Guidance on the use of logic models in health technology assessments of complex interventions

6

AUTHORS: *Anke Rohwer, Andrew Booth, Lisa Pfadenhauer, Louise Brereton, Ansgar Gerhardus, Kati Mozygemba, Wija Oortwijn, Marcia Tummers, Gert Jan van der Wilt, Eva Rehfuess*

INTEGRATE-HTA

This project is co-funded by the European Union under the Seventh Framework Programme (Grant Agreement No. 306141)

PLEASE CITE THIS PUBLICATION AS:
ROHWER, A., BOOTH, A., PFADENHAUER, L., BRERETON, L., GERHARDUS, A., MOZYGEMBA, K., OORTWIJN, W., TUMMERS, M., VAN DER WILT, G.J., REHFUESS, E. (2016) Guidance on the use of logic models in health technology assessments of complex interventions [Online]. Available from: http://www.integrate-hta.eu/downloads/

CONTACT:
For questions regarding this document, contact INTEGRATE-HTA (info@integrate-hta.eu)

DATE:
Version of 01/02/2016

PROJECT:
Integrated Health Technology Assessment for Evaluating Complex Technologies (INTEGRATE-HTA)

COORDINATOR:

Universität Bremen

PARTNER:

UNIVERSITÀ CATTOLICA del Sacro Cuore · ECORYS · UiO : University of Oslo · The University Of Sheffield. · Radboudumc university medical center · LMU

The research leading to these results has received funding from the European Union Seventh Framework Programme ([FP7/2007-2013] [FP7/2007-2011]) under Grant Agreement No. 306141.

About this guidance

Who would find this guidance useful?

This guidance is intended for individuals and institutions that develop guidelines, perform or commission health technology assessments (HTAs) and systematic reviews (SRs) and that have an interest in the use of logic models as a guiding framework for the HTA or SR.

Purpose and scope of this guidance

This guidance summarises current thinking and practice in the use of logic models in HTAs and SRs from question specification through to analysis and presentation of results. It offers direction on how to choose between distinct types and sub-types of logic models, describes each type and its application in detail, and provides templates for getting started with the development of an HTA- or SR-specific logic model.

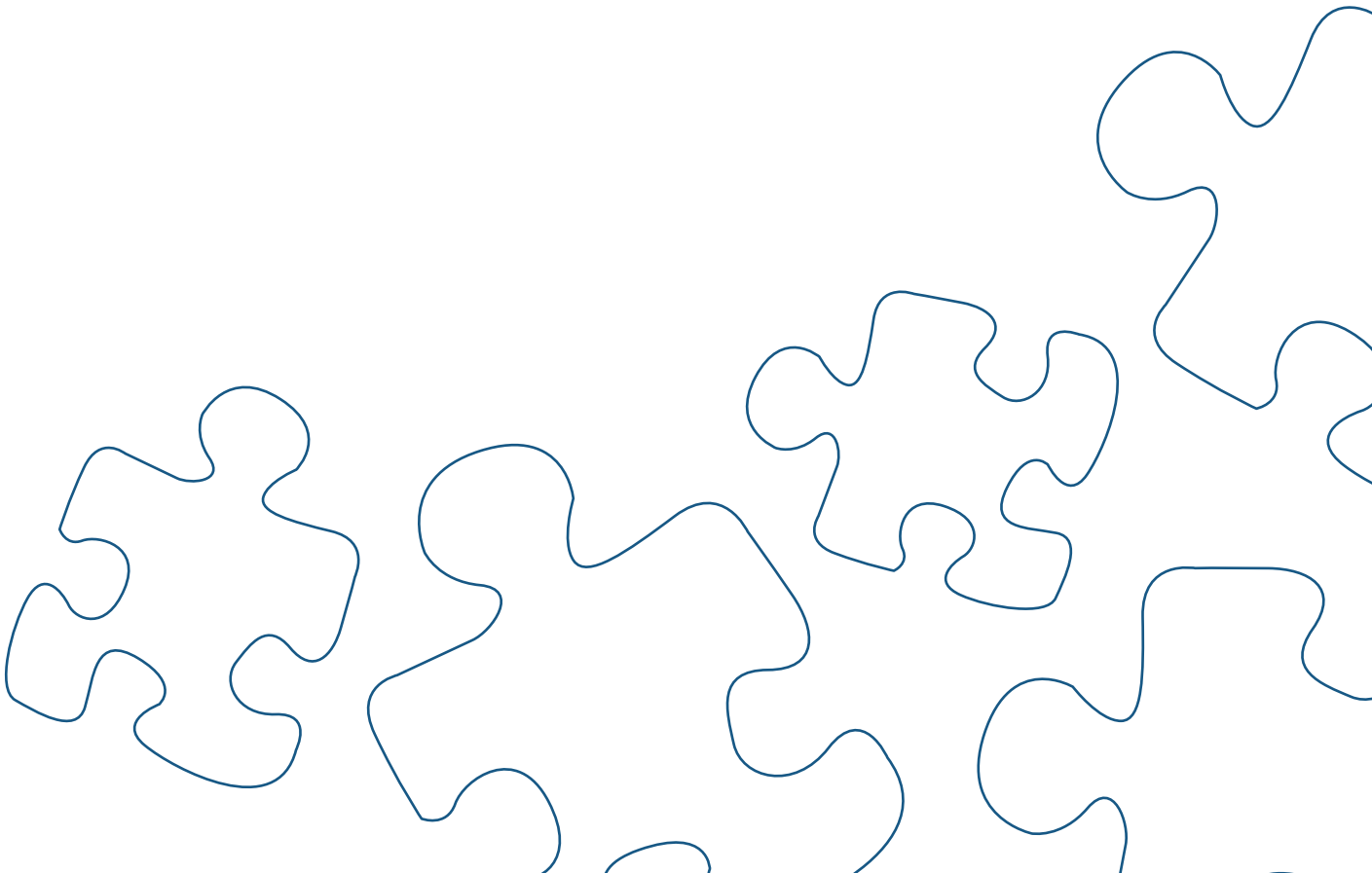
Added value for an integrated assessment of complex technologies

A logic model can be used to "think through" the multiple components of a complex technology in context, and can assist in communication within the HTA/SR author team and with a range of stakeholders. This guidance facilitates use of logic models as a framework by which various types of information, including quantitative and qualitative data, may be juxtaposed for synthesis and interpretation.

INTEGRATE-HTA

INTEGRATE-HTA is an innovative project that has been co-funded by the European Union under the Seventh Framework Programme from 2013 until 2015. Using palliative care as a case study, this project has developed concepts and methods that enable a patient-centred, comprehensive, and integrated assessment of complex health technologies.

Guidance on the use of logic models in health technology assessments of complex interventions



Executive Summary

Challenges in assessments of health technologies

In recent years there have been major advances in the development of health technology assessment (HTA). However, HTA still has certain limitations when assessing technologies, which

- are complex, i.e. consist of several interacting components, target different groups or organisational levels, have multiple and variable outcomes, and/or permit a certain degree of flexibility or tailoring;
- are context-dependent, with HTA usually focusing on the technology rather than on the system within which it is used;
- perform differently depending on the way they are implemented; and/or
- have distinct effects on different individuals.

Logic models are one important means of conceptualising and handling complexity in HTAs or systematic reviews (SRs) of complex technologies, as well as integrating the findings of multi-component HTAs. A logic model is described as "... a graphic description of a system ... designed to identify important elements and relationships within that system". When evaluating complex health technologies, logic models can serve an instrumental purpose at every stage of the HTA/SR process, from scoping the topic of the HTA/SR, including formulating the question and defining the intervention; conducting the HTA/SR; interpreting results and making the HTA/SR relevant for decision makers to implement in policy and practice.

Purpose and scope of the guidance

This guidance is targeted at commissioners, producers and users of guidelines, HTAs and SRs with an interest in using logic models as an overarching framework for their work. It aims to make the use of logic models as straightforward as possible by facilitating the systematic identification or development as well as utilisation of different types and sub-types of logic models. In principle, logic models are a useful tool in any kind of SR or HTA, as they aid with the conceptualisation of the intervention and the review question. This is particularly useful for complex technologies, where conceptualising the intervention and its implementation within a system is critical. In addition, logic models can enhance communication within the HTA/SR team and with relevant stakeholders.

Three types of logic model are described: With a priori logic models the logic model is specified upfront and remains unchanged during the HTA/SR process. With iterative logic models the logic model is subject to continual modification throughout the course of an HTA/SR. The staged logic model harnesses the strengths of both a priori and iterative approaches by pre-specifying revision points at which major data inputs are anticipated. In

addition, two subtypes are identified, namely logic models that seek to represent structure (system-based) and those that focus on processes or activities (process-orientated).

This guidance offers direction on how to choose between distinct types and sub-types of logic models, describes each logic model type and its application in detail, and provides templates for getting started with the development of an HTA/SR-specific logic model.

Development of the guidance

This guidance was informed by a combination of (i) systematic searches for published examples of logic models supplemented by purposive sampling of iterative logic modelling approaches; (ii) searches for existing guidance on the use of logic models in primary research, SRs and HTAs; (iii) development of two draft templates for system-based and process-orientated logic models in an iterative process within the research team and in consultation with external methodological experts; and (iv) application of these draft templates in multiple SRs and one HTA of different complex health technologies covering technical, educational and policy interventions in environmental health, e-learning for health professionals and models of palliative care.

Application of this guidance

For a comprehensive integrated assessment of a complex technology we have developed a five step process, the INTEGRATE-HTA model. In Step 1 the HTA objective and the technology are defined with the support from a panel of stakeholders. A system-based logic model is developed in Step 2. It provides a structured overview of technology, the context, implementation issues, and relevant patient groups. It then frames the assessment of the effectiveness, as well as economic, ethical, legal, and socio-cultural aspects in Step 3. In Step 4 a graphical overview of the assessment results, structured by the logic model, is provided. Step 5 is a structured decision-making process informed by the HTA (and is thus not formally part of the HTA but follows it). Logic models therefore form an integral element of the INTEGRATE-HTA model but may also be useful in individual steps.

This guidance starts off by offering support in identifying and, as needed, adapting existing logic models from the literature or developing an HTA-/SR-specific logic model de novo. In either case, the user will need to decide upfront whether to pursue an a priori, staged or iterative approach to logic modelling, and the guidance offers criteria on how to decide between these distinct types of logic modelling. The system-based and process-orientated logic model templates provide a starting point for the de novo development of either type of logic model. The guidance also discusses the advantages and drawbacks of adopting the system-based or process-orientated sub-type, and offers some general considerations in applying logic models, such as the variety of data sources used, transparency in reporting and necessary trade-offs between comprehensiveness and complexity of the logic model in communicating with stakeholders.

For a priori logic modelling, a six-step process comprises: (1) defining the PICO elements of the HTA/SR as well as relevant aspect of context and implementation; (2) deciding on a system- vs. process-orientated logic model subtype with the former focusing on a conceptualization of the question and the latter more concerned with an explanation of the pathways from the intervention to the outcomes; (3) populating the logic model template with information obtained through literature searches, discussions within the author team and consultations with content experts; (4) asking stakeholders for input and refining the logic model accordingly; (5) repeating steps 3 and 4 until all members of the author team agree that the logic model accurately represents the framework for the specific HTA/SR; and (6) publishing the final logic model with the protocol of the HTA or SR. This logic model remains unchanged during the HTA/SR process.

For iterative logic modelling, a five-step process includes: (1) creating an initial logic model as a starting point for subsequent exploration, where a logic model template is used to create an initial logic model de novo; (2) identifying data on the whole system or entire process, or on individual components of the model, where data may come from stakeholders, the review team, ongoing primary research or the published literature; (3) making

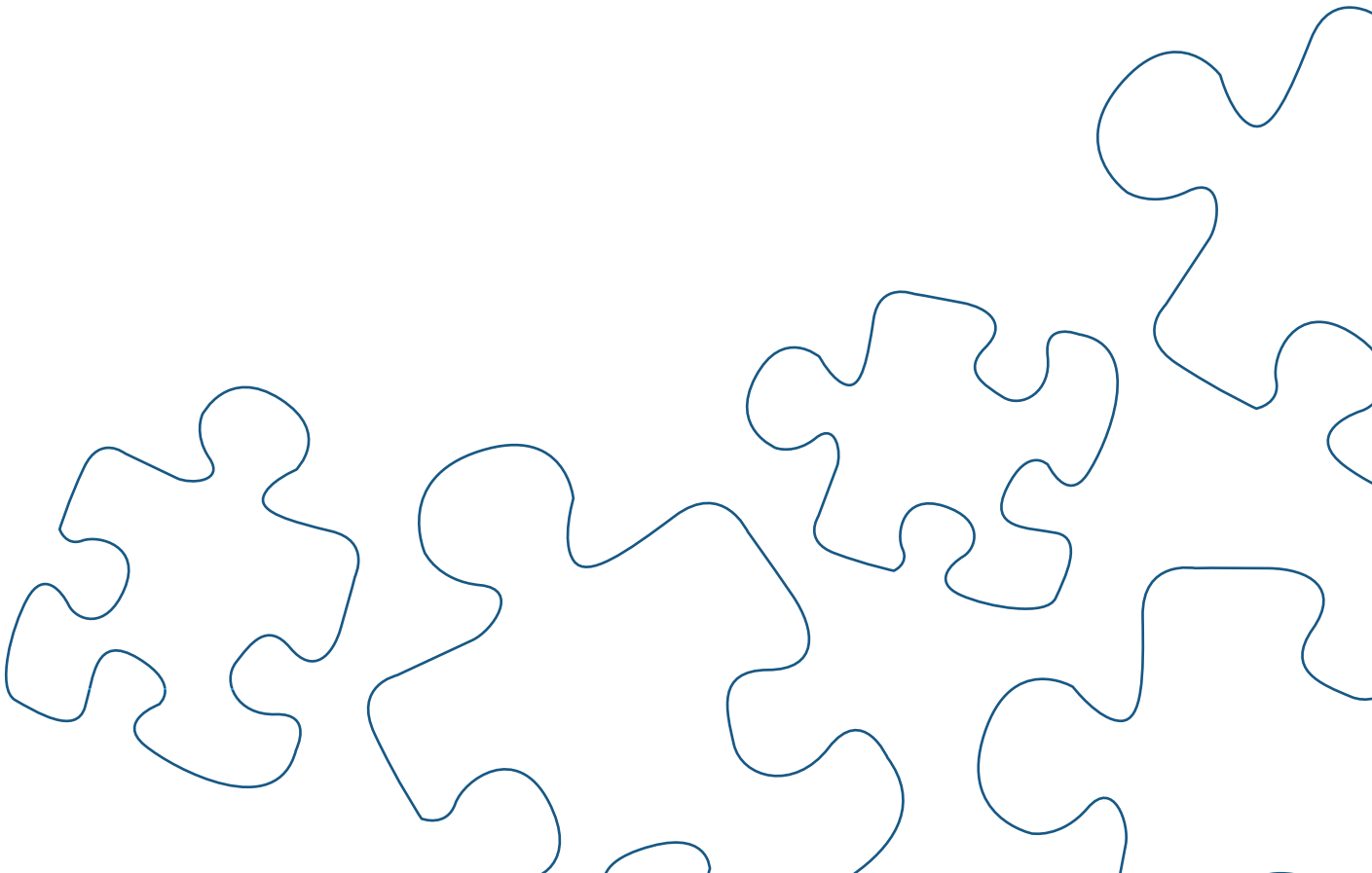
changes to the initial logic model repeatedly and at any point of the review and documenting these changes carefully; (4) creating a new numbered version of the logic model, where changes are considered substantive or stepwise; and (5) recording a definitive version of the logic model for the purpose of publication within the final HTA/SR report. It is recognised that this version of the logic model is only definitive with regard to the specific project timeframe and may well be subject to subsequent modification by the HTA/SR team, or indeed by other teams.

For staged logic modelling, a four-step process consists of: (1) developing an initial logic model, using one of the templates and various mechanisms to populate them, in particular input from stakeholders and literature searches; (2) pre-specifying points within the HTA/SR process at which significant inputs, defined in terms of quantity or importance, are likely to have an impact on the structure and content of the HTA/SR and thus the logic model; (3) revisiting the logic model at the pre-specified review and revision points, and creating new and clearly labelled versions, documenting how and based on which data sources changes were made; and (4) presenting selected versions of the logic model, as a minimum the initial and the final logic models, in the HTA/SR report.

Conclusions

Logic models are an important tool when conducting HTAs or SRs of complex health technologies, as they enhance transparency on underlying assumptions and help understand complexity by depicting the entire system, its parts and the interactions between intervention and outcomes; they also play a key role in integrating across different parts of a multi-component HTA. Nonetheless, logic models are not a panacea in addressing or resolving complexity and each type shows its specific strengths and limitations. This guidance provides a state-of-the-art overview of current practices in the use of logic models within HTAs and SRs. By providing templates for generating a logic model de novo, it aims to make the process of logic model development and application as straightforward as possible. Certain types and sub-types of logic models are more or less suitable depending on the technology concerned and the HTA/SR question addressed and approach pursued. This guidance offers a series of considerations on how to choose between a priori, iterative and staged logic models, illustrated with example applications of each type.

