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Development of a prioritisation tool for the updating of clinical guideline questions: the UpPriority Tool protocol

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Complete List of Authors:	Martínez García, Laura; Iberoamerican Cochrane Centre, Biomedical Research Institute Sant Pau (IIB Sant Pau) Pardo-Hernandez, Hector; Iberoamerican Cochrane Centre, Biomedical Research Institute Sant Pau (IIB Sant Pau); CIBER of Epidemiology and Public Health (CIBERESP) Niño de Guzman, Ena; Iberoamerican Cochrane Centre, Biomedical Research Institute Sant Pau (IIB Sant Pau) Superchi, Cecilia; Iberoamerican Cochrane Centre, Biomedical Research Institute Sant Pau (IIB Sant Pau) Ballesteros, Monica; Iberoamerican Cochrane Centre, Biomedical Research Institute Sant Pau (IIB Sant Pau) McFarlane, Emma; National Institute for Health and Care Excellence Posso, Margarito; Iberoamerican Cochrane Centre, Biomedical Research Institute Sant Pau (IIB Sant Pau) Roqué, Marta; Iberoamerican Cochrane Centre, Biomedical Research Institute Sant Pau (IIB Sant Pau) Sanabria, Andrea; Iberoamerican Cochrane Centre, Biomedical Research Institute Sant Pau (IIB Sant Pau) Selva, Anna; Corporació Sanitaria Parc Taulí, Clinical Epidemiology and Cancer Screening. Sparrow, Katrina; National Institute for Health and Care Excellence Vernooij, Robin W.M. ; Iberoamerican Cochrane Centre, Biomedical Research Institute Sant Pau (IIB Sant Pau) Alonso-Coello, Pablo; Iberoamerican Cochrane Centre, Biomedical Research Institute Sant Pau (IIB Sant Pau); CIBER of Epidemiology and Public Health (CIBERESP)
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Development of a prioritisation tool for the updating of clinical guideline questions: the UpPriority Tool protocol

Authors

Martínez García L[1]*, Pardo-Hernandez H[1,2], Niño de Guzman E[1], Superchi C[1], Ballesteros M[1], McFarlane E[3], Posso M[1], Roqué i Figuls M[1], Sanabria AJ[1], Selva A[4], Sparrow K[3], Vernooij RWM[1], Alonso-Coello P[1,2,5]

Author affiliations

(1) Iberoamerican Cochrane Centre, Biomedical Research Institute Sant Pau (IIB Sant Pau), Barcelona, Spain. (2) CIBER of Epidemiology and Public Health (CIBERESP), Spain. (3) National Institute for Health and Care Excellence, UK. (4) Clinical Epidemiology and Cancer Screening. Corporació Sanitaria Parc Taulí, Sabadell, Spain. (5) Clinical Epidemiology and Biostatistics Department, McMaster University, Hamilton, Canada.

Correspondence to:

Laura Martínez García. Iberoamerican Cochrane Centre. Hospital de la Santa Creu i Sant Pau, Sant Antoni Maria Claret 167, 08025, Barcelona, Spain. Tel: +34 93 553 78 08. E-mail: laura.martinez.garcia@cochrane.es.

Abstract

Introduction

Due to a continuous emergence of new evidence, clinical guidelines (CG) require regular surveillance of evidence to maintain their trustworthiness. The updating of CGs is resource-intensive and time-consuming; therefore, updating may include a prioritisation process in order to efficiently ensure recommendations remain up to date. The objective of our project is to develop a pragmatic tool to prioritise clinical questions for updating.

Methods and analysis

We will develop an initial list of items based on a systematic review of research evidence on prioritisation processes for updating. A multi-step process will be used to develop the UpPriority Tool, including a feasibility test, interviews with key informants, a Delphi consensus survey, an external review by both CGs methodologists and users, and a pilot testing.

Ethics and dissemination

We have obtained a waiver of approval from the Clinical Research Ethics Committee at the Hospital de la Santa Creu i Sant Pau, since this study will not involve patients or biological samples.

