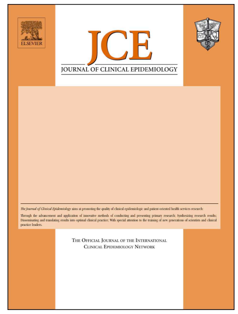
Article:

Rohwer, A., Pfadenhauer, L., Burns, J. et al. (5 more authors) (2017) Logic models help make sense of complexity in systematic reviews and health technology assessments. Journal of Clinical Epidemiology, 83. pp. 37-47. ISSN 1878-5921

https://doi.org/10.1016/j.jclinepi.2016.06.012

Accepted Manuscript



Logic models help make sense of complexity in systematic reviews and health technology assessments

Anke Rohwer, Lisa Pfadenhauer, Jacob Burns, Louise Brereton, Ansgar Gerhardus, Andrew Booth, Wija Oortwijn, Eva Rehfuess

PII: S0895-4356(16)30279-7

DOI: 10.1016/j.jclinepi.2016.06.012

Reference: JCE 9223

To appear in: *Journal of Clinical Epidemiology*

Received Date: 23 April 2015

Revised Date: 26 May 2016

Accepted Date: 10 June 2016

Please cite this article as: Rohwer A, Pfadenhauer L, 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* (2016), doi: 10.1016/j.jclinepi.2016.06.012.

Logic models help make sense of complexity in systematic reviews and health technology assessments

Anke Rohwer[a,b], Lisa Pfadenhauer[a], Jacob Burns[a], Louise Brereton[c], Ansgar Gerhardus[d], Andrew Booth[c], Wija Oortwijn[e], Eva Rehfuess[a]

[a]Institute for Medical Informatics, Biometry and Epidemiology, Ludwig-Maximilians-University Marchioninistrasse 15, 81377, Munich, Germany

[b]Centre for Evidence-based Health Care, Faculty of Medicine and Health Sciences, Stellenbosch University, Francie van Zijl drive, 7500, Parow, South Africa

[c]School of Health and Related Research (ScHARR), University of Sheffield, 30 Regent Street, Sheffield S1 4DA, United Kingdom

[d]Department of Health Services Research, Institute of Public Health and Nursing Research, University of Bremen, Grazer Str. 4, D-28359 Bremen, Germany

[e]Ecorys Nederland B.V., Watermanweg 44, 3067 GG, Rotterdam, The Netherlands

Contact author:

Ms Anke Rohwer

Centre for Evidence-based Health Care,

Faculty of Medicine and Health Sciences, Stellenbosch University

Francie van Zijl drive, Parow

7500 Cape Town, South Africa

Tel: +27-21-9389886

Email: arohwer@sun.ac.za

Abstract

Objective: To describe the development and application of logic model templates for systematic reviews and health technology assessments (HTA) of complex interventions

Study design and setting: This study demonstrates the development of a method to conceptualise complexity and make underlying assumptions transparent. Examples from systematic reviews with specific relevance to sub-Saharan Africa (SSA) and other low- and middle-income countries (LMICs) illustrate its usefulness.

Results: Two distinct templates are presented: the system-based logic model, describing the system in which the interaction between participants, intervention and context takes place; and the process-orientated logic model, which displays the processes and causal pathways that lead from the intervention to multiple outcomes.

Conclusion: Logic models can help authors of systematic reviews and HTAs to explicitly address and make sense of complexity, adding value by achieving a better understanding of the interactions between the intervention, its implementation and its multiple outcomes among a given population and context. They thus have the potential to help build systematic review capacity –in SSA and other LMICs - at an individual level, by equipping authors with a tool that facilitates the review process; and at a system-level, by improving communication between producers and potential users of research evidence.

Keywords

Africa, complexity, evidence synthesis, analytical framework, conceptual framework, systems-based thinking

Running title: Logic models for systematic reviews and HTAs of complex interventions

Word count: 198

Box 1: LMIC challenges and opportunities

- In the light of the significant burden of disease, Sub-Saharan Africa (SSA) faces huge challenges related to health systems and delivery of healthcare. Interventions required to address these challenges are often complex, and management should be informed by the current best evidence.
- Evidence synthesis of complex interventions is an intricate process. Logic models can help build capacity by equipping authors of systematic reviews and health technology assessments (HTAs) of complex interventions with a tool to develop their own intervention-, question- and context-specific logic model; they can also help improve communication of research evidence between evidence producers and users.
- The system-based and process-orientated logic model templates described are a valuable tool to guide the entire process of a systematic review or HTA of a complex intervention. In this way, evidence synthesis can be made more relevant and applicable to SSA and other low- and middle-income countries.

1. Introduction

1.1 Role of evidence synthesis in Sub-Saharan Africa

Sub-Saharan Africa (SSA) is affected by an overwhelming burden of diseases and injuries [1] and faces considerable challenges in health service provision. Addressing this burden requires a well-functioning health system and a variety of curative and preventive interventions relevant to the African context, many of which can be considered complex. Policy-makers and healthcare practitioners need to consider the evidence about the benefits and harms of these interventions, if they are to make optimal use of limited resources [2]. Systematic reviews provide the most complete and reliable evidence on intervention effectiveness, whilst taking stock of existing research and critical gaps [3]. This is crucial to reduce wasting resources on unnecessary research, especially in SSA and other low-and middle income countries (LMICs) [4, 5]. In these settings, a number of challenges hinder research evidence use, including a paucity of existing systematic reviews relevant to LMICs [2, 3, 6] and limited capacity for research synthesis. In a recent situation analysis, Oliver et al. (2015) identified a lack of overall systematic review capacity in LMICs, including individual, team, institutional and system capacity. The authors highlight a need to develop methods and build capacity to address complex heath system and health policy questions; a need linked to strengthening the relationship between producers and users of evidence [7].

1.2 Evidence synthesis of complex interventions

The UK Medical Research Council's guidance on complex interventions [8] resulted in wide use of the term. However, the complexity of the intervention itself is only one of many sources of complexity [9]. In evidence synthesis, complexity can relate to the characteristics of any part of the PICO question, i.e. population, intervention, comparison or outcomes, and to methodological issues inherent in the included primary studies [10]. Additional complexity can be found in the unique circumstances under which the intervention is delivered and in non-linear pathways and feedback loops between intervention and outcomes, interactions between direct and indirect effects of the intervention, as well as between different intervention components [11]. Petticrew (2011) explains that complexity does not have to be an inherent characteristic of an intervention, but rather that interventions can have simple and complex explanations, depending on the perspective adopted and the research question asked [11].

A series of six papers published in the *Journal of Clinical Epidemiology* in 2013, provides the first concerted attempt to address complexity in systematic reviews at each stage of the process from formulating the question [10], to synthesizing evidence [12] and assessing heterogeneity [13] to reviewing the applicability of findings [14]. The series concludes with a research agenda, emphasizing methodological areas needing further development and testing [15].

1.3 Logic models

Logic models have been defined in various ways [16] and can be described, inter alia, as conceptual frameworks, concept maps or influence diagrams. Anderson et al (2011) argue that logic models "describe theory of change", "promote systems thinking" and contribute both in a conceptual and analytical way [17]. This resonates with our understanding of the use of logic models in systematic reviews and health technology assessments (HTA). For the purpose of this paper, we refer to a logic model as *"… a graphic description of a system … designed to identify important elements and relationships within that system"* [17, 18]. Logic models can help conceptualize complexity [19] by (i) depicting intervention components and the relationships between them, (ii) making underlying theories of change and assumptions about causal pathways between the intervention and multiple outcomes explicit [17], and (iii) displaying interactions between the intervention and the system within which it is implemented. Such a graphic representation is particularly helpful as a mechanism for making transparent assumptions among researchers and other stakeholders, and making results more accessible to a potentially broad range of decision-makers, including clinicians, public health practitioners and policy-makers. In essence, logic models provide a framework to support the entire systematic review or HTA process and help to interpret the results, as well as to identify areas where further evidence is needed.

