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Determinants of complexity in clinical practice guidelines: a Delphi study including perspectives from guideline developers and implementers

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ABSTRACT

The Medical Research Council proposed a framework to develop and implement complex interventions in practice. How to adopt these interventions is described in recommendations of evidence-based clinical practice guidelines. Many factors may influence the complexity of a guideline. The aim of this paper is to describe the determinants of complexity in the development and implementation of an evidence-based clinical practice guideline.

A working group with 16 participants was established, consisting of a debate team and a Delphi panel. The debate team discussed online to define the key elements of the MRC's definition of a complex intervention to see whether these elements are applicable to guidelines. These elements were presented to the Delphi panel to assess their relevance. After the first round, consensus was reached on eight elements, with the inter-rater reliability varying from 0.83 to 1.00. After the second Delphi round, consensus was reached on two more elements. The consensus stated that these ten elements all define an aspect of the complexity in guidelines. There was no agreement regarding the exclusion of a specific element.

Developers and end-users consider that the complexity of a guideline and its implementation is affected when the number of components, settings, targeted behaviors, and stakeholders increase; when a gap exists between the guideline and the reality of clinical practice; or when differences in education are evident between end-users. Moreover, the level of collaboration required of the different end-users, the scope of change, the level of evidence in the guideline, and the workload for end-users also determine complexity.

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Keywords: complexity; determinants; guidelines; evidence-based practice; implementation science

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What is already known about the topic

- The Medical Research Council produced a framework describing the complexity of interventions to facilitate the development and implementation of such interventions.
- The implementation of clinical practice guidelines can be challenging.
- The use of an evidence-based implementation theory, model, or framework increases the chances of successful implementation.

What this paper adds

- This paper describes the complexity in guidelines.
- An international working group of experts agreed on ten determinants via consensus and a Delphi procedure.
- The ten determinants include: the number of components; setting; targeted behaviors; stakeholders; level of collaboration needed; scope of change; level of evidence in the guideline; workload for end-users; differences in education; and when a gap exists between the guideline and reality.

INTRODUCTION

The Medical Research Council (MRC) produced a framework to develop and implement complex interventions in practice. This framework was first developed in 2006 and updated in 2021.[1] The MRC defines complex interventions as those that contain several interacting components. These components may include behaviors, parameters of behaviors (e.g., frequency, timing), and methods of organizing and delivering those behaviors (e.g., type and level of support provided to the recipient). The complexity of an intervention increases depending on the properties of the intervention itself or through interactions between the intervention and the context in which it is implemented.[1] How to adopt these interventions should be described in recommendations of evidence-based clinical practice guidelines.

Many factors may affect the complexity in the content of a guideline. In the Handbook for Guideline Development, the World Health Organization (WHO) defined this complexity through features of the intervention and the system in which the guideline recommendations will be applied.[2] In 2019, the WHO emphasized that the complexity of an intervention must be considered *while formulating* the recommendations.[3] Thus, it is important to properly describe the complexity of an intervention in the related recommendations in a guideline, as this will support its implementation in practice. Thus, the WHO stresses that complexity should be considered during the guideline *development* process.[4]

However, it is also important for care providers to understand complexity in terms of the *implementation* process. The use of an evidence-based methodology during implementation increases the chances of successful implementation. During the last decade, the use of evidence-based implementation strategies increased,[5] and many theories, models, and frameworks have highlighted various aspects of the implementation process.[6] However, little is known about the context in which a given method works.[6] By linking the implementation method to the guidelines in an effective way and selecting the appropriate implementation method, the complexity in guideline development and implementation can be reduced.

The aim of this paper is to describe the determinants, as used by guideline developers in the text of a guideline, which influence the complexity of the implementation of evidence-based clinical practice guidelines.

