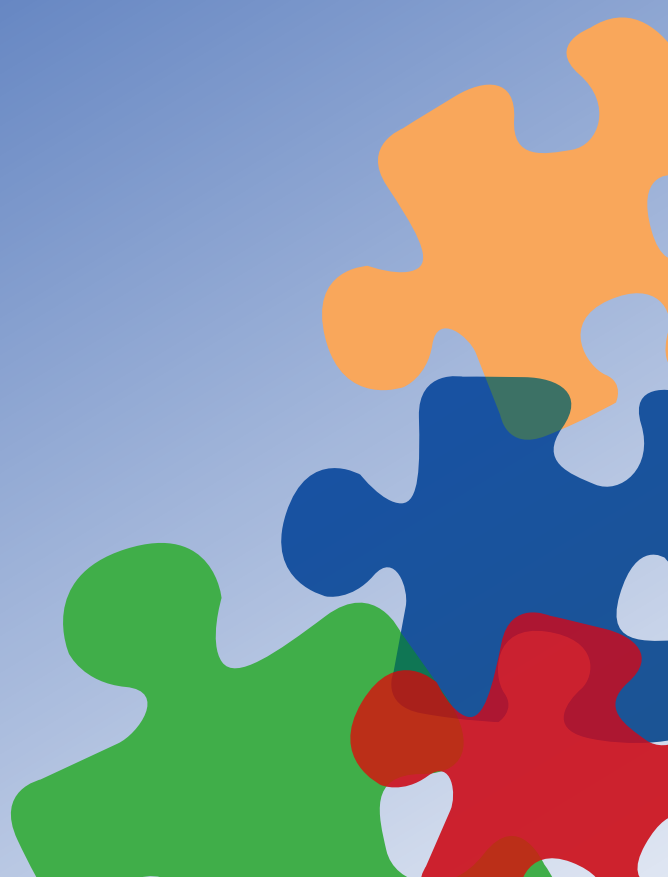


Guidance for the Assessment of Context and Implementation in Health Technology Assessments (HTA) and Systematic Reviews of Complex Interventions:

The Context and Implementation of Complex Interventions (CICI) Framework

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INTEGRATE-HTA



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About this guidance



Who would find this guidance useful?

Producers and users of health technology assessments and systematic reviews of complex interventions.

Purpose and scope of this guidance

The purpose of this guidance is to facilitate the systematic assessment and documentation of the context and implementation of a complex intervention. It introduces an overarching framework of the interacting dimensions of context (including setting) and implementation. This framework comprises eight domains of context (i.e. setting, geographical, epidemiological, socio-cultural, socio-economic, ethical, legal and political) and four domains of implementation (i.e. provider, organisation and structure, funding and policy) including definitions and descriptions of each of these domains.

Added value for integration / complex technologies

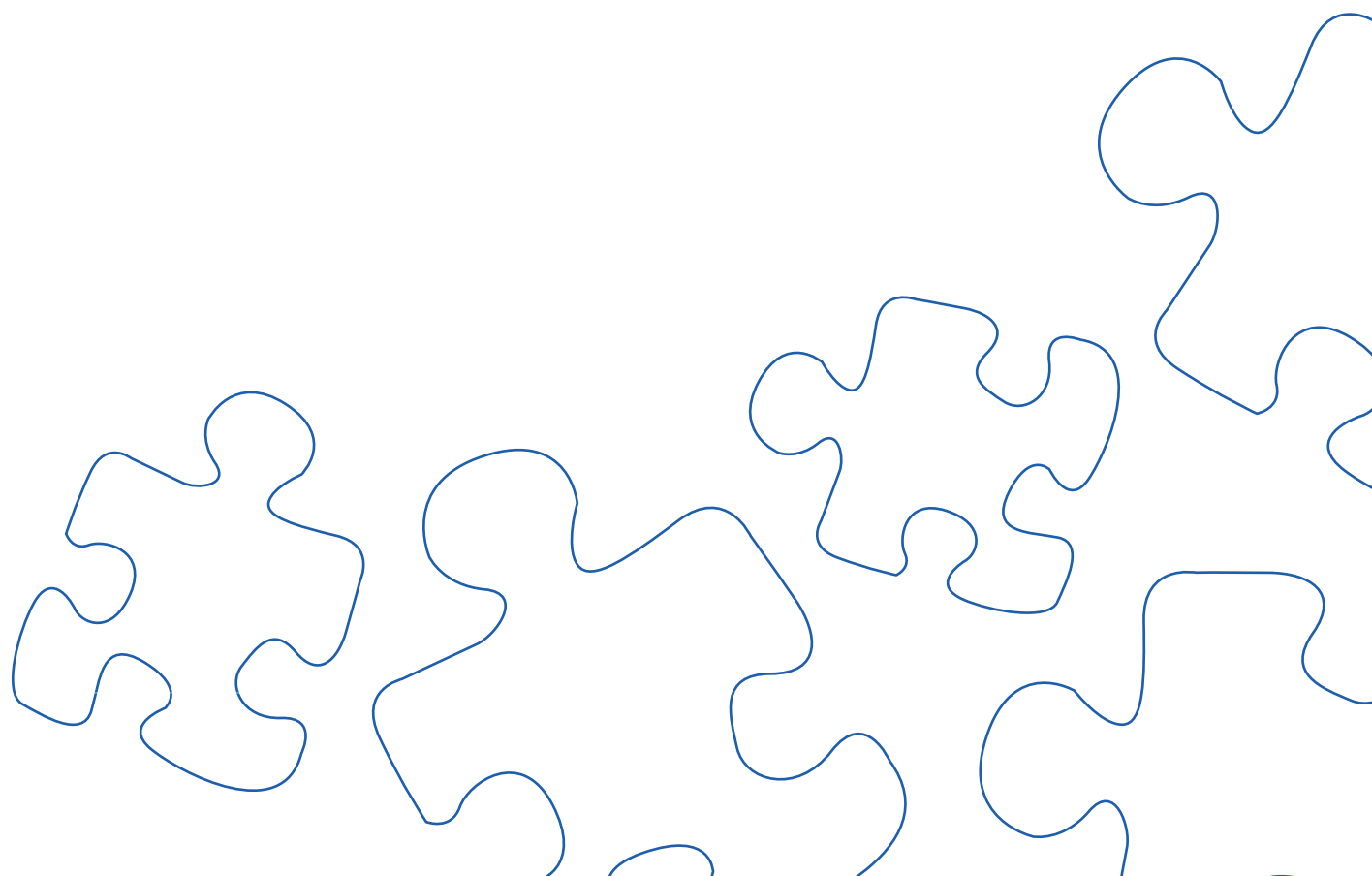
Context and implementation often directly affect the effectiveness and reach of a complex intervention, and their assessment is therefore crucial in an HTA or systematic review. The framework also provides a means of presenting the information on various domains in an integrated fashion.

INTEGRATE-HTA

INTEGRATE-HTA is an innovative project that has been co-funded by the European Union under the Seventh Framework Programme from 2013 till 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.

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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 organizational levels, have multiple and variable outcomes, and/or permit a certain degree of flexibility or tailoring,
- ▶ are context-dependent - current HTA usually focusses on the technology, not on the system within which it is used,
- ▶ perform differently depending on the way they are implemented,
- ▶ have different effects on different individuals.

Furthermore, HTA usually assesses and appraises aspects side-by-side, while decision-making needs an integrated perspective on the value of a technology. In the EU-funded INTEGRATE-HTA project, we developed concepts and methods to deal with these challenges, which are described in six guidances.

Where context-dependency and implementation of a technology matter, it is critical to make this explicit, to document available information as fully as possible and to assess if and how this may affect intervention reach and effectiveness.

Purpose and scope of the guidance

The purpose of this guidance is to provide a framework to commissioners, producers and users of systematic reviews and health technology assessments (HTA) that allows for the systematic conceptualisation, assessment and documentation of the setting, context and implementation of a complex intervention. It presents an overarching framework comprising eight domains of context (i.e. setting, geographical, epidemiological, socio-cultural, socio-economic, ethical, legal and political issues) and four domains of implementation (i.e. provider, organisation and structure, funding and policy), including definitions and descriptions of each of these domains.

Development of the guidance

The Context and Implementation of Complex Interventions (CICI) framework was developed in an iterative fashion. Based on a scoping review of existing theories, models and frameworks concerned with "context", "setting" and "implementation", an initial framework for conceptualising, assessing and documenting the interacting dimensions of context (including setting) and implementation was developed. Due to the lack of conceptual clarity identified in the scoping review, and in order to provide a sound scientific basis for this framework,

systematic literature searches were performed for the concepts “setting”, “context” and “implementation”. The three concepts were appraised as partially mature. Pragmatic utility concept analysis, as developed by Morse and colleagues, was selected as the most suitable method to evaluate concept use by comparing and contrasting applications across the health field. During data extraction, relevant constructs informing the selected theories, models and frameworks were also extracted and integrated with the initial CICI framework. This revised initial framework was applied in four systematic reviews (three quantitative and one qualitative review), as well as in one HTA. The findings from the applications were used to create the revised CICI framework presented in this guidance.

Application of the guidance

The CICI framework can be applied in HTA and systematic reviews of effectiveness, as well as in qualitative systematic reviews. The guidance provides definitions and descriptions of domains of context and implementation and provides examples which may be of relevance for each domain. In addition, it proposes a list of questions to assess each domain: a) to retrieve quantitative information about the domain (which characteristics influence ...?) and b) to generate a more in-depth understanding of the domain’s influence (how do the characteristics influence ...?). Moreover, the list encourages the researcher to assess relevant interactions between domains (e.g. ethical and socio-cultural domain). Additionally, we suggest a graphical representation of the domains contained in the CICI framework that supports researchers in systematically assessing domains of context and implementation.

The CICI framework can moreover be used to assess the applicability of a technology to a specific context. The domains serve as the basis for a semi-structured questionnaire that can be used with experts when exploring potential contextual barriers and facilitators to the implementation of a specific technology.

Conclusion

The CICI framework can be applied in quantitative, qualitative or mixed-method systematic reviews and in HTAs. In quantitative systematic reviews, it supports the documentation of relevant context and implementation aspects through data extraction, examination of heterogeneity and subgroup analysis. In qualitative or mixed-method systematic reviews, it serves as a starting point for identifying and formulating specific research questions to understand how context and/or implementation influence the intervention. In HTAs, an appraisal of the respective domains can be conducted by asking stakeholder panels about their importance and relevance. Overall, the framework helps to present context and implementation issues in an integrated fashion, and supports the assessments of applicability and generalizability of HTAs and systematic reviews.

List of abbreviations

BLL	Blood lead level
CBA	Controlled before-after study
CFIR	Consolidated framework for implementation research
CICI	Context and implementation of complex Interventions
CONSORT	Consolidated Standard of Reporting Trials
EPOC	Effective Practice and Organization of Care
ELSI	Ethical, Legal and Social Issues
EUnetHTA	European network for Health Technology Assessment
HBPC	Home-based palliative care
HTA	Health Technology Assessment
INAHTA	International Network of Agencies for Health Technology Assessment
ITS	Interrupted time-series
MRC	Medical Research Council
PARiHS	Promoting Action on Research Implementation in Health Services
PRISM	Practical, Robust Implementation and Sustainability Model
PU	Pragmatic Utility
RCT	Randomized controlled trial
RE-AIM	Reach Effectiveness Adoption Implementation Maintenance framework
rHBPC	Reinforced home-based palliative care
STROBE	STrengthening the Reporting of OBservational studies in Epidemiology
TREND	Transparent Reporting of Evaluations with Nonrandomized Design
UBA	Uncontrolled before-after study
WHO	World Health Organization
WP	Work Package

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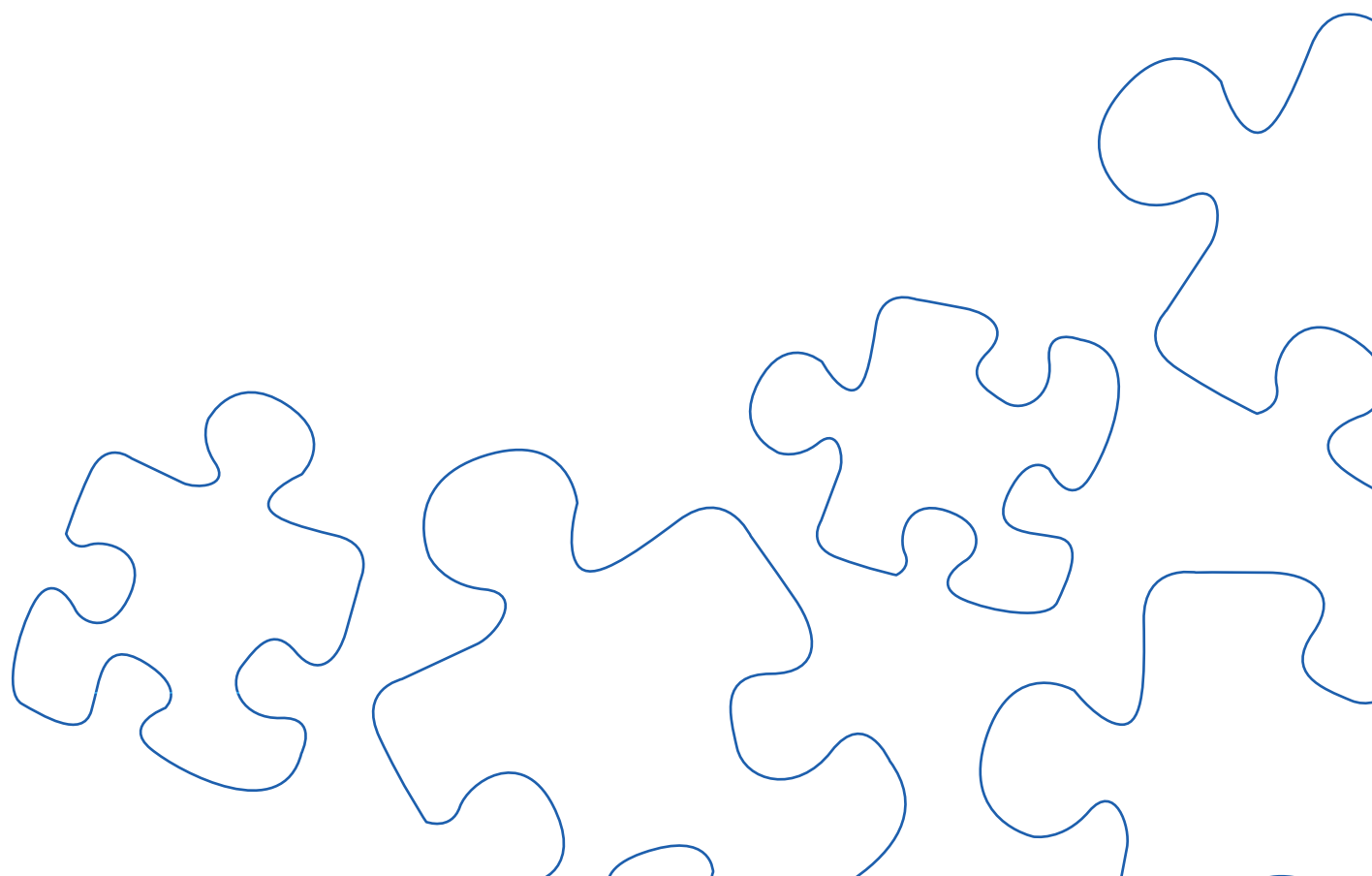
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1 PURPOSE AND SCOPE OF THE GUIDANCE

1.1 AIM OF THIS GUIDANCE

This guidance is intended to assess context and implementation of complex interventions in a comprehensive way. It is an important tool for examining the influence of context and implementation as modifiers in a health technology assessment (HTA), by helping to develop appropriate research questions for other forms of evidence collection (e.g. stakeholder advisory panels, non-systematic literature searches) concerned with factors enabling or limiting intervention uptake, and by facilitating a careful examination of the influence of these factors on the population reach and effectiveness of an intervention as well as its generalizability and applicability. Therefore, all identified domains of context and implementation relevant for a particular intervention should be integrated into a thorough assessment of complex interventions. It also provides a tool for systematically documenting and presenting information on context and implementation in systematic reviews of effectiveness, as well as qualitative or mixed-method systematic reviews of complex interventions. Please note that the term intervention is more commonly referred to in the context of systematic reviews, whereas referring to health technologies is common practice with HTAs. Throughout this guidance we use the term intervention as synonymous for technology. This guidance comprises:

- ▶ definitions of context (including setting) and implementation;
- ▶ a comprehensive framework including the interacting dimensions of context and implementation and the domains within them; and
- ▶ a description of how the framework can be applied in HTAs and/or systematic reviews of complex interventions.