Two main approaches to logic modeling can be distinguished: a priori and iterative logic modeling. With an a priori approach, the logic model is developed at the protocol stage to refine the research question, identify sources of heterogeneity and subgroups, design the data extraction form and plan data synthesis. This type of logic model is finalized prior to data collection and remains unchanged throughout the systematic review or HTA process [17, 20]. In an iterative approach, the logic model is conceived as a mechanism to incorporate the results of the systematic review or HTA and is subject to repeated changes during the process of data collection [21]. While both approaches have their advantages and drawbacks (Booth et al, manuscript in preparation), this paper focuses mainly on a priori logic modeling.

Examples of logic models in systematic reviews and HTAs of public health and healthcare interventions exist, but specific guidance on how to develop an appropriate logic model is lacking. Noyes et al (2013) highlight the need for a taxonomy of logic models, logic model templates and a better understanding of the impact of the choice of logic model [15].

As part of the EU-funded INTEGRATE-HTA project (www.integrate-hta.eu) we designed two distinct logic model templates, and applied these across several Cochrane and non-Cochrane systematic reviews and one HTA addressing different types of complex interventions. This paper describes how these templates were developed and examines their applicability and usefulness in making sense of complexity. We have included three completed logic models on questions of particular relevance to SSA, i.e. interventions to reduce ambient air pollution, community-level interventions for improving access to food in LMICs and e-learning interventions to increase evidence-based healthcare competencies in healthcare professionals.

2. Methods

2.1 Development of logic model templates

We conducted systematic searches in the Cochrane Library, the Campbell Library and Medline via PubMed (date of last search 10 December 2013) to identify systematic reviews and HTAs that used logic models. After removal of duplicates and exclusion of irrelevant studies, 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 [22-34] of the reviews identified, used logic models at the beginning of the review process *(a priori)* to describe different aspects in the population, interventions, outcomes and context or pathways linking the intervention to final outcomes. Four of the reviews developed logic models to summarize and synthesize the results of the systematic review [35-38]. One review mapped the results of the review to an *a priori* logic model [39].

We then examined aims and various elements of the logic models identified and, using a snowball technique, reviewed existing guidance for developing logic models in primary research. We particularly looked at the guidance of the Kellogg Foundation [18] and the U.S. Preventive Services Task Force [40], both of which are frequently cited. These shaped our thinking around the distinction between system-based and process-orientated logic models. Drawing on the conceptualization of complexity within the INTEGRATE-HTA project, we developed two draft templates. For the system-based logic model, our starting point was the PICO framework to formulate clear research questions [41, 42], represented through a box for each of the elements: participants (P), interventions (I), comparisons (C) and outcomes (O). We then added boxes on context and implementation given their recognized importance for complex interventions. Elements within these “empty boxes” were specified based on existing definitions of complex interventions [8, 9, 11, 43] and a concept analysis for context and implementation [44]. For the process-orientated logic model, we started by representing the intervention components with boxes and adding separate boxes for each level of outcomes. We used arrows to illustrate various pathways from the intervention to final outcomes. Subsequently we refined both draft templates in an iterative process through discussions within the research team and in consultation with experts.

Finally, we applied the draft templates to three ongoing systematic reviews and one ongoing HTA. These are a Cochrane review of interventions to reduce particulate matter air pollution [45], a Campbell review of e-learning to increase evidence-based healthcare competencies in healthcare professionals [46], a review of interventions to reduce exposure to lead through consumer products and drinking water within a guideline developed by the World Health Organization [47] and an HTA of home-based palliative care within the INTEGRATE-HTA project [48]. We also shared the draft templates with the author teams of several ongoing Cochrane reviews of complex interventions including community-level interventions for improving access to food in LMICs [49]. Based on our own applications and the feedback from external author teams, comprising experienced as well as novice systematic reviewers, we revised the templates and accompanying definitions and explanations.

3. Results

3.1. Distinct logic model templates

A system-based logic model shown in Figure 1 (also described as a conceptual framework by some authors) depicts the system in which the interaction between the participants, the intervention and the context takes place. This perspective is mostly static: while it recognizes that interactions between different elements of the model take place, these are not investigated in detail. The PICO elements form the core elements of the logic model, supplemented with context and implementation elements. An example of a completed system-based logic model is presented in Figure 2.

A process-orientated logic model graphically displays the processes and causal pathways that lead from the intervention to its outcomes. Unlike the system-based logic model, it recognizes a temporal sequence of events and aims to explain how an intervention exerts its effect. It can also be described as an analytical framework or theory of change. The process-orientated logic model template is shown in Figure 3. As the causal pathways will differ between interventions, often combining several linear and non-linear pathways, the template suggests four general pathways. Figure 4 presents an example of a completed process-orientated logic model.

3.2 Applicability and usefulness of logic model templates

These logic model templates may be used in systematic reviews of effectiveness, systematic reviews of broader questions (e.g. regarding values and preferences, implementation or prevalence) and HTAs. While the illustrative examples provided in this paper adhere to an a priori logic modeling approach, the same templates provide the starting point for iterative logic modeling. Importantly, logic model development takes place upon initiation of a systematic review or HTA. With an a priori logic modeling approach, the initial logic model forms part of the protocol and typically does not change once the review or HTA process has started. The templates aim to facilitate the development of an appropriate initial logic model and to guide a research team in considering a broad range of issues that might be of relevance. They are a tool to be adapted to the needs of specific research questions, not a straitjacket. The template elements are thus neither essential nor exhaustive, i.e. elements might be added to or removed as necessary.

When applying the templates, a review team needs to start by considering which of the two types of logic model would be most suitable. This primarily depends upon (i) the nature of a given complex intervention and (ii) the specific research question asked. Generally, starting with a system-based logic model affords a holistic perspective, which is especially relevant for broad interventions such as packages or approaches to healthcare management or delivery. A process-orientated logic model may be used in addition to, or in rare circumstances, as stand-alone, where the composition of the intervention is well understood but the focus is on elucidating the details of how the intervention operates. For the logic model on interventions to reduce ambient particulate matter air pollution (Figure 2), a system-based logic model helped us to understand the relationship between various interventions, ambient air quality and human health outcomes in their societal and environmental context [45]. This type of logic model was appropriate, because we wanted to depict the system in which interactions take place rather than the causal pathways that link intervention and outcomes. The authors of the Cochrane review on community-level interventions for improving access to food in low- and middle-income countries [49] developed a process-orientated logic model (Figure 4) to display and understand the pathways from intervention to final outcomes. For the systematic review on evidence-based health care e-learning, we applied both templates [46]. The system-based logic model was critical for conceptualising the question, unpacking the various e-learning interventions and considering important contextual factors, enabling us to pre-specify subgroup analyses and plan data synthesis (Figure 5). The process-orientated logic model was also useful to illustrate how the intervention works, interpret the importance of outcomes and identify gaps in the evidence-base (Figure 6).

Once a research team has selected the appropriate type of logic model, they need to populate the template. This multi-step evolving process, starting with one of the templates and adapting and refining it to fit the specific intervention and research question, may take from a few days to several months. To ensure the comprehensiveness and comprehensibility of the logic model in the HTA of home-based palliative care [48], we included information from a literature review, stakeholder advisory panels, consultations with palliative care experts and discussions within the research team. This application showed the value of drawing on multiple sources of evidence, with each making unique and complementary contributions.