METHODS

Participants

To understand the determinants that may influence the complexity in guideline development and implementation, a working group of 16 participants was formed, consisting of a national Belgian debate team and a Delphi panel. The participants were purposefully selected because of their expertise. For the discussion team, only Belgian researchers were considered to facilitate discussion. For the Delphi procedure, international researchers were contacted because of their expertise. Some members of the national group also participated in the Delphi panel. Researchers and/or clinicians in the working group were classified into four categories according to whether they were involved in development, implementation, use, and/or evaluation of guidelines, with six to eight participants per category. Their years of experience in relevant fields ranged from as little as 2 years to 25 years, highlighting a mix of relatively new professionals and highly experienced ones. Educational backgrounds and professions varied significantly. More details on the participants can be found in Table 1.

Discussion team

The discussion team met online to define the key elements of the MRC's definition of a complex intervention to determine whether these elements were applicable to guidelines. After rigorous deliberation during two 1-hour meetings, the team identified 16 key elements that they believed potentially influenced complexity in guideline development and implementation. The notes from the meetings and a transcript were used to define these elements and

Table 1: Characteristics of the working group

Profession	Educational degree	Expertise in guideline				Years in relevant field	City / country
		development	implementation	use	evaluation		
College professor, researcher	RN, MSc		x			8	Antwerp, Belgium
Implementation coordinator, nurse at GP practice	RN, PhD		x			25	Leuven, Belgium
GP	MD	x		x		19	Bruges, Belgium
Health psychologist, research fellow	PhD		x	x		17	Leuven, Belgium
Associate professor, University of Liège	PhD	x				2	Liège, Belgium
Podiatrist, researcher, teacher	Msci	x				2	Brussels, Belgium
Coordinator cel validation, Cebam	Msci, PhD				x	20	Leuven, Belgium
GP	PhD	x		x	x	20	Liège, Belgium
Speech and language pathologist Associate professor, University of Liège	PhD	x				19	Liège, Belgium
Professor, Researcher, Methodologist	BMed Rad, GradDip Hlth Sc, PhD	x	x		x	17	Adelaide, Australia
Nurses manager	RN, MPH, MSc			x	x	24	Charleroi, Belgium
Senior research fellow	PhD, PostGrad Dip-Teach, MEd, BEd		x			10	Melbourne, Australia
Assistant professor	RN, PhD			x	x	4	Montreal, Quebec
Research director	PHN/RN, PhD	x	x		x	7	Helsinki, Finland
Physician expert	MD, MAS,	x	x		x	15	Brussels, Belgium
Implementation scientist, epidemiologist	PT, MPH, PhDc		x	x		31	Leuven, Belgium

indicate the reasons for their inclusion in the list. The technique of member-checking was used to increase credibility of the data. The list and the accompanying rationales are reported in Appendix I, http://links.lww.com/IJEBH/A326.

Delphi process

The 16 key elements were then presented to the Delphi panel to assess their relevance. All elements, along with the reasons why they could influence complexity, were presented via a Qualtrics questionnaire. The questionnaire used a four-point Likert scale, ranging from 1= strongly disagree to 4 = strongly agree, and a box was provided for open feedback.

The Delphi method is a structured communication technique, originally developed as a systematic, interactive forecasting method which relies on a panel of experts. Delphi techniques are used in health care to systematically bring together explicit and implicit knowledge from experts with a research or practical background, often with the goal of reaching group consensus.[8] Consensus standards and findings are important for promoting the exchange of information and ideas on an interdisciplinary and transdisciplinary basis, and for guaranteeing comparable procedures in diagnostic and therapeutic approaches. It is important to involve the relevant groups to take into account all relevant perspectives.[7]

After each Delphi round, one of the authors (HV) provided an anonymous summary of the experts' forecasts from the previous round. Consensus among the experts was determined based on inter-rater reliability (IRR). If the IRR was 0.8 or more, it was considered that consensus had been reached on that element. This threshold was chosen as it is generally accepted as a

good strength of agreement in statistical analysis.[9] In between the second and third Delphi round, an extra online meeting was held with the debate group to clarify the remaining elements. Through this methodical and collaborative approach, the research aimed to provide a more nuanced understanding of the elements that define complexity, and how these can be effectively incorporated into implementation frameworks.