Guidance on the use of logic models in health technology assessments of complex interventions



List of abbreviations

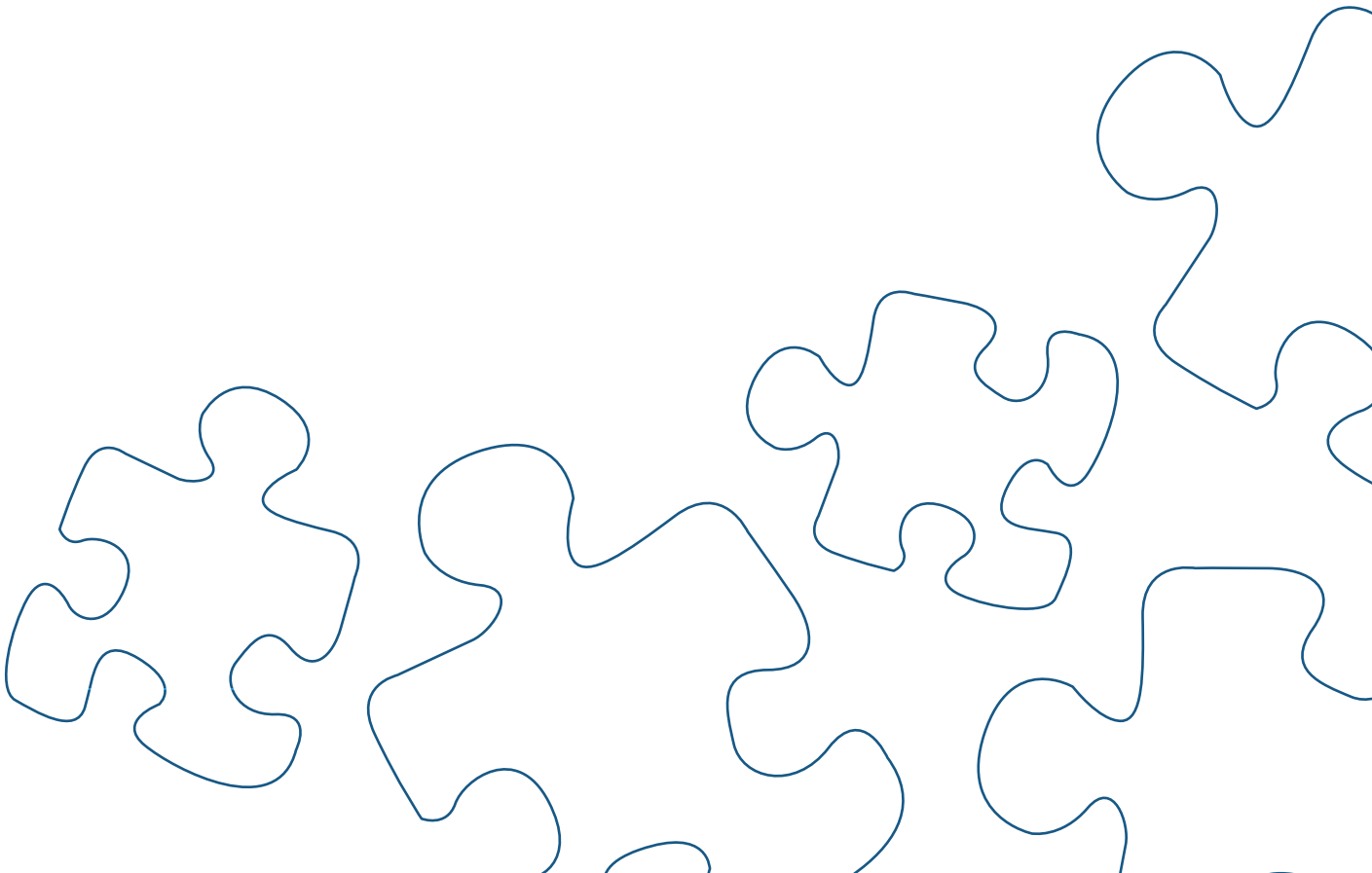
BeHeMoTh	Behaviour-Health Conditions-Exclusions-Models or Theories
CDC	Centre for Disease Control
CRD	Centre for Reviews and Dissemination
HIV	Human Immunodeficiency Virus
HTA	Health Technology Assessment
MeSH	Medical Subject Heading
MRC	Medical Research Council
NICE	National Institute of Health and Clinical Excellence
PICO	Population-Intervention-Comparison-Outcome
PICOC	Population-Intervention-Comparison-Outcome-Context
SAP	Stakeholder Advisory Panel
SR	Systematic review
UK	United Kingdom
US	United States

Table of contents

List of Tables

List of Figures

Guidance on the use of logic models in health technology assessments of complex interventions



1 PURPOSE AND SCOPE OF THE GUIDANCE

Recent years have seen acknowledgement that evidence-based decision-making can be considerably enhanced by the use of a logic model. This applies to systematic reviews, which attempt to identify, appraise and synthesise all the empirical evidence that meets pre-specified eligibility criteria to answer a given research question, as well as to HTAs, which systematically evaluate the properties, effects, and/or impacts of a health technology through an interdisciplinary approach. Systematic reviews of effectiveness are an integral part of an HTA. The purpose of this guidance is to provide a framework for commissioners, producers and users of HTAs and systematic reviews (SRs), which facilitates the systematic identification, selection and utilisation of different types of logic models when undertaking an evaluation of a complex intervention.

This guidance reviews current practice in the use of logic models within the context of HTAs and research synthesis. Two principal types of logic models are described, namely a priori (where the logic model is specified upfront and remains unchanged during the HTA/SR process) and iterative logic models (where the logic model is subject to continual modification throughout the course of an HTA/SR). A third type, the staged logic model, is proposed to harness the strengths of both a priori and iterative approaches by pre-specifying revisions at points where major data inputs are expected. Within these three logic model types two subtypes are identified, namely those logic models that seek to represent structure (system-based) and those that focus on processes or activities (process-orientated).

1.1 AIM OF THIS GUIDANCE

When evaluating complex health interventions, logic models can serve an instrumental purpose at every stage of the HTA/SR process, from scoping the topic of the HTA/SR, including formulating the question and defining the intervention; conducting the review; interpreting results and making the HTA/SR relevant for decision makers to implement in policy and practice (Anderson et al., 2011). This guidance offers direction on how to choose between distinct types and sub-types of logic models, describes each logic model type and its application in detail, and provides templates for getting started with the development of an HTA/SR-specific logic model.

1.2 TARGET AUDIENCE FOR THIS GUIDANCE

The target audience for this guidance comprises individuals and institutions that develop guidelines, perform HTA- and HTA-related research or commission HTAs, as well as SR authors who are interested in the use of logic models as a framework for guiding all parts of the HTA/SR process from problem specification to data extraction and analysis.

1.3 THE ADDED VALUE OF THIS GUIDANCE IN RELATION TO EXISTING GUIDANCES

The use of logic models in primary research and evaluation is well documented (Kellogg, 2004). Those interested in developing logic models per se are referred to the Kellogg Foundation guidance (2004) and to Purposeful Program Theory: effective use of theories of change and logic models (Funnell & Rogers, 2011). Yet, while examples of the use of logic models in HTAs exist, and they are mentioned in passing in SR guidance, no specific guidance exists on how to apply logic modelling in either HTAs or SRs. For example, the CRD's guidance for undertaking reviews in health care, (Akers et al., 2009) only briefly refers to the use of logic models to guide their reviews and the use of theory to assist in formulation of the causal pathways.

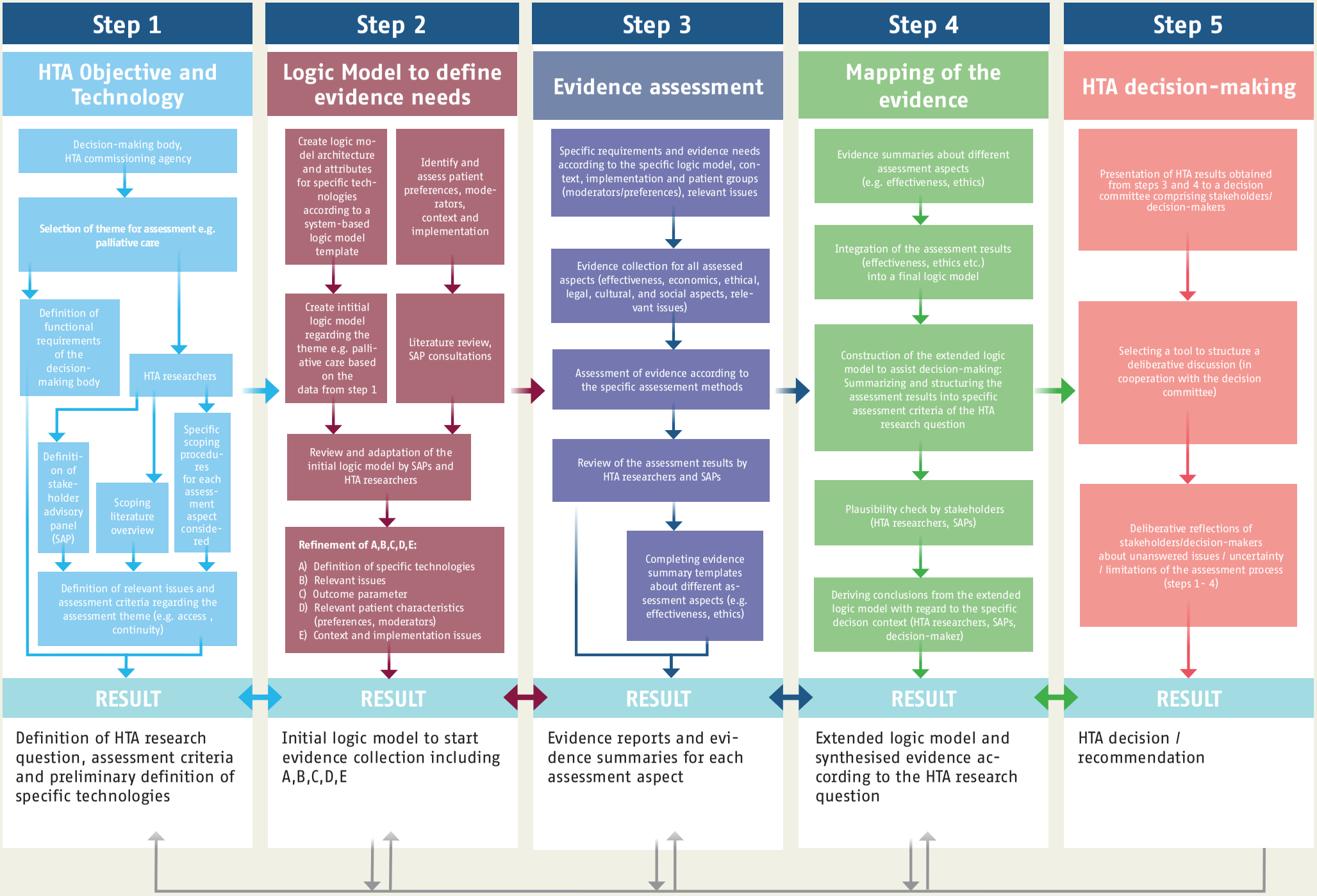
The National Institute of Health and Clinical Excellence's Public Health Methods Guidance (NICE, 2012) focuses on the use of a priori logic models as part of the initial scoping phase of the guidance. The intent is to use logic models to inform evidence identification. For NICE "logic models" are derived or developed from what are described as topic specific conceptual frameworks. These conceptual frameworks are, in turn, specific translations from a generic NICE public health conceptual framework. However the guidance does not detail explicit methods for production of any of these frameworks.

The guidance offered below attempts to overcome the deficits identified by Noyes et al. (2013) who highlight the need for a taxonomy of logic models, the development of logic model templates and a better understanding of the impact of choice of logic model on the review process and its findings . It draws heavily on two articles on the use of logic models in SRs (Anderson et al., 2011; Baxter et al., 2010). Indeed the different philosophical stances adopted in these documents led to the proposition of three types of logic modelling – a priori, iterative and staged – and influenced the development of systems-based and process-orientated logic model templates.

1.4 LOCATING THE GUIDANCE IN THE INTEGRATE-HTA PROJECT

In order to achieve an integrated HTA, the application of the methodological guidances was structured into a systematic

Figure 1 – Role of logic models in the INTEGRATE-HTA Model (Wahlster et al., 2016).



assessment process to address integration from the very beginning of the HTA. The INTEGRATE-HTA Model consists of 5 steps (Figure 1). After an initial definition of the HTA objective and the technology in accordance with the support of the stakeholders in step 1, the specific logic model in step 2 provides a structured overview of the factors and aspects around the technology. Patient characteristics, context and implementation issues feed into the assessment of effectiveness, and economic, ethical, legal, and socio-cultural aspects in step 3. In step 4, a graphical overview of the assessment results structured according to the HTA objective and the logic model is provided. Finally, the presentation of the results in step 5 forms the basis of a structured decision-making process.

As clearly visible in Figure 1, logic models are a key element in the five-step INTEGRATE-HTA Model and provide an important framework by which a team might organize all aspects that are to be included in an HTA for a complex intervention. These aspects include core elements of the HTA, in particular effectiveness and economic assessments, as well as socio-cultural, ethical and legal considerations (Lysdahl et al., 2016a), contextual and implementation aspects (Pfadenhauer et al., 2016), and patient preferences (van Hoorn et al., 2016a; van Hoorn et al., 2016b). This guidance thus provides a backdrop for all the remaining INTEGRATE-HTA guidance documents and for the HTA case study itself. Indeed, step 2 relates to crafting a logic model to define the distinct evidence needs for all relevant aspects and step 4 maps the findings of these evidence assessments to the extended logic model to assist decision-making, a major output to be considered in the HTA decision-making process.

2 BACKGROUND

A logic model is described as "... – a graphic description of a system – ... designed to identify important elements and relationships within that system" (Anderson et al., 2011). Such a graphic representation is particularly helpful for agreeing on assumptions between researchers and making results more accessible to decision makers. Traditionally, logic models are used to evaluate programmes. The basic logic model in programme evaluation systematically presents the relationships between available resources or inputs; planned activities; outputs and desired outcomes and impact (Guise et al., 2014). A logic model is a programme management tool and can offer an alternative way of visualizing the underlying theory of change beneath a particular programme. It thus presents a useful framework for describing and/or evaluating how a given intervention or programme is believed to achieve its effects. By presenting this information graphically, rather than in narrative form, researchers and decision makers can gain a clearer view of the relationship between constituent parts of the programme and how they interact.

2.1 DEFINITIONS

Logic models can be described as any of the following: conceptual frameworks, analytical frameworks, concept maps, or influence diagrams (Wildschut, 2014). They are a graphical representation and have been used in the fields of planning and evaluation of public health, social sciences and education.

We have identified two main influences on logic model methodology. The SR tradition, from which derives the a priori logic model, and the programme evaluation tradition, from which derives the iterative logic model. The a priori logic model is developed during the protocol phase; once the protocol is finalized and published, the logic model is fixed and prescribed. Consequently the logic model does not change during the HTA or SR process and may, in fact, be published with the authoritative version of the protocol. Such an approach is concordant with thinking specifically around SRs – the protocol specifies what will be done during the review process and this specification does not change. This contrasts with approaches that principally derive from programme evaluation where a definitive version of the logic model may only emerge once evaluation data have been collected and analysed. For example the Center for Disease Control (2003) depicts the logic model as "an iterative tool, providing a framework for program planning, implementation and evaluation" (Sundra et al., 2003). As part of an iterative logic model approach, the logic model is conceived as a mechanism by which to incorporate the results of the HTA and is subject to repeated changes during the process of data collection.

Drawing on the basic idea of a logic model described above, the Kellogg Foundation describes three types of logic models: the theory approach logic model; the outcomes approach logic model; and the activities approach model (Kellogg, 2004). The theory approach model emphasises theories and concepts that underlie the design of a programme and is particularly useful during the planning and designing phase of a programme. The activities approach model focuses on the implementation process and aims to describe the intention of a programme and the specific steps needed to achieve this intention; it is most useful for monitoring and management during the implementation phase of a programme. The outcomes approach model focuses on the connections between the resources, activities and the outcomes, which are usually subdivided into short-term outcomes (1 to 3 years), long-term outcomes (4 to 6 years) and impact (7 to 10 years); this model is most usefully applied during the evaluation of a large-scale programme (Kellogg, 2004).

Finally, a logic model may be used formatively (Burns et al., 2015) as a mechanism for engaging with stakeholders and for stimulating internal debate within the HTA/SR team or summatively (Khoo & Giersch, 2009) as a vehicle for the

presentation and analysis of HTA/SR findings and their implications.

2.2 PROBLEM DEFINITION AND THE ADDED VALUE OF LOGIC MODELS

HTAs and SRs are a powerful means by which to summarise a body of evidence and to inform decision making. Systematised processes specifically seek to minimise the potential for bias thus increasing confidence in the interpretation and application of findings. However, recent years have witnessed a major challenge to methodology given the complex nature of policy questions in diverse fields, such as education, health, social welfare, and criminal justice (Boaz et al., 2002; Booth et al., 2011; Shemilt et al., 2011). Systems-thinking has been proposed as one mechanism by which researchers might seek to map, measure and understand the dynamics of complex systems (Martin & Felix Bortolotti, 2010). Logic models, with their origins in the field of programme planning and evaluation research, are one important tool to put systems thinking into practice. However logic models have not commonly been used to guide synthesis methods and, although several authors provide an enticing glimpse of their potential, no formal guidance exists for their use within the context of HTAs/SRs.

2.2.1 Scoping the HTA

The first stage in an HTA requires defining the question and pre-specifying what evidence is of relevance to the problem or hypothesis of interest (Anderson et al., 2011). Indeed, defining the HTA research question and providing a preliminary definition of the technology under consideration is undertaken in step 1 of the INTEGRATE-HTA Model (Wahlster et al., 2016). The aim is to gain a sense of the "big picture" to inform those areas on which the subsequent HTA will focus. Provided this stage of the process is suitably wide-ranging and considered, which itself has an implication for time requirements, the HTA team can "consider potential contingencies or competing phenomena within a social system that might affect the success or failure of a programme or policy to achieve their objectives" (Anderson et al., 2011).

2.2.2 Collecting the research evidence

A logic model operates in a similar, but more complex and encompassing, way to the generally accepted PICO (Population-Intervention-Comparison-Outcomes) (Richardson & Wilson, 1997) or expanded PICOC (Population-Intervention-Comparison-Outcomes-Context (PICOC) (Petticrew & Roberts, 2008) framework. It communicates the rationale for data collection and evidence synthesis, thereby making the whole process transparent. A logic model thus facilitates identification of "study inclusion/exclusion criteria, for guiding the search strategy (such as search terms and databases and strategies or filters included), for identifying relevant outcomes, and for examining differences among studies and along dimensions of interest" (Anderson et al., 2011).

A priori logic models provide an early opportunity for the HTA/SR team to clarify their understanding of the theory of change (the programme theory) underpinning programmes or policies. This will in turn determine the type and extent of evidence required for each component of the logic model. As Anderson and colleagues (2011) state: "SRs can yield different conclusions based on how the research question is operationalized; literature is searched; studies are included or excluded from the review; data are analyzed; and cumulative research is interpreted and presented". Thus logic models offer "an accessible and transparent way of justifying such decisions, and of examining differences among related SRs" (Anderson et al., 2011).

2.2.3 Explicating theory

The main function of a logic model within the pragmatic context of an HTA/SR is to identify and communicate the underlying programme theory behind a policy, programme or intervention. This, in turn, informs an assessment of the extent to which that programme is effective. Nevertheless a further and important function of the logic model is as a potential vehicle for theory building. In order to test hypotheses regarding how exactly the programme theory might operate requires identification of a sufficiently sizeable body of theory-relevant research (Anderson et al., 2011). The resultant set of studies can be used "to examine common causal mechanisms and to clarify empirical relations between the mediator and the main effects" (Anderson et al., 2011). The logic model therefore offers an important vehicle by which to guide inquiry into the theory underpinning the intervention of interest.

2.2.4 Constructing an analytical map

In addition to its potential conceptual contribution a logic model may serve a more instrumental purpose as a "lens" for analysis. Analytic logic models seek "to demonstrate a chain of logic between inputs and outcomes and to capture any possible alternative explanations" (Anderson et al., 2011). Indeed a considerable methodological advantage, within the specific context of the science of evidence synthesis,

is that "specifying all relevant causal relationships a priori, uninfluenced by the findings…, should help reduce bias in researcher judgment" (Anderson et al., 2011). Selection of a suitably objective lens for evaluation, separated from considerations prompted by detailed evaluation of the data itself, offers the prospect of "a well articulated rationale for a practice recommendation with clear evidence in support of the conclusion" (Anderson et al., 2011). Some commentators question the extent to which "a priori knowledge and social science theory can adequately anticipate the effects that a given social program can be expected to have" (Chen & Rossi, 1980). However, this risk is comparatively minimised given that, within the context of HTA, the logic model is being applied retrospectively to published data, rather than prospectively within a programme evaluation.

