Context and implementation: A concept analysis towards conceptual maturity

Summary

Context and implementation of health interventions have received increasing attention over the past decade, in particular with respect to their influence on effectiveness and reach of complex interventions. The underlying concepts are both considered partially mature, limiting their operationalization in research and practice. We applied systematic literature searches and pragmatic utility (PU) concept analysis to provide a state-of-the-art assessment of the concepts "context" and "implementation" in the health sciences to create a common understanding for their use within systematic reviews and HTA.

We performed two separate searches for context (EMBASE, MEDLINE) and implementation (Google Scholar) to identify relevant models, theories and frameworks. 1~~8~~7 publications on context and 3~~6~~5 publications on implementation met our inclusion criteria. PU concept analysis comprises three guiding principles, selection of the literature, organization and structuring of the literature and asking analytic questions of the literature. Both concepts were analysed according to four features of conceptual maturity, i.e. consensual definitions, clear characteristics, fully described preconditions and outcomes, and delineated boundaries.

Context and implementation are highly intertwined, with both concepts influencing and interacting with each other. Context is defined as a set of characteristics and circumstances that surround the implementation effort. Implementation is conceptualized as a planned and deliberately initiated effort with the intention to bring an intervention into practice. The concept of implementation presents largely consensual definitions and relatively well-defined boundaries, while distinguishing features, preconditions and outcomes are not yet fully articulated. In contrast, definitions of context vary widely and boundaries with neighbouring concepts, such as setting and environment, are blurred; characteristics, preconditions and outcomes are ill-defined. Therefore, the maturity of both concepts should be advanced further to facilitate operationalization in systematic reviews and HTAs.

Key words

context, implementation, complex interventions, concept analysis, systematic review, health technology assessment

Abbreviations

CFIR	Consolidated Framework for Advancing Implementation Research
HTA	Health Technology Assessment

PARiHS	Promoting Action on Research Implementation in Health Services
PU	Pragmatic Utility

1. Introduction

The effectiveness of health interventions, as well as their success in reaching all relevant target populations, is critically influenced by their implementation in a given context; indeed, effectiveness, implementation and context are inextricably linked [1]. To date, however, limited information on implementation and contextual factors is reported in primary studies, nor are such considerations made sufficiently explicit in reporting guidelines, such as CONSORT, TREND or STROBE [2]. Likewise, systematic reviews and health technology assessments (HTA) fail to capture these factors in appropriate ways, which constitutes a major barrier in the appraisal of the generalizability of their findings and of their applicability in a specific setting [1]. Insufficient attention to context and implementation also contributes to the gap between research and practice as, even where there is adequate evidence of effectiveness, there may be insufficient detail to facilitate implementation [3].

The terms “context” and “implementation” are both widely used. Although the concept of implementation has received increasing attention over the past decades [4], both concepts are inconsistently defined and applied. According to widely used definitions, a concept is a mental representation of a phenomenon that combines and structures all of the characteristics of this phenomenon [5-8]. According to Morse, a mature concept is clearly and consensually defined, fully described, with clear characteristics, demonstrated preconditions and outcomes, and clearly delineated boundaries [9]. Based on these criteria, both “implementation” and “context” can be classified as only partially mature concepts. Such lack of conceptual maturity constitutes a major challenge to the advancement of theory, which tends to be built from clarified concepts or conceptual bricks, as well as the operationalization of concepts for research and practice [5,9-11]. Therefore, future research related to health interventions, including primary research as well as evidence synthesis, would greatly benefit from a clarification of both concepts.

In 2002, an analysis of the concept of context in a services setting was published, which was associated with the previously developed Promoting Action on Research Implementation in Health Services (PARiHS) framework [12]. This framework aims to represent the interplay of the many factors that influence the uptake of evidence into practice [13]. In this concept analysis, context was defined as the environment or setting, in which people receive health care services, or as the environment or setting, in which an intervention is to be implemented [12]. Being embedded within the PARiHS framework, the concept may be narrowly defined and have a limited extension. To our knowledge, no concept analysis of “implementation” has been undertaken to date.

2. Objective

Our objective was to conduct a concept analysis of the relevant research literature in an effort to provide a state-of-the-art assessment of the concepts “context” and “implementation” in the health sciences. This research was undertaken as part of the EU-funded Integrated health technology assessment for the evaluation of complex technologies (INTEGRATE-HTA) project (www.integrate-hta.eu). While addressing the two concepts from as broad a perspective as necessary for systematic reviews and HTAs, this research aims to create a common understanding of the concepts of context and implementation for use within systematic reviews and HTA.