The UpPriority Tool will be developed for assessing any clinical question within a CG and should be easy to use in CG institutions. The standardisation of prioritisation processes for updating using the UpPriority Tool will improve the efficiency of resource use in the CG field. The results of the study will be published in peer-reviewed journals and communicated to interested stakeholders in international conferences and other platforms.

Keywords

Clinical guidelines, evidence-based medicine, methodology, updating, prioritisation.

Strengths and limitations

- Our study has several strengths. The development of the tool, we systematically reviewed the evidence on CG updating prioritisation [1] and will adopt a methodological approach we have successfully implemented in the past [1]. Also, by applying a formal consensus method (Delphi consensus survey), collecting experts' (semi-structured interviews and external reviews) and users' opinions (semi-structured interviews), we will reach a fair understanding of different stakeholders' perceptions about CG updating prioritisation processes. Finally, we will focus on clinical questions rather than CG sections or recommendations because they are the most manageable updated unit [3].
- Limitations of the study may include the representativeness of participants, a low response rate, the quality of the collected information, and a lack of a large scale validation of the tool.

Introduction

Clinical guidelines (CG) are "statements that include recommendations intended to optimise patient care that are informed by systematic reviews (SRs) of evidence and an assessment of the benefits and harms of alternative care options" [1]. Due to a continuous emergence of new evidence [5, 6], CGs require regular surveillance of evidence to maintain their trustworthiness [3, 7].

Several studies have assessed length of time that CGs and their recommendations remain valid [3-11]. Based on this evidence, most CG developers have adopted updating strategies based on predetermined timeframes [12].

An updating strategy involves different processes including the identification of new evidence; the assessment of the impact of new evidence on the current CG recommendations and whether an update is required; and the update of the CG if needed [12]. The updating of CGs is resource-intensive and time-consuming [9]. In the current context of restricted resources, there is a growing interest in approaches that support decision-making for updating CGs [1].

We define the prioritisation process for updating of CGs as the methodology used to determine which CGs should be prioritised in order to ensure that resources are invested in updating the topics that are most relevant to different stakeholders [1]. Typically, the essential stages in a prioritisation process can be conceptualised as 1) assessment of CGs using some sort of prioritisation criteria, and 2) classification of CGs in groups according to their relevance (e.g. high, medium or low relevance for updating) [1].

Different prioritisation processes could be implemented at different time points within an updating strategy. For example, a prioritisation process could be implemented to identify the CGs in greatest need of update (prioritisation across available CGs) [13, 14] or to identify the clinical questions in greatest need of update within a prioritised CG (prioritisation within a CG) [15, 16].

Until now, there is wide variability and suboptimal reporting of the methods used to develop and implement processes to prioritise updating of CGs [1].

Aims and objectives

Primary objective

- To develop a pragmatic tool to prioritise clinical questions for updating.

Secondary objectives

- To identify the most important items required to prioritise clinical questions for updating.
- To describe each item, establish a rating scale of items, and provides a guidance on how to rate them.
- To develop guidance on how to calculate and present priority scores to support decision-making for updating clinical questions within a CG.

Methods and analysis

The development of the UpPriority Tool will consist of a multi-step process including 1) generation of an initial version of the tool, 2) optimisation of the tool (feasibility test of the tool, semi-structured interviews, Delphi consensus survey, external review by CG methodologists and users, and pilot test of the tool), and 3) approval of the final version of the tool [table 1, figure 1].

Generation of the initial version of the tool

- **Objective:** To develop the initial version of the tool (items, scoring calculation, and summary report).
- **Methods:** Brainstorming and discussion taking into account a systematic review of research evidence on prioritisation processes for updating and experience of the UpPriority Steering Group (UpSG) [1, 2].
- **Population:** UpSG.
- **Data collection:** We will circulate the initial version of the tool among the UpSG via email and collect feedback.