2.3 DESCRIPTION OF THEORETICAL BACKGROUND AND AVAILABLE APPROACHES

Currently, the choice of logic model approach is primarily determined by a HTA/SR team's prior familiarity with particular logic model methods and forms of presentation. It is further informed by a wider philosophical debate on the purpose and function of logic models (Pawson et al., 2005; Squires et al., 2013). This philosophical debate hinges on the extent to which logic models are to be considered a purpose-specific innovation within the context of HTAs and SRs (Noyes et al., 2013) and the extent to which they derive their pedigree from the broader context of programme evaluation (Brousselle & Champagne, 2011). Within the broad arena of SRs the influence of qualitative evidence syntheses has served to open the toolkit to more iterative and flexible methods. In parallel, the imperative to provide answers to time-critical policy-driven questions has driven a need to fast-track much of the conceptualisation and problem specification that can be seen as a necessary but delaying component of a conventional HTA/SR process (Best et al., 2009; Thomson, 2013).

2.4 COMPLEXITY

The UK Medical Research Council (MRC) defines complex interventions as being characterised by the number of interacting components within the experimental and control interventions, the number and difficulty of behaviours required by those delivering or receiving the intervention, the number of groups or organisational levels targeted by the intervention, the number and variability of outcomes, and the degree of flexibility or tailoring of the intervention permitted (Craig et al., 2008). Shiell et al. (2008) highlight that complexity is a characteristic of the system within which an intervention acts as well as being an inherent characteristic of an intervention itself. They describe complex systems as being adaptive to their local environment, as behaving non-linearly and as being part of hierarchies of other complex systems (Shiell et al., 2008) (Table 1).

Many of the traditional methods of analysis in HTA rely upon specific assumptions about the structure, content and objectives of an intervention, its implementation, the system within which it is intended to act and the potential interplay and co-evolution of the system and the intervention. However, to avoid misleading conclusions, HTA should take the complexity of a technology and/or the complexity of its environment into account. For example, when assessing a technology such as an educational programme to prevent the transmission of the human immunodeficiency virus (HIV) the success or failure might depend on the message itself (e.g. abstention or condoms or both), the messenger (a young celebrity or a respected religious leader), the target group (sexually active adolescents or elderly religious persons), the medium transmitting the message (internet spots or lectures), the perceived prevalence of the disease (omnipresent threat or small chance), and so on. Simply to focus on the content of the program without considering these other factors is not sufficient.

Complexity is not a binary property, and exists rather along a spectrum. All interventions could, therefore, be considered complex to a certain extent. This guidance, however, focuses on those health technologies where the presence of complexity has strong implications for the planning, conduct and interpretation of the HTA. Mitleton-Kelly (2003) lists potentially relevant characteristics of complexity (Table 1).

Consequently, when starting an assessment of (any) health technology these factors should be carefully reviewed with the purpose of

1. describing the complexity of an intervention and the system within which it acts,
2. understanding whether this complexity matters for decision making and therefore needs to be addressed in an HTA,
3. understanding the implications of complexity for the methods of HTA analysis in assessing the ethical, legal, effectiveness, economic and socio-cultural aspects of an intervention, and

Table 1 - Summary of potentially relevant aspects of complexity in HTAs and SRs.

Characteristic	Short explanation
1 Multiple and changing perspectives	The variety of perspectives is caused by the many components (social, material, theoretical, and procedural), actors, stakeholders and organisational levels that are involved in the intervention. These are interconnected and interacting, and accordingly exposed to changes.
2 Indeterminate phenomena	The intervention or condition cannot be strictly defined or delimited due to characteristics like flexibility, tailoring, self-organization, adaptivity and evolution over time.
3 Uncertain causality	Factors like synergy between components, feedback loops, moderators and mediators of effect, context and symbolic value of the intervention lead to uncertain causal pathways between intervention and outcome.
4 Unpredictable outcomes	The outcomes of the intervention may be many, variable, new, emerging and unexpected.
5 Historicity, time and path dependence	Complex systems evolve through series of irreversible and unpredictable events. The time, place and context of an intervention therefore impact on the effect, generalizability and repeatability of an intervention.

4. exposing important factors that decision makers need to consider in interpreting the HTA.

Delineating a large and complex topic into a series of questions can help an HTA/SR team to decide how to organise, and subsequently tackle, intervention topics. A logic model offers a coherent starting point that "provides a common understanding of the multiple causes of the problem and helps define the conceptual boundaries for a set of reviews [or other types of evidence, such as information provided by various stakeholders]. Seeing the broader picture also might point to those policies or contextual factors that might attenuate or boost programme effects (Anderson et al., 2011).

2.4.1 How does the guidance approach the issue of complexity?

Synthesising evidence in the presence of complexity is particularly challenging. A series of papers published in the Journal of Clinical Epidemiology (Anderson et al., 2013), discusses various issues relating to complexity in SRs, suggests ways of dealing with this complexity at each stage of the review and highlights methodological areas that need further development and testing. (Anderson et al., 2013; Burford et al., 2013; Noyes et al., 2013; Petticrew et al., 2013a; Petticrew et al., 2013b; Pigott & Shepperd, 2013; Squires et al., 2013). A repeatedly mentioned tool, to help make sense of complexity when synthesising evidence, is a logic model.

Logic models can help to handle complexity by

(i) describing the various components of complex interventions and the relationships between them,

(ii) making underlying theories of change and assumptions about causal pathways between the intervention and multiple outcomes at different levels explicit (Anderson et al., 2011), and

(iii) carefully describing interactions between the intervention and the system within which it is implemented.

When evaluating complex health interventions, logic models can serve an instrumental purpose at every stage of the HTA/SR process, from scoping the topic of the HTA/SR, including formulating the question and defining the intervention (e.g. deciding on whether to 'lump' or 'split' components or interventions (Squires et al., 2013; Weir et al., 2012); conducting the HTA/SR (e.g. guiding the literature searches, identifying subgroups or deciding on surrogate measures); interpreting results and making the HTA/SR relevant for decision makers to implement in policy and practice (Anderson et al., 2011) (Table 2).

2.4.2 How have existing methods been expanded to adequately assess complex interventions?

Logic models were originally derived within the context of programme evaluation (Funnell & Rogers, 2011). More recently, as HTA/SR questions have progressed beyond a basic consideration of what works to a more nuanced understanding of what works for whom under what circumstances (Charles et al., 2013), logic models have been conceived as an important vehicle for unpacking some of these questions, in particular in relation to complexity.

2.4.3 What challenges exist with using this method for assessing complex interventions?

Mark and Henry (2013) "question the extent to which linear logic models convey the contingent decision making emphasized by some evaluation theo-ries" (Mark & Henry, 2013). Clearly, a logic model may require quite substantial iteration if a HTA/SR team decides that it is intended to capture feedback loops or indeed to acknowledge interactions between components within the model. To add value, a logic model must therefore progress beyond linear caricature while seeking to anticipate the full scale and nature of feedback loops and iterations.

3 GUIDANCE DEVELOPMENT

Overall, the development of this guidance was heavily informed by systematic searches for published examples of logic models and searches for existing guidance on the use of logic models in primary research, SRs and HTA.

We conducted systematic searches to identify HTAs and SRs that used logic models. We searched The Cochrane Library and the Campbell Library using the key search terms "logic model" OR "logic models"; and PubMed using the following search string: (systematic review [Title/Abstract] OR meta-analysis OR review [Title/Abstract] OR review [Publication Type] OR meta-analysis [Publication Type]) OR HTA OR "health technology assessment") AND ("logic model" OR

Table 2 – Added value of using logic models in systematic reviews (reproduced from (Anderson et al., 2011).

Scoping the review
• Refining review question
• Deciding on lumping or splitting a review topic
• Identifying intervention components
Defining and conducting the review
• Identifying relevant study inclusion/exclusion criteria
• Guiding the literature search strategy
• Explaining the rationale behind surrogate outcomes used in the review
• Justifying need for subgroup analyses (e.g. age, sex/gender, socio-economic status)
Making the review relevant to policy and practice
• Structuring reporting of results
• Interpreting results based on intervention theory and systems thinking
• Illustrating how harms and feasibility are connected with interventions
• Interpreting results based on intervention theory and systems thinking

"logic models") AND Humans [MeSH]. After removal of duplicates and exclusion of irrelevant studies (most commonly when the study was not a completed systematic review or HTA or did not include a logic model), we identified 18 published systematic reviews that included a logic model and one HTA that referred to the different phases of a logic model, but did not include a diagram. Thirteen (A1-A13) of the reviews identified used logic models at the beginning of the review process (a priori). Four of the reviews developed logic models to summarise and synthesise the results of the SR (A14-A17). One review mapped the results of the review to an a priori logic model (A18) (see Appendix I).

We then examined the aims and the various elements of the logic models identified and reviewed existing guidance for developing logic models in primary research (Funnell & Rogers, 2011; Kellogg, 2004). Drawing on existing definitions of complex interventions and the conceptualisation of complexity within the INTEGRATE-HTA project, we developed draft templates (see Figures 3 and 4 in section 4.2 below). The templates were refined in an iterative process within the research team and in consultation with external methodological experts.

Subsequently we identified a need to purposively sample iterative logic models to inform our guidance. We therefore used the Google Scholar interface using keywords related to "logic models", "systematic reviews or health technology assessments" and one of the following words "iterative or iteration or revised or revision or version". As might be expected, these latter words lacked specificity. Fortunately, however, the relative shortage of logic models in a specific HTA or systematic review context meant that it proved feasible to examine the full text, where available, of all references retrieved by the Google Scholar search engine. In addition we contacted co-convenors of the Cochrane Collaboration Qualitative and Implementation Methods Group who were able to identify examples of iterative approaches to logic models with which they had been associated.

Finally, we applied the draft templates to three ongoing SRs and one ongoing HTA. These are a Cochrane review of interventions to reduce particulate matter air pollution (Burns et al., 2014), a Campbell review of e-learning to increase evidence-based health care competencies in healthcare professionals (Rohwer et al., 2014), a review of interventions to reduce exposure to lead through consumer products and drinking water within a guideline developed by the World Health Organization (Pfadenhauer et al., 2014) and an HTA of models of reinforced home based palliative care within the INTEGRATE-HTA project (Brereton et al. 2016). Based on our own testing and the feedback from external users of the templates, we revised the templates and the accompanying definitions and explanations.

4 APPLICATION OF THE GUIDANCE

This guidance has been shaped by two contrasting philosophies that underpin the generation and use of logic models. On the one hand there is an emerging SR 'tradition' which requires aspects of problem definition to be identified and secured as early as possible in an attempt to minimize the prospects of 'scope creep' and, of potentially more concern, the likelihood of bias (Booth, 2011). On the other hand the programme evaluation 'tradition' emphasises the pragmatic concerns of making use of all available data in seeking to identify a programme theory and thus address a particular practical question (Funnell & Rogers, 2011).

This guidance has resolved these tensions by distinguishing between three different types of logic modelling on a spectrum from "fully a priori" to "fully iterative", each with their inherent advantages and disadvantages. It outlines selection criteria by which a review team might determine the most appropriate logic model type for their purpose and provides a worked example of each type.

4.1 AVAILABLE METHODS

4.1.1 Development of a logic model

Logic models can either be adopted or adapted from the literature or they can be created de novo. In practice, both approaches may be combined but to differing degrees of intensity.

4.1.1.1 Identification of published logic models

We have been unable to identify any documentation of formal methods by which logic models can be identified from the literature. Identification of logic models is particularly problematic because the existence

of a logic model is unlikely to be flagged within the title or abstract of a SR. A tentative possibility in this task is to use information retrieval procedures recently developed for the systematic identification of theory.

Logic models can be variously described as: conceptual frameworks, analytical frameworks or concept maps. As such they would be retrieved by our generic Behaviour-Health Condition-Exclusions-Models or Theories (BeHEMoTh) search filter for papers reporting theory. This involves a string of terms based on theor* or concept* or model* or framework* (Booth & Carroll, 2015). A possible addition to this string, in the specific context of logic models might be: "influence diagrams" or, indeed diagram* more generally.

4.1.1.2 Adaptation of a logic model from the literature

Where theorising is relatively immature within the specific context of an HTA or SR, an existing but clearly "imperfect" logic model may offer a "scaffolding" framework, which is populated during the HTA/SR process. The contingent nature of this framework (i.e. it is not the finished framework) may be recognised by using a variant of synthesis known as best-fit framework synthesis (Booth & Carroll, 2015; Carroll et al., 2011; Carroll et al., 2013). Following this approach may be appropriate when a team has identified key elements of an intervention but not necessarily how these are interrelated. The approach is operationalised by elements of the initial logic model being "deconstituted" to become fields in a data extraction form. Once data extraction is completed, relationships identified from the data are depicted and a revised, expanded logic model is "reconstituted" (Booth & Carroll, 2015). Additional logic model components, identified from the literature or identified by stakeholders, may be added in a more inductive formal stage of development of the model.

4.1.1.3 Creation of a logic model de novo

In most cases, the existing literature is unlikely to offer a suitable logic model that could be used as a starting point for an HTA or SR. Consequently, much of this guidance is dedicated to offering help with the creation of a logic model de novo.

Creation of a logic model de novo may be initiated by taking into consideration and carefully thinking through, at the very least, the core elements of the HTA or SR as described by the PICO (Richardson & Wilson, 1997) or PICOC frameworks (Petticrew & Roberts, 2008). Several approaches can be combined to varying degrees in developing a new question-specific logic model, usually conceptualisation, brainstorming, literature searches and stakeholder involvement. The logic model templates proposed in this guidance (see section 3.2) are intended as a starting point for the development of an initial logic model.

The contribution of literature to development of a de novo logic model is often limited, with much emphasis being placed on mechanisms for consultation with stakeholders. Significantly, Purposeful Program Theory: effective use of theories of change and logic models (Funnell & Rogers, 2011) only provides one paragraph on the role of literature in developing a logic model, cautioning that examination of reviews of the literature is useful but may yield an outdated or obsolete perspective on a potential programme theory.

4.1.2 Available option(s) for logic modelling

This guidance identifies and describes three types of logic models related to the developmental phase on which the logic model focuses – i.e. a priori, staged or iterative – and two subtypes of logic models related to the structural elements of a logic model – i.e. system-based or process-orientated (Table 3).

Table 4 provides definitions for each logic model type and subtype. A logic model may be specified a priori (type A), close to the inception of an HTA or SR. Alternatively it may be seen more tentatively as a "best fit" framework by which a review team produces an approximation of the review problem and then progressively refines the logic model, in an iterative manner (type B), with the addition of data or additional perspectives. This added detail may result in enhanced granularity or in a novel insight into the relationship between included elements; unanticipated iteration can occur throughout the HTA/SR process. We have added a further approach, which harnesses the inherent advantages of the preceding types while minimizing their apparent weaknesses. This staged approach (type C) requires identification of important stages at which additional data might be anticipated and thus at which the logic model may be subject to revision. It thus pre-specifies the creation of successive versions of the logic model and recognises that the initial logic

model may have imperfectly conceived the original problem. At its simplest level the staged model might require revision of an a priori logic model in a single iteration at the end of the HTA/SR process.

These three types of logic models are not entirely independent. An initial logic model is the starting point for all three types of logic models. Investment of time and effort to clearly define the health technology and associated information requirements may be considered "central to planning reviews that are relevant, as well as conceptually appropriate and manageable" (Thomson, 2013). Indeed, the development of an initial logic model is a key means of integration across all aspects of an HTA (Wahlster et al., 2016). In the case of the a priori logic model the scoping process seeks to identify potential issues relating to heterogeneity and "factors that may mediate the impact of the intervention or independent variable" (Thomson, 2013). The scoping process may also help to establish the potential scale of the initial review question and reveal initial complexities inherent in associated questions. For the iterative logic model the scoping process seeks to characterise the parameters of the review topic as a framework for subsequent iterations of increasing granularity. For the staged model the scoping process may help to identify types of data that will need to be extracted from the literature or collected from primary data sources. This helps in the determination of points at which new data is to be added and the possibility of revision of the logic model is correspondingly high. In all cases the initial logic model offers a "way of mapping the outcome of discussions" within the HTA/SR team (Thomson, 2013).

A further important distinction is between system-based and process-orientated logic models. A system-based logic model is primarily used to describe the system in which the interaction between the intervention and the outcomes takes place and can also be described as a conceptual framework. In contrast, a process-orientated logic model is primarily used to describe and analyse the processes and causal pathways leading from an intervention to its multiple outcomes and thereby serves as an analytical framework (Table 4).

4.1.3 How to choose the right option

A HTA/SR team must first determine whether to use the a priori, iterative or staged logic model approach (section 4.1.3.1). Subsequently, they must decide whether to employ a system-based or a process-orientated approach to modelling the decision prob-

Table 3 – Overall taxonomy for logic models as operationalised by this guidance.

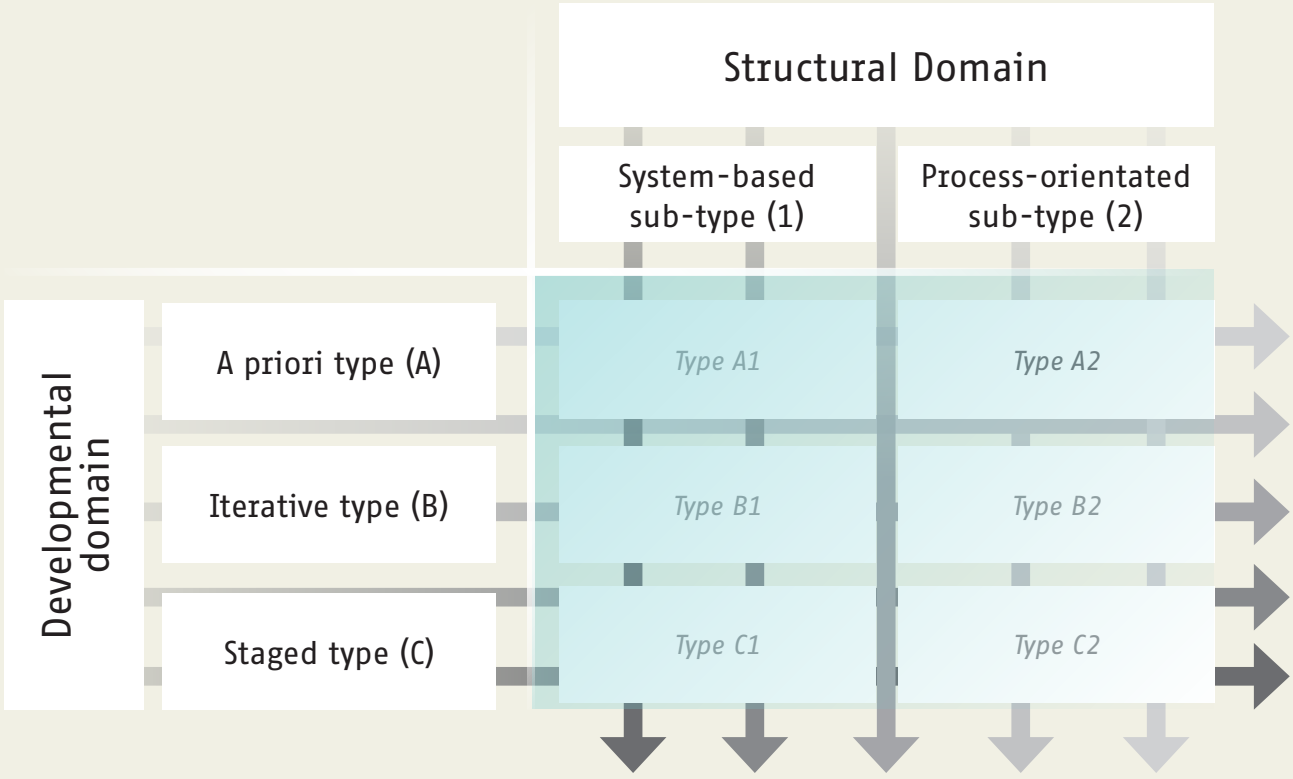


Table 4 – Three types of logic models and their two sub-types, as described in this guidance.