1.2 TARGET AUDIENCE FOR GUIDANCE

This guidance is intended for both producers of HTAs and systematic reviews of complex interventions, the organizations commissioning or using these outputs as well as HTA and systematic review methodologists.

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

This guidance is based on existing approaches to conceptualising and assessing context and implementation, in particular the widely cited Consolidated Framework for Implementation Research (CFIR) (Damschroder et al., 2009), but goes beyond these in four important ways:

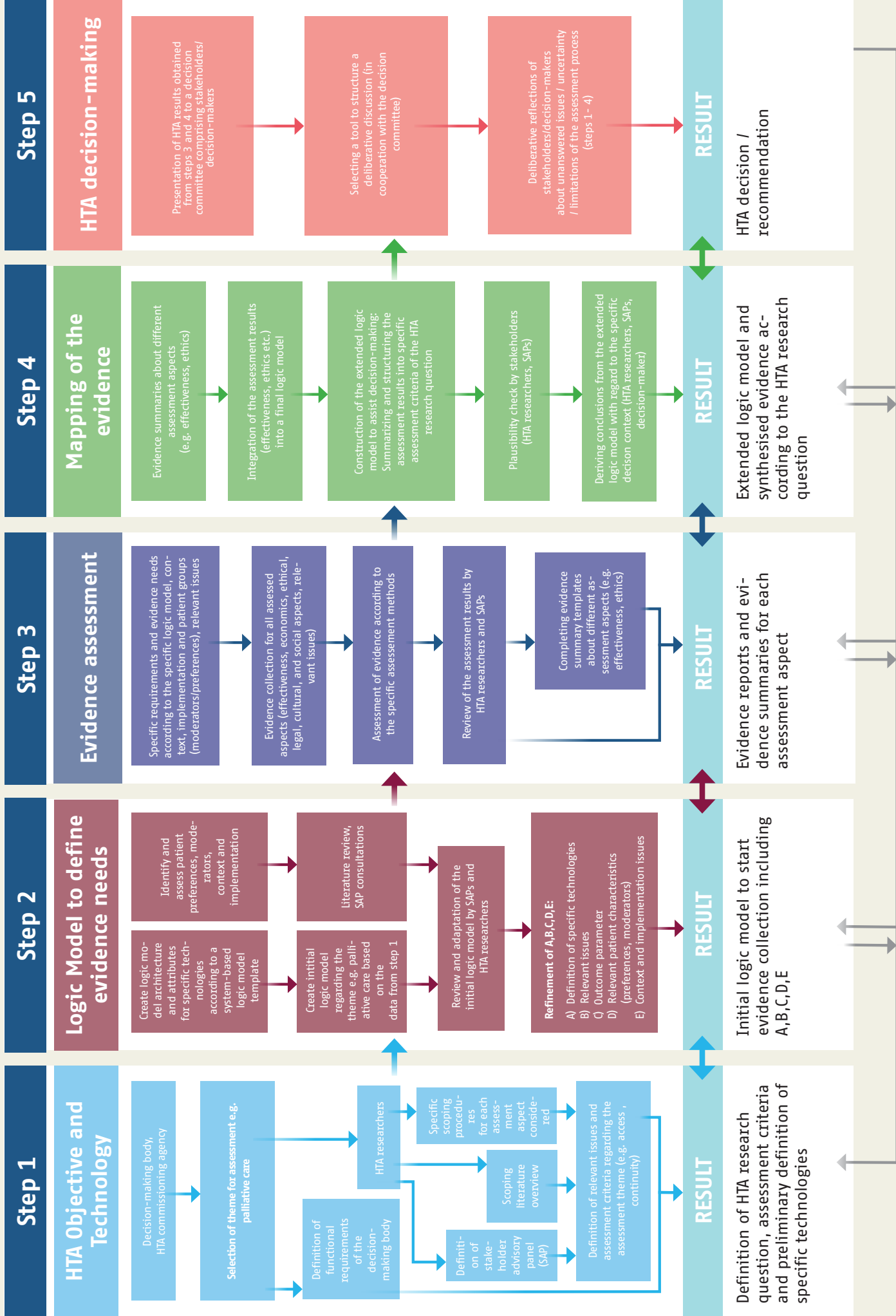
- ▶ Context and implementation are considered comprehensively, rooted in an understanding that domains in both dimensions overlap and interact with one another. In contrast, previous approaches have primarily focused either on context or on implementation.
- ▶ The framework, while developed with complex interventions in mind, is suitable across a broad spectrum from simple to complex interventions in healthcare as well as broader health areas. In contrast, previous approaches have tended to focus on interventions in a specific field, (e.g. clinical medicine - the Promoting Action On Research Implementation in Health Services (PARIHS) framework (Kitson et al., 1998)).
- ▶ An operationalization of the proposed framework forms an integral part of the guidance. In contrast, previous approaches often required users to figure out for themselves how to apply a framework in practice.

1.4 HOW THIS GUIDANCE RELATES TO AN INTEGRATED ASSESSMENT PROCESS

In order to achieve an integrated HTA, the application of the methodological guidances is structured into a systematic assessment process to strive for integration from the very beginning of the HTA. As shown in Figure 1, the INTEGRATE-HTA Model consists of five steps (Wahlster et al., 2016). After an initial definition of the HTA objective and the intervention 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 surrounding the intervention. Patient characteristics, context and implementation issues inform 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 created. Finally, the presentation of the results in step 5 forms the basis for a structured decision-making process.

Context, implementation as well as patient characteristics (Van Hoorin et al, 2016) act as factors that may modify HTA

Figure 1: The INTEGRATE-HTA Model.



results (Wahlster et al., 2016). As the shaded box in Figure 1 shows, the systematic identification and assessment of these factors facilitates not only the consideration but also the integration of these factors in the methodologies of traditional HTA aspects (Lysdahl et al., 2016).

The framework and the guidance on use of logic models in systematic reviews and HTAs of complex interventions (Rohwer, 2016) were developed in tandem. The CICI framework forms an integral component of the logic model. Informed by literature reviews, the CICI framework supports the integration of evidence extracted into a specific logic model regarding the intervention of interest. This logic model informs the evidence collection of ethical, legal, economic, socio-cultural as well as effectiveness aspects of the intervention.

Additionally, the CICI framework supports the integration of the findings obtained through the guidance for assessing effectiveness, economic, ethical, socio-cultural and legal aspects in complex technologies (Lysdahl et al., 2016) and provides an important input towards the extended logic model to assist decision-making on reinforced models of home-based palliative care. All evidence gathered within the HTA is processed and organised in this model (Wahlster et al., 2016).

2 BACKGROUND

2.1 DEFINITIONS

In a concept analysis of context and implementation, we elicited definitions of context, setting and implementation (Pfadenhauer et al., 2015). For a more thorough description, we refer to the section on “Process of guidance development”.

Context is conceptualized as a set of characteristics and circumstances that consist of active and unique factors that surround the implementation. As such it is not a backdrop for implementation but interacts, influences, modifies and facilitates or constrains the intervention and its implementation. Context is usually considered in relation to an intervention or object, with which it actively interacts. A boundary between the concepts of context and setting is discernible: setting refers to the physical, specific location in which the intervention is put into practice. Context is much more versatile, embracing not only the setting but also roles, interactions and relationships (Pfadenhauer et al., 2015).

Implementation can be considered a rather vague concept, with authors usually using the term without providing a distinct conceptualization. In our analysis, implementation emerged as an actively planned and deliberately initiated effort with the intention to bring a given object into policy and/ or practice. These efforts are undertaken

by agents, which either actively promote the use of the intervention or adopt the newly appraised practices. They are usually structured in an implementation process consisting of specific implementation strategies (Pfadenhauer et al., 2015).

2.2 PROBLEM DEFINITION

Policy makers and practitioners today are often challenged with understanding and consequently deciding on investment/ disinvestment in complex interventions. These usually comprise multiple components, which may act independently or interdependently, with the ‘active ingredient’ being difficult to specify (Bahtsevani et al., 2008). Complex interventions, merely due to their nature, are crucially dependent on the context within which they are implemented, and the boundaries between what constitutes the intervention, what constitutes its implementation and what constitutes context are often blurred (Funk et al., 1991; Wells et al., 2012). Ultimately, the effect results from the intervention itself, the way it is implemented and the context in which it takes place (Smith et al., 2011), and interactions between these may be effect-modifying (Rohrbach et al., 1993). Implementers are challenged by two conflicting demands: on the one hand, universal interventions are to be implemented with fidelity, on the other hand, these must be adapted to local needs and circumstances (Shortell et al., 2004). Within the process of adaptation for complex interventions, one thus needs to distinguish between core elements, which have to remain constant to guarantee the effectiveness of an intervention, and adaptable elements, which are required to make the intervention acceptable and feasible in a given setting and context (Damschroder et al., 2009).

2.3 CURRENT APPROACHES TO CONTEXT AND IMPLEMENTATION

2.3.1 Clarification of terminology:

Theory, models and frameworks

In recent years, the field of implementation research has been a breeding ground to a wide range of conceptual frameworks, models and theories that seek to explain implementation, its facilitators and barriers, the relationship between these factors as well as relevant mechanisms and outcomes. The terms theory, model and framework are often used interchangeably in implementation science (Kitson et al., 2008; Nilsen, 2015; Rycroft-Malone & Bucknall, 2011). To clarify:

A model is a “deliberate simplification of a phenomenon or a specific aspect of a phenomenon” (Nilsen, 2015). In the development and use of models, one makes precise assumptions about a limited set of parameters and variables (Green et al., 2002). By employing logic, experimentation, and a variety of simulations the consequences of assumptions can be systematically explored in a limited set of outcomes (Kitson et al., 2008). Models are heuristics, not raising the claim of being accurate representations of reality (Aarons, 2004; Melnyk et al., 2008). Applied to implementation, models aim to describe and/ or guide the process of translating research into policy and/or practice (Nilsen, 2015).

A theory provides a “denser and logically coherent set of relationships” (Kitson et al., 2008). Thus, it moves further than frameworks and models, describing a “set of analytical principles or statements designed to structure our observation, understanding and explanation of the world” (Dobbins et al., 2007). The quality of a theory is characterized by a clear explanation of how and why specific relationships lead to specific events (Green et al., 2002). A theory is supposed to have predictive capability (Kitson et al., 2008; Nilsen, 2015). In implementation sciences, theories specifically attempt to explain the causal mechanisms of implementation (Nilsen, 2015).

A conceptual framework identifies “a set of variables and the relationships among them that presumably account for a set of phenomena. The framework can provide anything from a modest set of variables to something as extensive as a paradigm” (Craig et al., 2008). As such, a framework can contain structures, overviews, outlines, systems or plans consisting of various descriptive categories (e.g. concepts, constructs or variables) (Nilsen, 2015; Peters et al., 2002). The construction of a conceptual framework is a way of simplifying complexity in order to generate understanding and knowledge. The heuristic nature of this approach is due to the realization that it is impossible to look for and see everything (Peters et al., 2002). Two presuppositions are important: first, frameworks tell the observer which critical factors to look for and which factors can be easily ignored. Second, categories according to which phenomena are to be grouped are developed (Corrigan et al., 1992; Costa et al., 1992; Kelley et al., 2010; Melnyk et al., 2008; Peters et al., 2002). A framework thus does not seek to provide explanations about relationships (Dobbins et al., 2007). In the field of implementation research, frameworks fulfil a descriptive purpose by pointing to factors believed or found to influence implementation (Nilsen, 2015).

2.3.2 *Current approaches to setting, context and implementation*

This inconsistency in terminology as well as conceptualization continues in relation to our three main concepts of interest: setting, context and implementation.

The use of the terms context and setting in the literature as well as the systematic review and HTA communities varies widely. The Cochrane Collaboration defines context as “the conditions and circumstances that are relevant to the application of an intervention, including time, type of practice and whether it is routine or emergency” (Lunn et al., 2011), a definition also adopted by the International Network of Agencies for Health Technology Assessment (INAHTA). Following the definition of the European network for Health Technology Assessment (EUnetHTA), context and setting refer to the place and time from which the evidence for the HTA report has come and/or in which the HTA report will be used. Setting in particular is commonly used in HTA to refer narrowly to an organisational dimension of health care, such as primary, secondary and tertiary care, or community care (European Network for Health Technology Assessment (EUnetHTA), 2007). In the broader health literature context is often used synonymously with setting and environment (Kitson et al., 1998; McCormack et al., 2002), embracing static (e.g. physical environment) and dynamic aspects (e.g. relationships, networks) as well as the theory underpinning the intervention and its implementation (Shortell et al., 2000).

The concept of implementation has received increasing attention over the past decades, with a whole field of research focusing on implementation (Cane et al., 2012). In the current literature, implementation is defined as the process, constellation of processes or means of assimilating or putting an intervention into use - either evidence-based or theory-based - in an organisation or a setting (Damschroder et al., 2009; Nash et al., 2006; Thompson et al., 2003). While we are not aware of any frameworks, models or theories for the systematic assessment of context - except for the consideration of context as the so-called “outer setting of implementation” (e.g. (Damschroder et al., 2009)) - various frameworks and models have been published to facilitate the assessment of determinants of implementation, its processes and mechanisms, and underlying theories. A recent non-systematic literature review of theories, models and frameworks of implementation distinguished between process models, determinant frameworks, classic and implementation theories as well as evaluation frameworks (Nilsen, 2015). While frameworks such as the Promoting Action on Research Implementation in Health Services (PARIHS) framework (Kitson et al., 1998), the Consolidated Framework For Implementation Research (CFIR) (Damschro-

der et al., 2009) or the Conceptual Model by Greenhalgh (Greenhalgh et al., 2004b) are considered determinant frameworks that aim at understanding and/or explaining influences on implementation outcomes (Nilsen, 2015), others are labelled evaluation frameworks, which describe aspects to be evaluated in order to determine implementation success. Examples are the Reach Effectiveness Adoption Implementation Maintenance (RE-AIM) framework (Edmondson et al., 2001) or the PRECEDE-PROCEED framework (Green & Kreuter, 2005). Another category are process models that aim to describe and/or guide the process of translating research into policy and/or practice (Nilsen, 2015). Examples of relevant models include the Stetler Model (Stetler, 2011), or the Quality Implementation Framework (Meyers et al., 2012). Apart from these models and frameworks, Nilsen describes classic and implementation theories. Classic theories embrace the Theory of Diffusion (Rogers, 2003) as well as the whole range of social cognitive theories, social network theories, organizational theories etc. In addition, various theories have been published regarding the behaviours accompanying and/or facilitating the implementation of evidence, on an individual as well as on a community level (Duckers et al., 2008; Fineout-Overholt & Melnyk, 2006; Goh et al., 2007; Good & Nelson, 1971; Helfrich et al., 2007b; Lubomski et al., 2008; Marsick & Watkins, 2003; Mathisen et al., 2004). Implementation theories aim to provide understanding and/or explanation of aspects of

implementation, as does the Implementation Climate Theory (Klein & Sorra, 1996) or the Absorptive Capacity Theory (Zahra & George, 2002).

2.4 COMPLEXITY

2.4.1 Definitions

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.