Face validity

The Qualtrics questionnaire with the 16 key elements was presented to the participants of the Guidelines International Network (GIN) Implementation Working Group workshop during the September 2023 Conference in Glasgow and during the National Conference of Primary Care (AVDEL) in November 2023 in Brussels. The results of the Delphi panel, GIN, and AVDEL are presented in Table 2.

RESULTS

In total, three 1-hour debate meetings and three online Delphi rounds were held. The final process is presented in Figure 1. Aided by virtual Post-it notes, the participants brainstormed to define 16 elements that could potentially influence the complexity in guideline development and implementation (Table 2). The complexity was viewed and considered from four different standpoints (development, implementation, use, and evaluation). A description of each element and an accompanying example is provided in Appendix I, http://links.lww.com/IJEBH/A326.

After the first round (twelve participants), consensus was reached on eight elements, with the IRR varying from 0.83 to 1.00. After the second Delphi round (ten participants), consensus was reached on two more elements. The consensus stated that these ten elements all define an aspect of the complexity in guideline development and implementation. No agreement was reached regarding the exclusion of a specific element.

The feedback gathered from the Delphi panel highlighted challenges in determining the specific phase within guideline development and use where the complexity aligns. To remedy this problem, an additional team was formed to clarify the remaining elements presented to the Delphi panel.

Table 2: Estimation of relevance of the presented elements

	Elements from debate team	Delphi 1 *(IRR)*	Delphi 2 *(IRR)*	Delphi 1 & 2	GIN (n = 7)	AVDEL (n = 19)
1	Number of components in a guideline	0.75	>Relevant	>Relevant		>Relevant
2	Number of settings involved in a guideline	>Relevant		>Relevant	>Relevant	>Relevant
3	Number of behaviors targeted by the guideline	>Relevant		>Relevant		>Relevant
4	Number of outcomes targeted by the guideline	0.67	0.7		>Relevant	
5	Fit with reality of clinical practice of the guideline	>Relevant		>Relevant	>Relevant	>Relevant
6	Number of stakeholders involved in the development of the guideline	0.75	>Relevant	>Relevant		
7	Level of flexibility in the use of the guideline	0.67	0.6			
8	Differences in education of the targeted users of the guideline	>Relevant		>Relevant		
9	Applicability of the guideline to current practice	0.5			>Relevant	
10	Level of collaboration required of the different users of the guideline	>Relevant		>Relevant	>Relevant	>Relevant
11	Urgency of change	0.43	0.7		>Relevant	
12	Willingness to change (readiness)	0.75	0.6		>Relevant	
13	Scope of change required	>Relevant		>Relevant	>Relevant	
14	Level of evidence in the guideline	>Relevant		>Relevant		
15	Workload for the users of the guideline	>Relevant		>Relevant	>Relevant	>Relevant
16	Hardware needed for the users of the guideline	0.64	0.7		>Relevant	

IRR, Inter-rater reliability.