Label	Meaning
A priori logic model	A logic model that is specified as close to the inception of an HTA or SR as scoping the literature and/or stakeholder consultation permit and that remains unchanged during the HTA/SR process.
Iterative logic model	A logic model that is subject to continual modification and revision throughout the course of an HTA or SR.
Staged logic model	A type of iterative logic model that pre-specifies points at which major data inputs are anticipated to prompt a subsequent version of the logic model, thereby increasing transparency and minimising problems with version control.
Process-orientated logic model	A sub-type of logic model, applicable within a priori, iterative or staged logic modelling approach, that seeks to capture elements of process within a programme or policy.
System-based logic model	A sub-type of logic model, applicable within a priori, iterative or staged logic modelling approaches, that employs systems-based approaches to unpick the complexity of a policy or programme.

lem (section 4.1.3.2). Table 5 provides an overview of the key considerations in relation to choosing between different logic model types and sub-types, which are further described in the following sections; together with some additional considerations that are relevant to all logic modelling approaches (section 4.1.3.3).

4.1.3.1 Considerations to determine choice of logic model type (a priori, iterative or staged)

A key consideration for the HTA/SR team is the purpose to which they want to put the logic model and the consequent HTA or SR. It is the research question that should primarily determine the chosen approach. As such the "right" tool is selected judiciously for the appropriate question/purpose in relation to (i) the broad or narrow scope of the HTA/SR (i.e. lumping vs. splitting), with narrow/specific questions lending themselves more to an a priori approach, (ii) whether the HTA/SR is expected to be theory-generating or theory-testing, with theory testing placing a requirement that a logic model be determined sooner rather than later and (iii) the types of evidence to be considered, with sources offering a single or finite anticipable number of perspectives pointing towards an a priori model whereas multiple, potentially dissonant perspectives may require a more iterative approach.

Ultimately, of course, such concerns are firmly located within the decision as to which kind of HTA/SR approach the team decides to pursue, as determined by the funder's requirements or by the available resources and expertise of the HTA/SR team. Fundamental to such approaches is a broader distinction between two different schools of evidence synthesis methodology, i.e. the traditional "Cochrane-style", (now also widely practiced outside of the Cochrane Collaboration), a priori world of defined pre-specified questions and defined prescriptive processes – and the iterative fluid nature of many of these same processes exercised descriptively within many qualitative and mixed method reviews. As such the differences in choice of logic models may be seen as a natural consequence of these two schools of thought. Furthermore this choice may also be orientated within evidence syntheses characterised as aggregative, where the review team seeks to identify all studies meeting predefined PICO or PICOC

inclusion criteria, or configurative, where the review team starts with a broad direction of travel and then subsequently responds to patterns that emerge from the data (Gough et al., 2012).

The HTA/SR team should discuss to what extent the assessment is concerned with the analysis of a tightly prescribed intervention or with a broader societal perspective. A priori logic modelling holds considerable strength within the context of single, well-focused technology appraisals where much is already known about the intervention itself. Indeed such logic models are very useful when depicting the complexity of the intervention components and delivery mechanisms, as well as the outcomes and the context, where these are well-theorised and well-explored. Iterative and staged logic modelling may be more suited for the types of HTA/SR commissioned around programmes or packages of care or, equally for public health and social interventions. In such cases an HTA/SR team often faces the reality that consensus around the definitions associated with the individual PICO or PICOC elements does not yet exist.

Another important consideration is the extent to which the various PICO or PICOC components are "pre-specified, secure, and well-defined" (Dixon-Woods et al., 2006) and the extent of likely heterogeneity in these elements (Petticrew et al., 2013b). Where there is broad general agreement, within the team, within the literature or among stakeholder groups, on the components or processes of a particular HTA/SR topic, it may be preferable to use an a priori logic model approach. Here, the logic model defines the problem under consideration from the very beginning, as a relatively inflexible reference point for the subsequent HTA/SR. With an iterative or staged logic model approach, one or more of the initial question components may be undefined, poorly defined, or lacking consensual terms. As an example, "palliative care", "multidisciplinary rehabilitation" or "group clinics" share a need to first identify, define and explore their characteristics as a necessary prequel to an HTA/SR. Similar complexities may exist in connection with a population (e.g. "deprived populations"), a comparator (e.g. "usual care") or outcomes (e.g. "satisfactory", "successful" etc.) and, indeed, with the surrounding temporal and geographical context. In such a situation the intervention or programme may be defined descriptively further down the line by the presence or absence of certain mechanisms instead of proscriptively by secure definitions of all the PICO or PICOC elements; if so, an iterative or staged approach clearly adds value compared to an a priori approach.

Additional complexity may be contributed by the interaction and interplay of multiple factors not readily identified a priori. These factors may be independent, synergistic or antagonistic, they may operate as alternatives, may be interdependent and may be required to be present individually or collectively, or in an optimal sequence. Indeed, these factors may operate such that an increase in one effect is only achieved at the expense of a diminution of another. Therefore, an additional consideration in choosing between an a priori, staged or iterative logic model approach is the extent to which extent the HTA/SR team and the stakeholders consulted at the beginning of the process can readily anticipate all the issues relating to complexity. Where it is difficult to specify all elements of complexity upfront, an iterative or staged approach is likely to add value over an a priori approach.

HTAs and/or SRs are often undertaken or commissioned within very tight timelines; in some European countries such as the UK, an HTA must be completed within 12 months, other countries and their commissioning bodies tend to be more flexible. Timelines and financial as well as personnel resources may influence whether continual revisions of the logic model in a truly iterative approach or revisions at set stages during the HTA/SR process are even feasible, where adopting an iterative approach is likely to be more time-consuming and difficult to organise than an a priori approach. Linked to this, philosophical stances within the HTA/SR team as well as commissioning bodies may determine whether, and to what extent, iterative features are taken forward. We recognize that a completely iterative model may be problematic within the context of a multi-component HTA, particularly if it is being coordinated across multiple academic centres. The staged model carries more flexibility than the a priori model but removes the risk of teams working on different versions of a logic model simultaneously.

4.1.3.2 Considerations to determine choice of logic model sub-type (system-based or process-orientated)

A system-based logic model, which describes the system in which the interaction between the participants, the intervention and the context takes place, should generally be the starting point for an HTA or SR. It offers a holistic perspective and can thus serve to integrate all elements of the HTA (Wahlster et al., 2016); it is also highly suited to broad interventions,

such as packages or approaches to health care. A process-orientated logic model, which graphically displays the processes and causal pathways that lead from the intervention to its outcomes, may be used in addition or, in rare circumstances, as stand-alone where the composition of the intervention is generally well-understood but the focus is on elucidating the details of how the intervention operates.

Broad HTA or SR questions are best addressed by adopting a system-based logic modelling approach. A process-orientated logic model adds value where the question focuses on how an intervention exerts its effect, i.e. where the assessment attempts to elucidate the mechanism of action in terms of the causal chains or pathways.

4.1.3.3 Considerations irrespective of logic model choice

An HTA/SR team should be explicit about the use or adaptation of an existing logic model versus the creation of a new logic model (see section 4.1.1). Importantly, it should indicate and describe in detail the various data sources used to construct or populate the logic model, including conceptualisation, brainstorming, literature searches, feedback from content experts and stakeholder consultations. The latter play an important role in ensuring that the perspectives of different stakeholder groups (e.g. policy-makers, funders, implementers, patients, patient relatives) are represented. Importantly, a multi-component HTA may comprise more than one logic model. For example, a broad system-based logic model may serve to integrate the whole HTA process (Wahlster et al., 2016), whereas one or more additional logic models of different types or subtypes could guide individual components, such as the assessment of effectiveness (Burns et al., 2016) or of context and implementation factors (Pfadenhauer et al., 2016).

The HTA/SR team should be transparent with respect to the overall approach adopted, whether a priori, iterative or staged (see section 4.1.3.2). If the team agrees that the logic model is to change after the protocol stage, it should identify at what points in the conception and development of the logic model and the project as a whole it is feasible and appropriate to make changes to the model. This is especially important as logic models represent an important overall means of integration across the HTA (Wahlster et al., 2016).

An HTA/SR team should specify whether the logic model is intended to hypothesise how processes should work (prescriptive) or to depict how they actually work (descriptive). For example the US Preventive Services Task Force defines a logic model as "a schematic that shows the hypothesised relation between interventions and their intended outcomes" (Harris et al., 2001).

Logic models, when attempting to be comprehensive, may contain a complexity that is difficult to explain and communicate to those commissioning or wanting to use an HTA or SR. The HTA team must seek to capture a level of detail proportionate to the intended purpose and audience of the logic model. The graphical presentation of the logic model is usually supplemented with a more detailed description of the different elements in the text; in this way, additional detail can be placed in the text without overcrowding the graphical presentation. With respect to the graphical presentation, the HTA/SR team may consider whether the accuracy and complexity of a detailed logic model is being achieved at the expense of clarity. It may be necessary to revise the logic model to a higher level of abstraction specifically for communication and dissemination purposes. In such cases, it should be made clear that a more detailed version is available. Whatever the team's decision it is clearly advantageous to ensure that a logic model is able to reflect a variety of levels of granularity so that textual and graphical presentations of the interventions or programmes may be both complementary and explicative. Within the context of presentation we should also highlight that a logic model may serve a formative function as a vehicle for securing engagement and input from stakeholders or internally within the review team, and summatively where it is conceived as a device for concise presentation of results to the intended final audience. The exact graphical presentation (e.g. vertical vs. horizontal page format, placement of context box, placement of comparison box) can vary depending on aspects, such as the SR/HTA question and scope, communication needs or layout constraints.

4.2 USING TEMPLATES TO DEVELOP AN INITIAL LOGIC MODEL

Irrespective of the type of logic model approach – a priori, iterative or staged – adopted, an initial logic model must be developed. The templates described in this section should help those conducting an HTA or SR to think through all key elements in relation to the HTA or SR question. They are not intended as a straitjacket but to make the development of a logic model de novo as straightforward as possible.

4.2.1 System-based logic model template

The system-based logic model template is shown in Figure 2[1]. The PICO or PICOC elements to formulate clear research questions form the core of the logic model, supplemented with context and implementation elements.

Participants refers to the targeted population. Necessary details, such as geographical scope, health condition or socio-economic characteristics, and relevant subgroups should be included.

The intervention component is often the most important aspect of an HTA or SR as the intervention is typically the technology that is being assessed. The intervention must therefore be well defined. It may be further divided into theory, design and delivery elements.

The theory underpinning the design and planning of an intervention is critical. Here the term "theory" is used in a broad way to describe a body of implicit or explicit ideas on how an intervention works (Pope et al., 2007; Wells et al., 2012) and includes the overall aims of the intervention.

Intervention design describes the "What?" of the intervention under the headings components and execution. The components of the intervention can be categorised as technology and infrastructure; education; or policy and regulations. The execution of the intervention comprises a more detailed "prescription" of the intervention – timing (when), duration (how long), dose (how much) and intensity (how often).

Intervention delivery describes the "How?", "Who?" and "Where?" of the intervention and distinguishes between delivery mechanisms, delivery agents and setting. Individuals form the basis of every organisation and organisational change (Damschroder et al., 2009), and knowledge, skills, motivation and beliefs are critical for successful implementation. Setting refers to the location where the intervention is delivered as well as its characteristics.

Outcomes can be listed separately under the headings intermediate (as opposed to ultimate) outcomes, health outcomes and non-health outcomes. Health outcomes may be categorised as short-, intermediate- and long-term. In addition to depicting desired or positive outcomes, it is important to note potential undesired or negative outcomes.

Process outcomes refer to outcomes regarding intervention implementation. They can be quantitative or qualitative in nature and may include participation, implementation fidelity (Carroll et al., 2007) (whether the intervention was implemented as per protocol), reach (the degree to which the target group receives the intervention), barriers experienced, contamination of the comparison group by study or non-study interventions, and experiences of participants and intervention providers (Audrey et al., 2006; Linnan & Steckler, 2002).

Behaviour outcomes include participant behaviours required for the intervention to have an effect, such as adherence or compliance (sometimes as a direct outcome of a behavioural intervention), but can also refer to other behavioural outcomes occurring intentionally or unintentionally. According to this template, the behaviours of those delivering an intervention are best captured under "intervention delivery".

Surrogate outcomes are used as proxies for "hard" clinical outcomes. These refer to direct, measurable, often short-term effects of an intervention (e.g. biomarker levels, knowledge scores). They need to be validated as reliable predictors for meaningful health endpoints (Burzykowski et al., 2006; Furgerson et al., 2012).

Health outcomes comprise more narrow clinical outcomes, such as morbidity and mortality, as well as broader health outcomes, such as wellbeing, life expectancy and quality of life. They may occur and/or be measured at the individual-level, population-level (e.g. herd immunity) or both.

Non-health outcomes refer to all other relevant societal impacts of an intervention.

The explicit depiction of context and implementation acknowledges the importance of a broad range of factors for the effectiveness of complex interventions. The context and implementation for complex

---

1 A manuscript on the use of a priori logic models for research synthesis has been submitted to the Journal of Clinical Epidemiology. The information on the development of the templates for the a priori logic models (both system-based and process-orientated logic models), as well as the application thereof to various systematic reviews and the palliative care case study, contained in this guidance has been taken from the manuscript (Rohwer et al., submitted manuscript)

interventions (CICI) framework (Pfadenhauer et al., 2016) provides an overarching approach for considering these two distinct but interacting dimensions. Context is composed of seven domains, i.e. (i) geographical, (ii) epidemiological, (iii) socio-cultural, (iv) socio-economic, (v) ethical, (vi) legal and (vii) political issues. The four domains of the implementation dimension are the provider, organisation and structure, finance and policy (Pfadenhauer et al., 2016).

4.2.2 Process-orientated logic model template

The process-orientated logic model template (Figure 3) depicts the distinct processes linking the intervention and its multiple outcomes. As the causal pathways of complex interventions differ between interventions, often combining several linear and non-linear pathways, the template suggests four general pathways.

Table 5 - Considerations in choosing and applying different logic model types.

Considerations to determine choice of logic model type (a priori, iterative or staged)
• What is the purpose of the logic model in the context of a specific HTA/SR process, which kind of HTA/SR is being conducted in terms of scope, generating versus testing theory and types of evidence considered?
• To what extent will the HTA/SR team be analyzing a tightly prescribed intervention (a priori) and to what extent will they be adopting a broad societal perspective (iterative, staged)?
• To what extent are the various PICO or PICOC components pre-specified, secure and well-defined (a priori) or not (iterative, staged)?
• To what extent can the HTA/SR team and stakeholders anticipate issues relating to the complexity of the HTA/SR topic (a priori) or are such issues likely to emerge from the data analysis (iterative, staged)?
• To what extent is it feasible to revise the logic model continually throughout the HTA/SR process (iterative) or at set stages through the HTA/SR as new data is added (staged)?
Considerations to determine choice of logic model sub-type (system-based or process-orientated)
• What is the nature of the given complex intervention, is it likely to benefit from a system-based approach or a more process-orientated approach?
• What is the specific research question being asked, is it likely to benefit from a system-based 'lens' or a process-orientated 'lens'?
Considerations irrespective of logic model choice
• An HTA/SR team should clearly indicate data sources used to construct and/or populate the logic model or logic models.
• An HTA/SR team should identify at what points in the conception and development of the logic model and the project as a whole it is feasible and appropriate to make changes to the model.
• An HTA/SR team should agree whether the logic model is intended to hypothesise how processes should work or to depict how they actually work.
• An HTA/SR team should discuss how to present the logic model or logic models, considering presenting different levels of granularity in relation to the needs of different target audiences.

This template is read from top to bottom, starting with the intervention, which may comprise multiple components of different types and, if applicable, their execution, as detailed in the system-based logic model template (Figure 2). The two-way arrows between the different components illustrate their possible interaction.

Different steps along the short or long pathway from intervention to outcomes are described as direct effects and intermediate effects, with two-way arrows suggesting possible interactions. Outcomes can be divided into intermediate, health and non-health outcomes, as detailed in Figure 3.

Option A shows a simple pathway, where the intervention leads to a direct effect, which in turn leads to outcomes. Options B and C illustrate pathways with direct as well as one (B) or more (C) intermediate effects leading to outcomes. Option D shows the possibility of a feedback loop in the pathway from the intervention to outcomes.