A step-by-step guide to the application of the templates is described in Box 2.

Box 2: Step-by-step guide to the application of templates for a priori logic modeling [21]

1. Clearly define the PICO(C) elements of the systematic review/HTA and unpack the question by describing key characteristics of participants, intervention components, intervention delivery and the comparison (if applicable) and agree on the relevant outcomes.
2. Decide within the author 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 conceptualize 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.
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, e.g. 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 systematic review or HTA.
6. Publish the final logic model with the protocol. This logic model remains unchanged during the systematic review or HTA process.

The two logic model templates have proven to be useful tools in a variety of applications. They helped to conceptualize the interventions, clarify the research questions and consider contextual factors. They also guided protocol development by informing the search strategy, inclusion and exclusion criteria, possible sources of heterogeneity, data analysis plans as well as subgroup and sensitivity analyses. All of the reviews and the HTA are currently ongoing, so the full value of the logic models in the later stages of the reviews is yet to be realized. We anticipate that the logic model will provide a framework within which the results can be anchored and assist in the interpretation thereof.

3.3 Limitations of our methods

We limited our search for existing logic models to systematic reviews indexed in PubMed, or published in the Cochrane or Campbell Libraries. We acknowledge that our search was not exhaustive as other databases could have provided additional information.

Additionally, we did not formally test the templates with potential users but instead have based our description on our own experience in using them and the unstructured reports from other author teams. Formal user-testing could provide insight into users' perceptions on the usefulness, usability, value, desirability, credibility and accessibility of the logic model templates [59].

Furthermore, we have only applied the templates to questions related to the effects of interventions. Even though our intention is not to limit their use to intervention questions, application of the templates to other types of questions (e.g. questions on risk factors, prevalence, diagnostic tests) is needed to further explore their benefits.

3.4 Limitations of logic models

By adopting a systems perspective, our proposed use of logic models overcomes many of the commonly cited problems with logic models (e.g. oversimplification of context [60, 61]). Nevertheless there are some limitations to their use.

Firstly, the intended use of our templates is to clarify assumptions at the beginning of a review or HTA process. The logic model is developed for a specific review and therefore does not have to be a perfect reflection of the world but should depict the assumptions contained in the review. Therefore, the logic model can have a substantial impact on the way a review is conducted. Commencing with a different logic model, and/or development by another review team, might lead to different results.

Secondly, the process of logic model development might take an extensive amount of time, delaying subsequent stages of the already time-consuming review process. Yet, we found that investing in a logic model is time well spent, as this clarifies inclusion criteria and the search strategy, and lends structure to data extraction and analysis.

A third limitation relates to potential overcrowding of the logic model. As this aims to depict a complex system and the processes involved comprehensively, readers might find it difficult to understand breadth and depth of information in a single graphic. When developing the palliative care logic model, we realized how important this was in avoiding confusion among stakeholders and even within the research team. Ideally, a logic model should capture the essence of the system with core concepts detailed in accompanying text.

4. Discussion and conclusion

Systematic reviews that can help provide answers for the vast array of challenges in SSA have become a necessity [2, 62]. Our logic model templates equip review authors with a tool to address complexity in an explicit manner, thereby mainly building capacity at an individual level. However, they also have the potential to enhance the capacity of the system [7] through improved communication between producers and users of evidence. They add value to the review process in terms of achieving a better understanding of the many interactions between the intervention and its multiple health outcomes among a given population. An example of this is the logic model for the review on food security (Figure 4). This enables authors to synthesise the results in a meaningful way so that various stakeholders might find them more useful.

Another key feature of our templates is that they enable an assessment of the context within which the intervention takes place. This is essential for interventions in LMICs, where the context differs considerably from high-income countries. For example, although ambient air pollution is a global problem, its mitigation requires different strategies in different contexts. The system-based logic model on interventions for reducing ambient air pollution depicts the essential contextual factors that need to be taken into consideration when planning the implementation of a particular intervention.

Strengthening research capacity in conducting research synthesis is of utmost importance and has been widely advocated as a means of overcoming the paucity of evidence relevant to SSA and other LMICs [3, 5, 7, 63-65]. We envisage that the logic model templates will support novice and experienced review authors by making complexity less daunting.

Acknowledgements

The research leading to this publication is part of the project INTEGRATE-HTA and has received funding from the European Union Seventh Framework Programme under grant agreement n° 306141.

INTEGRATE-HTA-Work Package (WP) 5 working group (in alphabetical order): W Awa, A Booth, L Brereton, J Chilcott, KB Lysdahl, K Mozygemba, A Gerhardus, W Oortwijn, L Pfadenhauer, P Refolo, E Rehfuess, A Rohwer, D Sacchini, M Tummers, GJ van der Wilt, P Wahlster.

Author contributions

AR, ER, LP developed the logic model templates with input from the rest of the WP5 working group. AR, ER, LP, JB, and LB were involved in application of the logic model templates in the various systematic reviews and the HTA. AR and ER drafted the manuscript and LP, JB, LB, AG, AB and WO critically engaged with the content and provided input. All authors approved the final manuscript before submission.

Conflicts of interest

None known.

References

[1] Lozano R, Naghavi M, Foreman K, Lim S, Shibuya K, al. e. Global and regional mortality from 235 causes of death for 20 age groups in 1990 and 2010: a systematic analysis for the Global Burden of Disease Study 2010. The Lancet 2012;380:2095-128.
[2] Chinnock P, Siegfried N, Clarke M. Is Evidence-Based Medicine Relevant to the Developing World? PLoS Medicine. 2005;2:e107.
[3] Birbeck GL, Wiysonge CS, Mills EJ, Frenk JJ, Zhou XN, Jha P. Global health: the importance of evidence-based medicine. BMC medicine. 2013;11.
[4] Chalmers I, Bracken MB, Djulbegovic B, Garattini S, Grant J, Gulmezoglu AM, et al. How to increase value and reduce waste when research priorities are set. Lancet. 2014;383:156-65.
[5] Wiysonge CS, Volmink J. Strengthening research capacity. Lancet. 2002;359:713.
[6] Wilson MG, Moat KA, Lavis JN. The global stock of research evidence relevant to health systems policymaking. Health research policy and systems / BioMed Central. 2013;11:32.
[7] Oliver S, Bangpan M, Stansfield C, Stewart R. Capacity for conducting systematic reviews in low- and middle-income countries: a rapid appraisal. Health research policy and systems / BioMed Central. 2015;13:23.
[8] Craig P, Dieppe P, Macintyre S, Michie S, Nazareth I, Petticrew M. Developing and evaluating complex interventions: the new Medical Research Council guidance. Bmj. 2008;337:a1655-a.
[9] Petticrew M, Anderson L, Elder R, Grimshaw J, Hopkins D, Hahn R, et al. Complex interventions and their implications for systematic reviews: a pragmatic approach. J Clin Epidemiol. 2013;66:1209-14.
[10] Squires JE, Valentine JC, Grimshaw JM. Systematic reviews of complex interventions: framing the review question. J Clin Epidemiol. 2013;66:1215-22.
[11] Petticrew M. When are complex interventions 'complex'? When are simple interventions 'simple'? European journal of public health. 2011;21:397-8.
[12] Petticrew M, Rehfuess E, Noyes J, Higgins JP, Mayhew A, Pantoja T, et al. Synthesizing evidence on complex interventions: how meta-analytical, qualitative, and mixed-method approaches can contribute. J Clin Epidemiol. 2013;66:1230-43.
[13] Pigott T, Shepperd S. Identifying, documenting, and examining heterogeneity in systematic reviews of complex interventions. J Clin Epidemiol. 2013;66:1244-50.
[14] Burford B, Lewin S, Welch V, Rehfuess E, Waters E. Assessing the applicability of findings in systematic reviews of complex interventions can enhance the utility of reviews for decision making. J Clin Epidemiol. 2013;66:1251-61.
[15] Noyes J, Gough D, Lewin S, Mayhew A, Michie S, Pantoja T, et al. A research and development agenda for systematic reviews that ask complex questions about complex interventions. J Clin Epidemiol. 2013;66:1262-70.
[16] Wildschut LP. Theory-based evaluation, logic modelling and the experience of SA non-governmental organisations. 2014.
[17] Anderson LM, Petticrew M, Rehfuess E, Armstrong R, Ueffing E, Baker P, et al. Using logic models to capture complexity in systematic reviews. Research Synthesis Methods. 2011;2:33-42.
[18] Kellog WK. Using Logic Models to Bring Together Planning, Evaluation, and Action: Logic Model Development Guide. Michigan: Kellog foundation; 2004.
[19] Guise JM, Chang C, Viswanathan M, al. e. Systematic Reviews of Complex Multicomponent Health Care Interventions: Rockville (MD): Agency for Healthcare Research and Quality (US); 2014.
[20] Anderson LM, Oliver SR, Michie S, Rehfuess E, Noyes J, Shemilt I. Investigating complexity in systematic reviews of interventions by using a spectrum of methods. J Clin Epidemiol. 2013;66:1223-9.
[21] Rohwer A., Booth A, Pfadenhauer L, Brereton L, Gerhardus A, Mozygemba K, et al. Guidance on the use of logic models in health technology assessments of complex interventions 2016.