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

Table 1: Synthesis of potentially relevant characteristics of complexity in HTA.

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.

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 an intervention and/or the complexity of its environment into account. For example, when assessing an intervention such as an educational program to prevent the transmission of the human immunodeficiency virus (HIV) the success or failure might depend on the message itself (e.g. abstinence 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. Table 1 lists potentially relevant characteristics of complexity.

Consequently, when starting an assessment of (any) intervention 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
4. exposing important factors that decision makers need to consider in interpreting the HTA.

2.4.2 Approach to complexity

Context and implementation are among the most prominent issues leading to complexity. This guidance provides an overarching framework for considering relevant domains of context and implementation that may result in or add to complexity. Moreover, it offers an approach for assessing these through quantitative documentation or qualitative means of enquiry, and for carefully examining the findings in an integrated manner (Lysdahl et al., 2016; Rohwer et al., 2016; Wahlster et al. 2016). The guidance therefore furthers our understanding of complexity in systematic reviews and HTAs.

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

The assessment of complex interventions formed one criterion in our assessment of the application of the framework. Therefore, this aspect is discussed in detail in the section "Strengths and limitations of the CICI framework as a tool".

3 GUIDANCE DEVELOPMENT

The Context and Implementation of Complex Intervention (CICI) framework was developed following a seven steps process as described in Table 2. The complete development process is described in detail in the appendix (please view section "Guidance Development Process" in the Appendix).

Based on a scoping exercise, an initial framework was developed. In rapid assessments of its applicability, we became aware of inconsistencies in the use of both the terms context and implementation. Thus, we decided to analyze both concepts by employing pragmatic utility (PU) concept analysis (Morse, 2000) which was based on a systematic literature search for original publications describing models, theories and frameworks of context and/or implementation. Based on this concept analysis and its results, the initial framework was applied in three quantitative and one qualitative systematic review both within and outside of INTEGRATE-HTA. These reviews were chosen because of the different degrees of complexity of interventions of interest as well as the variety of methodologies employed. In order to test the applicability of the CICI framework throughout the stages of application, the following assessment criteria were used to guide the exercise (see Table 3).

After the application was completed, the framework was revised by integrating both findings from the application in the HTA and systematic reviews as well as the findings from other guidances (Lysdahl et al., 2016). All revisions are reflected in the shading in the tables describing both context and implementation domains as well as respective subdomains (view Table 5- Table 7; revisions based on application → green, revisions based on concept analysis → blue)

Table 2: Guidance Development Process of Context and Implementation of Complex Interventions framework (CICI framework).

Step	Description
1 Scoping review	Review of existing models, theories and frameworks and guidance on how to assess context, setting and implementation issues
2 Development of initial framework	Development of initial framework and draft guidance drawing on existing frameworks and rapid assessments of applicability
3 Systematic literature searches	Searches for models, theories and frameworks in EMBASE, MEDLINE (for context and setting) and Google Scholar (for implementation) and selection of relevant publications
4 Pragmatic utility concept analysis:	Pragmatic utility concept analysis of the concepts setting, context and implementation and clarification of concepts and definitions (Morse, 2000)
5 First revision of initial framework	Revision of initial framework based on clarified concepts and definitions
6 Applications of revised initial framework	Application of revised framework to several quantitative systematic reviews within and external to the case study, one qualitative systematic review conducted in course of the demonstration HTA as well as in a pilot study of a consultation guide assessing the applicability of HTA findings to three specific contexts (i.e. United Kingdom, Germany, Poland)
7 Final revision of framework	Integration of findings from other guidances developed within the INTEGRATE-HTA project and formal applications of revised framework to derive the final framework

Table 3: Criteria for the assessment of the applicability of the CICI framework.

Internal coherence and completeness of framework	
• Coherence of framework	Is the framework internally coherent? Are the definitions clear? Is the framework internally consistent?
• Completeness of framework	Is the framework comprehensive?
• Theory advancement/development	To what extent does the framework facilitate the advancement or development of theories?
• Compatibility of framework	To what extent is the framework compatible with other theories/frameworks/models?
• Relationships	To what extent does the framework allow the assessment and appraisal of relationships between components of the framework?
Applicability of framework	
• Adaptation and applicability of framework	To what extent can the framework be applied to different technologies/interventions? To what extent can the framework be adapted to respective technologies/interventions?
• Flexibility of framework	To what extent can the framework be applied in systematic reviews and HTA employing different methods (e.g. qualitative, quantitative, mixed-method)?
• Capability of framework	To what extent does the framework allow to capture complexity?
User-friendliness/Ease of application	
• Feasibility of application of framework	Can the framework easily be applied?

4 APPLICATION OF THE GUIDANCE: ASSESSING CONTEXT AND IMPLEMENTATION

4.1 THE CONTEXT AND IMPLEMENTATION OF COMPLEX INTERVENTIONS (CICI) FRAMEWORK

The CICI framework (see Figure 2) consists of two dimensions – context and implementation – that comprise eight (i.e. socio-cultural, ethical, socio-economic, legal, political, geographical, epidemiological context and the setting) and four domains (i.e. policy, funding, organisation & structure and the provider) respectively. These twelve domains each contain several subdomains.

While implementation may take place within any single or multiple layers of context, and contextual factors affect different aspects of implementation, their somewhat artificial structural separation in the framework is intended to simplify the documentation and interpretation process in HTAs and systematic reviews and/or HTAs.

Table 5 to Table 7 provide the definitions of all domains of context and implementation as well as respective subdomains.

4.1.1 Intervention

4.1.1.1 Description of intervention

Context and implementation become relevant when a specific object is considered. Such objects can be labeled as technology (Avgar et al., 2012; Hage et al., 2013), intervention (Damschroder et al., 2009; Glanz & Bishop, 2010; Rycroft-Malone et al., 2013; Talsma et al., 2014; Tomoaia-Cotisel et al., 2013), innovation (Chaudoir et al., 2013; Emmons et al., 2012; Meyers et al., 2012; Simpson, 2011), evidence-based practice (Aarons et al., 2014; Aarons et al., 2012; Aarons et al., 2011; Beidas et al., 2013; Damschroder & Hagedorn, 2011; Helfrich et al., 2009; Packard, 2013; Palmer & Kramlich, 2011; Proctor et al., 2013; Stetler et al., 2011;

Taxman & Belenko, 2012; VanDeusen Lukas et al., 2010) or quality improvement (Flottorp et al., 2013; Kaplan et al., 2010). We generally refer to these kinds of changes as “intervention”. When conducting a systematic review and/or HTA it is important to describe the intervention in detail (Van Herck et al., 2010). Based on the guidance on use of logic models in systematic reviews and HTAs of complex interventions, the intervention comprises theory, design and intervention delivery (Rohwer et al., 2016).

4.1.1.2 Intervention Design

The design of the intervention in terms of its components (e.g. technology, education) and execution (e.g. dose, duration, timing) lies at the heart of this framework; how these should be documented appropriately is described in detail elsewhere (Rohwer et al., 2016)

4.1.1.3 Intervention Theory

The theory underpinning the design and planning of an intervention is also critical (Cambon et al., 2012). These theories making causal assumptions can be derived from social theory as well as past experience and common sense (Moore et al., 2015). For the purpose of this guidance, the term intervention theory is used in a broad way to describe a body of implicit or explicit ideas on how an intervention works (Wells et al., 2012).

The intervention, informed by theory, lies at the heart of the CICI framework. Its reach and effectiveness are determined by the two distinct but interacting dimensions of context and implementation. The former comprises eight domains; the latter comprises four domains. Both the intervention and the implementation effort are underpinned by respective theories. Both the provider as domain of implementation and setting as domain of context are embedded in the organization and structure domain of implementation in which they interact.

4.1.2 Context

4.1.2.1 Description of the context dimension

Context is conceptualized as a set of characteristics and circumstances that consist of active and unique factors that surround the implementation. As such it is not a backdrop for implementation but interacts, influences, modifies and facilitates or constrains the intervention and its implementation. Context is

usually considered in relation to an intervention or object, with which it actively interacts. A boundary between the concepts of context and setting is discernible: setting refers to the physical, specific location in which the intervention is put into practice. Context is much more versatile, embracing not only the setting but also roles, interactions and relationships. (Pfadenhauer et al., 2015)

4.1.2.2 Domains of context

The CICI framework comprises eight domains of context, i.e. setting, geographical, epidemiological, socio-economic, socio-cultural, political, legal and ethical.

The **setting** encompasses the immediate physical and organizational environment, in which an interventi-

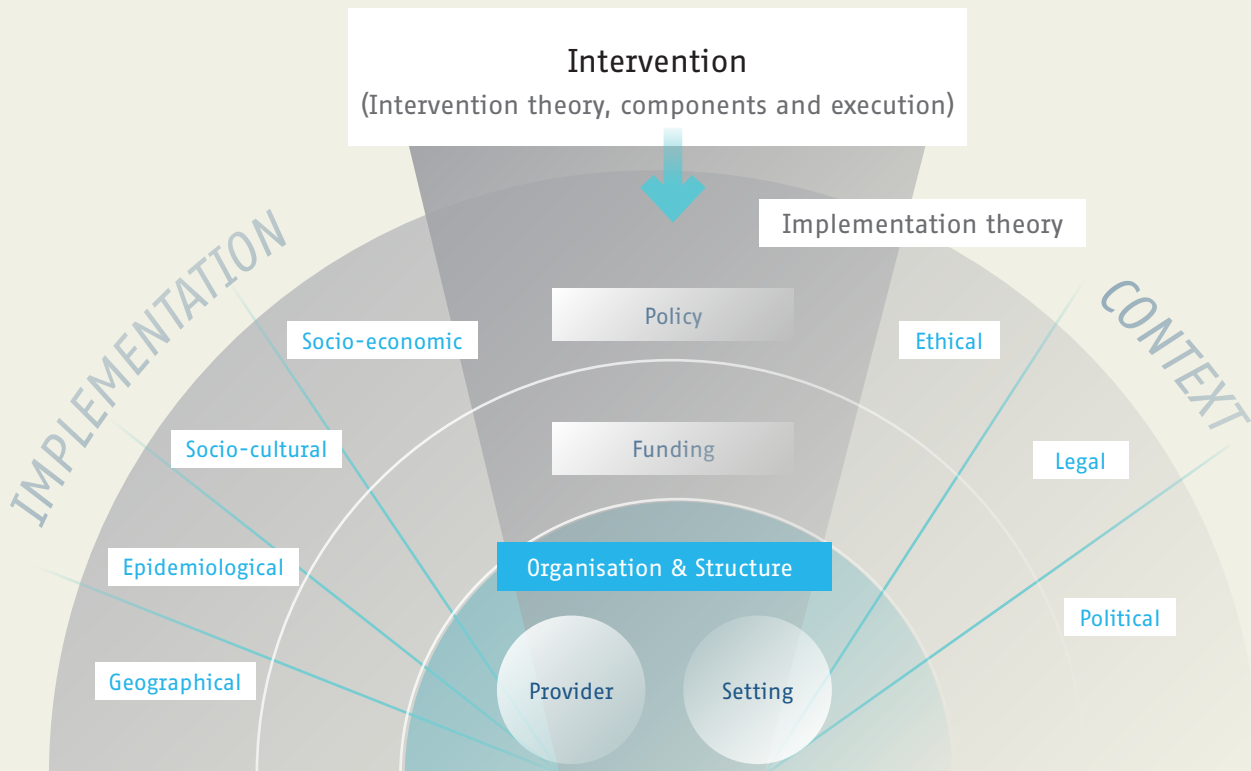
on is delivered (e.g. primary care setting) and where recipients and providers interact in an organizational structure. It also comprises the effect the location has on the affected stakeholders, i.e. by taking in a specific role. For example, many relatives of palliative care patients take on the role of a lay caregiver as soon as they enter their home which is at the same time the setting of HBPC delivery.

The **geographical** characteristics refer to the broader physical environment, landscapes and resources, both natural and transformed by humans, available at a given location. As such they also comprise the infrastructure at a given location. The supply with reinforced HBPC, for example, might be hindered by geographical isolation of potential recipients of palliative care.

The **epidemiological** domain refers to the distribution of diseases/conditions, the attributable burden

Figure 2: The Context and Implementation of Complex Interventions (CICI) framework.

The intervention, informed by theory, lies at the heart of the CICI framework. Its reach and effectiveness are determined by the two distinct but interacting dimensions of context and implementation. The former comprises eight domains; the latter comprises four domains. Both the intervention and the implementation effort are underpinned by respective theories. Both the provider as domain of implementation and setting as domain of context are embedded in the organization and structure domain of implementation in which they interact.



of disease as well as determinants of needs in populations (Rychetnik et al., 2002). Therefore, it also includes demographics (Castro et al., 2004; Hage et al., 2013). Psychosocial and physical needs of lay caregivers of palliative care patients as well as needs of palliative care patients themselves would fall into this category.

The **socio-economic** domain comprises the social and economic resources of a community and the access of a population to these resources (Damschroder et al., 2009; Victora et al., 2005). This could, for example, comprise the loss in income in lay caregivers as they enter the caregiver role.

The **socio-cultural** domain comprises explicit and implicit behaviour patterns, including their embodiment in symbols and artefacts; the essential core of culture consists of historically derived and selected ideas and values that are shared among members of a group (Sabatier, 2007). It not only refers to the conditions in which people are born, grow, live, work and age but also embraces the social roles a human being takes on as a family member, community member or citizen and the relationships inherent to these roles. Constructs such as knowledge, beliefs, conceptions, customs, institutions and any other capabilities and habits acquired by a group are included in this domain (Mozygemba, 2016). An example could be families and communities that fulfil specific roles according to the values and norms predominating in their specific setting.

The **political** domain focuses on the distribution of power, assets and interests within a population, as well as the range of organisations involved, their interests and the formal and informal rules that govern interactions between them (Nash et al., 2006). The domain also comprises the health care system and the securing of its accessibility (e.g. delivery of services, leadership and governance, health information, human resources and financing). The political context can, for example, fail to guarantee reliable access to HBPC, thus compromising equality.

The **legal** domain is concerned with the rules and regulations that have been established to protect a population's rights and societal interests (European Network for Health Technology Assessment (EUnetHTA), 2011). Legal rules in the material sense are sovereign norms that address an unspecified number of natural and legal persons by regulating an unspecified number of cases in an abstract way. Formally, these norms have to be based on specific norm-set-

ting rules. For example they have to be passed by a competent legislative body like a parliament. Legal norms can mostly be enforced with order and compulsion, which distinguishes them from ethical and social norms (Brönneke, 2016). A legal issue arising in HBPC is, for example, the sharing of information with relatives who wish to be informed about the medical condition of the palliative care patient. This might, however, contradict the legal framework in which care is delivered.

The **ethical** domain comprises reflections of morality, which encompasses beliefs, standards of conduct and principles that guide the behaviour of individuals and institutions (European Network for Health Technology Assessment (EUnetHTA), 2011). Ethics or moral philosophy is the part of philosophy that deals with questions about moral values and norms. The ethical domain in HTA is concerned with moral norms and values of relevance to the intervention in question, including prevailing norms and values at stake or in conflict, as well as those constructed by putting the intervention into use (European Network for Health Technology Assessment (EUnetHTA), 2014). In addition ethical aspects address moral questions related to performing the HTA itself (European Network for Health Technology Assessment (EUnetHTA), 2014)). Ethical and socio-cultural aspects of HTA are strongly interrelated (also with legal aspects, and together labelled ELSI (Ethical, Legal and Social, Issues)) (Lehoux & Williams-Jones, 2007; Potter et al., 2008; Statens Beredning för Medicinsk Utvärdering (SBU), 2014).