4.3 APPLICATION OF A PRIORI LOGIC MODELS (TYPE A)

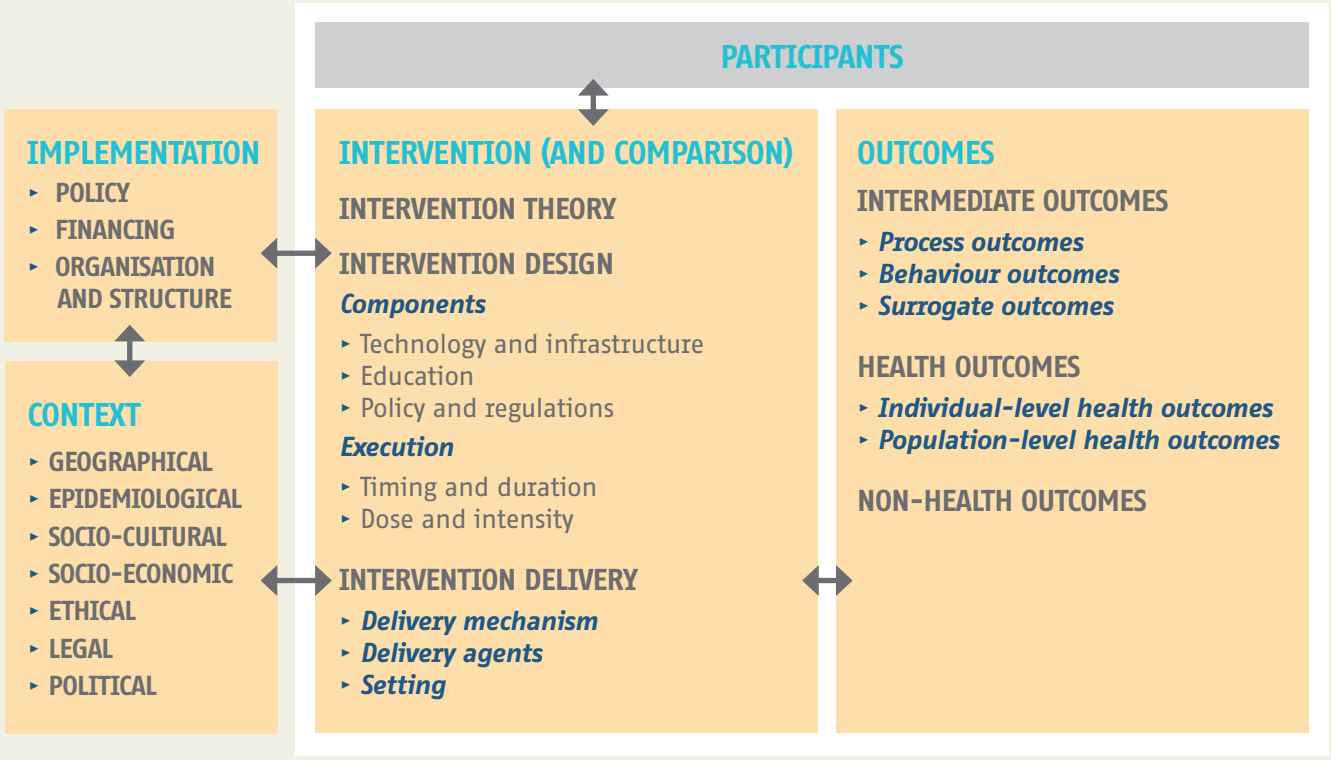
4.3.1 Description of the method

When an a priori logic model approach is pursued, the initial logic model is equivalent to the a priori logic model used at the protocol stage of an HTA or SR; it remains unchanged throughout the subsequent HTA/SR process. As described in section 4.1.1.3, developing the logic model may draw on brainstorming and expertise within the HTA/SR team, literature searches and various ways of engaging with other stakeholders and advisory groups, time and resources permitting. It may be a rather time-consuming process, as the objective is to produce a logic model that is as comprehensive as possible, clearly representing the underlying assumptions that guided conceptualisation of the question at hand and providing a framework for the review within which the results can be anchored. Importantly, while the system-based or process-orientated logic model templates (Figures 2 and 3) should be carefully thought through and populated as much as possible, selected elements may not be critical in relation to a given intervention or HTA/SR question and may therefore be removed.

We pursued an a priori system-based logic modelling approach in a SR to assess interventions to reduce ambient particulate matter air pollution, which is registered with the Cochrane Collaboration (Figure 4; (Burns et al., 2014)). The system-based logic model facilitated the definition of the various interventions to be considered and their unpacking in terms of intervention components and delivery mechanisms. It also helped to generate an understanding of the relationship between various interventions, ambient air quality and human health outcomes in their specific societal and environmental context. We were more interested in depicting the system in which these interactions take place as opposed to the causal pathways that link the intervention and outcomes. The first draft of this logic model was informed by a thorough literature review, as well as discussions within the author team. Having subject matter experts as part of the review author team proved to be key in ensuring that all important and relevant items were captured. In addition, we consulted our Review Advisory Group, comprising internationally recognised ambient air pollution specialists and policy-makers, which led to further refinement of the logic model. The final logic model was agreed on by all authors and was published in the review protocol (Burns et al., 2014). Figure 4 shows the completed a priori system-based logic model for this SR.

For an SR on the effectiveness of evidence-based health care e-learning, registered with the Campbell Collaboration, we pursued an a priori process-orientated logic modelling approach (Rohwer et al., 2014). Illustrating the pathway that leads from evidence-based health care teaching and learning interventions to improved patient outcomes was important, since the intervention does not directly lead to the ultimate outcome, but rather involves a number of intermediate outcomes that need to be achieved in order to have an effect. The process-orientated logic model (Figure 5) helped us to understand the relationships between the direct, intermediate and ultimate outcomes and together with the system-based logic model for this question, provided a solid framework for the review. Indeed, a process-orientated logic model is often considered in addition to the system-based logic model, which can be regarded as the default logic model. Populating the process-orientated logic model was largely based on a literature search, as well as discussions and evidence-based health care teaching expertise within the author team. The final graphic was published with the protocol (Rohwer et al., 2014).

Figure 2 – System-based logic model template (Rohwer et al., submitted manuscript).



4.3.2 How to apply the method (step-by-step)

1. Clearly define the PICO(C) elements of the HTA/SR and unpack the question by describing key characteristics of participants, intervention components as well as intervention delivery and, where relevant, the comparison, and agree on the various outcomes of relevance.
2. Decide within the HTA/SR team whether a system-based or a process-orientated logic model is to be developed. If the main aim of the logic model is to conceptualise the question, the system-based logic model will be appropriate, but if it is more important to explain the pathways from the intervention to the outcomes, a process-orientated logic model should be chosen, ideally in addition to the system-based logic model (section 4.1.3.2).
3. Populate the logic model template with information obtained through literature searches, discussions within the author team and consultations with content experts. Ensure that the logic model reflects all the factors that can potentially cause heterogeneity between studies.
4. Ask important stakeholders, for example members of a Stakeholder Advisory Panel or Review Advisory Group, for input and refine the logic model accordingly.
5. Repeat steps 3 and 4 until all members of the author team agree that the logic model accurately represents the framework for the specific HTA/SR.
6. Publish the final logic model with the protocol of the HTA or SR; this logic model remains unchanged during the HTA/SR process.

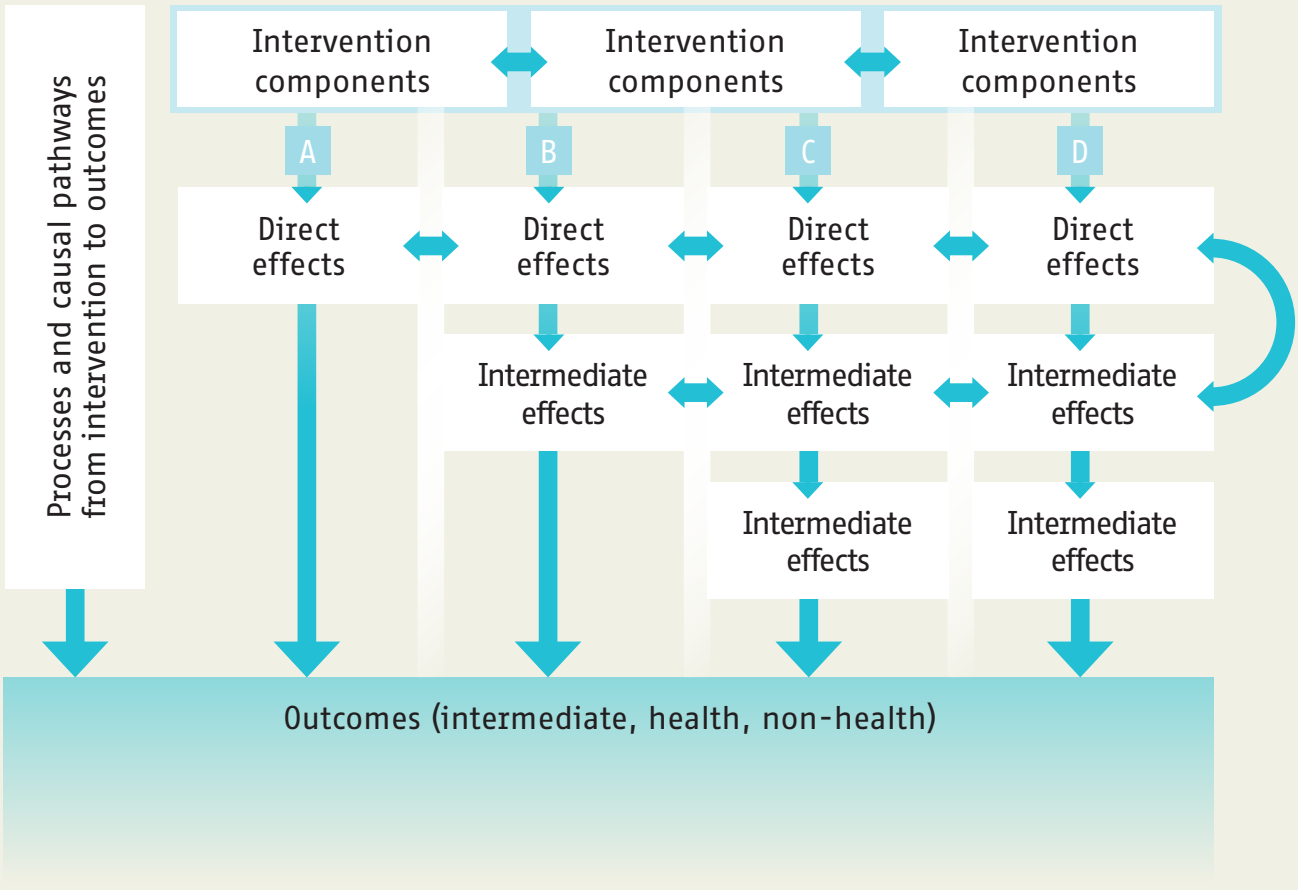
4.4 APPLICATION OF ITERATIVE LOGIC MODELS (TYPE B)

4.4.1 Description of the method

In an iterative logic model the logic model templates introduced in section 4.2, or simply the PICOC elements (Petticrew & Roberts, 2008), act as a prompt for discussion of scope and for constructing an initial sampling frame for the literature search. The initial logic model essentially starts as a sketch that is not expected to faithfully map all elements and all possible causal links (Pawson et al., 2005). Detail is added iteratively as iterative searching, exploration and analysis takes place. Whenever data is unearthed that does not fall outside the scope of the initial boundaries of the HTA or SR, this may add granularity to the logic model. In such a case the contribution of this additional data may be (i) to identify new components within the logic model, not previously identified; (ii) to establish interrelationships between either new or existing components, not previously explored; or (iii) to effect a move of existing components to a more appropriate position within the logic model.

For example, in their HTA of free bus travel for young people, Green et al. (2014) (A20) revised their logic model to achieve greater clarity relating to both the context and the intervention. In a program evaluation on strengths-based family support Crane (2010) illustrates the value of refining a logic model, although not in an HTA-specific context. Crane (2010) identified two missing constructs, namely the role of families (supplied by the stakeholders but overlooked by the initial evaluator) and the centrality of training (critical to achieve programme implementation), and therefore "added some constructs to the model, removed some, and moved others into different columns" (Crane, 2010).

Figure 3 – Process-orientated logic model template (Rohwer et al., submitted manuscript).



For the iterative logic model the initial process, perhaps selecting a generic or best-fit framework as a starting point for the logic model, may be significantly faster compared to the same point in the development of an a priori logic model. The corollary is that some of this analytical burden is transferred to the data extraction process.

Broadly speaking iteration takes place whenever additional types of data, particularly those that offer new or refined insights, are identified within the course of a review. Mechanisms for iteration may be broadly characterised as those that are occasioned by discovery of additional published or unpublished research data throughout the course of the review and those for which interaction internally among the review team or externally with wider stakeholders may be the catalysts.

The following mechanisms for iteration, refinement and revision of logic models are prompted by identification of empirical research data:

1. Follow up of initial searches through pursuit of references and bibliographies or through formal mechanisms of cluster searching (Booth et al., 2013)
2. Identification of process evaluations or other "sibling" studies that provide increased or enhanced understanding of the trial evidence (Booth, 2011)
3. Acquisition of empirical data from primary research or analysis of routine datasets.

The following mechanisms for iteration, refinement and revision of logic models prompted by interactions, with or within the team, have been identified:

1. Focus groups (Butler et al., 2014)
2. Email correspondence (Hayes et al., 2011)
3. Regular meetings (Hayes et al., 2011).

These mechanisms appear to pose a particular challenge to the production of a standardised technology assessment as they occasion concerns about communication and version control.

A SR on workplace mental well-being developed by Baxter et al. (2010) (A19) provides a nice and transparent example of iterative logic modelling. An initial logic model (Figure 6) was developed by the review team, and subsequently refined through (i) data extraction of relevant articles, (ii) examination of data for relationships between processes and (iii) inserting or modifying additional mediating factors:

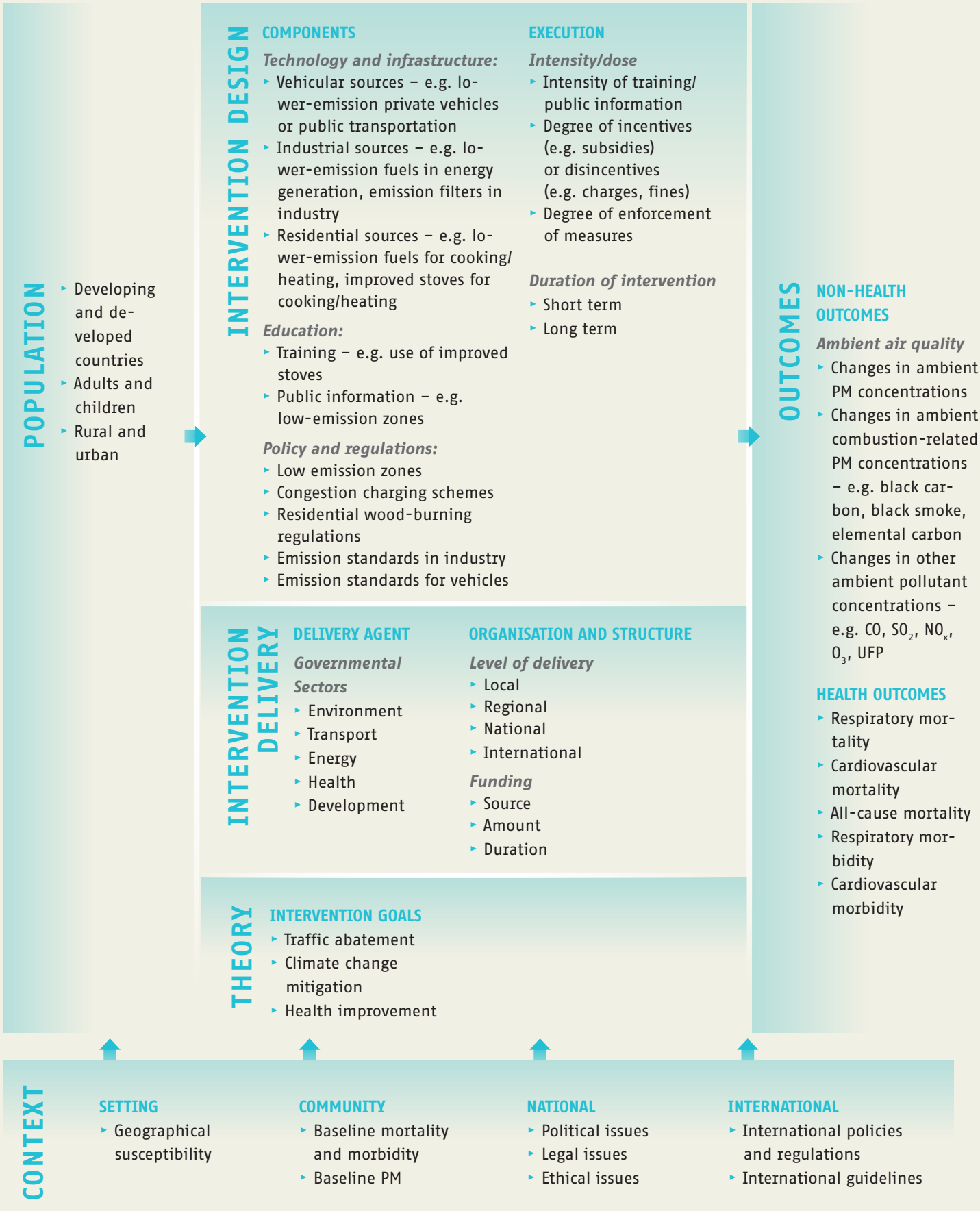
"A revised logic model was built by the process of examining the coded data…in an iterative process….Examination of the data also highlighted where authors reported that stronger potential associations between causative elements and outcomes may be found. By examining where these associations are reported, the revised model suggested that wellbeing should be considered a mediating factor in behavioural and attitudinal outcomes, which are then mediating factors in any business outcomes. This contrasted with the initial model in which wellbeing was directly linked to outcomes" (A19).

In particular, progressive accumulation of data revealed additional complexity relating to outcomes as indicated in the circled area in Figure 7. In this revised logic model the "unpicking" of an improved understanding of the outcomes, from what had been understood at the start of the review process, is clearly evidenced.

4.4.2 How to apply the method (step-by-step)

1. Create, or identify the existence of, an initial logic model as a starting point for subsequent exploration. For this purpose a logic model template (see section 4.2) may be used. This initial model may be published in the accompanying HTA/SR protocol. However, a statement would clearly indicate that this logic model is provisional to the stage of model development and that further iterations will be produced during the course of the HTA/SR.
2. Identify data on the whole system or entire process, or on individual components of the model. Preferably this should indicate a causal path or, in the case of a system component, a relationship to other system resources. This data may come from stakeholders, the review team, ongoing primary research or the published literature.
3. Make changes to the initial logic model repeatedly and at any point of the review and documented. Reference is made to the source literature or, in the case of stakeholder involvement, to documented suggestions in formally recorded meetings or from emails or other correspondence.

Figure 4 – System-based logic model on interventions to reduce ambient air pollution and their impact on health (Burns et al., 2014).