[22] Baird S, Fereirra FHG, Özler B, Woolcock M. Relative effectiveness of conditional and unconditional cash transfers for schooling outcomes in developing countries: A systematic review. Campbell systematic reviews. 2013.
[23] Baker PRA, Francis DP, Soares J, Weightman AL, Foster C. Community wide interventions for increasing physical activity. Cochrane Database of Systematic Reviews. 2011.
[24] Chamberlain C, O'Mara-Eves A, Oliver S, Caird JR, Perlen SM, Eades SJ, et al. Psychosocial interventions for supporting women to stop smoking in pregnancy. Cochrane Database of Systematic Reviews 2013:Art. No.: CD001055.
[25] Coren E, Hossain R, Pardo Pardo J, Veras MMS, Chakraborty K, Harris H, et al. Interventions for promoting reintegration and reducing harmful behaviour and lifestyles in street-connected children and young people. Cochrane Database of Systematic Reviews. 2013.
[26] De-Regil LM, Suchdev PS, Vist GE, Walleser S, Peña-Rosas JP. Home fortification of foods with multiple micronutrient powders for health and nutrition in children under two years of age. Cochrane Database of Systematic Reviews. 2011.
[27] Goerlich Zief S, Lauver S, Maynard RA. Impacts of After-school programs on student outcomes. Campbell systematic reviews. 2006.
[28] Harris R, Mosedale S, Garner J, Perkins E. 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 (1982). 2014;108:54-9.
[29] Mazerolle L, Bennett S, Davis J, Sargeant E, M M. Legitimacy in Policing: A Systematic Review. Campbell Systematic Reviews. 2013;1.
[30] Sandoval JA, Lucero J, Oetzel J, Avila M, Belone L, Mau M, et al. Process and outcome constructs for evaluating community-based participatory research projects: a matrix of existing measures. Health education research. 2012;27:680-90.
[31] Segal L, Opie RS, Dalziel K. Theory! The missing link in understanding the performance of neonate/infant home-visiting programs to prevent child maltreatment: A systematic review. The Milbank quarterly. 2012;90:47-106.
[32] Taylor-Robinson DC, Maayan N, Soares-Weiser K, Donegan S, Garner P. Deworming drugs for soil-transmitted intestinal worms in children: effects on nutritional indicators, haemoglobin and school performance. Cochrane Database of Systematic Reviews. 2012.
[33] Tripney J, Hombrados J, Newman M, Hovish K, Brown C, Steinka-Fry K, et al. 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. 2013;9.
[34] Turley R, Saith R, Bhan N, Rehfuess E, Carter B. Slumupgrading strategies involving physical environment and infrastructure interventions and their effects on health and socio-economic outcomes. Cochrane Database of Systematic Reviews. 2013.
[35] Glenton C, Colvin CJ, Carlsen B, Swartz A, Lewin S, Noyes J, et al. Barriers and facilitators to the implementation of lay health worker programmes to improve access to maternal and child health: qualitative evidence synthesis. Cochrane Database of Systematic Reviews. 2013:Art. No.: CD010414.
[36] Subirana M, Long A, Greenhalgh J, Firth J. A realist logic model of the links between nurse staffing and the outcomes of nursing. Journal of Research in Nursing. 2014;19:8-23.
[37] Rachlis B, Sodhi S, Burciul B, Orbinski J, Cheng AH, Cole D. A taxonomy for community-based care programs focused on HIV/AIDS prevention, treatment, and care in resource-poor settings. Global health action. 2013;6:1-21.
[38] Thomson H, Thomas S, Sellstrom E, Petticrew M. Housing improvements for health and associated socio-economic outcomes. Cochrane Database of Systematic Reviews. 2013.
[39] Urstad KH, Wahl AK, Andersen MH, Oyen O, Hagen KB. Limited evidence for the effectiveness of educational interventions for renal transplant recipients. Results from a systematic review of controlled clinical trials. Patient education and counseling. 2013;90:147-54.

[40] Harris RP, Helfand M, Woolf SH, Lohr KN, Mulrow CD, Teutsch SM, et al. Current Methods of the U.S. Preventive Services Task Force: A Review of the Process. American journal of preventive medicine. 2001;20:21-35.
[41] Higgins JPT, Green SE. Cochrane Handbook for Systematic Reviews of Interventions: The Cochrane Collaboration and Wiley-Blackwell; 2008.
[42] Stone PW. Popping the (PICO) question in research and evidence-based practice. Applied Nursing Research. 2002;15:197-8.
[43] Shiell A, Hawe P, Gold L. Complex interventions or complex systems? Implications for health economic evaluation. BMJ: British Medical Journal. 2008;336:1281.
[44] Pfadenhauer LM, Mozygemba K, Gerhardus A, Hofmann B, Booth A, Lysdahl KB, et al. Context and implementation: A concept analysis towards conceptual maturity. Z Evid Fortbild Qual Gesundhwes. 2015;109:103-14.
[45] Burns J, Boogaard J, Turley R, Pfadenhauer LM, van Erp AM, Rohwer AC, et al. Interventions to reduce ambient particulate matter air pollution and their effect on health. Cochrane Database of Systematic Reviews. 2014:Art.No.: CD010919.
[46] Rohwer A, Rehfuess E, Young T. E-learning of Evidence-Based Health Care to Increase EBHC Competencies in Healthcare Professionals. 2014.
[47] Pfadenhauer L, Burns J, Rohwer A, Rehfuess EA. A protocol for a systematic review of the effectiveness of interventions to reduce exposure to lead through consumer products and drinking water. Systematic reviews. 2014;3.
[48] Brereton L, Wahlster P, Lysdahl KB, Mozygemba K, Burns J, Chilcott JB, et al. Integrated assessment of home based palliative care with and without reinforced caregiver support: 'A demonstration of INTEGRATE-HTA methodological guidances' [2016.
[49] Durao S, Schoonees A, Ramokolo V, Oliveira JMD, E. K. Community-level interventions for improving access to food in low- and middle-income countries. . Cochrane Database of Systematic Reviews 2015: Art. No.: CD011504.
[50] May C, Finch T, Mair F, Ballini L, Dowrick C, Eccles M, et al. Understanding the implementation of complex interventions in health care: the normalization process model. BMC health services research. 2007;7:148.
[51] Wells M, Williams B, Treweek S, Coyle J, Taylor J. 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. 2012;13:95.
[52] Damschroder LJ, Aron DC, Keith RE, Kirsh SR, Alexander JA, Lowery JC. Fostering implementation of health services research findings into practice: a consolidated framework for advancing implementation science. Implement Sci. 2009;4:50.
[53] Carroll C, Patterson M, Wood S, Booth A, Rick J, Balain S. A conceptual framework for implementation fidelity. Implementation science : IS. 2007;2:40.
[54] Linnan L, Steckler A. Process Evaluation for Public Health Interventions and Research. 2006.
[55] Audrey S, Holliday J, Parry-Langdon N, Campbell R. Meeting the challenges of implementing process evaluation within randomized controlled trials: the example of ASSIST (A Stop Smoking in Schools Trial). Health education research. 2006;21:366-77.
[56] Furgerson JL, Hannah Jr WN, Thompson JC. Challenge of surrogate endpoints. Southern medical journal. 2012;105:156-60.
[57] Burzykowski T, Molenberghs G, Buyse M. The evaluation of surrogate endpoints. New York: Springer; 2005.
[58] Pfadenhauer L, Rohwer A, Burns J, Booth A, Lysdahl KB, Hofmann B, et al. 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 2016.
[59] Morville P. User Experience DEsign. 2004.