Optimisation of the tool

1. Feasibility test of the tool

- **Objective:** To explore the feasibility and refine the initial version of the tool.
- **Methods:** Methodological survey.
- **Population:** A CG developed within the Spanish National Health System Clinical Guideline Program, published within the last two years, and with <50 clinical questions.
- **Sample size:** Convenience sample.
- **Data collection:** Two reviewers from the original Guideline Development Group (GDG) and two reviewers from the UpSG will apply the initial version of the tool. We will use online software to design the survey and collect responses (www.digestepiclin.com). The survey will be available online for one month; weekly email reminders will be sent to participants in order to increase participation.

- **Variables:** Response rate, characteristics of participants, characteristics of clinical questions, priority scores (single-item and overall-items), and overall assessment of the tool [table 2].
- **Data analysis:** For quantitative data, we will calculate absolute frequencies and proportions. For qualitative data, we will use content analysis to summarise and draw conclusions (atlasti.com) [17]. Questionnaires with no response in over 20% of the items will be withdrawn. We will draft a final report, discuss results, and refine the initial version of the tool with the UpSG.

2. Semi-structured interviews

- **Objective:** To identify current practices in prioritisation processes across CG development institutions and to refine the initial version of the tool.
- **Methods:** Semi-structured interviews (face-to-face, telephone or Internet).
- **Population:** CG developers that 1) have experience in CG development and/or updating (defined as having participated in GDG and/or Guideline Updating Group [GUG] at least once in the past year), and 2) are fluent in English or Spanish. We will identify participants with the help of the UpSG. When someone does not respond or cannot participate, another contributor will be recruited.
- **Sample size:** Convenience sample (≤ 10 participants). We will recruit participants and collect data until information becomes repetitive and no new information emerges (data saturation).
- **Data collection:** We will design an interview script to conduct the interviews. Interviews will be audiotaped and transcribed.
- **Variables:** Characteristics of participants, characteristics of CG development institutions, current practices in prioritisation processes for CG development and/or updating, and overall assessment of the tool [table 2].
- **Data analysis:** For quantitative data, we will calculate absolute frequencies and proportions. For qualitative data, we will use content analysis to summarise and draw conclusions (atlasti.com) [17]. We will draft a final report, discuss results, and refine the initial version of the tool with the UpSG.

3. Delphi consensus survey

- **Objective**: To reach a consensus about the included items and refine the initial version of the tool.
- **Methods**: Delphi consensus survey. Using a seven point Likert scale (one meaning strongly disagree and seven meaning strongly agree) [18], we will ask participants to rate whether each item should be included in the tool and its clarity. We will calculate the median score for inclusion of each item and will classify them as 1) excluded (median score of 0 - 3 points), 2) review, modify and retest (median score of 4 - 5 points or with substantial comments), and 3) included (median score of 6 to 7 points and without substantial comments). We will conduct additional Delphi rounds until consensus for inclusion or exclusion is reached and no more relevant comments were provided (two or three rounds, as needed).
- **Population:** CG methodological experts that 1) have methodological experience in CGs development and/or updating (defined as having participated in a CG technical team at least once in the past year and/or in methodological research), and 2) are fluent in English or Spanish. We will identify participants by contacting professionals associated with the Guidelines International Network (G-I-N) Updating Guidelines Working Group (http://www.g-i-n.net/working-groups/updating-guidelines) or authors of methodological research.
- **Sample size:** Convenience sample (20 - 30 participants) [19].
- **Data collection:** We will use online software to design the survey and collect responses (www.digestepiclin.com). The survey will be available online for one month; weekly email reminders will be sent to participants in order to increase participation.
- **Variables (per round):** Response rate, characteristics of participants, characteristics of CG development institution, assessment the inclusion of the items, of the scoring calculation and summary report, and overall assessment of the tool [table 2].
- **Data analysis:** For quantitative data, we will calculate absolute frequencies and proportions. For qualitative data, we will use content analysis to summarise and

draw conclusions (atlasti.com) [17]. Questionnaires with no response in over 20% of the items will be withdrawn. We will draft a final report, discuss results, and refine the initial version of the tool with the UpSG.