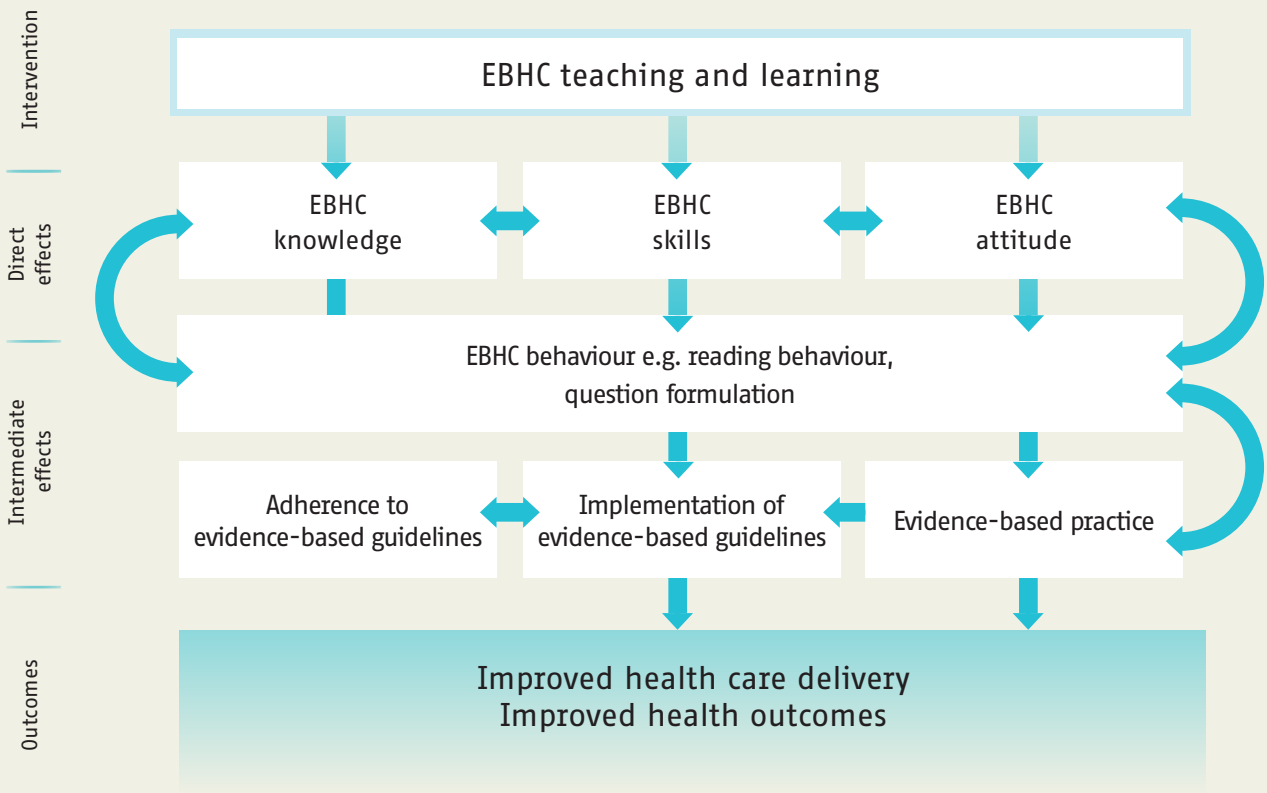
4. Where changes are considered substantive or step-wise create a new numbered version. It is recognised that the HTA/SR team will have to make subjective and defensible judgements on when a new version is required. If substantive versions are produced too frequently this may well pose challenges to ongoing documentation and to dependant activities within sub-projects.
5. Record a definitive version of the logic model for the purpose of publication within the final HTA/SR report. It is recognised that this version of the logic model is only definitive with regard to the specific project timeframe and may well be subject to subsequent modification by the HTA/SR team, or indeed by other teams, beyond the timeframe of the project.

4.5 APPLICATION OF STAGED LOGIC MODELS (TYPE C)

4.5.1 Description of the method

Staged logic models seek to anticipate significant points at which new data may feed into the further development of the logic model. They therefore seek to optimize the requirement for pre-determined project management (which is necessary for the coordination and conduct of an HTA or SR) and the requirement of flexibility (which allows the HTA/SR team to new findings emerging from the data, as can be expected in an HTA/SR of a complex technology). An HTA team, which is often located across multiple locations, and its stakeholders can therefore preserve a shared understanding of points during the review process at which changes can be anticipated and factor these into their own review components.

Figure 5 – Process-orientated logic model on e-learning of evidence-based health care to increase evidence-based health care competencies in health care professionals (Rohwer et al., 2014).



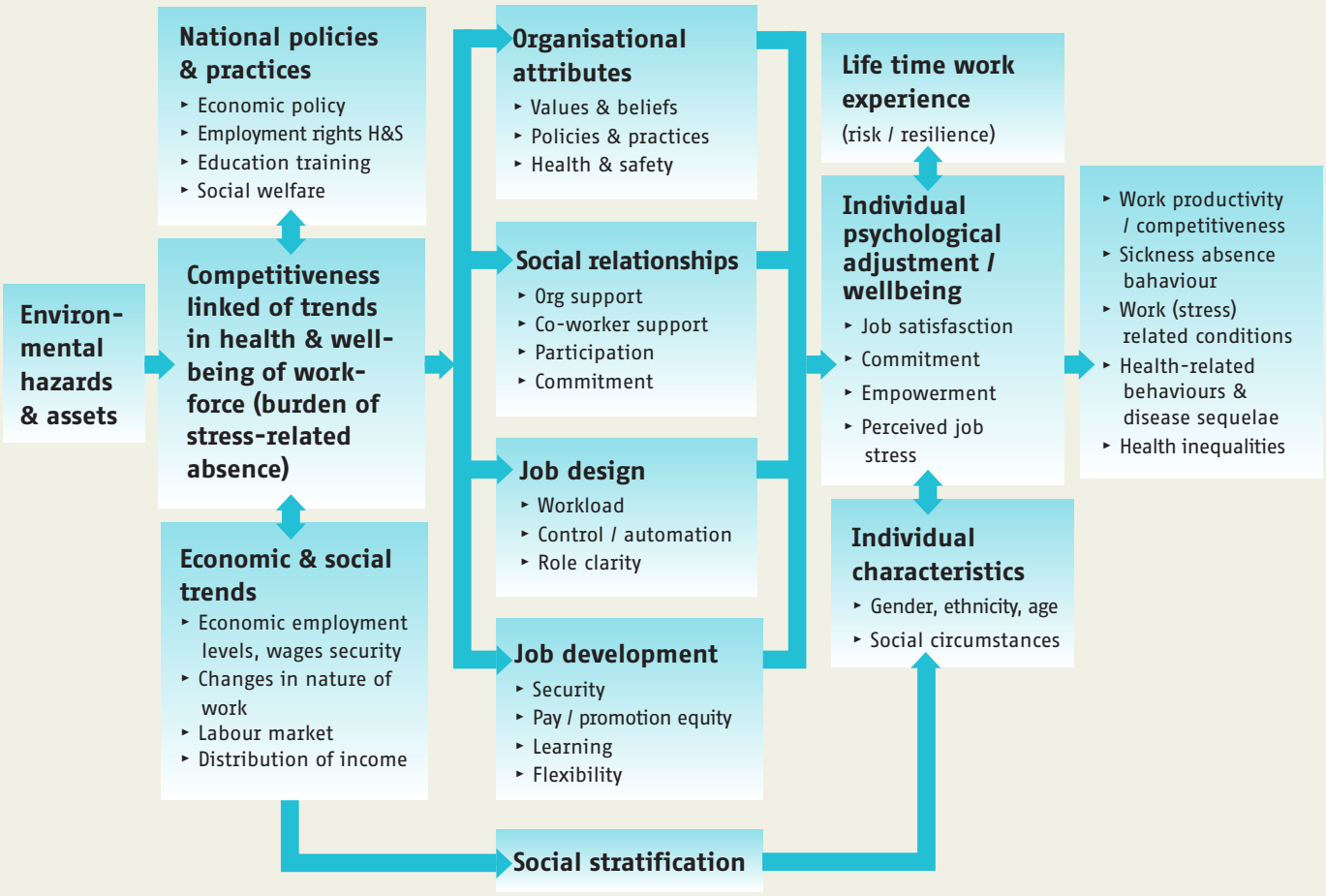
Unlike the iterative model, where modification and adaptation is organic and ongoing, the staged approach requires that, for each iteration, a clear description is provided for which data/information changed the model and how. Such documentation is intended as an enabling mechanism, not a straitjacket, and it holds the potential to change how the 'messy' iterative logic model is perceived within the evidence-based context of SRs, not least by offering improved transparency. Moreover, concerns about a lack of replicability with regard to iterative logic models are moderated with the staged logic model by combining an acknowledgement of the fluidity of an initial model with a series of fixed points at which a new version is produced.

Where a staged model is used, important additional considerations must be incorporated into the HTA/SR team's work processes. These include: (i) a requirement for formalized iteration stages, (ii) version control and (iii) the need for an audit trail.

Iteration stages: These must be clearly specified upfront and may most usefully be organised in terms of major sources of data input. For example, version 1.0 may reflect the a priori thinking of the review team and version 2.0 may be the product of stakeholder engagement. Subsequently, version 3.0 might emerge from a SR of effectiveness and then be enhanced, as version 4.0, following a qualitative SR or in-depth qualitative interviews with a view to producing a nuanced understanding of the heterogeneity of findings.

Version control: The number of versions (e.g. 2.0, 3.0 etc. representing step-wise changes to the team's thinking) should be kept to a minimum. Where appropriate, minor revisions can be signaled on a more regular basis (e.g. 2.1, 2.2 etc.). In this way, the HTA/SR report will only contain the significant stages of change; at a minimum the initial logic model (e.g. version 1.0) and the final logic model (e.g. version 5.7) could be used.

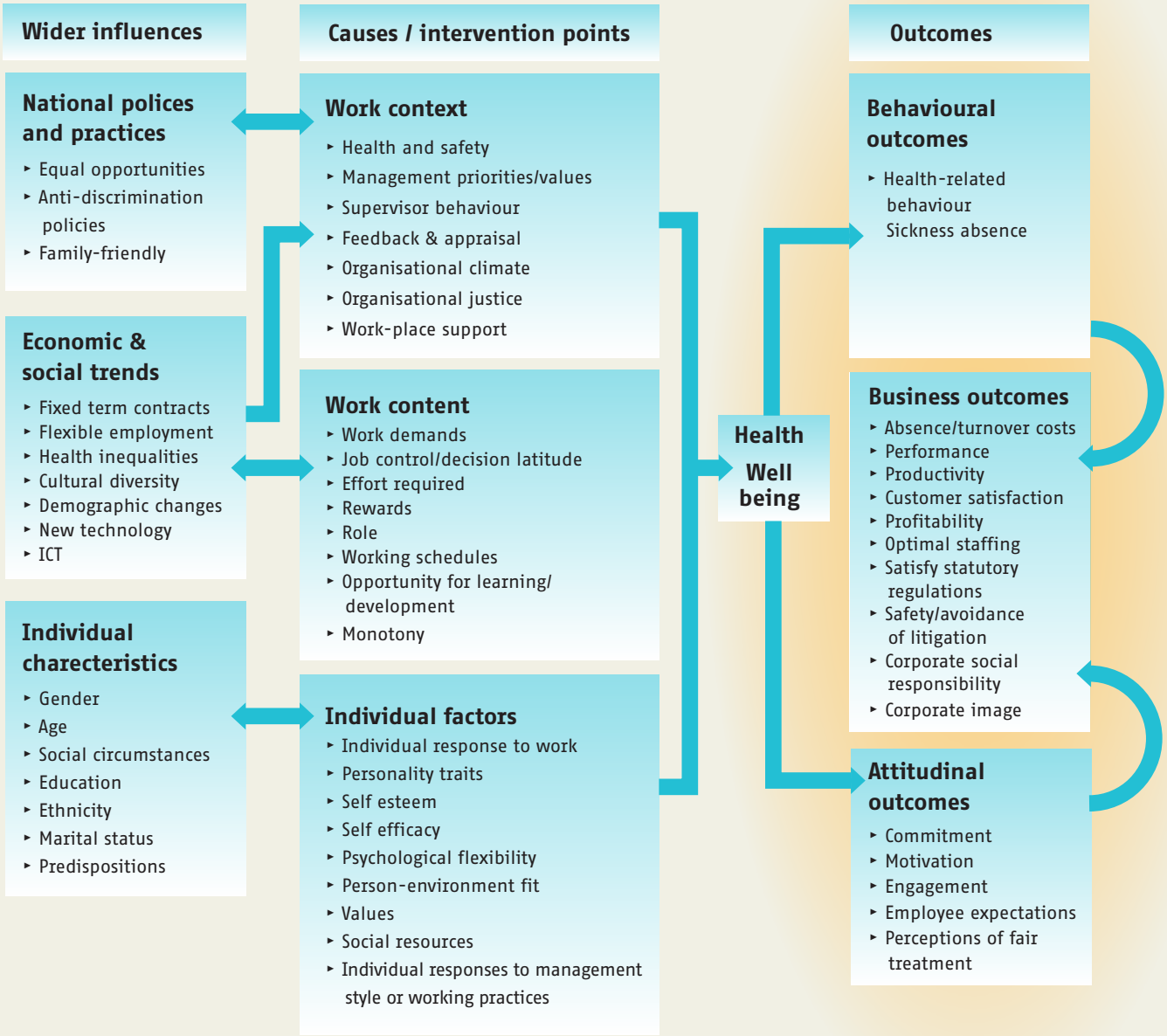
Figure 6 – The initial logic model in an iterative logic model approach for workplace mental wellbeing (Baxter et al., 2010) (Reproduced with permission).



Audit trail: Related to version control is the requirement to demonstrate a clear audit trail for the various iterations (Mays & Pope, 2000). The CDC Guidance emphasizes that "logic models change over time with changes in the scientific evidence, improvements to the programme, shifting resources and new initiatives" (Sundra et al., 2003). It will be helpful for the review team to include a revisions log (Table 6) so that reasons for adapting the model, and the evidence that informed the change, are transparently documented. Although this actual instance within an HTA context is hypothetical it is based on documented accounts of the construction of an audit trail in other contexts. Alternatively, individual versions may be specified in a narrative form.

We applied the staged logic model approach in the INTEGRATE-HTA case study on palliative care (Brereton et al. 2016). We created an initial logic model, populating the system-based logic model template (Figure 8) for the HTA question "Are reinforced home care models of palliative care effective in providing patient-centred palliative care [compared to usual home care models of palliative care] in adults (defined as those aged 18 years old and over) and their families?" through team discussions, selected literature and input from the Stakeholder Advisory Panels (SAPs) across seven countries. This logic model was subsequently populated and modified based on evidence assessments, i.e. a review of effectiveness, a qualitative re-

Figure 7 – The revised logic model in an iterative logic model approach for workplace mental wellbeing (Baxter et al., 2010) (Reproduced with permission).



view on contextual barriers and enablers, assessments of socio-cultural, ethical and legal considerations and an analysis of patient preferences and moderators of effectiveness. New insights gained through these assessments fed into the development and presentation of a final logic model (Figure 8). Additionally, with a view to integrating results across all aspects of the HTA and bringing in the decision-making criteria acceptability, feasibility, appropriateness, meaningfulness, effectiveness and cost-effectiveness an extended logic model to assist decision-making was presented as well (Wahlster et al., 2016).

A challenge in applying the staged logic model approach in our case study on reinforced home-based palliative care was that method development across different work packages, including adaptation of the guidance on logic models, and application of methods within the case study took place in parallel. Therefore, we were unable to pre-specify the stages at which the logic model was to be revised and to coordinate updates through version control; instead, all the updating took place in a single revision from the initial to the final logic model. If we were able to revisit the application of the staged logic model approach in the case study, we would specify the following revision stages, linked to the process model for integration (Wahlster et al., 2016):

- Version 1 (initial logic model) based on the agreed HTA question and a combination of team discussions, literature and SAPs.
- Version 2 based on an analysis of patient preferences and moderators of treatment.
- Version 3 based on the results of the effectiveness review and economic assessment, as well as insights generated through the socio-cultural, ethical and legal assessments.
- Version 4 (final logic model) based on any additional findings generated through an assessment of context and implementation.

Within these versions that represent substantial changes, minor revisions (e.g. data inputs from SAPs in England, SAPs in Germany, SAPs in Poland etc.) could be signalled through versions 1.1, 2.2 etc.

4.5.2 How to apply the method (step-by-step)

1. Develop an initial logic model, using one of the templates proposed in section 4.2 and various mechanisms to populate them, in particular input from stakeholders and literature searches.
2. Pre-specify points within the HTA/SR process at which significant inputs, defined in terms of quantity or importance, are likely to have an impact on the structure and content of the HTA/SR and thus the logic model. Include logic model together with review and revision points, within the HTA or review protocol.
3. Revisit the logic model at the pre-specified review and revision points, and create new and clearly labelled versions of the logic model, documenting how and based on which data sources changes were made.
4. Present selected versions of the logic model, as a minimum the initial and the final logic models, in the HTA/SR report.

5 CONCLUSIONS

We have described the use of three types – a priori, iterative and staged – and two sub-types – system-based and process-orientated – of logic models in HTAs or SRs of complex interventions. In the following, we summarise the implications of using these logic models for assessments of complex technologies, briefly reviewing their specific strengths and limitations. We also provide an outlook for the use of logic models within assessments of complex health technologies.

Even though logic models are increasingly common in evidence synthesis there have been relatively few attempts to describe how they might be applied in practice. Indeed the two leading articles (Anderson et al., 2011; Baxter et al., 2010) on logic models in SRs reveal a tension between the requirements of the SR tradition and those from formal programme evaluation. In seeking to identify and explain these differences we believe that we have opened up the prospect of wider application of a logic model "toolkit". We have also attempted to guide the user through the most important decisions and methods available in the development of logic models within the context of an HTA/SR. As described in more detail in the guidance on the integrated assessment of complex health technologies (Wahlster et al., 2016), logic models are also a key means of integration across different parts of the HTA of a complex technology.

Logic models may be considered useful in HTAs or SRs of complex interventions, as they enhance transparency on underlying assumptions and can help understand complexity by depicting the entire system, its parts and the interactions between intervention and outcomes (Anderson et al., 2011). Nonetheless, logic models are not a panacea in addressing or resolving complexity and present with certain strengths as well as limitations. As discussed in Table 5 and section 4.1.3, certain types and sub-types of logic models are more or less suitable depending on the intervention concerned and the HTA/SR question or approach. Here, we address the specific advantages and disadvantages related to logic models in general as well as related to the three types of logic models. These are summarised in Table 7; a few additional considerations with respect to time, complexity and replicability and transparency are outlined below.

Time considerations: The process of developing any type of logic model can take a significant amount of time (several days of work spread over a period of several weeks or months) potentially delaying subsequent stages of the already time-consuming HTA/SR process. Depending on the type of logic model, this time investment is made primarily at the beginning (for a priori logic models) or distributed across the HTA/SR process (for iterative and staged logic models). Yet, investing a significant amount of time in the application of a logic model approach is likely to add value, in particular for complex technologies or complex systems, as the logic model provides a framework for the entire HTA/SR by informing aspects related to the search strategy and identification of included studies and lends structure to the planned data extraction and analysis. It is important, however, that the effort to develop "the perfect logic model" does not become an obsession – logic models are a tool to make the SR/HTA process simpler, better and more transparent, they are not an end in themselves.