4.1.3 Implementation

4.1.3.1 Description of the implementation dimension

As described above, implementation can be considered a rather vague concept, with authors usually using the term without providing a distinct conceptualization. In our analysis, implementation emerged as an actively planned and deliberately initiated effort with the intention to bring a given object into policy and/or practice. These efforts are undertaken by agents, which either actively promote the use of the intervention or adopt the newly appraised practices. They are usually structured in an implementation process consisting of specific implementation strategies (Pfadenhauer et al., 2015).

As described above, implementation is dynamic or active, planned, deliberately initiated (May, 2013), complex (Kitson et al., 2013), multi-faceted (Kitson et al., 2013), orchestrated (Rycroft-Malone et al., 2013), iterative and driven by and embedded in organizational strategy (Rycroft-Malone et al., 2013).

Implementation can occur at various levels, such as at macro-level (e.g. large-scale policy implementation across a health system), at meso-level (e.g. organisations or cluster of organisations that form a sub-set of a large-scale implementation program) and at micro-level (e.g. workplace, team, family or other small group). An intervention can also target the individual (Chaudoir et al., 2013). Most of the times, implementation occurs across multiple levels (May, 2013).

4.1.3.2 *Domains of implementation*

The CICI framework comprises four domains of implementation, i.e. policy, funding, organisation and structure as well as provider. The first two domains - policy and funding - have a more programmatic character while the latter - organisation and structure as well as provider - refer to the actual delivery of the intervention. Importantly, while programming issues are usually not considered in the design or delivery of a clinical intervention in clinical effectiveness studies as well as in the reporting thereof, many of these issues may be part and parcel of the design and delivery of public health and health system interventions (Fishbein & Yzer, 2003). For example, a specific policy might be put into place that performs as trigger of implementation, and subsequently supported through the allocation of sufficient funding.

Policy comprises policy measures and processes of government, public, private or other organisations directly concerning or indirectly influencing the implementation of an intervention. It thus relates to the broader political context mentioned above, which provides a framework for issuing policy measures that critically influence how, when and why an intervention is implemented. This is, for example, the case when a policy explicitly enforcing the rights of a lay caregiver in HBPC is put into place. Such a policy could trigger the integration of psychosocial intervention components, transforming HBPC models to reinforced HBPC models.

Funding relates to short-term or longer-term funding mechanisms by governmental, non-governmental,

private sector and philanthropic organisations used to implement an intervention (Mendel et al., 2008). Funding mechanisms may include subsidies, tax incentives, reimbursement schemes or grants made directly or indirectly available to the organisation delivering an intervention, or could be concerned with how such funding is distributed through budget lines within the organisation.

Provider refers to the individuals that actually deliver the intervention. Individuals form the basis of every organisation and organisational change is initiated by individual change (Damschroder et al., 2009). A wide range of models, frameworks and theories of behaviour and behaviour change are applied in the implementation sciences (Nilsen, 2015). Our framework contains influences from several models, frameworks and theories, among them the Theory of Planned Behaviour (Ajzen, 1991), the Transtheoretical Model of Health Behaviour Change (Prochaska & Velicer, 1997), and the Theoretical Domains Framework (Lehoux & Williams-Jones, 2007). Drawing largely on the theoretical domains framework (Lehoux & Williams-Jones, 2007), the provider domain comprises the subdomains (1) general attributes and characteristics, (2) knowledge, (3) skills, (4) social/professional role and identity, (5) beliefs about capabilities and self-efficacy, (6) beliefs about consequences, (7) motivation, intention and goals, (8) memory, attention and decision processes, (9) social influences and norms, (10) emotions, (11) individual behavioural regulation, (12) nature of the behaviour as well as (13) attitude towards intervention.

Providers are exposed to influences from the organisation and structure they are embedded in as well as to influences from the overall context (Lehoux & Williams-Jones, 2007). This domain consists of several subdomains.

As proposed by Emmons et al. (2012) implementation efforts require an organizational perspective, moving beyond the individual as unit of analysis. Structure and size encompass the social architecture, age, maturity, and size of an organization. Social architecture describes how large numbers of people are clustered into smaller groups and differentiated and how the independent actions of these differentiated groups are coordinated to produce a holistic product or service (Aarons et al., 2014; Damschroder et al., 2009; Rabin et al., 2008; Tomoiaia-Cotisel et al., 2013). It also comprises the organizational structures (e.g. formalization (Greenhalgh et al., 2004b), centralization (Greenhalgh et al., 2004b),

boundaries (McCormack et al., 2009)) as well as staffing (e.g. demographics, selection, stability of workforce) (Aarons et al., 2014; Aarons et al., 2011; Fixsen et al., 2009; Tomoaia-Cotisel et al., 2013). The formal and informal networks and ways of communication and information-sharing through which an organisation operates can contribute to the successful implementation of an intervention. Indeed, the relationships between individuals within social networks may play a greater role in influencing the diffusion of an intervention than their personal attributes (Aunger & Curtis, 2007; Fishbein & Ajzen, 1975; Rogers, 1995). Also, external networks influence implementation, with the degree to which an organization is networked with other external organizations being referred to as cosmopolitanism (Damschroder et al., 2009). Organisational policies, guidelines and practices are employed by organizations to put the innovation into place and to support innovation use; means by which an organization assimilates an innovation in order to achieve an acceptable level of operational, cultural and strategic fit. The assimilation process entails a mutual adaptation of the innovation and the organization. Organisational culture (Bergstrom et al., 2012, Helfrich et al., 2009, Aarons et al., 2014, Fineout-Overholt and Melnyk, 2006, Glisson et al., 2008, Shortell et al., 2000, Lehman et al., 2002, Packard, 2013, Damschroder et al., 2009) comprises the fundamental values, assumptions, and beliefs held in common by members of an organisation (Martin, 2002, Bate, 1994), and this critically influences the adoption of innovation within an organisation (Gershon et al., 2004, Damschroder et al., 2009, Helfrich et al., 2007, Ostroff et al., 2003). Employees impart the organisational culture to new members, and culture influences how employees relate to one another and their work environment. Several diverse (and possibly conflicting) cultures can operate within an organisation (Drennan, 1992, Kennedy, 2001, van Eijnatten and Galen, 2002). Varying between units or even teams is the organizational climate (Cane et al., 2012), a phenomenon that is typically less stable over time compared to culture (Damschroder et al., 2009).

Team dynamics (Cane et al., 2012, Bergstrom et al., 2012, Emmons et al., 2012, Duckers et al., 2008, McCormack et al., 2009) refer to the collaboration, coordination and roles provider take in when working in a team. This is also influenced by leadership, supervision and guidance experienced by

all team members. Training and knowledge transfer is of further influence. Two less tangible concepts referring to inherent characteristics of the respective organisation have predictive value both for the success of the implementation as well as the succeeding effectiveness of the intervention: implementation climate and system readiness for change. Implementation climate (Damschroder et al., 2009) is a construct referring to the absorptive capacity for change, shared receptivity of involved individuals to an intervention (Greenhalgh et al., 2004b), and the extent to which use of that intervention will be 'rewarded, supported, and expected within their organization' (Klein & Sorra, 1996; Weiner et al., 2009). Capacity for organisational change refers to organizations that are systematically able to identify, capture, interpret, share, reframe, and recodify new knowledge (Greenhalgh et al., 2004b). Organisations with this ability do not change just once, but consider change as a normal course of events in response to and in anticipation of internal and external shifts, constantly adapting to and anticipating changes in its environment (Emmons et al., 2012; Flottorp et al., 2013; Greenhalgh et al., 2004b; Packard, 2013). Implementation climate further comprises relative priority of the implementation within an organization and its members, incentives and rewards, goals and feedbacks as well as a learning climate supporting the implementation of an intervention. System readiness for change refers to the tangible and immediate indicators of organizational commitment to its decision to implement an intervention (Damschroder et al., 2009). This construct embraces leadership engagement, available resources as well as access to knowledge and information. Organisations are also subject to peer pressure, a mimetic or competitive pressure to implement an intervention, typically because most or other key peer or competing organizations have already implemented or are in pursuit of a competitive edge (Damschroder et al., 2009). Pressure can also be exerted by change agents or champions of change (Damschroder et al., 2009; Greenhalgh et al., 2004b), such as consultants.

4.1.3.3 *Implementation theory*

The implementation effort is based on theories of how change needs to be executed (Hage et al., 2013; Metz & Bartley, 2012; Proctor et al., 2013). The "how" is – or should be – based on implementation

theory. As previously mentioned, implementation theories specifically attempt to explain the causal mechanisms of implementation (Nilsen, 2015). The implementation sciences include different types of theories, such as motivational theories, action and organisational theories (Lehoux & Williams-Jones, 2007; MacMahon & Pugh, 1970). Motivational theories aim to explain behaviour change in people who have not yet established an intention to engage in a particular behaviour while action theories explain the behaviour of those who are motivated to change (Lehoux & Williams-Jones, 2007; MacMahon & Pugh, 1970). Organisational theories approach a higher order of social and systems level where change takes place (Lehoux & Williams-Jones, 2007; MacMahon & Pugh, 1970).

4.2 APPLICATION OF THE CICI FRAMEWORK

The CICI framework can be applied in HTAs, quantitative systematic reviews, qualitative or mixed-method systematic reviews. It can be operationalised through the set of simple questions compiled in the checklist in Table 4. Each domain is assessed by three questions, with one aiming at the documentation of the domain (Which characteristics influence ...?), the other aiming at a more in-depth understanding of the domain's influence on the intervention, its implementation and outcomes (How do characteristics influence ...?) and the third aiming at identifying interactions with other domains of context or implementation (How do characteristics interact...?).

In an HTA, the CICI framework can be applied in multiple ways. As described in the Guidance "Integrated assessment of complex health technologies – The INTEGRATE-HTA model" (Wahlster et al., 2016), the CICI framework is used in the second step in which evidence needs are identified. In this step, not only patient preferences and moderators of treatments are identified and assessed (Van Hoorn et al., 2016b; Van Hoorn et al., 2016a), but also context and implementation of relevance for the technology of interest. These act as modifying factors which should be considered in the actual assessment of socio-cultural, ethical, economic, legal and effectiveness aspects (Lysdahl et al., 2016); the framework may also serve to provide detailed insights with respect to one or a few selected domains

requiring more thorough assessment. An intervention may, for example, if context and implementation only are of interest be critically influenced by geographical factors (e.g. climate and altitude.) necessitating a more in-depth understanding of the impact of these factors.

Furthermore, data extraction forms based on the CICI framework may be used as part of effectiveness reviews, while qualitative data extractions may be employed as part of a separately conducted qualitative or mixed-method review.

A data extraction form based on the CICI framework was developed for facilitating data extraction of primary studies for three effectiveness reviews. While the data extraction form provided the same questions as adduced in Table 4, the details reported in primary studies mainly allowed answering the "which..." questions.

A data extraction form based on the CICI framework was developed for facilitating data extraction of qualitative primary studies (view Data Extraction Form for Qualitative Systematic Reviews) in the context of conducting a qualitative systematic review using best-fit framework synthesis based on the CICI framework. This form also contains the respective subdomains (view Table 5 - Table 7) in order to compensate for the high granularity of the framework. Thus, it contains three questions for each of the domains, and an additional three questions for each of the subdomains. This data extraction form also allows for the identification of additional domains, when the data do not fit the framework as it stands.

5 CONCLUSIONS

5.1 MAIN INSIGHTS FOR THE ASSESSMENT OF COMPLEX TECHNOLOGIES

In our concept analysis and with the development of the CICI framework we provided definitions for context and implementation as well as a conceptual framework facilitating the systematic assessment of both dimensions in systematic reviews and HTAs.

Our framework is applicable to systematic reviews of effectiveness, qualitative or mixed-method syste-

Table 4: Context and Implementation of Complex Interventions (CICI) Checklist.

Implementation Strategy	
● Implementation theory	What were the theoretical underpinnings of the implementation efforts?
Context	
● Setting	<ul style="list-style-type: none"> ▶ Which characteristics of setting influence the intervention, its implementation, its population reach and its effectiveness? ▶ How does the setting exert its influence on the intervention, its implementation and their outcomes? ▶ How does the setting interact with other domains of context?
● Geographical	<ul style="list-style-type: none"> ▶ Which geographical characteristics influence the intervention, its implementation, its population reach and its effectiveness? ▶ How do geographical characteristics exert its influence on the intervention, its implementation and their outcomes? ▶ How do geographical characteristics interact with other domains of context?
● Epidemiological	<ul style="list-style-type: none"> ▶ Which epidemiological characteristics of the community influence the intervention, its implementation, its population reach and its effectiveness? ▶ How do epidemiological characteristics exert its influence on the intervention, its implementation and their outcomes? ▶ How do epidemiological characteristics interact with other domains of context?
● Socio-economic	<ul style="list-style-type: none"> ▶ Which socio-economic characteristics of the community influence the intervention, its implementation, its population reach and its effectiveness? ▶ How do socio-economic characteristics exert their influence on the intervention, its implementation and their outcomes? ▶ How do socio-economic characteristics interact with other domains of context?
● Socio-cultural	<ul style="list-style-type: none"> ▶ Which socio-cultural characteristics of the community influence the intervention, its implementation, its population reach and its effectiveness? ▶ How do socio-cultural characteristics exert their influence on the intervention, its implementation and their outcomes? ▶ How do socio-cultural characteristics interact with other domains of context?
● Political	<ul style="list-style-type: none"> ▶ What aspects of the political environment influence the intervention, its implementation, its population reach and its effectiveness? ▶ How do political aspects exert their influence on the intervention, its implementation and their outcomes? ▶ How do political characteristics interact with other domains of context?
● Legal	<ul style="list-style-type: none"> ▶ What aspects of the legal environment influence the intervention, its implementation, its population reach and its effectiveness? ▶ How do legal aspects exert their influence on implementation the intervention, its implementation and their outcomes? ▶ How do legal characteristics interact with other domains of context?
● Ethical	<ul style="list-style-type: none"> ▶ What aspects of the ethical environment have influenced the intervention and its effectiveness? ▶ How do ethical aspects exert their influence on the intervention, its implementation and their outcomes? ▶ How do ethical characteristics interact with other domains of context?

Implementation

- **Provider**
 - What mechanisms and processes in the providers are applied in the implementation of the intervention?
 - How do these mechanisms and processes enable or limit implementation?
 - How do provider characteristics interact with other domains of implementation or context?
- **Organisation and structure**
 - What mechanisms and processes of organisation and structure are applied in the implementation of the intervention?
 - How do these mechanisms and processes enable or limit implementation?
 - How do organisation and structure interact with other domains of implementation or context?
- **Funding**
 - Which funding measures and mechanisms are applied in the implementation of the intervention?
 - How do these mechanisms and processes enable or limit implementation?
 - How does funding interact with other domains of implementation or context?
- **Policy**
 - Which policy measures and mechanisms are applied in the implementation of the intervention?
 - How do these mechanisms and processes enable or limit implementation?
 - How does policy interact with other domains of implementation or context?

matic reviews and HTAs. In systematic reviews of effectiveness, it supports the documentation in terms of data extraction, examination of heterogeneity and subgroup analysis. In qualitative or mixed-method systematic reviews, it serves as a starting point for identifying and formulating specific research questions that further the understanding of how context and/or implementation influence the intervention. Overall, the framework helps to present context and implementation issues in an integrated fashion and aids with assessments of applicability and generalizability of HTAs and systematic reviews.

The framework is intended to apply to all complex as well as simple health interventions. Given its broad applicability, the framework should not be considered a straitjacket. Indeed, flexibility and adaptation in its application to a specific intervention is both sensible and permissible and could broadly be undertaken in two major ways.

First, a given systematic review or HTA may be primarily concerned with processes of implementation or with contextual characteristics, and may there-

fore decide to conduct an in-depth assessment of only one of the two dimensions of the framework. In doing so, those conducting systematic reviews or HTAs must, however, be aware that implementation and context are not easily separated from one another and interact across domains and dimensions; thus dissecting context from implementation or vice versa runs the risk of losing important interactions. The assessment of, for example, political context as well as the specific policy measure undertaken with the intention of bringing an intervention into practice helps the user identify contextual preconditions and specific implementation measures.