[60] Hummelbrunner R. Beyond logframe: critique, variations and alternatives. In: Fujita N, editor. Beyond logframe: using systems concepts in evaluation. Tokyo: Foundation for Advanced Studies on International Development; 2010.
[61] Rogers P. Representing simple, complicated, and complex aspects in logic models for evaluation quality. 24th Annual Conference of the American Evaluation Association. San Antonio, Texas2010.
[62] Meremikwu M, Udoh E, Nwagbara B, Effa E, Oringanje C, Edet B, et al. Priority setting for systematic review of health care interventions in Nigeria. Health policy (Amsterdam, Netherlands). 2011;99:244-9.
[63] Forland F, Rohwer A, Klatser P, Boer K, Mayanja-Kizza H. Strengthening evidence-based healthcare in Africa. Evidence-Based Medicine. 2013;18.
[64] English M, Opiyo N. Getting to grips with GRADE-perspective from a low-income setting. J Clin Epidemiol. 2011;64:708-10.
[65] Nachega JB, Uthman OA, Ho YS, Lo M, Anude C, Kayembe P, et al. Current status and future prospects of epidemiology and public health training and research in the WHO African region. International journal of epidemiology. 2012;41:1829-46.

Figure legends:

Figure 1: System-based logic model template

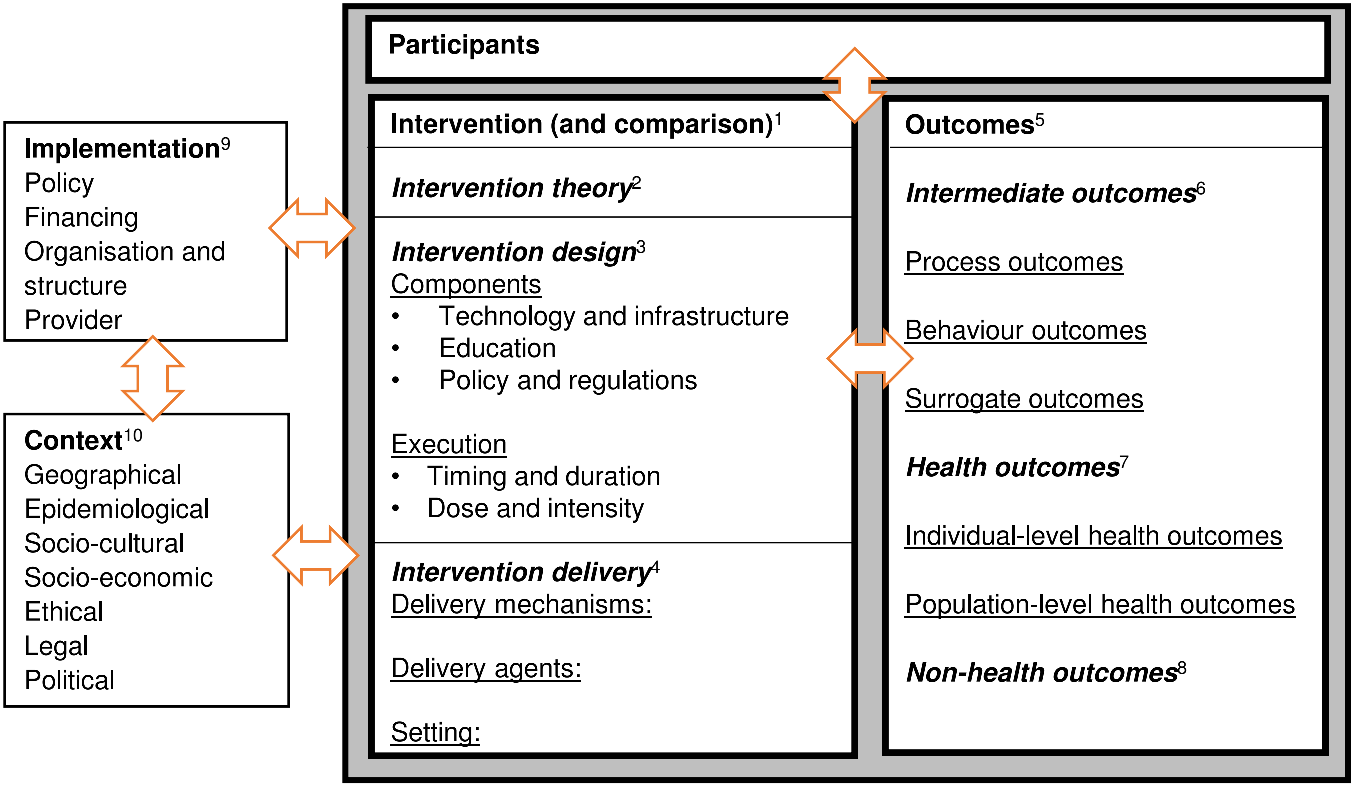
Figure 2: Example of a system-based logic model of interventions to reduce particulate matter air pollution [45]. Reprinted with permission