Complexity considerations: As the logic model aims to depict a complex system and the processes involved

Table 6 – Hypothetical example revisions log in a staged logic model.

Version	Change	Data requiring change
3.09	"Consultation" split into "Completion of Diagnostic Tool" followed by "Provision of Brief Advice"	Matt & Cardle (2011) report that there are two essential components to the brief advice consultation (p. 12).
3.10	"Provision of Brief Advice" further subdivided into "Discussion of Information Leaflet" and "Opportunity for Personalised Questions"	Lee, Ona & Lewis (2009) document that, in contrast to group based approaches individualised consultation provides opportunity for client to ask questions and to receive tailored responses. (p. 10)

Figure 8 – System-based logic model of reinforced and non-reinforced home-based palliative care, drawing on team discussions (green), literature (blue) and SAP and expert input (red) (Brereton et al. 2016).

IMPLEMENTATION

- Policy
  - Quality of care and service organisation strategies
  - Financing/Reimbursement strategies
- Funding
  - Public (e.g. taxation; insurance)
  - Private/self-funding
  - Third sector/charity
- Organisation and structure
  - Public/private sector
  - Private sector
  - Charitable/voluntary sector
  - Integration/coordination of services
  - Organisational culture

CONTEXT

- Geographical
  - European Union
  - Urban vs. rural
- Epidemiological
  - Cancer focused palliative care
  - Other diseases
- Socio-cultural
  - Ethnicity
  - Religion
  - Individual patient preferences
  - Family and community preferences
- Socio-economic
  - Education
  - Wealth
  - Housing
- Ethical
  - Autonomy
  - Sanctity of Life
  - Beneficence
  - Non-maleficence
  - Justice
- Legal
  - Mental capacity act
  - Advanced Directives
  - Shared decision-making
- Political
  - Current political climate
  - Political system

PARTICIPANTS

- Patients: adults with life limiting conditions (malignant and non-malignant) receiving palliative care at home
- Lay caregivers: family members of patients or others (friends, neighbors) who may take on the role of lay caregiving (≥18 years)

INTERVENTION AND COMPARISON: REINFORCED AND NON-REINFORCED HOME-BASED PALLIATIVE CARE

INTERVENTION THEORY

- holistic approach to improve quality of life and to enable a good death for patient
- aim to allow the patient to be treated for and die at home, if desired
- (Reinforced) explicit, structured support for the lay caregiver to alleviate burden due to caregiving

INTERVENTION DESIGN

Components:

- Services addressing physical, psychological, social and spiritual needs of patients
- (Reinforced) Services explicitly providing psychosocial or psychoeducational support to lay caregiver
- Active and reactive support

Execution

- Timing, duration and frequency
- May commence at any time from diagnosis to end of life and bereavement
- Models of transition to palliative care e.g. concurrent palliative and curative care; palliative care upon cessation of curative care

INTERVENTION DELIVERY

Delivery mechanism:

- Face-to-face /distant (telephone, online)/mixed
- Individual/group/patient-carer dyad/mixed

Delivery agent characteristics:

- Generalist and/or Specialist health and social care professionals
- Lay caregivers
- Others: Self-care, complementary and alternative therapists, charity workers/volunteers
- Within-team coordination and continuation of care

Setting:

- Community health/social services
- Home

OUTCOMES [1,2]

INTERMEDIATE OUTCOMES

Process outcomes

- Quality of care
- Hospitalisation
- Reach
- Professional caregiver outcomes

Surrogate outcomes (of patients and carers)

- Coping
- Mastery
- Self-efficacy

HEALTH OUTCOMES

Patients

- Quality of life
- Physical well-being (reduced symptoms)
- Psychological well-being
- Spiritual well-being
- Good death/achieving preferred place of death
- Survival

Lay caregivers

- Psychological health
- Physical health
- Quality of life

NON-HEALTH OUTCOMES

Economic costs
Non-economic costs
Acceptability of models of care

[1] *includes short-, medium-, and long-term outcomes*

[2] *includes proxy outcomes (need to be indicated)*

comprehensively, readers might find it difficult to understand this breadth and depth of information in a single graphic. One must therefore carefully balance the need for being comprehensive and the potential danger of overcrowding. When developing the home based palliative care logic model in the INTEGRATE-HTA case study (Figure 8; Brereton et al. 2016), we realised just how important this consideration was in seeking to avoid confusion among stakeholders and even within the research team. Ideally, a logic model should capture the essence of the system with elaboration and explanation of core concepts detailed in the accompanying text.

Replicability and transparency considerations: One must recognise that "different groups of researchers might construct different logic models for the same problem" (Anderson et al., 2011). Using one or another logic model as a framework can thus have a significant impact on the findings of the HTA/SR and their interpretation. For those involved in interpretative, and to a lesser extent, aggregative HTAs or SRs such an observation is unsurprising. Yet, this is not necessarily a weakness but a strength of a logic model approach, as this can serve as a vehicle for signalling idiosyncratic differences in the researchers' conceptual interpretation of the relationships between a programme's activities and its intended outcomes.

Logic modelling is a pragmatic process dictated by the needs of a particular HTA/SR and, to some extent, the composition of an HTA/SR team. As such there are infrequent opportunities to conduct empirical comparative investigations to explore the relative advantages and disadvantages of different types and sub-types of logic models. Generally, we believe that logic models hold the potential to inform two specific requirements of an HTA/SR:

(i) As a conceptual framework to develop the HTA/SR process: As an analytic "lens", logic models offer a unique contribution to identifying the complexity of "links between determinants, outcomes, and intervention components, thereby encouraging the translation of evidence into policy (Anderson et al., 2011).

(ii) As an instrumental framework to guide the technical aspects of the HTA/SR process: Logic models can add value at all stages of the HTA/SR process, including with respect to developing the literature searches, specifying and applying inclusion/exclusion criteria and defining and undertaken data extraction and analysis (Anderson et al., 2011).

Notwithstanding the absence of comparative evaluations of different types of logic model creation and use we believe that the a priori logic model offers a feasible mechanism for enhancing the problem specification beyond the limited ambition of a PICO or PICO(C) formulation. It certainly offers the facility to get beyond a single "simple" intervention to itemization and investigation of multiple intervention components, processes and structures (Anderson et al., 2011). Furthermore, we propose that the iterative logic model offers a useful vehicle for HTAs/SRs where concepts are not initially secure and therefore where data collection elements cannot be completely defined at the inception of the HTA/SR. The challenge for the completely iterative logic model remains in ensuring transparency and version control, particularly within a geographically-spread or discipline-diverse context. These challenges are overcome by the staged logic model, which combines conceptual development with the complex demands of HTA/SR project management and offers a feasible way forward for the conduct of multi-component HTAs for complex interventions.

Table 7 – Strengths and limitations of generic, a priori, iterative and staged logic models.

Type	Generic logic model	A priori logic model	Iterative logic model	Staged logic model
Strengths	Acts as vehicle for orienting multiple HTA/SR questions and relationship between them. Offers flexibility to address HTA questions through multiple contiguous reviews or through single, broad mixed method synthesis Provides a mechanism for communication within HTA team and with external stakeholders Offers rich pictorial way of communicating complex inter-relationships	Is a graphical way of presenting a priori view of intervention in context and to clarify assumptions at the beginning of the HTA/SR process Facilitates the testing of theory (where this is purpose of review) Is consonant with standard HTAs or Cochrane-style SRs Offers a transparent, replicable process	Can flexibly react to new knowledge derived from multiple disciplines Facilitates the generation of theory (where this is purpose of review) Rough version may be an appropriate, "good enough" starting point, which is subsequently adjusted and refined Is consonant with iterative approaches pursued through qualitative or mixed method HTAs/SRs	Offers stability in allowing for efficient HTA/SR processes Shows flexibility that is focused around HTA-/SR-critical issues and stages and distinct data inputs Facilitates easy planning and management through a pre-defined and limited number of checkpoints
Limitations	Places additional demands on time Does not represent a tested theory of how a programme functions and arrives at intended outcomes Will look different depending on the HTA/SR team that develops it May become unintelligible when overcrowded Is an imperfect vehicle for depicting the contingent and dynamic nature of real world complexity	Requires labour-intensive development of a priori logic model, as getting it "right" is critical for subsequent steps of HTA/SR Lacks flexibility to react to new knowledge derived from multiple disciplines ("straitjacket") Has a big impact on the way the HTA/SR is conducted	Is associated with difficulty in implementing iterative HTA/SR processes (e.g. when to stop, when is a "definitive" or even "fit-for-purpose" model achieved) Shows problems of replicability and transparency in populating and refining logic model May be vulnerable to reporting bias, i.e. an important causal pathway may be overlooked where no data are available	Requires pre-specification of main areas of uncertainty at the beginning of the HTA/SR process May overlook other areas of uncertainty requiring more frequent or extensive revision than anticipated

6 REFERENCES

AKERS, J., AGUIAR-IBANEZ, R., BABA-AKBARI SARI, A. (2009) CRD's Guidance for Undertaking Reviews in Health Care. York (UK): Centre for Reviews and Dissemination (CRD).

ANDERSON, L.M., PETTICREW, M., CHANDLER, J., GRIMSHAW, J., TUGWELL, P., O'NEILL, J., WELCH, V., SQUIRES, J., CHURCHILL, R., SHEMILT, I. (2013) Introducing a series of methodological articles on considering complexity in systematic reviews of interventions. Journal of clinical epidemiology, 66, 1205.

ANDERSON, L.M., PETTICREW, M., REHFUESS, E., ARMSTRONG, R., UEFFING, E., BAKER, P., FRANCIS, D., TUGWELL, P. (2011) Using logic models to capture complexity in systematic reviews. Research synthesis methods, 2, 33-42.

AUDREY, S., HOLLIDAY, J., PARRY-LANGDON, N., CAMPBELL, R. (2006) Meeting the challenges of implementing process evaluation within randomized controlled trials: the example of ASSIST (A Stop Smoking in Schools Trial). Health education research, 21, 366-377.

BAXTER, S., KILLORAN, A., KELLY, M.P., GOYDER, E. (2010) Synthesizing diverse evidence: the use of primary qualitative data analysis methods and logic models in public health reviews. Public health, 124, 99-106.

BEST, A., TERPSTRA, J.L., MOOR, G., RILEY, B., NORMAN, C.D., GLASGOW, R.E. (2009) Building knowledge integration systems for evidence-informed decisions. J Health Organ Manag, 23, 627-641.

BOAZ, A., ASHBY, D., YOUNG, K., ESRC, U.K. (2002) Systematic reviews: what have they got to offer evidence based policy and practice? : ESRC UK Centre for Evidence Based Policy and Practice London.

BOOTH, A. (2011) Chapter 3: searching for studies. Supplementary guidance for inclusion of qualitative research in Cochrane systematic reviews of interventions.

BOOTH, A., CARROLL, C. (2015) How to build up the actionable knowledge base: the role of 'best fit' framework synthesis for studies of improvement in healthcare. Bmj Quality & Safety, 24, 700-708.

BOOTH, A., HARRIS, J., CROOT, E., SPRINGETT, J., CAMPBELL, F., WILKINS, E. (2013) Towards a methodology for cluster searching to provide conceptual and contextual "richness" for systematic reviews of complex interventions: case study (CLUSTER). BMC Med Res Methodol, 13, 118.

BOOTH, A., PAPAIOANNOU, D., SUTTON, A. (2011) Systematic approaches to a successful literature review. Sage.

BRERETON, L., WAHLSTER, P., LYSDAHL, K.B., MOZYGEMBA, K., BURNS, J., CHILCOTT, J.B., WARD, S., BRÖNNEKE, J.B., TUMMERS, M., VAN HOORN, R., PFADENHAUER, L., POLUS, S., INGLETON, C., GARDINER, C., VAN DER WILT, G.J., GERHARDUS, A., ROHWER, A., REHFUESS, E., OORTWIJN, W., REFOLO, P., SACCHINI, D., LEPPERT, W., BLAZEVICIENE, A., SPAGNOLO A.G., PRESTON, L., CLARK, J., GOYDER, E., ON BEHALF OF THE INTEGRATE-HTA TEAM (2016) Integrated assessment of home based palliative care with and without reinforced caregiver support: 'A demonstration of INTEGRATE-HTA methodological guidances' [Online]. Available from: http://www.integrate-hta.eu/downloads/

BROUSSELLE, A., CHAMPAGNE, F.O. (2011) Program theory evaluation: Logic analysis. Evaluation and Program Planning, 34, 69-78.

BURFORD, B., LEWIN, S., WELCH, V., REHFUESS, E., WATERS, E. (2013) Assessing the applicability of findings in systematic reviews of complex interventions can enhance the utility of reviews for decision making. Journal of clinical epidemiology, 66, 1251-1261.

BURNS, J., BOOGAARD, H., TURLEY, R., PFADENHAUER, L.M., VAN ERP, A.M., ROHWER, A.C., REHFUESS, E. (2014) Interventions to reduce ambient particulate matter air pollution and their effect on health. The Cochrane Library.

BURNS, J., CHILCOTT, J.B., VAN HOORN, R., KIEVIT, W., REHFUESS, E. (2016) Guidance to assess effectiveness aspects. In: LYSDAHL, K.B., MOZYGEMBA, K., BURNS, J., CHILCOTT, J.B., BRÖNNEKE, J.B., HOFMANN, B. (eds.). Guidance for assessing effectiveness, economic aspects, ethical aspects, socio-cultural aspects and legal aspects in complex technologies [Online]. Available from: http://www.integrate-hta.eu/downloads/

BURNS, K.K., GRAMLICH, L., BISTRITZ, L., MCCARGAR, L., OLSON, K., AVDAGOVSKA, M. (2015) Piloting online WellnesRx learning modules: Demonstration of developmental evaluation. Evaluation and Program Planning, 49, 76-85.

BURZYKOWSKI, T., MOLENBERGHS, G., BUYSE, M. (2006) The evaluation of surrogate endpoints. Springer Science & Business Media.

BUTLER, M.M., BROSNAN, M.C., DRENNAN, J., FEENEY, P., GAVIGAN, O., KINGTON, M., O'BRIEN, D., SHEEHY, L., WALSH, M.C. (2014) Evaluating midwifery-led antenatal care: using a programme logic model to identify relevant outcomes. Midwifery, 30, e34-e41.

CARROLL, C., BOOTH, A., COOPER, K. (2011) A worked example of" best fit" framework synthesis: A systematic review of views concerning the taking of some potential chemopreventive agents. BMC medical research methodology, 11, 1-9.

CARROLL, C., BOOTH, A., LEAVISS, J., RICK, J. (2013) "Best fit" framework synthesis: refining the method. BMC medical research methodology, 13, 37.

CARROLL, C., PATTERSON, M., WOOD, S., BOOTH, A., RICK, J., BALAIN, S. (2007) A conceptual framework for implementation fidelity. Implement Sci, 2, 40.

CHARLES, J.M., EDWARDS, R.T., WILLIAMS, N., DIN, N., GROUP, F.E.R.R.S. (2013) The application of realist synthesis review methods in public health economics. The Lancet, 382, S28.

CHEN, H.T., ROSSI, P.H. (1980) The multi-goal, theory-driven approach to evaluation: A model linking basic and applied social science. Social Forces, 59, 106-122.

CRAIG, P., DIEPPE, P., MACINTYRE, S., MICHIE, S., NAZARETH, I., PETTICREW, M., MEDICAL RESEARCH COUNCIL, G. (2008) Developing and evaluating complex interventions: the new Medical Research Council guidance. BMJ, 337, a1655.

CRANE, B. (2010) Using qualitative data to refine a logic model for the Cornell family development credential program. The Qualitative Report, 15, 899-931.

DAMSCHRODER, L.J., ARON, D.C., KEITH, R.E., KIRSH, S.R., ALEXANDER, J.A., LOWERY, J.C. (2009) Fostering implementation of health services research findings into practice: a consolidated framework for advancing implementation science. Implement Sci, 4, 50.

DIXON-WOODS, M., CAVERS, D., AGARWAL, S., ANNANDALE, E., ARTHUR, A., HARVEY, J., HSU, R., KATBAMNA, S., OLSEN, R., SMITH, L. (2006) Conducting a critical interpretive synthesis of the literature on access to healthcare by vulnerable groups. BMC medical research methodology, 6, 35.

FUNNELL, S.C., ROGERS, P.J. (2011) Purposeful program theory: Effective use of theories of change and logic models. John Wiley & Sons.

FURGERSON, J.L., HANNAH JR, W.N., THOMPSON, J.C. (2012) Challenge of surrogate endpoints. Southern medical journal, 105, 156-160.

GOUGH, D., THOMAS, J., OLIVER, S. (2012) Clarifying differences between review designs and methods. Syst Rev, 1, 28.

GUISE, J.M., CHANG, C., VISWANATHAN, M., GLICK, S., TREADWELL, J., UMSCHEID, C.A., WHITLOCK, E., FU, R., BERLINER, E., PAYNTER, R., ANDERSON, J., MOTU'APUAKA, P., TRIKALINOS, T. (2014) Agency for Healthcare Research and Quality Evidence-based Practice Center methods for systematically reviewing complex multicomponent health care interventions. J Clin Epidemiol, 67, 1181-1191.

HARRIS, R.P., HELFAND, M., WOOLF, S.H., LOHR, K.N., MULROW, C.D., TEUTSCH, S.M., ATKINS, D., PREVENTIVE, M.W.G., FORCE, S. (2001) Current methods of the US Preventive Services Task Force: a review of the process. American journal of preventive medicine, 20, 21-35.

HAYES, H., PARCHMAN, M.L., HOWARD, R. (2011) A logic model framework for evaluation and planning in a primary care practice-based research network (PBRN). The Journal of the American Board of Family Medicine, 24, 576-582.

KHOO, M., GIERSCH, S. (2009) Planning A Digital Library Evaluation With Logic Models. In: PAPATHEODOROU, C., TSAKONAS, G. (eds.). Evaluating Digital Libraries Oxford: Chandos Publishing House.

LINNAN, L., STECKLER, A. (2002) Process evaluation for public health interventions and research. Jossey-Bass San Francisco, California.

LYSDAHL, K.B., MOZYGEMBA, K., BURNS, J., CHILCOTT, J.B., BRÖNNEKE, J.B., HOFMANN, B. (eds.) (2016a) Guidance for assessing effectiveness, economic aspects, ethical aspects, socio-cultural aspects and legal aspects in complex technologies [Online]. Available from: http://www.integrate-hta.eu/downloads/

MARK, M.M., HENRY, G.T. (2013) Logic models and content analyses for the explication of evaluation theories: The case of emergent realist evaluation. Evaluation and Program Planning, 38, 74-76.

MARTIN, C.M., FELIX BORTOLOTTI, M. (2010) W (h) ither complexity? The emperor's new toolkit? Or elucidating the evolution of health systems knowledge? Journal of evaluation in clinical practice, 16, 415-420.