Secondly, not all domains of context and implementation may apply to a given intervention. For example, for the implementation dimension policy and funding levels may be more usefully considered as part of the intervention in the assessment of high-level policy interventions. Therefore, a given systematic review or HTA may exclude a number of domains but should pay attention that the richness of context and implementation issues is not unduly simplified.

5.2 STRENGTHS AND LIMITATIONS OF CURRENT METHOD(S)

5.2.1 Strengths and limitations of the approach to the development of the CICI framework

One major strength of the way this guidance was developed lies in the combination of systematic searches to identify existing frameworks of context and implementation and formal methods to derive definitions of the relevant concepts and to advance these concepts.

We systematically searched the literature for published frameworks/models/theories of context; however, these searches were performed in only two databases. These databases do not specifically consider literature from management and organizational studies. However, many definitions and conceptualizations collected during screening are derived from organizational and management studies. Moreover, as previous studies accessed relevant parts of the organizational and management body of literature, this limitation is likely to be of minor significance.

For reasons of feasibility, implementation frameworks were not identified by employing standard systematic searches but by following an innovative approach to searching based on identifying and screening all articles that cite one of the frameworks used to develop the CFIR. As the CFIR pursued an intention very similar to our objective (theories facilitating translation of research findings into practice, primarily within the healthcare sector) and points to similar application (can be used to guide formative evaluations and build the implementation knowledge base across multiple studies and settings), this approach appeared highly suitable.

In terms of concept analysis, the method developed by Morse and colleagues also has its limitations. In a recent review of concept analysis methods, the limited applicability of pragmatic utility (PU) to partially mature concepts for which an adequate sample of literature exists has been criticised (Weaver & Mitcham, 2008). Two other researchers referred to pragmatic utility as a method of concept advancement however, from studies having used PU (Hupcey & Penrod, 2005; Penrod & Hupcey, 2005), it

becomes clear that the method allows both analysis and advancement (Weaver & Mitcham, 2008). Moreover, there is no comprehensive manual to guide the approach (Weaver & Mitcham, 2008). However, a clear strength of PU is that it does not promote to adhere to steps or a linear format which may limit cognitive effort and freedom needed to follow emerging nuances (Morse, 2000). PU informs about the use and relevance of a concept to science and extends knowledge beyond the boundaries of what is currently known in an individual discipline (Weaver & Mitcham, 2008). Moreover, PU has been positively appraised as guiding further research (Weaver & Mitcham, 2008).

A second major strength of this guidance lies in the testing of the initial framework across multiple distinct complex interventions within and outside of INTEGRATE-HTA. The framework was applied in four systematic reviews of complex health interventions, assuring the applicability of the framework to a variety of interventions reaching from medical to environmental interventions affecting diverse populations and differing in terms of their underlying sources of complexity. In addition, we tested the applicability of the framework using a variety of methodological approaches (qualitative and quantitative systematic reviews as well as an HTA). Based on these applications, the framework was evaluated and adapted.

5.2.2 Strengths and limitations of the CICI framework as a tool

Strengths and limitations of the framework will be discussed according to the criteria presented in "Fehler! Verweisquelle konnte nicht gefunden werden." on page Fehler! Textmarke nicht definiert.

5.2.2.1 Coherence of CICI framework

Frameworks should provide a meta-theoretical language that can be used to compare theories (Ostrom et al., 2014). With our framework being based on a comprehensive literature search and concept analysis, we have attempted to advance the field of implementation sciences in terms of conceptual and terminological clarity. The definitions of the framework were appraised as internally consistent in their generic version. Thus, the coherence of the framework was given and also supported by our finding that no new do-

main was created in the case study application of the framework.

In the qualitative systematic review, data extractors experienced blurring borders between specific domains. For example, it was sometimes considered difficult to differentiate between data extracts being attributable to the organization and structure or to the provider. Another difficulty encountered was identifying ethical aspects from the primary studies. Therefore, a more consistent definition for ethical context was required and subsequently developed.

In the quantitative reviews, the framework was appraised as consistent. Difficulties of attributing specific text extracts to the respective domain were simplified due to the limited availability of relevant information. Therefore, the consistency of the framework was less likely to be compromised.

As found in all applications, subdomains could potentially be allocated to more than one domain (e.g. access to healthcare). Similar challenges were previously encountered in other frameworks, such as the Theoretical Domains framework (Klein & Sorra, 2008). This further emphasises the relevance of constructs across different domains and dimensions, as well as the interactions between them (Cane et al., 2012).

5.2.2.2 *Completeness of CICI framework*

Frameworks aim to identify the universal elements that any theory relevant to the same kind of phenomena would need to include. The application of the CICI framework has shown that the initial framework was relatively comprehensive in comprising relevant enablers and barriers to the implementation of complex interventions. However, some subdomains were missing or not displayed in a way in which it was applicable to the interventions that were assessed in the case study or in the external application. For example, the needs of people indirectly affected by a condition (i.e. lay caregivers of palliative care patients) were missing in the initial framework. Moreover, some domains were restructured after the concept analysis was conducted (e.g. organisation and structure). Changes were incorporated into the CICI framework in an iterative manner, as shown in Table 5 to Table 7 (revisions based on application → green, revisions based on concept analysis → blue).

5.2.2.3 *Theory advancement/development*

Our framework aims to capture all elements relevant to the phenomena of interest - context and implementation. While its generic version does not display relationships, the framework allows for their assessment when applied to a complex intervention. Our framework is also helpful in guiding the formulation of questions about these links, which in return inspires the advancement of theory of both interactions between domains as well as between the context and implementation dimensions.

5.2.2.4 *Compatibility of CICI framework with other theories/frameworks*

As mentioned before, frameworks provide a meta-theoretical language that can be used to compare theories (Ostrom et al., 2014). With our framework being based on a systematic search, it integrates both terminology and conceptualization of current approaches to implementation and context. It thus advances the compatibility and comparability of theories in this field.

Theories can focus on frameworks, making assumptions necessary for the analysis and diagnosis of a phenomenon, the explanation of its processes as well as the prediction of its outcomes. Usually, multiple theories are compatible with any given framework (Kitson et al., 2008). Especially the provider domain showed the compatibility of our framework with other theories. This domain was structured according to propositions of the Theoretical Domains Framework (Lehoux & Williams-Jones, 2007).

5.2.2.5 *Relationships between dimensions, domains and subdomains of CICI framework*

The framework in its generic form portrays all relevant domains of context and implementation but does not display relationships between domains or dimensions. As such, it falls into the tradition of previous implementation frameworks (Nilsen, 2015).

Yet, as the application in our qualitative systematic review has shown, the framework allows for the assessment of these relationships. Due to its granularity, data extracts can be attributed to several domains. This shows the interconnectedness of subdomains

within the framework, such as “access to healthcare” which emerged as a subdomain of three domains (geographical, political, and socio-economic). The clear graphical portrayal of the various dimensions, domains and subdomains is intended to facilitate an understanding of how these aspects may interact within a complex system. Thus, while not explicitly pointing towards interactions, the framework does encourage the user to consider them.

5.2.2.6 *Adaptation and applicability of CICI framework*

One of the most critical aspects of the application of the framework was its applicability to different types of complex interventions.

In the external review, interventions were either educational, environmental or a combination of both (Pfadenhauer et al. submitted manuscript). Due to the study designs and interventions focusing on meso or macro levels (e.g. water supplier), the implementation process itself could be outlined, embracing both programming and delivery of the interventions. This facilitated an explicit assessment of implementation domains such as policy or funding.

The application was more challenging with respect to HBPC. Interventions in HBPC were highly heterogeneous, targeting the professional provider (e.g. educational), the lay caregiver (e.g. psychosocial or psychoeducational intervention) and the patient (e.g. physical, psychological, social and spiritual). With our inclusion criteria being rather broad (e.g. formative, parallel to intervention, evaluative), in many cases the implementation process was more advanced, with relevant information related to funding or policy efforts not being reported. Most studies reported on the delivery of the intervention, more commonly in the micro context where the intervention was delivered (e.g. family) rather than in the macro context.

Flexibility with regard to which domains should be considered in association with a specific intervention is a benefit of the framework, and ensures that the framework can be applied to a broad range of more or less complex interventions.

It should be emphasized, however, that the decision of which domains to be considered should be a structured and transparent process, otherwise reviewers could “cherry pick” which context and implementation aspects they wish to emphasize.

5.2.2.7 *Flexibility of CICI framework*

In principle, the framework is applicable in quantitative, qualitative and mixed-method systematic reviews.

The framework was easily applicable to the qualitative systematic review including both mixed method as well as purely qualitative studies. This was primarily due to the richness of data provided in primary studies. Whenever data was not as rich as expected this was partly due to the study objectives and partly due to the quality of reporting.

Extracting data on context and implementation from quantitative studies was more challenging. The lack of detail reported in primary studies often limits the amount of useful data that can be extracted. This might be partly due to (i) reporting guidelines not sufficiently asking for details on context and implementation, (ii) journals imposing word limits and (iii) study conductors not evaluating the process of implementation.

In the external application to lead in consumer products and drinking water, the difficulty lay in extracting data from the quantitative primary studies. While five of the six included studies failed to report highly relevant information on context and implementation, one study reported rich data on context and implementation. This study encountered a very high loss-to follow up (Dugbately et al., 2005). While this imposed a major bias to the internal validity of the results, various barriers to the implementation of an intervention to reduce exposure to lead in consumer products and drinking water were documented and reported by the authors. These implementation (e.g. incentives not tailored to target population’s needs) as well as contextual barriers (e.g. instable family structures, inner-familial priority setting towards lead poisoning, low socio-economic status of neighbourhood, teenage pregnancies, gender inequality, lifestyle rendering outreach difficult) hindered the successful implementation of the intervention.

Mixed-method designs are more promising: These designs, where qualitative or process evaluations are identified, alongside or to supplement data collected on efficacy or effectiveness of an intervention, may be the most appropriate for applying the framework.

5.2.2.8 Capability of CICI framework

A complex intervention is commonly defined as an intervention that comprises multiple interacting components, with additional dimensions of complexity including the difficulty of their implementation as well as the number of organisational levels targeted (Craig et al., 2013).

When applied to the lead example, the framework sufficed in terms of capturing complexity of the intervention. The high granularity facilitated the systematic extraction of – partly scarcely – reported information and supported the structuring of relevant information.

The sources of complexity in palliative care are multiple. To a large extent, this complexity is owed to context and implementation, in particular with respect to the components of the intervention, the mode and frequency of delivery as well as the organisational levels targeted. Assuming that the primary studies allow for the identification and extraction of the various context and implementation domains, then the framework can facilitate the assessment of the complex relationships between the various domains and intervention effectiveness.

While we did not apply the framework to an intervention classified as “simple”, it should be stated that even though an intervention might be classified as simple, the interaction with its context may still be highly complex (Norton, 2012). Therefore, a systematic assessment of context and implementation may be critical for both simple and complex interventions.

5.2.2.9 Feasibility of application of CICI framework

The framework in itself should prove easy to use. Through the process of extracting data in a review of a complex intervention (where the extraction of a substantial amount of data may be necessary), the reviewer becomes very familiar with the individual studies. Locating relevant context and implementation information occurs at least in part, as the reviewer extracts other necessary information from the study. If, however, the level of reporting detail in quantitative studies does not sufficiently encompass these aspects, then little useful information can be obtained by applying the framework. In such a case, looking further into qualitative studies and/or process evaluations would possibly yield direct and useful information,

but of course with an associated increase in workload and possible risk of bias.

5.3 OUTLOOK

The CICI framework aims to do justice to the complexity of interventions. Its coherence, comprehensive nature, user friendliness as well as broad applicability across many different types of complex health interventions facilitate the systematic assessment and documentation of context and implementation in quantitative reviews, qualitative and mixed-method reviews and HTAs. Thus, it facilitates the provision of highly relevant information affecting the effectiveness as well as transfer of interventions from one setting and context to another. This information is intended to serve as the basis for decision and policy making when planning the implementation and, where needed, adaptation of evidence-based interventions.

The focus of further primary research should be to develop appropriate and consistent reporting and documentation of information concerning the implementation of an intervention in context. Ideally, reporting guidelines will comprise specific items concerning both dimensions. It is difficult to study the impact of the multitude of context and implementation factors and the interactions between them. Where these cannot be quantified, such potential modifiers of effectiveness should at least be reported openly and honestly (Wells et al., 2012).

Extensive practical application and further testing of the CICI framework will be essential for refining the framework and exploring how useful it is and how best it can be used for different purposes. Its value to decision makers will depend on whether it is shown to support better informed and more transparent decision making processes.

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8 APPENDICES

8.1 PROCESS OF GUIDANCE DEVELOPMENT

8.1.1 Scoping review

In order to gain a first impression of existing frameworks and guidance on how to assess context, setting and implementation issues, a scoping review was conducted. We used snowball sampling to identify relevant publications.

8.1.2 Development of initial framework

Based on the scoping review and iterative discussions within the project team, an initial framework for the assessment of context and implementation was developed. During the development of the initial framework, we became aware of the inconsistent use of the terms context and implementation. Therefore, we concluded that both concepts needed to be clarified. Therefore, systematic literature searches as well as a concept analysis were undertaken. This was published in *Zeitschrift für Evidenz, Fortbildung und Qualität im Gesundheitswesen* (Pfadenhauer et al., 2015). Consequently, systematic literature searches as well as a concept analysis were undertaken.

8.1.3 Systematic literature search

We conducted systematic searches of the literature on context and implementation theories, models, and frameworks.

For “setting” and “context”, the databases EMBASE (January 1974 – December 2013) and MEDLINE (January 1964 – December 2013) were searched for relevant publications. Search terms were “context”, “setting”, “environment”, combined using the Boolean operator AND with “model”, “theory”, “method”, “concept”, “conceptual model”, “conceptual framework” and “approach”.

For “implementation”, a recent systematic review published by Damschroder and colleagues (2009) offers the Consolidated Framework for Implementation Research (CFIR) providing the field with an overarching typology to promote implementation theory development and verification about what works where and why across multiple contexts (Damschroder et al., 2009). The CFIR is the most recent overview of widely used implementation frameworks and based on the widely cited and acknowledged Conceptual Model for considering the determinants of diffusion, dissemination and implementation of innovations in health service delivery and organization (Greenhalgh et al., 2004b). Based on this key publication, a search was undertaken in Google Scholar considering all publications published between January 2009 and May 2014 that cited either Damschroder et al. (2009) or any of the 19 theories, models, and frameworks included therein.

We included original publications that develop, propose or describe a theory, model, approach or framework (summarized under “framework”) for assessing, analysing and/or reporting context, setting, implementation and domains thereof. The frameworks could be theoretical (i.e. derived from theory or first principles) or empirical (i.e. hypotheses and theories that are tested against observations, experiences, experiments in nature). Empirical studies could employ qualitative and/or quantitative methods. Studies presenting extensions of an existing framework were also eligible for inclusion. Applications or empirical validations of an original framework were not eligible for inclusion but were documented alongside the original framework. The review is restricted to the health field, embracing clinical as well as public health applications. The frameworks consider context and implementation from the perspective of the provider or the receiver of an intervention or both.

8.1.4 Pragmatic Utility Concept Analysis

All eligible studies were analysed using Morse’s approach to concept analysis, Pragmatic Utility (PU) (1995).