3. Methods

We used a Pragmatic Utility (PU) concept analysis, as developed by Janice Morse [9,14,15]. PU concept analysis evaluates the current use of a concept by comparing and contrasting applications in particular disciplines, determining conceptual adequacy with competing concepts, and identifying gaps, inconsistencies, and boundaries. This approach sees concepts as combining probabilistic perspectives (attributes based on resemblances) with entity perspectives (must meet stringent criteria) [7], a view which can also be found in Critical Social Theory and Classical American Pragmatism, where the truth value is established by the usefulness of a concept to a discipline or program of research [16]. PU concept analysis is particularly suitable for the analysis of partially mature concepts, for which a significant body of theoretical and research papers exists but where uncertainties around the concept remain [9,15]. Based on four parameters of maturity, i.e. epistemological, pragmatic, linguistic and logical [9], and the fact that myriad definitions of “context” and “implementation” exist, both concepts can be categorized as partially mature, although implementation has been more theorized in the implementation science literature.

As proposed by Weaver and Mitcham (2008), PU concept analysis is based on guiding principles rather than a detailed series of steps [16]. First, relevant literature needs to be identified to ensure the validity of the concept analysis [16]. Secondly, this literature must be organized in a general way and then structured through decontextualization to reveal general features of the concept [9,16]. Finally, key analytical questions are formulated and asked of the literature to derive consistent dimensions and boundaries of the concept. Importantly, concept analysis is a non-linear, iterative process [16], which involves going back and forth between the different stages, which are described in more detail below.

3.1. Searching and selecting relevant literature

For this concept analysis, we included all original publications that develop, propose or describe a theory, model, approach or framework for assessing, analyzing and/or reporting

context, and/or implementation. The frameworks could be theoretical (i.e. derived from theory or first principles) or empirical (i.e. tested against observations, experiences or in experiments) in nature. Empirical studies could employ qualitative and/or quantitative methods and systematic reviews. Theoretical studies may comprise theory development based on literature reviews and/or experience.

For "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". We also used snowball searching in grey literature to identify relevant publications using the search terms "context", "setting" and "environment" For "implementation", a recent review by Damschroder and colleagues (2009), which comprises 19 frameworks, offers an overarching typology on implementation theory [17]. Based on this, forward searches were performed 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 included frameworks.

Titles and abstracts were screened by one researcher (LMP, KM, AG, AB, MT, KBL, BH, JB, EAR), Relevant full-text articles were screened by two researchers, with any differences in appraisal resolved through discussion.

3.2. Organizing and structuring the literature

The organization and structuring of the literature was initially undertaken by LMP and then reviewed by all team members. Included publications were organized according to the field from which the concepts used were originally derived (e.g. health, psychology, social science, organizational, business and management sciences), as well as definitions, characteristics, field of application (e.g. primary care) and contained model(s) (e.g. Consolidated Framework for Advancing Implementation Research (CFIR)). We also extracted information on the methods used to develop the concept (e.g. primary qualitative research).

For a more in-depth structuring of the concepts, we reviewed their features by decontextualizing information and attributing them to three major themes, i.e. characteristics, preconditions and outcomes, and boundaries of the concepts [9]. By applying exploratory and elemental methods of coding [18] to the decontextualized information, themes were identified within categories and compared with each other. Definitions, characteristics, preconditions and outcomes, and boundaries were also used as an overall structure for presenting the results.

3.3. Asking key questions of the literature

Key analytic questions were developed inductively and deductively, with questions arising from the literature (e.g. from implications for future research described in the included studies) and being proposed by the research team during the process of becoming acquainted with the included studies. Key questions comprised:

- How do agents 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?

These questions were answered from the included literature by LMP with assistance from all team members.

4. Results

4.1. Selection and organization of literature

For "**context**", the searches in EMBASE and MEDLINE yielded 2,266 records after de-duplication. Screening of titles and abstracts yielded 44 papers for full-text screening. 18 publications were identified via grey literature search. , with 187 publications were eventually being included in the concept analysis. With original definitions and concepts of context being derived from health, business and management sciences as well as social sciences, we were using the health literature as a lens through which to examine the other disciplines. Besides the concept analysis by McCormack et al. [12], tThe analysis of the concept of context was based on systematic reviews [19], non-systematic literature reviews [20-23][17,20,21], primary qualitative studies [2,22,23] and, mixed-method approaches [3,24-29]. [12] or theoretical approaches [3, 30, 31]. For two publications, the method of development was unclear [30,31].