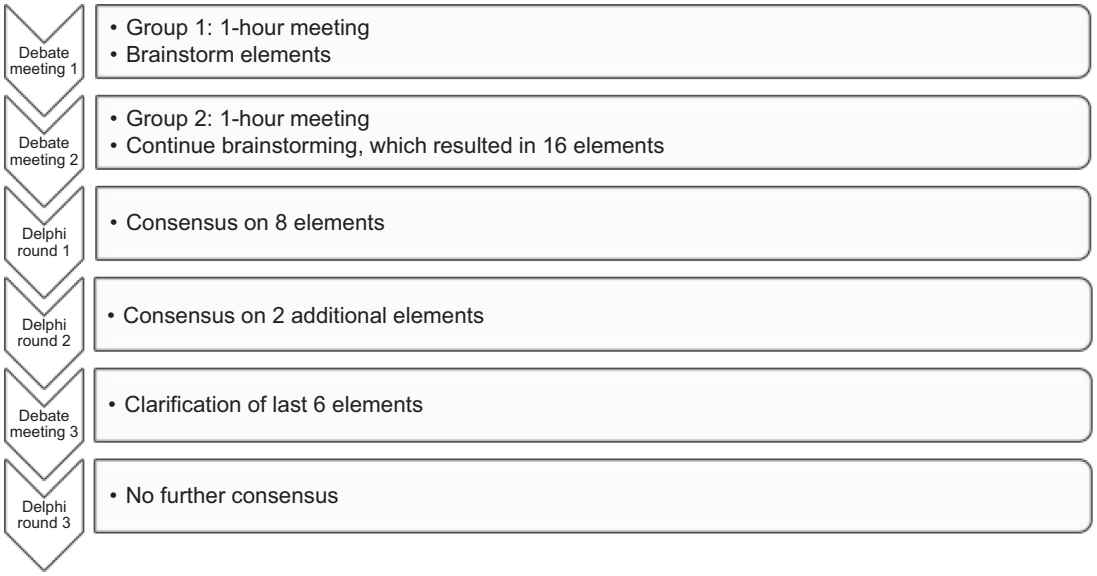

Figure 1: Delphi procedure.

At the debate, participants determined that the complexity within guidelines primarily stems from the challenges encountered during the implementation phase. Subsequently, the remaining elements were examined, and additional information was incorporated. This was then examined in the third Delphi round (eight participants). After this round, no further elements were identified as contributing to the complexity of guidelines.

Relevant determinants of the complexity in guidelines and their implementation include the number of components; setting; targeted behaviors; stakeholders; the fit with reality of clinical practice of the guideline; differences in education of the targeted users of the guideline; the level of education required of the different users of the guideline; the scope of change required; the level of evidence in the guideline; and the workload for the users of the guideline.

We tested face validity during the GIN conference and at the AVDEL conference. During the presentation at the GIN Implementation Working Group, seven participants completed the questions used in the second Delphi round. Ten determinants were considered relevant. However, the ten items identified as relevant differed from those identified as relevant by the Delphi panel. At the National Conference of Primary Care, six determinants were considered relevant by 19 participants. The details are presented in Table 2.

DISCUSSION

In this study, guideline developers and implementers sought to identify determinants in guidelines that interfere with the guidelines' development and implementation. During a brainstorming session, 16 potential elements were discussed and ten were identified as relevant to guideline complexity.

The results of our study confirm attributes of complexity, such as the scope of change or the number of components of a guideline, as identified by the WHO.[2] However, our study goes further and brings nuances to several of these features. In practice, it is the mixture of educational levels and skills of end-users that contribute to complexity when guidelines are brought into practice, where the WHO Handbook mentioned the high level of skills required. Numerous implementation projects use education as an important strategy. However, this study draws attention to the fact that education should be more than just knowledge transfer. It should also address the barriers, and therefore requires investigation of the knowledge base and skills of the targeted end-users.

The WHO Handbook describes adaptivity as the level of how "interventions may influence the context of implementation in a direct or more indirect way. . . The entire system adapts and responds in expected or unexpected ways."[2(p.246)] Therefore, we can expect that some interventions might have more influence than others. In our study, the experts emphasized the

fit with the reality of clinical practice of the guideline. This means that it is important to consider the perspective of the reader of the guideline. The implementation of an intervention that is far from the reality of daily practice will have an important influence on that practice and many adaptations will occur, expected or unexpected. This makes a sustainable implementation more complex. As an example, there will be a greater need to de-implement daily habits. Whereas the WHO Handbook states that a focus on behavior change increases complexity, the experts in our study stressed that it is the number of behaviors that must change that determines the complexity. Furthermore, our study describes two features that were not mentioned by the WHO Handbook: the level of evidence and the workload for the users. The level of evidence is an important facilitator for a guideline. Although this result may seem obvious, it is important to acknowledge the barriers to following the principles of evidence-based practice when guidelines do not exist or encompass low-level evidence. The workload element should be considered during the development of implementation plans at the prioritizing phase, together with the level of effectiveness, the risk for adverse events, and costs.