4. External review

4.1. External review with clinical guidelines developers

- **Objective**: To assess the usefulness of each item and refine the initial version of the tool.
- **Methods**: Survey.
- **Population:** CG developers that 1) have experience in CG development/updating (defined as having participated in GDG and/or GUG at least once in the past year), and 2) are fluent in English or Spanish. We will identify participants by contacting professionals associated with the G-I-N community (http://www.g-i-n.net).
- **Sample size:** Convenience sample (>250 organisations and individual members from the G-I-N community).
- **Data collection:** We will use online software to design the survey and collect responses (www.digestepiclin.com). The survey will be available online for one month; weekly email reminders will be sent to participants in order to increase participation.
- **Variables:** Response rate, characteristics of participants, characteristics of CG development institution, assessment the usefulness of the items, of the scoring calculation and summary report, and overall assessment of the tool [table 2].
- **Data analysis:** For quantitative data, we will calculate absolute frequencies and proportions. For qualitative data, we will use content analysis to summarise and draw conclusions (atlasti.com) [17]. Questionnaires with no response in over 20% of the items will be withdrawn. We will draft a final report, discuss results, and refine the initial version of the tool with the UpSG.

4.2. External review with clinical guidelines users

- **Objective**: To assess the usefulness of the tool and refine the initial version of the tool.
- **Methods**: Semi-structured interviews (face-to-face, telephone or Internet).
- **Population:** CG users (defined as healthcare professionals that use CGs on a regular basis) who are fluent in English or Spanish. We will identify participants with the help of the UpSG. When someone does not respond or cannot participate, a new contributor will be recruited.
- **Sample size:** Convenience sample (≤ 10 participants). We will recruit participants and collect data until information becomes repetitive and no new information emerges (data saturation).
- **Data collection:** We will design an interview script to conduct the interviews. Interviews will be audiotaped and transcribed.
- **Variables:** Characteristics of participants, and overall assessment of the tool [table 2].
- **Data analysis:** For quantitative data, we will calculate absolute frequencies and proportions. For qualitative data, we will use content analysis to summarise and draw conclusions (atlasti.com) [17]. We will draft a final report, discuss results, and refine the initial version of the tool with the UpSG.

5. Pilot test of the tool

- **Objective:** To explore the inter-observer reliability of the final version of the tool and refine the initial version of the tool.
- **Methods:** Methodological survey.
- **Population:** A CG developed within the Spanish National Health System Clinical Guideline Program, published within the last two years, and with <50 clinical questions.
- **Sample size:** Convenience sample.
- **Data collection:** Two reviewers from the original GDG and two reviewers from the UpSG will apply the initial version of the tool. We will use online software to design the survey and collect responses (www.digestepiclin.com). The survey will be available online for one month; weekly email reminders will be sent to participants in order to increase participation.

- **Variables:** Response rate, characteristics of participants, characteristics of clinical questions, and priority scores, and overall assessment of the tool [table 2].
- **Data analysis:** For quantitative data, we will calculate absolute frequencies and proportions. For qualitative data, we will use content analysis to summarise and draw conclusions (atlasti.com) [17]. Questionnaires with no response in over 20% of the items will be withdrawn. We will calculate the intraclass coefficient (ICC) with its 95% confidence interval (CI) as an indicator of agreement between reviewers for each item and overall. According to the scale proposed by Landis and Koch, the degree of agreement between 0.00 and 0.20 is poor, from 0.21 to 0.40 is fair, from 0.41 to 0.60 is moderate, from 0.61 to 0.80 is substantial, and from 0.81 to 1.00 is almost perfect [20]. We will draft a final report, discuss results, and refine the initial version of the tool with the UpSG.

Approval of the final version of the tool

- **Objective:** To approve the final version of the tool (items, scoring calculation, and summary report).
- **Methods:** Presentation and discussion of the final version of the tool.
- **Population:** UpSG.
- **Data collection:** We will circulate the final version of the tool among the UpSG via email and collect feedback.