For "**implementation**", the searches in Google Scholar yielded 4,445 records after de-duplication. The full texts of 72 publications were screened, and with 365 publications eventually metmeeting the predefined inclusion criteria. Definitions and concepts of implementation in included studies were based on health, psychology, social science, organizational, business and management sciences, and education. Findings were based on systematic reviews [19,32-34] non-systematic literature reviews [17,35-42], primary qualitative [23,43-46] or quantitative studies [47,48], mixed-method approaches [32,49,50] and theory [43,51-62][51-62]. Figure 1 shows the study selection process for all records identified through the searches.

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Both context and implementation are concerned with an "object". Objects were a specific technology [32,35], an intervention [17,23,37,41,44], innovations [19,34,36,60], evidence-based practices [38,39,42,43,45,47,48,50-53,59] or quality improvements [33,49]. However, terminology also varied within publications, comprising programs, policies, or, more generally, change. Moreover, conceptualizations differed in their objective: while some authors operationalized their conceptualization so as to facilitate the quantitative measurement of context [22], others applied a more descriptive qualitative conceptualization (e.g. [20]).

At a very early stage the concept analysis revealed that context and implementation are highly interconnected. Implementation of an object always takes place in a given context, and this context influences how implementation takes place [17]~~[52]~~. Likewise, the underlying concepts usually relate and refer to one another. Nevertheless, for the operationalization of both concepts in primary research, systematic reviews, and HTAs, we considered it useful to continue to treat the two concepts as distinct while taking significant overlaps and interactions into account. Therefore, whenever publications selected for the concept analysis of implementation yielded any information concerning the concept of context, the publication was also analyzed for context, and vice versa. In the following, findings are structured according to the anatomy of concepts, ~~,~~ i.e. definition, characteristics, preconditions and outcomes as well as boundaries.

4.2. Context

4.2.1. Definitions of context

In the included studies, the concept of "context" was either used in a discrete, specific way [17] with a definition being provided, or employed in a broader, general way [13]. Context has been described as environment [12,26], setting [12,26], a defined area or location [25], the work setting [24], a set of circumstances or unique factors surrounding an implementation effort [17], or any information that can be used to characterize the situation of an entity [27]. Such entities tend to be organizations [24,27] or communities [25]. "Setting" usually has a narrower focus [17]. It often refers to the place where an intervention is delivered (e.g. primary care setting [3]) or the circumstances of an intervention (e.g. low-income setting [22]). All definitions, where provided, can be found in ~~Table 1.~~Table 1.

4.2.2. Characteristics of context

Context is characterized as having a broad scope [17], being complex and dynamic [12], constantly changing ~~(B. McCormack et al., 2009)(Brendan McCormack et al., 2002)~~[26], and

rarely straightforward [26]. It can be perceived as something physical [30], or as a non-physical construct (e.g. [12,25]).

Elements of context exist within complex, multi-layered systems [3,52] and, within these systems, may be allocated to– formal or informal – groups or clusters [12,23]. These elements interact not only with each other, but also with a broader environment [12], usually in non-linear ways [23]. The interfaces or boundaries of these elements are dynamic and precarious [17]. This also reflects the subjectivity of context [23,25,27], with subjectivity not only relating to individuals or entities but also to the objects considered [19]. Despite this complexity, elements [12], levels of analysis or layers [19] and boundaries are discernible [12,26], where elements and subsystems are nested in larger systems or environments [3,12,19,24].

Propositions to structure interacting elements of context include: structural, organizational, provider and recipient levels [19]; outer setting, inner setting and characteristics of individuals [17]; inner and outer context [43,47,52]; potential (individual intentions, collective commitment) and capacity (material resources, social roles, social norms, cognitive resources) [56]; external and internal factors [38]; and contextual factors associated with micro-, meso- and macro-levels [44].

4.2.3. Preconditions for and outcomes of context

In the health sciences, context is usually considered in relation to an "object", such as the translation of knowledge [22] or the implementation of a technology or intervention [33]. It also applies to the practice context in which people receive care [12] or the broader context that exerts its influence on people's behaviors [28] or functioning [30].

