

Key domains of context and implementation and their assessment in systematic reviews/HTA of complex health interventions

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Background: The effectiveness of complex interventions is critically influenced by implementation and context. To date, limited information on implementation and contextual factors is included in primary studies and, consequently, in systematic reviews. This constitutes a major barrier to the appraisal of the generalizability of the findings of a systematic review and their applicability in a specific setting and context. To our knowledge, no framework exists that describes key domains of context and implementation comprehensively.

Objectives: To review concepts of setting, context and implementation, to propose a comprehensive framework, and to operationalize this in an assessment template for systematic reviews.

Methods: We conducted literature reviews on terminology, concepts and frameworks of context and implementation, their constituent components and the use thereof in primary research and systematic reviews. In a first step, constituent components recurring under various labels across different frameworks were collected and reviewed. In a second step, existing components were selected for inclusion and supplemented with additional components, and structured under clearly defined key domains and integrated in a consolidated, comprehensive framework.

Results: We propose a multi-layered framework comprising implementation and context - with setting being one domain of context - as distinct dimensions. Implementation embraces the key domains programming and delivery; context includes setting, community and key domains related to social, cultural, political and other aspects. Based on this framework, we developed a matrix to assess generalizability and applicability, which allows the assessment of each of these domains for systematic review authors. Conclusions: This guidance is designed to complement existing reporting and evaluation guidelines on context and implementation in primary as well as in synthesis research of complex interventions. The guidance will be tested in several systematic reviews of complex interventions and revised as needed.