markov model</td>
<td>State transition diagram</td>
</tr>
<tr>
<td>System dynamics</td>
<td>Influence diagram / stock and flow diagram</td>
</tr>
<tr>
<td>Individual event history model</td>
<td>State transition diagram</td>
</tr>
<tr>
<td>Discrete event simulation</td>
<td>Activity cycle diagram</td>
</tr>
<tr>
<td>Agent based model</td>
<td>A flow diagram</td>
</tr>
</tbody>
</table>

4. Discussion

A framework has been developed as a helpful tool for modellers of Public Health economic models. In 2011 Chilcott et al. highlighted the lack of formal methods for model development and when this research began, there were no publications associated with conceptual moulding within health economic modelling. Since then the International Society for Pharmacoeconomics and Outcomes Research and the Society for Medical Decision Making (ISPOR-SMDM) Joint Modeling Good Research Practices Task Force have developed guidance around conceptual moulding for health economic modelling and a Technical Support Document has been developed for the National Institute for Health and Care Excellence Decision Support Unit (NICE DSU) around identifying and reviewing evidence to inform the conceptualisation and population of cost-effectiveness models. The recent development of these two conceptual moulding frameworks highlights the importance and timely nature of this work. The conceptual moulding framework developed here complements and adds to these existing frameworks by focusing upon Public Health economic moulding. The main contribution of this research is that it provides a systematic approach to developing Public Health model structures, and in particular, systematic consideration of:

a. Dynamic complexity (feedback loops, unintended consequences);
b. The broader determinants of health;
c. How to progress from an understanding of the problem to the model structure;
d. Stakeholder involvement.

Initial evaluation will be via a focus group with modellers. It is offered for further testing within case studies. The conceptual moulding framework that has been developed aims to provide a reference document which can be continually improved following its use within different Public Health economic moulding projects and according to developments within other related research areas (eg. modelling human behaviour, quantifying relevant outcomes). The framework has been developed within a UK context and would benefit from testing within an international arena. For more information about how the conceptual moulding framework was developed and the evaluation of the framework please see the doctoral thesis by Squires (in preparation).
References
(3) Squires H. A methodological framework for developing the structure of Public Health economic models [thesis in preparation].
Ref Type: Report
Ref Type: Report


Ref Type: Report


Ref Type: Report