Context is not only a "backdrop" for implementation [17], but is attributed a concrete role in influencing or interacting with an object [27]; thereby it can directly influence implementation outcomes and success [33]. These objects are structured [3], modified [24], facilitated [3], enabled [3] and constrained [3,30] by context. Context can be receptive [35] and ready for change [17], and have absorptive, normative or relational capacities for change [35,49,56]. As such, some attributes of context can be modified to make them an active component of the intervention to enhance implementation and effectiveness [29].

4.2.4. Boundaries of context

As described above, the terms context, setting and environment are sometimes used interchangeably in the literature, although boundaries do emerge. Whenever a distinction between context and setting is made, setting refers to something narrower, more specific, organized and "physical" than context [3,17]. Whenever a distinction between context and environment is made, environment is described as something external to the organization

[23,37], as the social or monetary environment [32] or the community or society within which a smaller system operates [33]. In contrast, for Damschroder et al (2009), setting embraces the "environmental characteristics in which implementation occurs" [17]. Importantly, context comprises both concrete, physical and more abstract, social, cultural and economic dimensions, although many applications focus on only one of the two, often determined by the specific object under investigation [61].

4.3. Implementation

4.3.1. Definitions of implementation

The concept of ~~i~~"implementation" is defined as a process [19], a constellation of processes [17], a stage of adoption [35], a transition period [17], efforts [53], methods [60] or means [17] designed to get practices into use or to apply new practices in a specific setting or context [34], a gateway between the decision to adopt and the routine use of an intervention [17], a social organization of bringing a practice into action ~~[63]~~[57] or a function of various factors [61]. Some authors remain deliberately vague when describing implementation as "putting an innovation into practice" [34]. All definitions provided in included publications are shown in Table 2.

4.3.2. Characteristics of implementation

Implementation is characterized as dynamic or active, planned, deliberately initiated [56], complex [55], multi-faceted [55], orchestrated [44], iterative and driven by and embedded in organizational strategy [44]. Implementation is not an all-or-nothing construct, but exists in degrees along a spectrum [34].

In view of the growing research area of implementation science, concept analysis has identified rich insights into the characteristics of implementation. These are presented here according to implementation goal, levels, process, strategy and agents.

4.3.2.1. Implementation goal

The general goal of implementation is for targeted populations or entities to use the object in effective ways [54], to facilitate improved patient and/or organization outcomes [24], ideally over extended periods of time to ensure sustainability [45,46] . Examples of more specific goals are to implement evidence-based practice, to deliver a new intervention, technology or policy, to improve a management process, to maximize effectiveness or efficiency, and to change organizational culture [38].

4.3.2.2. Implementation levels

Implementation can occur at multiple levels, where it interacts with multiple contextual factors [17,19]. These levels include the individual [19], the community [32,58], a unit within an organization, the organization as a whole [19] as well as the broader system (e.g. [19,43]). The implementation of objects can target one level (e.g. [37]) or several levels (e.g. [19,60]).

4.3.2.3. Implementation process

The implementation process can be considered as a whole (i.e. umbrella process) or structured into sub-processes [17], steps, phases, stages or activities [17] involving multiple decisions, actions, corrections, refinements, re-evaluations, expansions [17,58], methods and tactics [38] undertaken by agents [56]. The implementation process is characterized as active [17], multistage [60], recursive [54], cyclical and non-linear [54], interactive [54], formal or informal [17], and dynamic [38]. These processes may simultaneously occur at multiple levels [17], with processes overlapping when activities relating to one stage continue to occur or re-occur even after activities related to the next stage have begun [58].

4.3.2.4. Implementation strategies

Implementation strategies comprise specific means or methods to ensure that objects are adopted and sustained, thereby becoming part of routine practice [35,47]. They relate to assumptions on how change needs to be executed [32,58,59] through a set of activities chosen and tailored to fit the specific implementation context [43,53], or to create such a context [43]. Therefore, implementation strategies can be considered complex interventions in their own right, as they often address multifaceted processes within interpersonal, organizational, and community contexts [59].

Implementation strategies can serve a task-oriented (a strategy is implemented within a relatively short timeframe) or broader purpose (a strategy is targeted at long-term transformational change within an institution) [45]. They include push and pull schemes ~~[62]~~ [59], carrot or stick strategies [59] and bottom-up and top-down approaches [32,59]. Additionally, intervention strategies can be discrete (e.g. toolkits, checklists, algorithms, protocols, guidelines [59]) or complex (e.g. learning collaborative [59], support teams [58], economic, fiscal and regulatory strategies [59]).