The objective of concept analysis is to develop distinct concepts in order to establish a scientific basis for a given discipline, thus creating conceptual clarity (Glisson & James, 2002). Concept analysis is necessary if the concept needs to be operationalized (Cooke & Rousseau, 1988). PU aims to evaluate the state of the art of concept use by comparing and contrasting applications in particular disciplines, determining conceptual adequacy with competing concepts, and identifying gaps, inconsistencies, and boundaries of the concepts. In order to utilize concepts in theory, research and practice, it is necessary to be able to evaluate the level of maturity of a respective concept (Brehaut et al., 2010). A mature concept is consensually defined, with clearly described characteristics, fully described and demonstrated preconditions and outcomes and delineated boundaries (Brehaut et al., 2010). PU is suitable for analyzing mature or partially mature concepts for which a significant body of theoretical and research papers already exists (Brehaut et al., 2010; Gurses et al., 2010). While the concepts of setting and context had previously been appraised as “partially mature”, the concept of implementation had not previously been appraised. Pragmatic utility concept analysis involves three key steps: 1. Searching and selecting relevant literature; 2. Organizing and structuring this literature; and 3. asking key questions of this literature.

Step 1: Searching and selecting relevant literature

The search strategy as well as inclusion criteria are described in the previous section (please view section “Systematic literature search”).

For context, 2,266 records were retrieved in EMBASE and MEDLINE. 44 records were screened on a full-text basis, with 18 publications included in the analysis. In these, concepts on context were developed or conceptualized based on systematic reviews (Chaudoir et al., 2013), non-systematic literature reviews (Burchett et al., 2011; Damschroder et al., 2009; Kayser-Jones, 1992), primary qualitative studies (Bergstrom et al., 2012; Tomoaia-Cotisel et al., 2013; Wells et al., 2012) and mixed-method approaches (Anderson et al., 2003; Estabrooks et al., 2009; Frohlich et al., 2002; McCormack et al., 2009; Mendel et al., 2008; Riedmann et al., 2011; Sorensen et al., 2003). For two publications, the method of development was unclear (SURE Collaboration, 2011; World Health Organization (WHO), 2013).

For implementation, 72 out of 4,455 records were included for full-text screening and 36 records finally met the inclusion criteria. Findings were based on systematic reviews (Chaudoir et al., 2013; Emmons et al., 2012; Hage et al., 2013; Kaplan et al., 2010; Meyers et al., 2012), non-systematic literature reviews (Avgar et al., 2012; Damschroder et al., 2009; Glanz & Bishop, 2010; Packard, 2013; Palmer & Kramlich, 2011; Suter et al., 2013; Talsma et al., 2014; Taxman & Belenko, 2012), primary qualitative (Aarons et al., 2014; Rycroft-Malone et al., 2013; Stetler et al., 2011; Suter et al., 2011; Tomoaia-Cotisel et al., 2013) or quantitative studies (Beidas et al., 2013; Helfrich et al., 2009), mixed-method approaches (Flottorp et al., 2013; Green et al., 2012; VanDeusen Lukas et al., 2010) and theory (Aarons et al., 2012; Aarons et al., 2011; Damschroder & Hagedorn, 2011; Fixsen et al., 2009; Kitson et al., 2013; May, 2013; May et al., 2009; Metz & Bartley, 2012; Proctor et al., 2013; Simpson, 2011; Weiner, 2009; Weiner et al., 2009). The process of study selection is displayed in Figure 3.

As previously mentioned, both concepts are highly intertwined. While aware of this, we decided to consider both concepts separately to facilitate operationalization while paying particular attention to overlaps and links. Therefore, whenever one publication included information relevant for the conceptualization of the respective other concept, this publication was also analysed for the second concept. / Figure 3: Study selection process.

Step 2: Organising and structuring the literature

All included literature was organised according to the field of publication (e.g. health, psychology, social sciences, organisational, business or management sciences), the field of application (e.g. prevention), and contained models (e.g. CFIR). The method of theory, framework or model development was also used to structure the included literature. The information identified from each included study was assigned to characteristics, preconditions and outcomes, and boundaries of the concepts (Brehaut et al., 2010). By applying exploratory and elemental coding as proposed by Saldana (Morse et al., 1996), themes and categories were developed (Pfadenhauer et al., 2015).

Step 3: Asking key questions of the literature

Key questions, as asked by other researchers in discussion sections or as proposed by the co-authors during the searching and organising stage, were then asked and answered as much as possible from included publications. These questions comprised – among others – the following:

- ▶ How do agents (e.g. care provider) interact within an implementation effort?
- ▶ How do context and implementation interact?
- ▶ How are the intervention and the implementation/ context intertwined?
- ▶ How is success of implementation conceptualized?
- ▶ How does time exert its influence on the conceptualization of context?

8.1.5 First revision of initial framework

While extracting data for the concept analysis, constructs contained in the included theories, models and frameworks were also extracted from the original publications and collected in a table. After the concept analysis was completed and published (Pfadenhauer et al., 2015), the constructs were reassessed, clustered into groups and labelled. While we were not able to identify a new domain apart from the eight domains already contained in the initial framework, we were able to form new subdomains which were assigned to existing domains.

8.1.6 Case study and external applications of framework

8.1.6.1 Rationale for testing the framework

In order to assess its applicability, the CICI framework was applied in three quantitative and one qualitative systematic review of complex health interventions (i.e. home-based palliative care, lead in consumer products and drinking water; ambient air pollution). Within INTEGRATE-HTA, we differentiated between an external application and a case study application. An external application refers to any instance in which the proposed methods were applied outside of INTE-

GRATE-HTA. The case study application refers to the application of methods within the demonstration HTA of reinforced palliative care models (Brereton et al., 2016). Two quantitative systematic reviews were conducted outside of INTEGRATE-HTA while one quantitative review and the qualitative review were embedded in the case study on palliative care (Brereton et al., 2016).

8.1.6.2 Selection of systematic reviews for application

Since we wanted to test the applicability of the CICI framework, the reviews were chosen for the following reasons:

- ▶ Applicability of framework to a variety of complex health interventions: the quantitative systematic reviews represent a wide range of fields in terms of interventions (medical, educational, environmental, political interventions), populations (e.g. children, people in the end-of-life stage, general population) and complexity.
- ▶ Applicability of framework to a variety of methodological approaches: applications range from quantitative systematic reviews (i.e. WHO review on lead in drinking water and consumer products, HBPC) to a qualitative systematic review on palliative care; moreover, the application within systematic reviews can be compared to the application within HTA.

8.1.6.3 Case study application in “Integrated assessment of home based palliative care with and without reinforced care-giver support: ‘A Demonstration HTA’”

The CICI framework was applied in both a qualitative and quantitative systematic review. It also provided the basis for a consultation guide aiming at assessing the applicability of the HTA findings to three specific contexts, Germany, the United Kingdom as well as Poland.

8.1.6.3.1 Quantitative systematic review: “Home-based and reinforced Palliative Care: Assessing effectiveness through harvest plots and post-review qualitative interviews”

Within the case study, a quantitative review assessing the effectiveness of HBPC and rHBPC was conducted (Burns et al., manuscript in preparation).

Within this review, the CICI framework informed the system-based logic model at protocol stage, and served as the basis for a data extraction form facilitating the extraction of information on context and implementation as reported in primary quantitative studies (see checklist in Table 4) (Brereton et al., 2016).

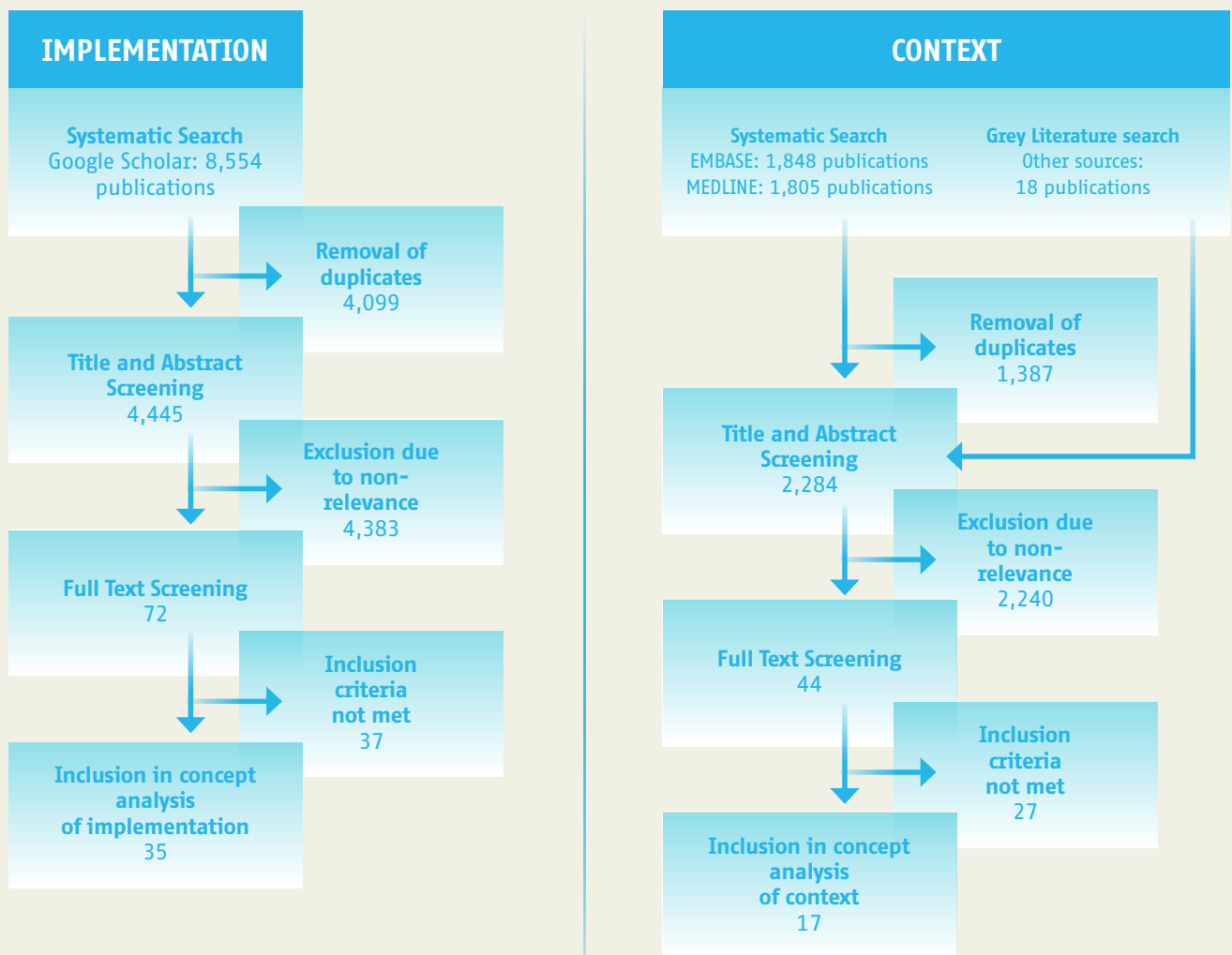
8.1.6.3.2 *Qualitative systematic review: "Contextual enablers and barriers to the implementation of home-based palliative care interventions"*

Parallel to the quantitative review, a qualitative review assessing contextual enablers and barriers to the implementation of home-based palliative care interventions was conducted (Pfadenhauer et al., manuscript in preparation).

The primary objective of this review was to identify enablers and barriers of context and implementation of home-based palliative care services in Europe. Our secondary objective was to test the CICI framework in terms of its applicability for synthesis of qualitative evidence in relation to home-based palliative care as well as its internal logic and fit with the evidence base.

The CICI framework was used as the a priori framework in best-fit framework synthesis. By employing secondary thematic analysis, data is attributed to a priori categories as described in the CICI framework or – in cases where data does not fit – new categories are formed. Thus, a new framework is created as applied to the respective intervention (Carroll et al., 2011; Carroll et al., 2013). The data extraction form can be found in the appendix.

Figure 3: Study selection process.



8.1.6.3.3 *Assessment of applicability of findings of "Integrated assessment of home based palliative care with and without reinforced caregiver support: 'A Demonstration HTA'"*

The CICI framework was moreover used as basis for a consultation guide with the objective of assessing the applicability of the findings of the Demonstration HTA to three specific contexts, i.e. UK, Germany and Poland (Brereton et al., 2016). We conducted two consultations per contexts, one with an academic expert and one with a clinician working in palliative care.

8.1.6.4 *External application*

8.1.6.4.1 *Quantitative systematic review: "Effectiveness of Interventions to Reduce Exposure to Lead through Consumer Products and Drinking Water"*

The CICI framework was applied in one quantitative review, i.e. "Effectiveness of Interventions to Reduce Exposure to Lead through Consumer Products and Drinking Water" (Pfadenhauer et al. submitted manuscript) conducted outside of the INTEGRATE-HTA project.

At protocol stage, the framework informed the system-based logic model (Pfadenhauer et al., 2014). We also extracted information on context and implementation using a detailed data extraction form (see checklist in Table 4).

8.1.6.4.2 *Quantitative systematic review: "Interventions to reduce ambient particulate matter air pollution and their effect on health"*

The aim of this Cochrane systematic review is to assess the effectiveness of interventions to reduce ambient PM air pollution concentrations, and their effects on health outcomes (Burns et al., 2014).

Due to the early stage of the systematic review, the framework was applied at the protocol stage to inform the system-based logic model. The revised framework will – comparable to the other quantitative reviews – serve as the basis for the development of a detailed data extraction form.

8.1.7 *Revision of framework*

The initial framework was revised twice, first after the concept analysis was conducted and second after it was applied to the systematic reviews and demonstration HTA (Brereton et al., 2016).

While the concept analysis focused primarily on advancing the conceptual maturity of both concepts, constructs, domains, structures, processes, components or elements suggested by models, theories or frameworks included into the concept analysis were extracted and collected. These components were synthesized and compared to constructs collected by Damschroder et al. (2009). Any construct that was missing in the CFIR was added to the respective domain in the CICI framework.

Moreover, our findings from the application in the systematic reviews, the Demonstration HTA and the applicability assessment were integrated into the framework. Whenever subdomains were missing, relationships between domains needed to be specified or interactions shown in a different way, these findings were noted. All information gathered during application was collected and integrated into the final framework.

8.2 SUPPORTING DOCUMENTS

8.2.1 *Domains and subdomains of the CICI framework*

8.2.1.1 *Domains of context*

Table 5: Domains of Context.