Figure 3: Process-orientated logic model template

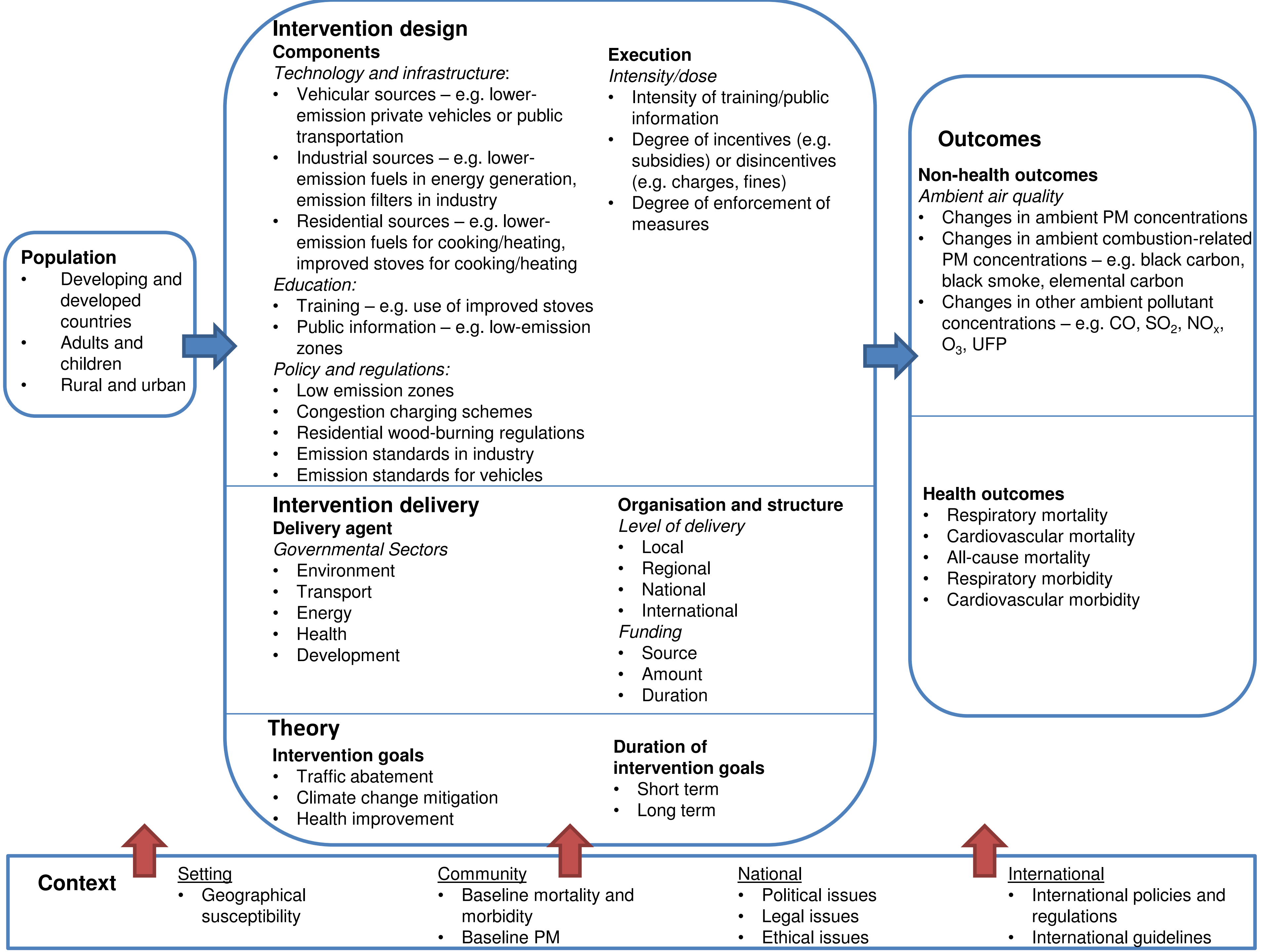
Figure 4: Example of a process-orientated logic model of interventions to improve food and nutritional security [49]. Reprinted with permission

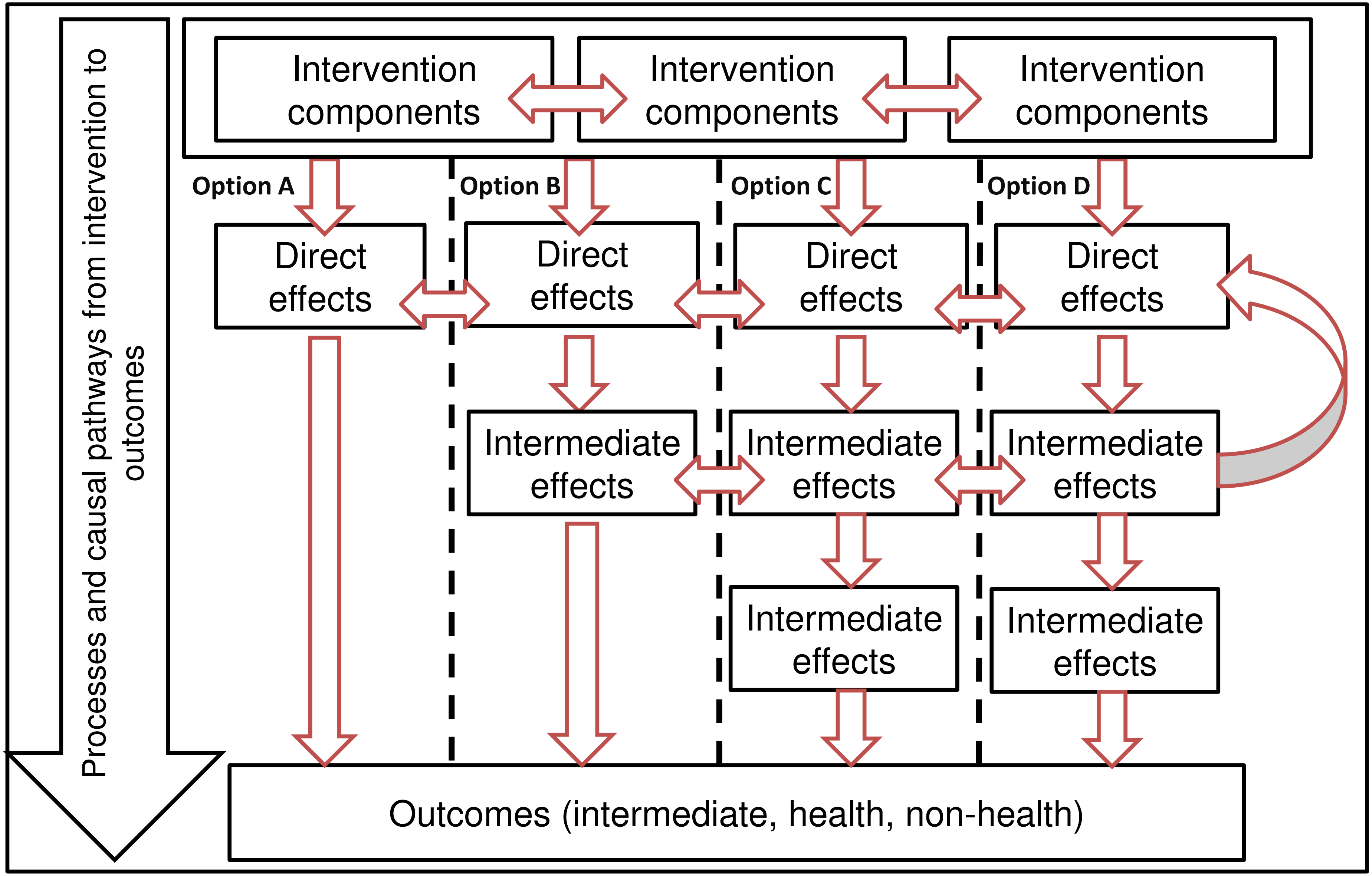
Figure 5: Example of system-based logic model of EBHC e-learning to increase EBHC competencies amongst healthcare professionals [46]

Figure 6: Example of process-orientated logic model of EBHC e-learning to increase EBHC competencies amongst healthcare professionals [46]