4.3.2.5. Implementation agents

Broadly, implementation agents comprise all individuals engaged with deciding to implement a given object (e.g. funders, administrators), implementing a given object (e.g. providers, advocates) or being the target or otherwise affected by that same object (e.g. patients, consumers). Indeed, as an intervention is adopted and used by individuals within a unit,

organization, community or system these individuals are also key stakeholders ~~-~~and act as active agents whose buy-in is critical for successful implementation [19]~~ [17]~~. Individuals have agency, make choices and can wield power and influence on one another [17]. Therefore, suitable individuals need to be carefully involved in implementation as opinion leaders, internal implementation leaders, champions and external change agents [17].

4.3.3. Preconditions for and outcomes of implementation

Elements of context act as predictors [35], precedents [35], antecedents [56] and preconditions for implementation, its outcomes [35] and success [19]. Different aspects of context may impact different phases of the implementation process differently [47,52]. A further characteristic is the fit of the object with the system into which it is implemented [17,39,43,46]. Clearly, the characteristics of an object, in particular its effectiveness, influence implementation and thus must be taken into account [53]. More specifically, the quality [17,19] of the evidence supporting effectiveness, the relative advantage of utilizing an innovation above existing practices or alternative solutions [17,19], cost [17] and intervention source (external or internal) [17] are of importance.

Principally, effectiveness outcomes must be differentiated from implementation outcomes [38,47,53], with the latter occurring at different stages of implementation [19]. They may be intended or unintended [32], can be assessed at different levels [32], and may be process (e.g. fidelity) or content outcomes (e.g. organizational performance) [38]. It should be noted that implementation outcomes, in turn, have implications for continuing and future implementation efforts [61]. Important implementation outcomes identified in the literature are fidelity [19,38,47], adoption [19], uptake [42,45], acceptability [42], implementation cost [19], penetration [19], sustainability [17,19] and dissemination to other contexts [17].

4.3.4. Boundaries of implementation

Neighbouring concepts encountered in included publications are dissemination, diffusion and normalization. Dissemination and diffusion both relate to the transmission of information about an object, with the former being purposive and proactive and the latter being unintentional and passive. Diffusion is described as an informal, unplanned [36], natural and passive process [60] of transferring information within a given context [60], where, as a result, agents may or may not adopt an object [36]. Dissemination, on the other hand, is characterized as a formal, planned and active process, effort or method [34,36,60], which intends to transmit information about an object [34,60] and/or to persuade a target group to adopt the object [42]. In this way, dissemination can also be considered a specific implementation strategy [32]. Normalization into practice occurs when an object is fully

integrated with everyday practice [56] and therefore is related to the long-term outcomes of implementation and the idea of sustainability.

5. Discussion

5.1. Key findings

This concept analysis has provided a broad and in-depth overview of the current use of context and implementation in the health sciences with the purpose of clarifying the use of both concepts in primary research as well as evidence synthesis. Although implementation and context are two highly intertwined concepts, we found it fruitful to separate context and implementation in two dimensions while being explicit about the interactions between both.

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

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 practice. These efforts are undertaken by agents, which are either actively promoting the use of the intervention or adopt the newly appraised practices. They are usually structured in an implementation process consisting of specific implementation strategies. Context and its characteristics are preconditions for implementation, and implementation is measured in terms of outcomes such as adoption, uptake or sustainability. Fidelity was described as the outcome of an implementation effort by various authors, however, fidelity is also considered a moderator of the relationship between interventions and their intended outcomes [63]. Considering neighbouring concepts such as dissemination and diffusion, clear boundaries can be recognized in relation to the degree of planning and the formalization of processes.

~~As described in the introduction, a~~A fully mature concept has clear and consensual definitions, clearly described characteristics, fully described and demonstrated preconditions and outcomes as well as delineated boundaries [9]. Broadly speaking, implementation definitions are consensual although they vary in breadth; boundaries to neighbouring concepts are relatively well-defined. On the other hand, the distinguishing features of

implementation are not yet fully articulated, nor are its preconditions and outcomes. Therefore, while some aspects of the concept of implementation are clearly delineated, conceptual maturity can still be advanced further. Context, on the other hand, clearly represents a concept that is only partially mature with definitions and terminology varying widely and blurred boundaries with neighbouring concepts, such as setting and environment. Characteristics, preconditions and outcomes of context are not clearly delineated.