Domain	Definition	Description
● Setting	<p>The setting encompasses the immediate physical and organisational environment, in which an intervention is delivered. It also comprises the effect the location has on affected stakeholder, i.e. by taking in a specific role.</p>	<p>Depending on the specific intervention, describing this domain may include:</p> <p>Refinement according to applications:</p> <ul style="list-style-type: none"> ▶ Effect of location on affected stakeholder <p>Refinement according to concept analysis:</p> <ul style="list-style-type: none"> ▶ physical characteristics (Kayser-Jones, 1992) ▶ work environment (Helfrich et al., 2007) <p>Initial framework as based on the scoping review:</p> <ul style="list-style-type: none"> ▶ City, region, country (e.g. urban, rural) (Ostroff et al., 2003) (Kauth et al., 2010) ▶ Type of study site (e.g. primary care, hospital, home, school, occupational setting) (Ostroff et al., 2003) ▶ Number of study sites (Kauth et al., 2010; Ostroff et al., 2003) ▶ Relevant changes over time (e.g. urbanisation)
● Geographical	<p>The geographical characteristics refer to the broader physical environment, landscapes and resources, both natural and transformed by humans, available at a given location. As such it also comprises the infrastructure at a given location, which could result in geographical isolation.</p>	<p>Depending on the specific intervention, describing this domain may include:</p> <p>Refinement according to applications:</p> <ul style="list-style-type: none"> ▶ Access to health care system <p>Refinement according to concept analysis:</p> <ul style="list-style-type: none"> ▶ geographical isolation (Hage et al., 2013) <p>Initial framework as based on the scoping review:</p> <ul style="list-style-type: none"> ▶ Geography (e.g. altitude, desert, forest, water) ▶ Climate (e.g. temperature, rainfall) ▶ Human land use (e.g. degree of urbanisation, agriculture, industry) (Drennan, 1992; Kennedy, 2001) ▶ Infrastructure (e.g. water and sanitation, energy, transport) (Chaudoir et al., 2013) ▶ Relevant changes over time (e.g. infrastructure development, crop failures)
● Epidemiological	<p>This domain refers to the distribution of disease/conditions, the attributable burden of disease as well as determinants of needs in human populations (Rychetnik et al., 2002). Therefore, it also includes demographics (Castro et al., 2004; Hage et al., 2013).</p>	<p>Depending on the specific intervention, describing this domain may include:</p> <p>Refinement according to applications:</p> <ul style="list-style-type: none"> ▶ Determinants of needs of people indirectly affected by disease/condition (e.g. lay caregivers of palliative care patients cared for at home) <p>Refinement according to concept analysis:</p> <ul style="list-style-type: none"> ▶ Determinants of needs of people directly affected by disease/condition ▶ Burden of disease (Burchett et al., 2011) <p>Initial framework as based on the scoping review:</p> <ul style="list-style-type: none"> ▶ Demographics (life expectancy, gender, age, ethnicity, genetic factors) (Castro et al., 2004; Hage et al., 2013) ▶ Population density, fertility patterns, family size (Kennedy, 2001) ▶ Incidence/prevalence and severity of disease, morbidity and mortality (Burchett et al., 2011) ▶ Spatial distribution of disease across geographical areas ▶ Relevant changes over time (e.g. epidemics)
● Socio-cultural	<p>This domain comprises explicit and implicit behaviour patterns, including their embodiment in symbols and artefacts; the essential core of culture consists of historically derived and selected ideas and values that are shared among members of a group (Sabatier, 2007) It not</p>	<p>Depending on the specific intervention, describing this domain may include:</p> <p>Refinement according to applications:</p> <ul style="list-style-type: none"> ▶ none <p>Refinement according to concept analysis:</p> <ul style="list-style-type: none"> ▶ Sociodemographic profiles (Burchett et al., 2011) ▶ Psychosocial factors (Kayser-Jones, 1992; McCormack et al., 2009) ▶ Social and societal context (McCormack et al., 2002; Peters et al., 2002)

only refers to the conditions in which people are born, grow, live, work and age but also embraces the social roles a human being takes in as a family member, community member or citizen and the relationships inherent to these roles. Constructs such as knowledge, beliefs, conceptions, customs, institutions and any other capabilities and habits acquired by a group are comprised by this domain (Guidance for assessing effectiveness, economic aspects, ethical aspects, socio-cultural aspects and legal aspects in complex technologies

- ▶ Structural social inequalities (e.g. Gender inequalities, caste system) (Hage et al., 2013)
- ▶ Community characteristics and level of coordination/involvement with community (Tomoaia-Cotisel et al., 2013)
- Initial framework as based on the scoping review:**
- ▶ Language and means of communication
- ▶ Symbols, heroes, rituals (van Eijnatten & Galen, 2002)
- ▶ Values (e.g. evil vs. good, dirty vs. clean, dangerous vs. safe, abnormal vs. normal) (van Eijnatten & Galen, 2002)
- ▶ Beliefs (e.g. superstition, fate or destiny)
- ▶ Religiosity and spirituality
- ▶ Knowledge and perceptions (e.g. with respect to significance of health issue, options for resolving health issue, multiple benefits and drawbacks of technology)
- ▶ Lifestyle (population's patterns in nutrition, smoking, substance abuse) (Weaver & Mitcham, 2008)
- ▶ Income equality, and racial discrimination (Hupcey et al., 1996)
- ▶ Social capital (i.e. ability of actors to secure benefits by virtue of membership in social networks and other social structures (Putnam, 2001)) and resources available through social relationships (Dugbatey et al., 2005) (Jordan et al., 2003), specifically social networks, norms of reciprocity, and trust (Fertmann et al., 2004; Sherlock et al., 1984).
- ▶ Social structure: Social cohesion, including relational, material, and political dimensions, information exchange, networks of support, and informal social control (Frohlich et al., 2002; Macintyre et al., 1998)
- ▶ Family structures
- ▶ Historical and contemporary social power relations (Drennan, 1992)
- ▶ Relevant changes over time (e.g. social changes or social movements (63)

▶ Socio-economic

This domain comprises the economic resources of a community and the access of a population to these resources (Dam-schroder et al., 2009; Kennedy, 2001). It also shows the relationship between an economy and its society.

Depending on the specific intervention, describing this domain may include:

Refinement according to applications:

- ▶ Access to health care system

Refinement according to concept analysis:

- ▶ Fiscal environment (McCormack et al., 2009)
- ▶ Market environment (Tomoaia-Cotisel et al., 2013)

Initial framework as based on the scoping review:

- ▶ Social or socio-economic status (Hupcey et al., 1996), attributed to education, income, occupation marriage, or gender
- ▶ Financial aspects (income, wealth, poverty) (Castro et al., 2004; Hage et al., 2013)
- ▶ Economic climate (e.g. reliance upon and stability of private, state, federal funding). (Chaudoir et al., 2013; McCormack et al., 2009)
- ▶ Education
- ▶ Occupational aspects (employment status, working conditions) (Hage et al., 2013)
- ▶ Living conditions (housing, neighbourhood characteristics) (Vishwanath et al., 2008)
- ▶ Relevant changes over time (e.g. inflation, recession, economic crisis)

▶ Political

The political domain focuses on the distribution of power, assets and interests within a population, as well as the range of organisations involved, their interests and the formal and informal rules that govern interactions between them (The Cochrane Collaboration, c2004-2006). The domain also comprises the health care system and the securing of its accessibility.

Depending on the specific intervention, describing this domain may include:

Refinement according to applications:

- ▶ Access to health care system

Refinement according to concept analysis:

- ▶ Ideology (SURE Collaboration, 2011)
- ▶ Short-term thinking (SURE Collaboration, 2011)
- ▶ Influential people (SURE Collaboration, 2011)
- ▶ Payer, donor or funder policies (Flottorp et al., 2013; SURE Collaboration, 2011)
- ▶ Political authority (Tomoaia-Cotisel et al., 2013)
- ▶ Health Care System (Aarons et al., 2014; Bandura, 1986; Flottorp et al., 2013; Glasgow et al., 1999; SURE Collaboration, 2011) (e.g. governance and leadership, resources, service delivery, integration of patient's needs and perspective)

Initial framework as based on the scoping review:

- ▶ Political system and civil society's structure
- ▶ political or social climate (e.g., liberal versus conservative) (Chaudoir et al., 2013)
- ▶ Players, interests, resources, objectives, formal and informal rules
- ▶ public policies (e.g., presence of state laws that criminalize HIV disclosure), (Aarons et al., 2014; Chaudoir et al., 2013)
- ▶ Political culture and socio-political climate (Greenhalgh et al., 2004b)
- ▶ State-society relations
- ▶ Political situation including political stability and absence of violence, government effectiveness, voice and accountability, control of corruption, rule of law, regulatory quality, participation, accountability, transparency, efficiency, decency, and fairness(Flottorp et al., 2013; SURE Collaboration, 2011)
- ▶ Economic management, economic policy and political framework of markets
- ▶ Politics and gender
- ▶ International integration (The Cochrane Collaboration, c2004-2006)
- ▶ Relevant changes over time (e.g. political reform, change of government)

• Legal

The legal domain is concerned with the rules and regulations that have been established to protect a population's rights and societal interests (European Network for Health Technology Assessment (EUnetHTA), 2007).

Depending on the specific intervention, describing this domain may include:

Refinement according to applications:

- ▶ Decision-making in care delivery
- ▶ Sharing of information with indirectly affected stakeholders

Refinement according to concept analysis:

- ▶ Legislation (Aarons et al., 2014; Flottorp et al., 2013)

Initial framework as based on the scoping review:

- ▶ Norms, values and beliefs underlying legislation
- ▶ Specific legislation (e.g. patient rights, data protection, malpractice liability) (Aarons et al., 2014) (Flottorp et al., 2013)
- ▶ Regulatory provisions concerning healthcare personnel and their rights and duties
- ▶ Guidelines (Damschroder et al., 2009)
- ▶ Relevant changes over time (e.g. introduction of new regulation or legislation)

• Ethical

The ethical domain embraces reflections of morality, which encompasses beliefs, standards of conduct and principles that guide the behaviour of individuals and institutions (European Network for Health Technology Assessment (EUnetHTA), 2007). Ethical issues at stake or in conflict, within systematic reviews/health technology assessments on a complex intervention, are addressed.

Depending on the specific intervention, describing this domain may include:

Refinement according to applications:

- ▶ Autonomy
- ▶ Moral stress
- ▶ Privacy
- ▶ Conflicting interests

Refinement according to concept analysis:

- ▶ none

Initial framework as based on the scoping review:

- ▶ Morality and beliefs influencing the behaviours of individuals in their private or professional capacity, and/or of institutions (Burchett et al., 2011; European Network for Health Technology Assessment (EUnetHTA), 2007)
- ▶ Standards of conduct and principles guiding the behaviours of individuals in their private or professional capacity, and/or of institutions (European Network for Health Technology Assessment (EUnetHTA), 2007)
- ▶ Relevant changes over time (e.g. changes in standards of conduct within a healthcare organisation)

Table 6: Domains of Implementation - Delivery.

Domain	Definition	Description
<ul style="list-style-type: none"> Provider 	<p>This domain focuses on the characteristics of the individuals adopting and delivering the intervention. It includes both the personal attributes, knowledge, skills, emotions, motivations, intentions and goals. Apart from the attitude towards an intervention, professional and social roles, beliefs about capabilities as well as consequences of the adoption, social influences as well as behavioural regulation are relevant for behaviour change in relation to the adoption of a new intervention.</p>	<p><i>Depending on the specific intervention, describing this domain may include:</i></p> <p>Refinement according to applications:</p> <ul style="list-style-type: none"> Interaction with recipients of intervention <p>Refinement and restructuring according to concept analysis:</p> <ul style="list-style-type: none"> Personality attributes (Damschroder et al., 2009) (e.g. openness, curiosity) Skills (Greenhalgh et al., 2004b): An ability or proficiency acquired through training and/or practice (American Psychological Association (APA), 2002; Cane et al., 2012); this subdomain comprises physical, cognitive and interpersonal skills Knowledge: An awareness of the existence of something (Cane et al., 2012), Knowledge (including knowledge of condition /scientific rationale), Procedural knowledge, Knowledge of task environment (Cane et al., 2012) Emotion (Cane et al., 2012): Fear, Anxiety, Affect, Stress, Depression, Positive/negative affect, Burn out (Cane et al., 2012) Memory, attention and decision processes (Cane et al., 2012) Beliefs about consequences and optimism: Characteristics of the cognitive, emotional and behavioural outcomes that individuals believe are associated with future or intended behaviours and that are believed to either promote or inhibit these behaviours. (American Psychological Association (APA), 2002; Cane et al., 2012) Beliefs about capabilities and self-efficacy (Cane et al., 2012): Perceived behavioural control refers to people's perceptions of their ability to perform a given behaviour (Ajzen, 1991) Attitude towards intervention: The learned, relatively stable tendency to respond to people, concepts, and events in an evaluative way (78) Motivation, intention and goals (Greenhalgh et al., 2004b): (Intention = Intentions are assumed to capture the motivational factors that influence a behaviour; they are indications of how hard people are willing to try, of how much of an effort they are planning to exert, in order to perform the behaviour (Ajzen, 1991) Behavioural regulation (Cane et al., 2012): Self monitoring, Breaking habit, Action planning Social/professional role and identity (Cane et al., 2012): The behaviour considered appropriate for a particular kind of work or social position (Cane et al., 2012) <p>Initial framework as resulted from the scoping review:</p> <ul style="list-style-type: none"> Competence (Greenhalgh et al., 2004a): Cognitive resources: personal and interpersonal sensations and knowledge, information and evidence, real and virtual objects that reside in a social system and that are institutionally sanctioned, distributed and allocated to agents. It moreover includes the possibilities of sharing information within the organisation as well as the ability to find, interpret, recodify and integrate new knowledge (Greenhalgh et al., 2004a; May, 2013; Rycroft-Malone et al., 2004) Training Behaviour (Greenhalgh et al., 2004b): Workability: the social practices that agents perform when they operationalize a complex intervention (May, 2013) and social roles which agents take in (May, 2013); Morals and satisfaction (Chaudoir et al., 2013) Motivation (Greenhalgh et al., 2004b): including individual intentions and motivation (May, 2013), shared commitments (May, 2013) , self-efficacy, individual identification with organisation (Damschroder et al., 2009), individual values and goals (Greenhalgh et al., 2004b) and individual needs (Greenhalgh et al., 2004b) Capacity (Greenhalgh et al., 2004b): individual stage of change (Damschroder et al., 2009) (progress towards skilled, enthusiastic and sustained use of the intervention (Moher et al., 2010) (cp. Roger's Diffusion of Innovation Theory, Trans-Theoretical Model (Prochaska)) and learning Style (Greenhalgh et al., 2004b)

• Organisational and structure

This domain refers to the structural resources, social architecture and organisational culture of an organisation, as well as the internal and external, formal and informal networks through which it operates in implementing an intervention. It comprises the organisational policies, guidelines and practices as well as culture and climate that reside within an organisation and on different levels such as the organisation as a whole, units and teams through which an intervention is delivered. Therefore, constructs such as team dynamics, leadership, supervision and guidance are also comprised.

Depending on the specific intervention, describing this domain may include:

Refinement according to applications:

- ▶ Continuity of organisation, information and staff
- ▶ Coordination of teams
- ▶ Collaboration within teams
- ▶ Cooperation with other external providers

Refinement and restructuring according to concept analysis:

- ▶ Size and structure (Greenhalgh et al., 2004b) (VanDeusen Lukas et al., 2010): The social architecture, age, maturity, and size of an organisation. Social architecture describes how large numbers of people are clustered into smaller groups and differentiated, and how the independent actions of these differentiated groups are coordinated to produce a holistic product or service (Tomoaia-Cotisel et al., 2013). It comprises also the organisational structures (e.g. formalization, centralization, boundaries) as well as staffing (e.g. demographics, selection, stability of workforce)
- ▶ Networks & communication: The nature and quality of webs of social networks and the nature and quality of formal and informal communications within an organization (Damschroder et al., 2009).
- ▶ Cosmopolitanism: The degree to which an organization is networked with other external organizations. (Damschroder et al., 2009)
- ▶ Organisational policies, guidelines and practices employed by organization to put the innovation into place to support innovation use; means by which an organization assimilates an innovation in order to achieve an acceptable level of operational, cultural and strategic fit. The assimilation process, as others have noted, entails a mutual adaptation of the innovation and the organization (Weiner et al., 2009)
- ▶ Organisational culture (Aarons et al., 2014; Bandura, 1977; Bandura, 1986; Bergstrom et al., 2012a; Damschroder et al., 2009; Glisson et al., 2008; Helfrich et al., 2009; Lehman et al., 2002; Packard, 2013): vision (Barnett & Casper, 2001; Victora et al., 2005), shared norms, values, and basic assumptions of a given organization (Bergstrom et al., 2012a)
- ▶ Organizational climate (Aarons et al., 2014; Emmons et al., 2012; Glisson et al., 2008; Kayser-Jones, 1992; Lehman et al., 2002; Packard, 2013) phenomenon that can vary across teams or units, and is typically less stable over time compared to culture (Damschroder et al., 2009)
- ▶ Team dynamics (Bergstrom et al., 2012a; Cane et al., 2012; Carroll et al., 2013; Emmons et al., 2012) (Carroll et al., 2011) (McCormack et al., 2009):
- ▶ Leadership (Emmons et al., 2012) (Cane et al., 2012), supervision and guidance (Hofstede & Hofstede, 2001) (Flottorp et al., 2013) (Cane et al., 2012)
- ▶ Training and knowledge transfer (Aarons et al., 2011; Cane et al., 2012; Carroll et al., 2013; Fixsen et al., 2009; Flottorp et al., 2013; Hofstede & Hofstede, 2001)
- » **Implementation Climate (Damschroder et al., 2009):**
 - » Relative Priority (Damschroder et al., 2009): Individuals' shared perception of the importance of the implementation within the organization (Damschroder et al., 2009; Flottorp et al., 2013; Packard, 2013)
 - » Organizational Incentives & Rewards (Damschroder et al., 2009): Extrinsic incentives (Cane et al., 2012; Carroll et al., 2013; Flottorp et al., 2013) such as goal-sharing awards, performance reviews, promotions, rewards (Cane et al., 2012; Carroll et al., 2013; Flottorp et al., 2013), and financial incentives (Tomoaia-Cotisel et al., 2013), and less tangible incentives such as increased stature or respect (Damschroder et al., 2009).