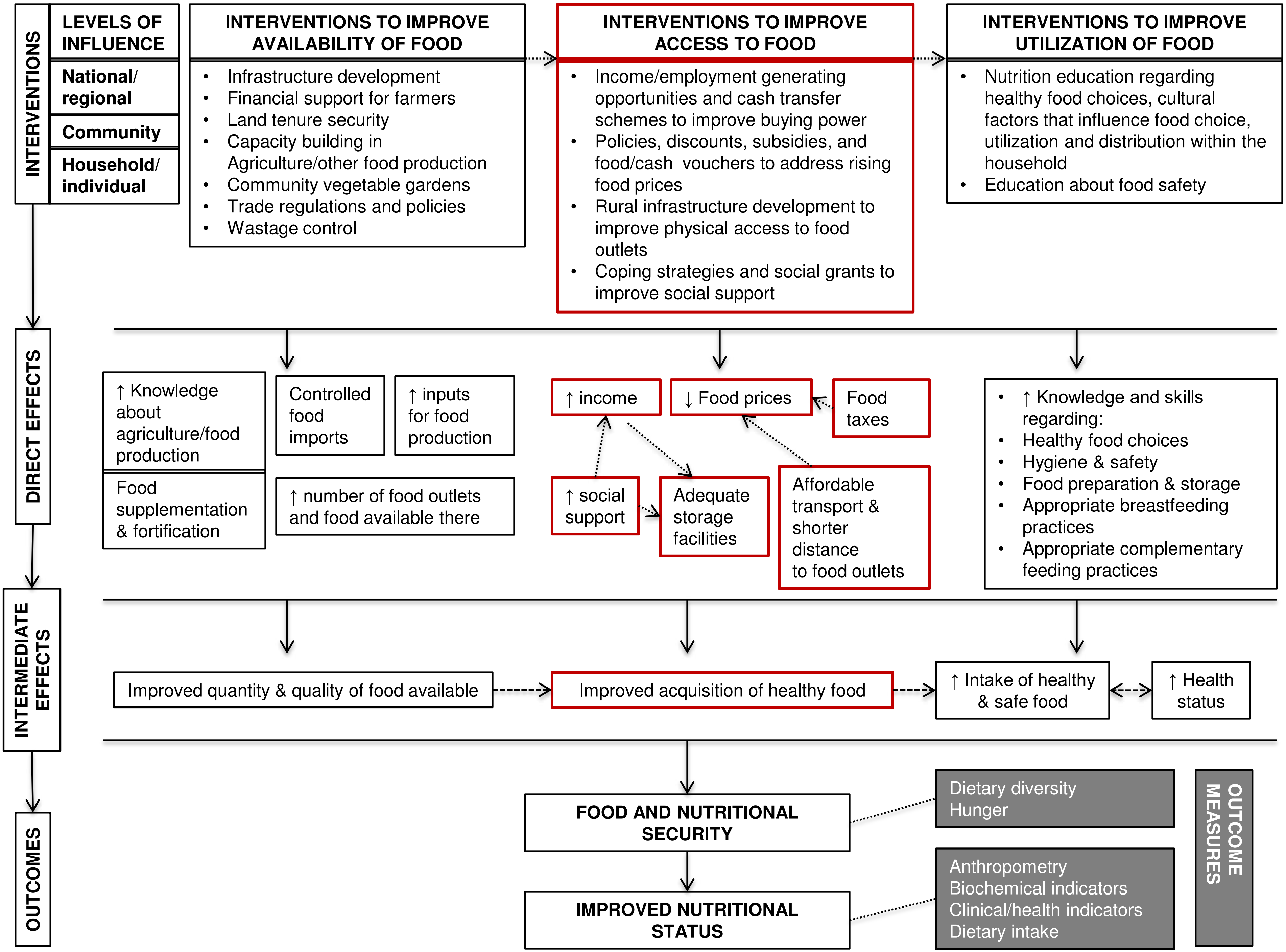


[1]The intervention(s) can be divided into theory, design and delivery elements.
[2]Here the term "theory" is used in a broad way to describe a body of implicit or explicit ideas about how an intervention works [50, 51] and includes the overall aims of the intervention.
[3]Intervention design describes the "What?" of the intervention. 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).
[4]Intervention delivery describes the "How?", "Who?" and "Where?" of the intervention. Individuals (delivery agents) form the basis of every organisation and organisational change [52], and knowledge, skills, motivation and beliefs are critical for successful delivery.
[5]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.
[6]Intermediate outcomes: Process outcomes can be quantitative or qualitative in nature and may include participation, implementation fidelity [53], reach, barriers experienced, contamination of the comparison group by study or non-study interventions, and experiences of participants and intervention providers [54, 55]. Behaviour outcomes include participant behaviours required for the intervention to have an effect, such as adherence or compliance, but can also refer to other behavioural outcomes occurring intentionally or unintentionally. Surrogate outcomes are used as proxies for "hard" clinical outcomes and refer to direct, measurable, often short-term effects of an intervention [56, 57].
[7]Health outcomes comprise clinical outcomes, such as morbidity and mortality, as well as broader outcomes, such as wellbeing, life expectancy and quality of life.
[8]Non-health outcomes refer to all other relevant societal impacts of an intervention.
[9,10]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 interventions (CICI) framework [58] provides an overarching approach for considering these two distinct but interacting dimensions.


Intervention design
Components
Technology and infrastructure:
• Vehicular sources – e.g. lower-emission private vehicles or public transportation
• Industrial sources – e.g. lower-emission fuels in energy generation, emission filters in industry
• Residential sources – e.g. lower-emission fuels for cooking/heating, improved stoves for cooking/heating
Education:
• Training – e.g. use of improved stoves
• Public information – e.g. low-emission zones
Policy and regulations:
• Low emission zones
• Congestion charging schemes
• Residential wood-burning regulations
• Emission standards in industry
• Emission standards for vehicles
Execution
Intensity/dose
• Intensity of training/public information
• Degree of incentives (e.g. subsidies) or disincentives (e.g. charges, fines)
• Degree of enforcement of measures
Population
• Developing and developed countries
• Adults and children
• Rural and urban
Outcomes
Non-health outcomes
Ambient air quality
• Changes in ambient PM concentrations
• Changes in ambient combustion-related PM concentrations – e.g. black carbon, black smoke, elemental carbon
• Changes in other ambient pollutant concentrations – e.g. CO, SO_2, NO_x, O_3, UFP
Health outcomes
• Respiratory mortality
• Cardiovascular mortality
• All-cause mortality
• Respiratory morbidity
• Cardiovascular morbidity
Intervention delivery
Delivery agent
Governmental Sectors
• Environment
• Transport
• Energy
• Health
• Development
Organisation and structure
Level of delivery
• Local
• Regional
• National
• International
Funding
• Source
• Amount
• Duration
Theory
Intervention goals
• Traffic abatement
• Climate change mitigation
• Health improvement
Duration of intervention goals
• Short term
• Long term
Context
Setting
• Geographical susceptibility
Community
• Baseline mortality and morbidity
• Baseline PM
National
• Political issues
• Legal issues
• Ethical issues
International
• International policies and regulations
• International guidelines



The two-way arrows between the different components illustrate possible interactions. Different steps along the short or long pathway from intervention to outcomes are described as direct and intermediate effects, with two-way arrows suggesting possible interactions. 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.