MAYS, N., POPE, C. (2000) Qualitative research in health care: Assessing quality in qualitative research. BMJ: British Medical Journal, 320, 50.

MITLETON-KELLY, E. (2003) Ten Principles of Complexity and Enabling Infrastructures. In: MITLETON-KELLY, E. (ed.). Complex systems and evolutionary perspectives on organisations : the application of complexity theory to organisations. Oxford Pergamon.

NICE, NATIONAL INSTITUTE FOR CLINICAL EXCELLENCE. (2012) Methods for the development of NICE public health guidance, 3rd edition. NICE: London.

NOYES, J., GOUGH, D., LEWIN, S., MAYHEW, A., MICHIE, S., PANTOJA, T., PETTICREW, M., POTTIE, K., REHFUESS, E., SHEMILT, I. (2013) A research and development agenda for systematic reviews that ask complex questions about complex interventions. Journal of clinical epidemiology, 66, 1262-1270.

PAWSON, R., GREENHALGH, T., HARVEY, G., WALSHE, K. (2005) Realist review: a new method of systematic review designed for complex policy interventions. Journal of health services research & policy, 10, 21-34.

PETTICREW, M., ANDERSON, L., ELDER, R., GRIMSHAW, J., HOPKINS, D., HAHN, R., KRAUSE, L., KRISTJANSSON, E., MERCER, S., SIPE, T. (2013a) Complex interventions and their implications for systematic reviews: a pragmatic approach. Journal of clinical epidemiology, 66, 1209-1214.

PETTICREW, M., REHFUESS, E., NOYES, J., HIGGINS, J.P.T., MAYHEW, A., PANTOJA, T., SHEMILT, I., SOWDEN, A. (2013b) Synthesizing evidence on complex interventions: how meta-analytical, qualitative, and mixed-method approaches can contribute. Journal of clinical epidemiology, 66, 1230-1243.

PETTICREW, M., ROBERTS, H. (2008) Systematic reviews in the social sciences: A practical guide. John Wiley & Sons.

PFADENHAUER, L.M., BURNS, J., ROHWER, A., REHFUESS, E.A. (2014) A protocol for a systematic review of the effectiveness of interventions to reduce exposure to lead through consumer products and drinking water. Systematic reviews, 3, 36.

PFADENHAUER, L., ROHWER, A., BURNS, J., BOOTH, A., LYSDAHL, K.B., HOFMANN, B., GERHARDUS, A., MOZYGEMBA, K., TUMMERS, M., WAHLSTER, P., REHFUESS, E. (2016) Guidance for the Assessment of Context and Implementation in Health Technology Assessments (HTA) and Systematic Reviews of Complex Interventions: The Context and Implementation of Complex Interventions (CICI) Framework [Online]. Available from: http://www.integrate-hta.eu/downloads/

PIGOTT, T., SHEPPERD, S. (2013) Identifying, documenting, and examining heterogeneity in systematic reviews of complex interventions. Journal of clinical epidemiology, 66, 1244-1250.

POPE, C., MAYS, N., POPAY, J. (2007) Synthesizing qualitative and quantitative health evidence. A guide to methods. New York: McGraw-Hill Open University

RICHARDSON, W.S., WILSON, M.C. (1997) On questions, background and foreground. Evidence Based Healthcare Newsletter, 17, 8-9.

ROHWER, A., PFADENHAUER, L.M., BURNS, J., BRERETON, L., GERHARDUS, A., BOOTH, A., OORTWIJN, W., REHFUESS, E. Logic models help make sense of complexity in systematic reviews and health technology assessments. Journal of Clinical Epidemiology (submitted for publication).

ROHWER, A., REHFUESS, E., YOUNG, T. (2014) E-learning of Evidence-Based Health Care to Increase EBHC Competencies in Healthcare Professionals.

SHEMILT, I., MUGFORD, M., VALE, L., MARSH, K., DONALDSON, C. (2011) Evidence-based decisions and economics: health care, social welfare, education and criminal justice. John Wiley & Sons.

SHIELL, A., HAWE, P., GOLD, L. (2008) Complex interventions or complex systems? Implications for health economic evaluation. BMJ: British Medical Journal, 336, 1281.

SQUIRES, J.E., VALENTINE, J.C., GRIMSHAW, J.M. (2013) Systematic reviews of complex interventions: framing the review question. Journal of clinical epidemiology, 66, 1215-1222.

SUNDRA, D.L., SCHERER, J., ANDERSON, L.A. (2003) A guide to logic model development for CDC's prevention research centre. Atlanta, GA: Prevention Research Centers Program Office, Centers for Disease Control.

THOMSON, H. (2013) Improving Utility of Evidence Synthesis for Healthy Public Policy: the Three Rs (Relevance, Rigor, and Readability [and Resources]). American journal of public health, 103, e17-e23.

VAN HOORN, R., TUMMERS, M., KIEVIT, W., VAN DER WILT, G.J. (eds.) (2016a) Guidance for the assessment of treatment moderation and patients' preferences [Online]. Available from: http://www.integrate-hta.eu/downloads/

VAN HOORN, R., TUMMERS, M., BOOTH, A., GERHARDUS, A., HOFMANN, B., REHFUESS, E., KIEVIT, W., VAN DER WILT, G.J. (2016b) The retrieval and critical appraisal of literature on moderators and predictors of treatment effects. In: VAN HOORN, R., TUMMERS, M., KIEVIT, W., VAN DER WILT, G.J. (eds.). Guidance for the assessment of treatment moderation and patients' preferences [Online]. Available from: http://www.integrate-hta.eu/downloads/

WAHLSTER, P., BRERETON, L., BURNS, J., HOFMANN, B., MOZYGEMBA, K., OORTWIJN, W., PFADENHAUER, L., POLUS, S., REHFUESS, E., SCHILLING, I., VAN HOORN, R., VAN DER WILT, G.J., BALTUSSEN, R., GERHARDUS, A. (2016) Guidance on the integrated assessment of complex health technologies - The INTEGRATE-HTA Model [Online]. Available from: http://www.integrate-hta.eu/downloads/

WEIR, M.C., GRIMSHAW, J.M., MAYHEW, A., FERGUSSON, D. (2012) Decisions about lumping vs. splitting of the scope of systematic reviews of complex interventions are not well justified: a case study in systematic reviews of health care professional reminders. Journal of clinical epidemiology, 65, 756-763.

WELLS, M., WILLIAMS, B., TREWEEK, S., COYLE, J., TAYLOR, J. (2012) Intervention description is not enough: evidence from an in-depth multiple case study on the untold role and impact of context in randomised controlled trials of seven complex interventions. Trials, 13, 95.

WILDSCHUT, L.P. (2014) Theory-based evaluation, logic modelling and the experience of SA non-governmental organisations. Stellenbosch: Stellenbosch University

7 ACKNOWLEDGEMENTS

We would like to thank all those who contributed to the development of this guidance: members of the INTEGRATE-HTA project, stakeholders who participated in the case study and external experts. We also thank the European Union for funding this project.

We gratefully acknowledge the contribution of Susan Baxter at the University of Sheffield, for her significant input into the discussion of iterative logic models. We would also like to thank Claudia Wild at the Ludwig Boltzmann Institute for HTA, Albert Brühl at the University of Vallendar, Paul Montgomery at the University of Oxford and Tom Ling at the RAND Corporation, for their careful review and constructive feedback on an earlier version of this guidance.

8 APPENDIX

8.1 EXAMPLES OF LOGIC MODELS IDENTIFIED FROM THE LITERATURE

A1. BAIRD, S., FEREIRRA, F.H.G., ÖZLER, B., WOOLCOCK, M. (2013) Relative effectiveness of conditional and unconditional cash transfers for schooling outcomes in developing countries: A systematic review. *Campbell systematic reviews*.

A2. BAKER, P.R., FRANCIS, D.P., SOARES, J., WEIGHTMAN, A.L., FOSTER, C. (2015) Community wide interventions for increasing physical activity. *Cochrane Database Syst Rev*, 1, CD008366.

A3. CHAMBERLAIN, C., O'MARA-EVES, A., OLIVER, S., CAIRD, J.R., PERLEN, S.M., EADES, S.J., THOMAS, J. (2013) Psychosocial interventions for supporting women to stop smoking in pregnancy. *Cochrane Database Syst Rev*, 10, CD001055.

A4. COREN, E., HOSSAIN, R., PARDO, J.P., VERAS, M., CHAKRABORTY, K., HARRIS, H., MARTIN, A.J. (2013) Interventions for promoting reintegration and reducing harmful behaviour and lifestyles in streetâ€•connected children and young people. *Evidence-Based Child Health: A Cochrane Review Journal*, 8, 1140-1272.

A5. DE-REGIL, L.M., SUCHDEV, P.S., VIST, G.E., WALLESER, S., PENA-ROSAS, J.P. (2011) Home fortification of foods with multiple micronutrient powders for health and nutrition in children under two years of age. *Cochrane Database Syst Rev*, CD008959.

A6. GOERLICH ZIEF, S., LAUVER, S., MAYNARD, R.A. (2006) Impacts of After-school programs on student outcomes. *Campbell systematic reviews*.

A7. HARRIS, R., MOSEDALE, S., GARNER, J., PERKINS, E. (2014) What factors influence the use of contracts in the context of NHS dental practice? A systematic review of theory and logic model. *Social Science & Medicine*, 108, 54-59.

A8. MAZEROLLE L, BENNETT S, DAVIS J, SARGEANT E, M, M. (2013) Legitimacy in Policing: A Systematic Review. *Campbell Systematic Reviews*, 1.

A9. SANDOVAL, J.A., LUCERO, J., OETZEL, J., AVILA, M., BELONE, L., MAU, M., PEARSON, C., TAFOYA, G., DURAN, B., IGLESIAS RIOS, L., WALLERSTEIN, N. (2012) Process and outcome constructs for evaluating community-based participatory research projects: a matrix of existing measures. *Health Educ Res*, 27, 680-690.

A10. SEGAL, L., SARA OPIE, R., DALZIEL, K. (2012) Theory! The missing link in understanding the performance of neonate/infant home-visiting programs to prevent child maltreatment: a systematic review. *Milbank Q*, 90, 47-106.

A11. TAYLOR-ROBINSON, D.C., MAAYAN, N., SOARES-WEISER, K., DONEGAN, S., GARNER, P. (2012) Deworming drugs for soil-transmitted intestinal worms in children: effects on nutritional indicators, haemoglobin and school performance. *Cochrane Database Syst Rev*, 11, CD000371.

A12. TRIPNEY, J., HOMBRADOS, J., NEWMAN, M., HOVISH, K., BROWN, C., STEINKA-FRY, K., WILKEY, E. (2013) Technical and vocational education and training (TVET) interventions to improve the employability and employment of young people in low-and middle-income countries: A systematic review. *Campbell Systematic Reviews*, 9.

A13. TURLEY, R., SAITH, R., BHAN, N., REHFUESS, E., CARTER, B. (2013) Slum upgrading strategies involving physical environment and infrastructure interventions and their effects on health and socio-economic outcomes. *Cochrane Database Syst Rev*, 1, CD010067.

A14. GLENTON, C., COLVIN, C.J., CARLSEN, B., SWARTZ, A., LEWIN, S., NOYES, J., RASHIDIAN, A. (2013) Barriers and facilitators to the implementation of lay health worker programmes to improve access to maternal and child health: qualitative evidence synthesis. *Cochrane Database Syst Rev*, 10, CD010414.

A15. SUBIRANA, M., LONG, A., GREENHALGH, J., FIRTH, J. (2014) A realist logic model of the links between nurse staffing and the outcomes of nursing. *Journal of Research in Nursing*, 19, 8-23.

A16. RACHLIS, B., SODHI, S., BURCIUL, B., ORBINSKI, J., CHENG, A.H., COLE, D. (2013) A taxonomy for community-based care programs focused on HIV/AIDS prevention, treatment, and care in resource-poor settings. *Glob Health Action*, 6, 1-21.

A17. THOMSON, H., THOMAS, S., SELLSTROM, E., PETTICREW, M. (2013) Housing improvements for health and associated socio-economic outcomes. *Cochrane Database Syst Rev*, 2, CD008657.

A18. URSTAD, K.H., WAHL, A.K., ANDERSEN, M.H., OYEN, O., HAGEN, K.B. (2013) Limited evidence for the effectiveness of educational interventions for renal transplant recipients. Results from a systematic review of controlled clinical trials. *Patient Educ Couns*, 90, 147-154.

A19. BAXTER, S., KILLORAN, A., KELLY, M.P., GOYDER, E. (2010) Synthesizing diverse evidence: the use of primary qualitative data analysis methods and logic models in public health reviews. *Public health*, 124, 99-106.

A20. BAXTER, S.K., BLANK, L., WOODS, H.B., PAYNE, N., RIMMER, M., GOYDER, E. (2014) Using logic model methods in systematic review synthesis: describing complex pathways in referral management interventions. *BMC medical research methodology*, 14, 62.

A21. GREEN, J., STEINBACH, R., JONES, A., EDWARDS, P., KELLY, C., NELLTHORP, J., GOODMAN, A., ROBERTS, H., PETTICREW, M., WILKINSON, P. (2014) On the buses: a mixed-method evaluation of the impact of free bus travel for young people on the public health. NIHR Journals Library.

A22. LORENC, T., CLAYTON, S., NEARY, D., WHITEHEAD, M., PETTICREW, M., THOMSON, H., CUMMINS, S., SOWDEN, A., RENTON, A. (2012) Crime, fear of crime, environment, and mental health and wellbeing: mapping review of theories and causal pathways. *Health Place*, 18, 757-765.

A23. NANCARROW, S.A., ROOTS, A., GRACE, S., MORAN, A.M., VANNIEKERK-LYONS, K. (2013) Implementing large-scale workforce change: learning from 55 pilot sites of allied health workforce redesign in Queensland, Australia. *Hum Resour Health*, 11, 66.

A24. SOUTH, J., BAGNALL, A., HULME, C., WOODALL, J., LONGO, R., DIXEY, R., KINSELLA, K., RAINE, G., VINALL-COLLIER, K., WRIGHT, J. (2014) A systematic review of the effectiveness and cost-effectiveness of peer-based interventions to maintain and improve offender health in prison settings. *Health Services and Delivery Research*, 2.

A25. THOMSON, H., THOMAS, S. (2015) Developing empirically supported theories of change for housing investment and health. *Soc Sci Med*, 124, 205-214.

Review Identifiers	Topic	Logic Model Type	Review Type
A1. Baird et al. (2013)	Conditional and unconditional cash transfers for schooling outcomes in developing countries	A priori	Campbell Collaboration
A2. Baker et al. (2015)	Community wide interventions for increasing physical activity.	A priori	Cochrane Collaboration
A3. Chamberlain et al. (2013)	Psychosocial interventions for supporting women to stop smoking in pregnancy	A priori	Cochrane Collaboration
A4. Coren et al. (2013)	Promoting reintegration and reducing harmful behaviour and lifestyles in street-connected children and young people	A priori	Cochrane Collaboration
A5. De Regil et al. (2011)	Home fortification of foods with multiple micronutrient powders for health and nutrition in children under two years of age.	A priori	Cochrane Collaboration
A6. Zief et al. (2006)	Impacts of After-school programs on student outcomes.	A priori	Campbell Collaboration
A7. Harris et al. (2014)	Factors influencing the use of contracts in the context of NHS dental practice	A priori	UK National Institute for Health Research Health Services and Delivery Research Programme
A8. Mazerolle et al. (2013)	Direct and indirect benefits of policing approaches that foster legitimacy in policing	A priori	Campbell Collaboration
A9. Sandoval et al. (2012)	Evaluating community-based participatory research projects	A priori	US National Institute on Minority Health And Health Disparities
A10. Segal et al. (2012)	Neonate/infant home-visiting programs to prevent child maltreatment	A priori	Australian Research Council (ARC)
A11. Taylor-Robinson et al. (2012)	Deworming drugs for soil-transmitted intestinal worms in children: effects on nutritional indicators, haemoglobin and school performance.	A priori	Cochrane Collaboration
A12. Tripney et al. (2013)	Technical and vocational education and training (TVET) interventions to improve the employability and employment of young people in low-and middle-income countries:	A priori	Campbell Collaboration
A13. Turley et al. (2013)	Slum upgrading strategies involving physical environment and infrastructure interventions and their effects on health and socio-economic outcomes.	A priori	Cochrane Collaboration

A14. Glenton et al. (2013)	Barriers and facilitators to the implementation of lay health worker programmes to improve access to maternal and child health	A priori	Cochrane Collaboration
A15. Subirana et al. (2013)	Links between nurse staffing and the outcomes of nursing	A priori	Fondo de Investigacio´n Sanitaria (Spanish Ministry of Health)
A16. Rachlis et al. (2013)	Community-based care programs for HIV/AIDS prevention, treatment, and care in resource-poor settings.	A priori	Unfunded
A17. Thomson et al. (2013)	Housing improvements for health and associated socio-economic outcomes.	A priori	Cochrane Collaboration
A18. Urstad et al. (2013)	Effectiveness of educational interventions for renal transplant recipients.	A priori	Oslo University College, Norway
A19. Baxter et al. (2010)	Interventions to improve mental wellbeing in the workplace	Iterative	National Institute for Health and Clinical Excellence (NICE)
A20. Baxter et al. (2014)	Complex pathways in referral management	Iterative	National Institute for Health Research (Health Service and Delivery Research Programme
A21. Green et al. (2014)	Impact of free bus travel for young people	Iterative	National Institute for Health Research Public Health Research programme
A22. Lorenc et al. (2012)	Crime, fear of crime, environment, and mental health and wellbeing	Iterative	National Institute of Health Research
A23. Nancarrow et al. (2013)	Implementing large-scale workforce change	Iterative	Health Workforce Australia
A24. South et al. (2014)	Peer-based interventions to maintain and improve offender health in prison settings.	Iterative	UK NIHR Health Services and Delivery Research Programme
A25. Thomson & Thomas (2015)	Housing investment and health.	Iterative	Campbell Collaboration/ Cochrane Collaboration

1 Integrated health technology assessment for evaluating complex technologies (INTEGRATE-HTA): An introduction to the guidances

2 Guidance on the integrated assessment of complex health technologies – The INTEGRATE-HTA Model

3 Guidance for assessing effectiveness, economic aspects, ethical aspects, socio-cultural aspects and legal aspects in complex technologies

4 Guidance for the assessment of treatment moderation and patients' preferences

5 Guidance for the Assessment of Context and Implementation in Health Technology Assessments (HTA) and Systematic Reviews of Complex Interventions: The Context and Implementation of Complex Interventions (CICI) Framework

7 Guidance on choosing qualitative evidence synthesis methods for use in health technology assessments of complex intervention

8 Integrated assessment of home based palliative care with and without reinforced caregiver support: A demonstration of INTEGRATE-HTA methodological guidances – Executive Summary

INTEGRATE-HTA

This project is co-funded by the European Union under the Seventh Framework Programme (Grant Agreement No. 306141)