A recent study by Boaz *et al.*[10] emphasized the need to determine which strategies worked where and why. The authors stress the need to evaluate strategies in their context. Our present study is a useful complement to that study. We identified which determinants can make implementation more complex. Together with proper retrospective evaluation, this means a step forward in implementation science.

This study has a number of limitations. According to the theory of consensus, we should have repeated the last meeting to verify consensus on the remaining determinants. For resource reasons, we decided not to include these in the definition of the determinants. It may be that some of the six elements in fact contribute to the complexity in guideline development and their implementation. The varying results for GIN and AVDEL confirms the need to maintain a broader perspective in future research.

Finding a mutual language for developers and implementers is complex in itself, which is why some of the determinants still seem to be described quite vaguely. Piloting and rewording will partially bridge this gap. A preliminary pilot has already led to some rewording of this mutual language and a better understanding of the determinants.

This study is part of a larger project on complexity in guideline development and implementation. The results will be used to compare existing implementation theories, models, and frameworks by identifying which determinants of complexity are considered. Depending on the results, recommendations will be formulated or a tool will be developed to guide implementation practitioners toward the most suitable implementation process for their project.

CONCLUSIONS

Based on a consensus method, our results reveal that both developers and end-users consider that the complexity of guideline development and its implementation is affected when the number of components, settings, targeted behaviors, and stakeholders increases; when a gap exists between the guideline and the reality of clinical practice; or when differences in education are evident between end-users. Moreover, the level of collaboration required of the different end-users, the scope of change, the level of evidence in the guideline, and the workload for the end-users determine the complexity. The findings of this study have the potential to enhance the development, dissemination, and implementation of guidelines, ultimately leading to improved health outcomes.

ETHICS

No ethics approval was needed for this study. However, all participants agreed to participate. It was explicitly stated that participants could withdraw from the study at any time. All data were anonymized before publication.

DECLARATIONS

Consent for publication

All participants gave their consent for publication.

Availability of data and materials

All data are available from the corresponding author upon request.

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Author contributions

HV led all meetings. MC wrote the draft version of the text. All authors made substantial contributions to the text and reviewed all versions. AB and MC prepared the manuscript for publication.

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REFERENCES

1. Skivington K, Matthews L, Simpson SA, Craig P, Baird J, Blazeby JM, *et al*. A new framework for developing and evaluating complex interventions: update of Medical Research Council guidance. BMJ 2021;374:n2061.
2. World Health Organization. WHO Handbook for Guideline Development [internet]. WHO; 2024. Available from: https://www.who.int/publications/i/item/9789241548960
3. Rehfuess EA, Stratil JM, Scheel IB, Portela A, Norris SL, Baltussen R. The WHO-INTEGRATE evidence to decision framework version 1.0: integrating WHO norms and values and a complexity perspective. BMJ Glob Health 2019;4(Suppl 1):e000844.
4. Norris SL, Rehfuess EA, Smith H, Tunçalp Ö, Grimshaw JM, Ford NP, *et al*. Complex health interventions in complex systems: improving the process and methods for evidence-informed health decisions. BMJ Glob Health 2019;4(Suppl 1):e000963.
5. Peters S, Sukumar K, Blanchard S, Ramasamy A, Malinowski J, Ginex P, *et al*. Trends in guideline implementation: an updated scoping review. Implement Sci 2022;17(1):50.
6. Nilsen P. Making sense of implementation theories, models and frameworks. Implement Sci 2015;10:53.
7. Lockwood CS, Ivers NM. Implementation science: a primer. JBI Evid Implement 2023;21(4):307–9.
8. Niederberger M, Köberich S. members of the DeWiss Network. Coming to consensus: the Delphi technique. Eur J Cardiovasc Nurs 2021;20(7):692–5.
9. Polit FD, Beck CT. Nursing research: generating and assessing evidence for nursing practice. Wolters Kluwer; 2008.
10. Boaz A, Baeza J, Fraser A, Persson E. 'It depends': what 86 systematic reviews tell us about what strategies to use to support the use of research in clinical practice. Implement Sci 2024;19(1):15.