INTERVENTIONS
LEVELS OF INFLUENCE
National/ regional
Community
Household/ individual
INTERVENTIONS TO IMPROVE AVAILABILITY OF FOOD
• Infrastructure development
• Financial support for farmers
• Land tenure security
• Capacity building in Agriculture/other food production
• Community vegetable gardens
• Trade regulations and policies
• Wastage control
INTERVENTIONS TO IMPROVE ACCESS TO FOOD
• Income/employment generating opportunities and cash transfer schemes to improve buying power
• Policies, discounts, subsidies, and food/cash vouchers to address rising food prices
• Rural infrastructure development to improve physical access to food outlets
• Coping strategies and social grants to improve social support
INTERVENTIONS TO IMPROVE UTILIZATION OF FOOD
• Nutrition education regarding healthy food choices, cultural factors that influence food choice, utilization and distribution within the household
• Education about food safety
DIRECT EFFECTS
↑ Knowledge about agriculture/food production
Food supplementation & fortification
Controlled food imports
↑ inputs for food production
↑ number of food outlets and food available there
↑ income
↓ Food prices
Food taxes
↑ social support
Adequate storage facilities
Affordable transport & shorter distance to food outlets
• ↑ Knowledge and skills regarding:
• Healthy food choices
• Hygiene & safety
• Food preparation & storage
• Appropriate breastfeeding practices
• Appropriate complementary feeding practices
INTERMEDIATE EFFECTS
Improved quantity & quality of food available
Improved acquisition of healthy food
↑ Intake of healthy & safe food
↑ Health status
OUTCOMES
FOOD AND NUTRITIONAL SECURITY
IMPROVED NUTRITIONAL STATUS
Dietary diversity
Hunger
Anthropometry
Biochemical indicators
Clinical/health indicators
Dietary intake
OUTCOME MEASURES

Participants
- Type of healthcare worker (e.g. medical doctor, Nurse, Physiotherapist etc.)
- Level of education (undergraduate, postgraduate, CME)

Educational context

Setting

Location where learning takes place
- Same place vs. distributed
- Home, workplace, university, library, classroom, bedside etc.

Learner context
- Background knowledge of EBHC
- Computer literacy
- Learning style
- Motivaton

Institutional context
- Structure of course within larger curriculum
- Role models

Socio-economic context
- Access to internet
- Access to information (databases and electronic journals)
- Affordability
- Availability of electricity
- Availability of personal computers

Intervention

Theory

Adult learning theory:
- Self-motivation
- Personalised learning
- Distributed learning

Intervention design

Components:
- Course, module, curriculum, workshop on EBHC
- Learning objectives and content of educational activity
    - EBHC enabling competencies (epidemiology, biostatistics, basic searching skills, critical thinking)
    - EBHC key competencies (asking questions, accessing literature, critically appraising literature, applying results, evaluating the process)
- Multifaceted intervention vs. Single intervention

Execution:
- Duration (6 weeks, one year etc)
- Intensity (e.g. 2 hours)
- Dose (e.g. twice a week; once a month)
- Timing (within study programme etc.)
- Integrated or stand-alone

Intervention delivery

Dimensions:
- Pure e-learning vs. Blended learning
- Collaborative (interactive) vs. Individual learning
- Synchronous vs. Asynchronous delivery

Delivery agent:
- Facilitators and tutors: Attitude, communication skills, teaching skills, engagement with learners

Organisation and structure:
- Institutions offering educational activity (cost, capacity, culture)

Outcomes

Intermediate outcomes

Process outcomes
- Barriers to method of teaching EBHC
- Enablers of method of teaching EBHC
- Learner satisfaction
- Teacher satisfaction
- Cost
- Attrition

Surrogate outcomes

•EBHC knowledge*

•EBHC skills*

•EBHC attitude*

Behaviour outcomes
- **EBHC behaviour* (e.g. Question formulation, reading habits etc)**
- Evidence-based practice
- Learner adherence

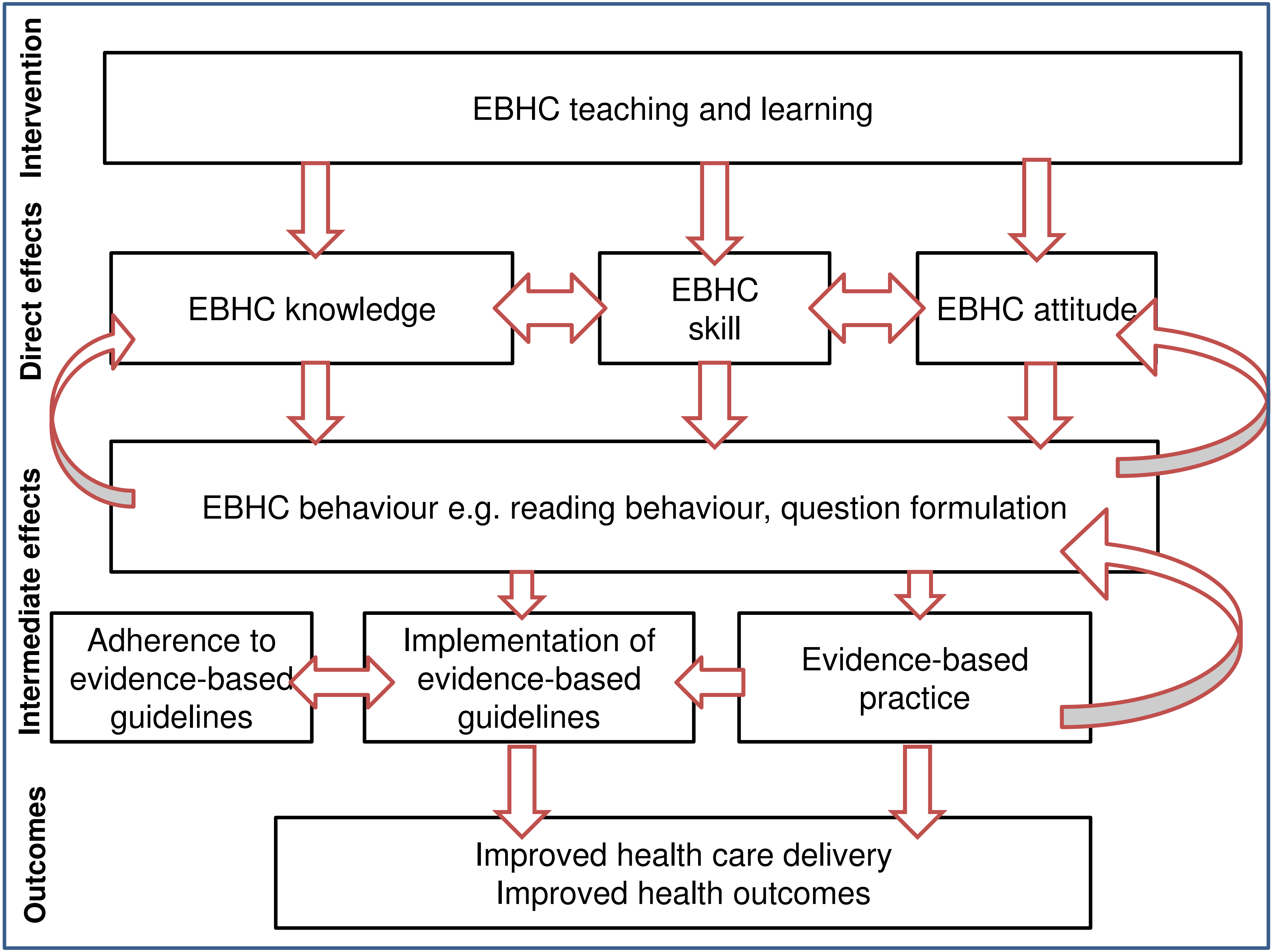
Non-health outcomes
- Evidence-based guideline implementation
- Health care delivery (health systems)

Health outcomes
- Individual health outcomes
- Population health outcomes

Healthcare context

Socio-cultural	Socio-economic
Epidemiological	Legal
Ethical	Political

*Bold outcomes represent primary outcomes, the rest refer to secondary outcomes


Intervention
Direct effects
Intermediate effects
Outcomes
EBHC teaching and learning
EBHC knowledge
EBHC skill
EBHC attitude
EBHC behaviour e.g. reading behaviour, question formulation
Adherence to evidence-based guidelines
Implementation of evidence-based guidelines
Evidence-based practice
Improved health care delivery
Improved health outcomes