5.2. Strengths and limitations

Our work combines the strengths of a systematic review approach, characterised by a precise research question, a broad search strategy and explicit pre-defined inclusion criteria, with the strengths of a concept analysis, which followed clearly described guiding principles but also pursued iterations in interpretation, in particular to assess the inter-connectedness between the two concepts under review. This allowed us to produce a valid and comprehensive assessment of conceptual maturity in relation to definitions, characteristics, preconditions and outcomes and boundaries of context and implementation.

Nevertheless, our work also shows important limitations.

First, while we employed a broad search strategy to ensure that the use of both concepts is captured as comprehensively as possible, for pragmatic reasons we limited our searches to key health sciences databases, and application in the health sciences was one of the inclusion criteria. Interestingly, the use of both context and implementation is strongly influenced by organizational, social, psychological, business and management sciences and other disciplines, and an ideal concept analysis should therefore also pursue broader searches in interdisciplinary databases. Nevertheless, we believe that the aspects most applicable to the health sciences are likely to be integrated with the included publications, especially as these represent a range of health disciplines, from clinical research to e-health technologies and public health.

Secondly, pragmatic utility concept analysis is considered an evolving method, whose strengths and limitations have been widely discussed in the literature. It has been criticized for being limited to partially mature concepts for which an adequate sample of literature exists, ~~[16]~~ and for not providing a comprehensive manual to guide the approach [16]. In our work, we did identify a significant body of literature and attempted to be as explicit as possible about how we put the method into practice. Nevertheless, we attempted to preserve an important advantage of the method in that it does not adhere to a linear sequence of steps but allows to follow emerging nuances [15]. While Penrod and Hupcey refer to pragmatic utility as a method that is only applicable to concept advancement [64,65], it becomes clear from those studies that have ~~have~~ actually employed pragmatic utility~~, it~~

~~becomes clear~~ that the method allows both analysis and advancement [16]. ~~, with o~~Our work ~~having~~ focused primarily on analysis. While other types of concept analyses could have been applied as well, there is no consensus in the literature regarding the most suitable approach.

Finally, the concept analysis was primarily performed by LMP. We attempted to limit subjective interpretation by applying both elemental (especially in-vivo coding) and exploratory coding [18], thus resulting in an analysis that is grounded in the included publications. Moreover, important steps in the analysis were conducted in cooperation with, or discussed with, the whole team.

5.3. Implications for primary research, systematic reviews and HTAs

This concept analysis is based on a comprehensive review of the state-of-the-art use of the concepts of context and implementation in health-related literature. It thus adds to current health research by contributing to greater conceptual clarity of two concepts that are of major importance for closing the gap between research and practice. Implementation can be considered a concept of intermediate maturity which would benefit from~~in terms of consensual definitions and clear boundaries, although~~ further development ~~will need to be undertaken~~ in terms of agreeing and structuring its characteristics as well as its preconditions and ~~specific~~ outcomes. The concept of context is relatively less mature~~, as it lacks a consensual definition and boundaries and is ill-defined in terms of characteristics, preconditions and outcomes. It~~ whereas ~~therefore~~ it requires much research to advance conceptual clarity.

Both concepts are of particular importance when working on complex health interventions, where context and implementation both play a critical role in relation to population reach and effectiveness. ~~both play a critical role in relation to population reach and effectiveness.~~ Both concepts should be used for the design and evaluation of complex interventions and the assessment of what works for whom in what circumstance. Therefore, they should be clearly documented and reported throughout primary as well as secondary research~~.~~ Given the breadth of health sciences, ranging from biomedical to population-level approaches, it might also be relevant to investigate differences in concept operationalization for different sub-disciplines.

Moreover, there is a need to develop comprehensive, yet flexible reporting guidelines for primary research, in particular effectiveness research (e.g. randomized controlled trials ~~or natural experiments~~ [[2]]), implementation research (e.g. process evaluations [[66]]) but also qualitative research (e.g. enablers and barriers to the uptake of interventions), which reflect the importance of context and implementation. An example for reporting guidelines of primary research comprising both concepts is the CReDECI guidelines that should be used

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alongside study design-specific reporting guidelines [67]. For systematic reviews and HTA, future research should work towards the development of a comprehensive framework and toolkit for assessing the relevance of context and implementation, in particular with respect to complex interventions.

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[17][68][69][70][17][71][26][12][12][13][33][72][17][73][74][53][75][56][76][34][77][44][60][78-81]

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