- » Goals & Feedback (Damschroder et al., 2009): Goals & Feedback: The degree to which goals are clearly communicated (Cane et al., 2012; Greenhalgh et al., 2004b), acted upon (Fixsen et al., 2009; Flottorp et al., 2013; Greenhalgh et al., 2004a; Helfrich et al., 2009), and fed back to staff, and alignment of that feedback with goals (Bergstrom et al., 2012b; Cane et al., 2012; Flottorp et al., 2013; Greenhalgh et al., 2004a)
- » Supportive and learning Climate (Damschroder et al., 2009; Packard, 2013): A climate in which: a) leaders express their own fallibility and need for team members' assistance and input; b) team members feel that they are essential, valued, and knowledgeable partners in the change process; c) individuals feel psychologically safe to try new methods; and d) there is sufficient time and space for reflective thinking and evaluation (Damschroder et al., 2009)
- » **System readiness to change:**
 - » Leadership Engagement: Commitment involvement, and accountability of leaders and managers with the implementation (Cane et al., 2012; Damschroder et al., 2009; Packard, 2013; VanDeusen Lukas et al., 2010).
 - » Available Resources: The level of resources dedicated for implementation and on-going operations, including money, training, education, physical space, and time (Damschroder et al., 2009)
 - » Access to Knowledge & Information: Ease of access to digestible information and knowledge about the intervention and how to incorporate it into work tasks (Damschroder et al., 2009).
- ▶ Peer pressure: Mimetic or competitive pressure to implement an intervention, typically because most or other key peer or competing organizations have already implemented or in pursuit of a competitive edge. (Damschroder et al., 2009)
- ▶ Change agents and champions of change (Damschroder et al., 2009)

Initial framework as resulted from the scoping review:

- ▶ Interorganisational Networks: communications (knowledge sharing & management) between different organisations and entities within the system (European Network for Health Technology Assessment (EUnetHTA), 2007): peer pressure (Damschroder et al., 2009), targeted Capacity-Building (Cavanagh & Chadwick, 2005), extrinsic incentives (Damschroder et al., 2009) and engaging (Champions (Damschroder et al., 2009; McNeill et al., 2006; Moher et al., 2010), external change agents who actively promote interventions (Mendel et al., 2008), external change agencies (Greenhalgh et al., 2004b), formally appointed internal implementation leaders (Damschroder et al., 2009; Greenhalgh et al., 2004b; Lubomski et al., 2008))
- ▶ Structure: mission and vision (Mendel et al., 2008), size and maturity (Damschroder et al., 2009), capacity (human, material, research development; resources beyond minimal requirement to maintain operations) (Greenhalgh et al., 2004b; May, 2013; Portes, 1998); Formalization, differentiation and centralization (McNeill et al., 2006); communication & information systems and structures, access to information and knowledge (Damschroder et al., 2009; European Network for Health Technology Assessment (EUnetHTA), 2007; Greenhalgh et al., 2004b); Quality and sustainability assurance (European Network for Health Technology Assessment (EUnetHTA), 2007)
- ▶ Organisational Culture:
 - ▶ Informal communication and networks (Aunger & Curtis, 2007; Institute of Medicine of the National Academy of Sciences (IOM), 2003)
 - ▶ Leadership (Aarons et al., 2014; Bandura, 1986; Barnett & Casper, 2001; Bergstrom et al., 2012a; Cane et al., 2012; Carroll et al., 2013; Damschroder et al., 2009; Emmons et al., 2012; Helfrich et al., 2009);
- ▶ Organisational climate: localized and thus a more tangible manifestation of the largely intangible, overarching culture; less stable over time than culture, varies across teams or units (Aarons et al., 2014; Cane et al., 2012; Emmons et al., 2012; Gershon et al., 2004; Glisson et al., 2008; Kayser-Jones, 1992; Lehman et al., 2002; Packard, 2013)

Table 7: Domains of Implementation - Programming.

Domain	Definition	Description
● Funding	<p>Funding relates to short-term or longer-term funding mechanisms by governmental, non-governmental, private sector and philanthropic organisations used to implement an intervention.</p>	<p>Depending on the specific intervention, describing this domain may include:</p> <p>Refinement according to applications:</p> <ul style="list-style-type: none"> ▶ none <p>Refinement according to concept analysis:</p> <ul style="list-style-type: none"> ▶ Availability of service, research and foundation grants (Aarons et al., 2011; Burchett et al., 2011; Green et al., 2012) ▶ Availability of payment models (Tomoia-Cotisel et al., 2013) ▶ Continuity of funding and fiscal support (Aarons et al., 2011; Packard, 2013) ▶ Support tied to federal and state policies (Aarons et al., 2011) ▶ Fit of funding with existing service funds (Aarons et al., 2011) ▶ Willingness of funding sources to adjust requirements (Green et al., 2012) <p>Initial framework as resulted from the scoping review:</p> <ul style="list-style-type: none"> ▶ Funding and reimbursement programs (Mendel et al., 2008) and also purchaser-provider contract (Kawachi et al., 2002) (Aarons et al., 2011) ▶ Financial incentives on all levels: ▶ Change In Income For Provider, Pay-For-Performance Incentives (Damschroder et al., 2009; Kreuter & Lezin, 2002) ▶ Changed Cost For Patient (Kreuter & Lezin, 2002) ▶ Changed Cost For Practice Organisation (Kreuter & Lezin, 2002) ▶ Changed Cost For Health Care System, Etc. (Kreuter & Lezin, 2002) ▶ Economic climate and the availability of resources (Portes, 1998)
● Policy	<p>Policy comprises policy measures and processes of government, public, private or other organisations directly concerning or indirectly influencing the implementation of an intervention.</p>	<p>Depending on the specific intervention, describing this domain may include:</p> <p>Refinement according to applications:</p> <ul style="list-style-type: none"> ▶ Meeting the needs of the society ▶ Navigation of health and social systems ▶ Social protection of all affected stakeholders <p>Refinement according to concept analysis:</p> <ul style="list-style-type: none"> ▶ Legislation, policies, programmes, incentives, initiatives, regulations (Aarons et al., 2014)(20) put in place to initiate, support or foster the implementation of an intervention and their impact (Aarons et al., 2014; Burchett et al., 2011; Damschroder et al., 2009; Dobbins et al., 2007; Greenhalgh et al., 2004b; Packard, 2013; Putnam) ▶ Policymakers use of evidence-based practice (El-Jardali et al., 2012) ▶ Advocacy of intervention and its implementation (Aarons et al., 2014) <p>Initial framework as resulted from the scoping review:</p> <ul style="list-style-type: none"> ▶ Donor policies (Kawachi et al., 2002) ▶ Prioritizing: priority on societal agenda (Aarons et al., 2014; Kawachi et al., 2002) ▶ Political Culture and Climate: ideology, short-term thinking, contracts, influential people, corruption, political stability (Greenhalgh et al., 2004b; Hawe & Shiell, 2000) ▶ External mandates (Damschroder et al., 2009; Greenhalgh et al., 2004b; Mendel et al., 2008) ▶ Public or benchmark reporting (Damschroder et al., 2009) ▶ Political directives or incentives, political mandates (must-dos)

8.2.2 *Data Extraction Form for Qualitative Systematic Reviews*

8.2.2.1 *Context*

Please try to answer the following questions regarding each domain of the context dimension!

- ▶ What aspects of the [respective domain] environment influence the intervention, its implementation, its population reach and its effectiveness?
- ▶ How do [respective domain] aspects exert their influence on implementation the intervention, its implementation and their outcomes?
- ▶ How do [respective domain] characteristics interact with other domains of context?

Table 8: Data Extraction Form Qualitative Systematic Review.

Definition		Coding Levels		
		Coding Level 1: Verbatim quotations (please indicate by italics) and participant	Coding Level 2: Interpretations of authors	
● Setting	▶ City, region, country (e.g. urban, rural)			
	▶ Type of study site (e.g. primary care, hospital, home, school, occupational setting)			
	▶ Number of study sites			
	▶ physical characteristics			
	▶ work environment			
	▶ Effect of location on affected stakeholder			
	▶ Relevant changes over time (e.g. urbanisation)			
	● Geographical	▶ Geography (e.g. altitude, desert, forest, water)		
		▶ Climate (e.g. temperature, rainfall)		
		▶ Human land use (e.g. degree of urbanisation, agriculture, industry)		
		▶ Infrastructure (e.g. water and sanitation, energy, transport)		
		▶ Access to health care system		
		▶ Geographical isolation		
		▶ Relevant changes over time (e.g. infrastructure development, crop failures)		
● Epidemiological	▶ Demographics (life expectancy, gender, age, ethnicity, genetic factors)			
	▶ Population density, fertility patterns, family size			

- ▶ Incidence/prevalence and severity of disease, morbidity and mortality

- ▶ Spatial distribution of disease across geographical areas

- ▶ Relevant changes over time (e.g. epidemics)

- ▶ Social or socio-economic status attributed to education, income, occupation marriage, or gender

- ▶ Financial aspects (income, wealth)

- ▶ Occupational aspects (employment status, working conditions)

- ▶ Living conditions (housing, neighbourhood characteristics)

- ▶ Determinants of needs of people directly affected by disease/condition

- ▶ Burden of disease

- ▶ Determinants of needs of people indirectly affected by disease/condition

- ▶ Fiscal environment

- ▶ Market environment

- ▶ Access to health care system

- ▶ Relevant changes over time (e.g. inflation, recession, economic crisis)

- ▶ Language and means of communication

- ▶ Symbols, heroes, rituals

- ▶ Values (e.g. evil vs. good, dirty vs. clean, dangerous vs. safe, abnormal vs. normal)

- ▶ Beliefs (e.g. superstition, fate or destiny)

➤ Socio-economic

➤ Socio-cultural

- ▶ Religiosity and spirituality
- ▶ Knowledge and perceptions (e.g. with respect to significance of health issue, options for resolving health issue, multiple benefits and drawbacks of technology)
- ▶ Lifestyle (population's patterns in nutrition, smoking, substance abuse)
- ▶ Discrimination
- ▶ Social capital and resources available through social relationships, specifically social networks, norms of reciprocity, and trust
- ▶ Social cohesion, including relational, material, and political dimensions, information exchange, networks of support, and informal social control
- ▶ Historical and contemporary social power relations
- ▶ Sociodemographic profiles
- ▶ Psychosocial factors
- ▶ Social and societal context
- ▶ Structural social inequalities (e.g. Gender inequalities, caste system)
- ▶ Community characteristics and level of coordination/involvement with community
- ▶ Relevant changes over time (e.g. social changes or social movements)
- ▶ Political system and civil society's structure
- ▶ Players, interests, resources, objectives, formal and informal rules

- ▶ Distribution of power
- ▶ Political culture and socio-political climate
- ▶ State-society relations
- ▶ Political situation including political stability and absence of violence, government effectiveness, voice and accountability, control of corruption, rule of law, regulatory quality, participation, accountability, transparency, efficiency, decency, and fairness
- ▶ Economic management, economic policy and political framework of markets
- ▶ Politics and gender
- ▶ International integration
- ▶ Ideology
- ▶ Short-term thinking
- ▶ Influential people
- ▶ Payer, donor or funder policies
- ▶ Political authority
- ▶ Health Care System (e.g. governance and leadership, resources, service delivery, integration of patient's needs and perspective)
- ▶ Access to health care system
- ▶ Relevant changes over time (e.g. political reform, change of government)
- ▶ Norms, values and beliefs underlying legislation
- ▶ Specific legislation (e.g. patient rights, data protection)

▶ Regulatory provisions concerning healthcare personnel and their rights and duties

▶ Guidelines

▶ Decision-making in care delivery

▶ Sharing of information with indirectly affected stakeholders

▶ Legislation

▶ Relevant changes over time (e.g. introduction of new regulation or legislation)

▶ Morality and beliefs influencing the behaviours of individuals in their private or professional capacity, and/or of institutions

▶ Standards of conduct and principles guiding the behaviours of individuals in their private or professional capacity, and/or of institutions

▶ Autonomy

▶ Moral stress

▶ Privacy

▶ Conflicting interests

▶ Relevant changes over time (e.g. changes in standards of conduct within a healthcare organisation)

Please add additional lines for new themes!

● Ethical

● Other
(please specify)

8.2.2.2 *Implementation*

Please try to answer the following questions regarding each domain of the implementation dimension!

- ▶ What mechanisms and processes in the [respective domain] are applied in the implementation of the intervention?
- ▶ How do these mechanisms and processes enable or limit implementation?
- ▶ How do provider characteristics interact with other domains of implementation or context?

Dimensions

Coding Levels

Coding Level 1: Verbatim quotations (please indicate by italics)
Coding Level 2: Interpretations of authors and participant

DELIVERY

Provider

- ▶ Personality attributes (e.g. openness, curiosity)
- ▶ Skills
- ▶ Knowledge
- ▶ Emotion Memory, attention and decision processes
- ▶ Beliefs about consequences and optimism
- ▶ Beliefs about capabilities and self-efficacy
- ▶ Attitude towards intervention/technology
- ▶ Motivation, intention and goals
- ▶ Behavioural regulation
- ▶ Social/professional role and identity

Organisation and Structure

- ▶ Continuity of organisation, information and staff
- ▶ Coordination of teams
- ▶ Collaboration within teams
- ▶ Cooperation with other external providers
- ▶ Size and structure
- ▶ Networks & communication
- ▶ Cosmopolitanism
- ▶ Organisational policies, guidelines and practices
- ▶ Organisational culture
- ▶ Organizational climate

- ▶ Team dynamics
- ▶ Leadership, supervision and guidance
- ▶ Training and knowledge transfer
- ▶ Implementation Climate
- ▶ System readiness to change
- ▶ Peer pressure
- ▶ Change agents and champions of change

● PROGRAMMING

- Finance
 - ▶ Funding and reimbursement programs and also purchaser-provider contract
 - ▶ Financial incentives on all levels:
 - ▶ Change In Income For Provider, Pay-For-Performance Incentives
 - ▶ Changed Cost For Patient (Mäkelä and Thorsen, 1999)
 - ▶ Changed Cost For Practice Organisation
 - ▶ Changed Cost For Health Care System, Etc.
 - ▶ Economic climate and the availability of resources
 - ▶ Availability of service, research and foundation grants
 - ▶ Availability of payment models
 - ▶ Continuity of funding and fiscal support
 - ▶ Support tied to federal and state policies
 - ▶ Fit of funding with existing service funds
 - ▶ Willingness of funding sources to adjust requirements

• Policy

- ▶ Donor policies Prioritizing: priority on societal agenda
- ▶ Political Culture and Climate: ideology, short-term thinking, contracts, influential people, corruption, political stability
- ▶ External mandates
- ▶ Public or benchmark reporting
- ▶ Political directives or incentives, political mandates (must-dos)
- ▶ Meeting the needs of the society
- ▶ Navigation of health and social systems
- ▶ Social protection of all affected stakeholders
- ▶ Legislation, policies, programmes, incentives, initiatives, regulations put in place to initiate, support or foster the implementation of an intervention/technology and their impact
- ▶ Policymakers use of EBP
- ▶ Advocacy of intervention/technology and its implementation

• Other
(please specify)

Please add additional lines for new themes!

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



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