Ethics

We have obtained a waiver of approval from the Clinical Research Ethics Committee at the Hospital de la Santa Creu i Sant Pau, since this study will not involve patients or biological samples.

Dissemination

We will develop the UpPriority tool through a comprehensive development process, including the use of previous methodological evidence, feasibility testing of the tool, and engagement of the international guideline community (semi-structured interviews, Delphi consensus survey, and external review), and finally a pilot testing of the tool. The results of the study will be published in peer-reviewed journals and

communicated to interested stakeholders in international conferences and other platforms. We are also planning a future study regarding the implementation of the UpPriority tool.

Previous SRs on CG updating strategies found limited evidence on processes that could inform the decision of which CGs should be prioritised for updating [12, 21, 22]. There are, nevertheless, new studies that underscore the relevance of the prioritisation process in CG updating [13, 23], coinciding with a growing interest among developers to shift from developing to updating CGs [24].

We recently systematically reviewed the available evidence on strategies to prioritise the updating of SRs, health technology assessments (HTAs), and CGs [1]. We observed that there is wide variability and suboptimal reporting of the methods used to develop and implement such prioritisation processes. Therefore, developers may have difficulties selecting and implementing a prioritisation method to optimise the updating process of CGs.

Agbassi et al. 2014 implemented an annual step-by-step prioritisation process of CGs for updating [13]. The authors reviewed CGs using two questionnaires; the process requires evidence search, evidence review, and review approval [13]. We will build our proposal on this process while addressing some of its shortcomings. Following a comprehensive development process, we will develop a pragmatic survey based tool that will likely be less resource-intensive and time-consuming compared to formal approaches (based on step-by-step algorithm that generally includes literature searches). We will also publish detailed and explicit guidance to allow developers to implement the tool in their institutions and to adapt it, if needed, to their specific circumstances.

We expect to develop a pragmatic tool (items, scoring calculation, and summary report) that will be applicable to all clinical questions within a CG and should be easy to uptake by CG developers. The UpPriority Tool could support the standardisation of prioritisation processes for updating CGs and therefore have important implications for a more efficient use of resources in the CG field.

Abbreviations

CG: Clinical Guideline; GDG: Guideline Development Group; G-I-N: Guidelines International Network; GUG: Guideline Updating Group; UpSG: UpPriority Steering Group.

Data sharing statement

Data from the study will be available on request.

Competing interests

None declared.

Funding

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Contributors

LMG and PAC participated in the conception of the study. All authors participated in the design. LMG, HPH, ENG and CS drafted a first version of the protocol. All authors participated revising it critically for important intellectual content and have given final approval of the version to be published.

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Tables

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- Figure 1. Multi-step development process

Table 1. Characteristics of the multi-step development process

	Generation of the initial version	Optimisation of the tool						Approval of the final version
		Feasibility test	Semi-structured interviews	Delphi consensus survey	External review with clinical guidelines developers	External review with clinical guidelines users	Pilot test	
Objective	To develop the initial version of the tool.	To explore the feasibility and refine the initial version of the tool.	To identify current practices in prioritisation processes and to refine the initial version of the tool.	To reach a consensus about the included items and refine the initial version of the tool.	To assess the usefulness of each item and refine the initial version of the tool.	To assess the usefulness of the tool and refine the initial version of the tool.	To explore the inter-observer reliability of the final version of the tool.	To approve the final version of the tool.
Methods	Brainstorming and discussion.	Methodological survey.	Semi-structured interviews.	Delphi consensus survey.	Survey.	Semi-structured interviews.	Methodological survey.	Presentation and discussion.
Population	UpSG	CG	CG developers	CG methodological experts from G-I-N Updating Guidelines Working Group	CG developers from G-I-N community	CG users	CG	UpSG
Sample size	-	Convenience sample (<50 clinical questions).	Convenience sample (≤ 10 participants).	Convenience sample (20 - 30 participants).	Convenience sample (>250 organisations and individual members)	Convenience sample (≤ 10 participants).	Convenience sample (<50 clinical questions).	-

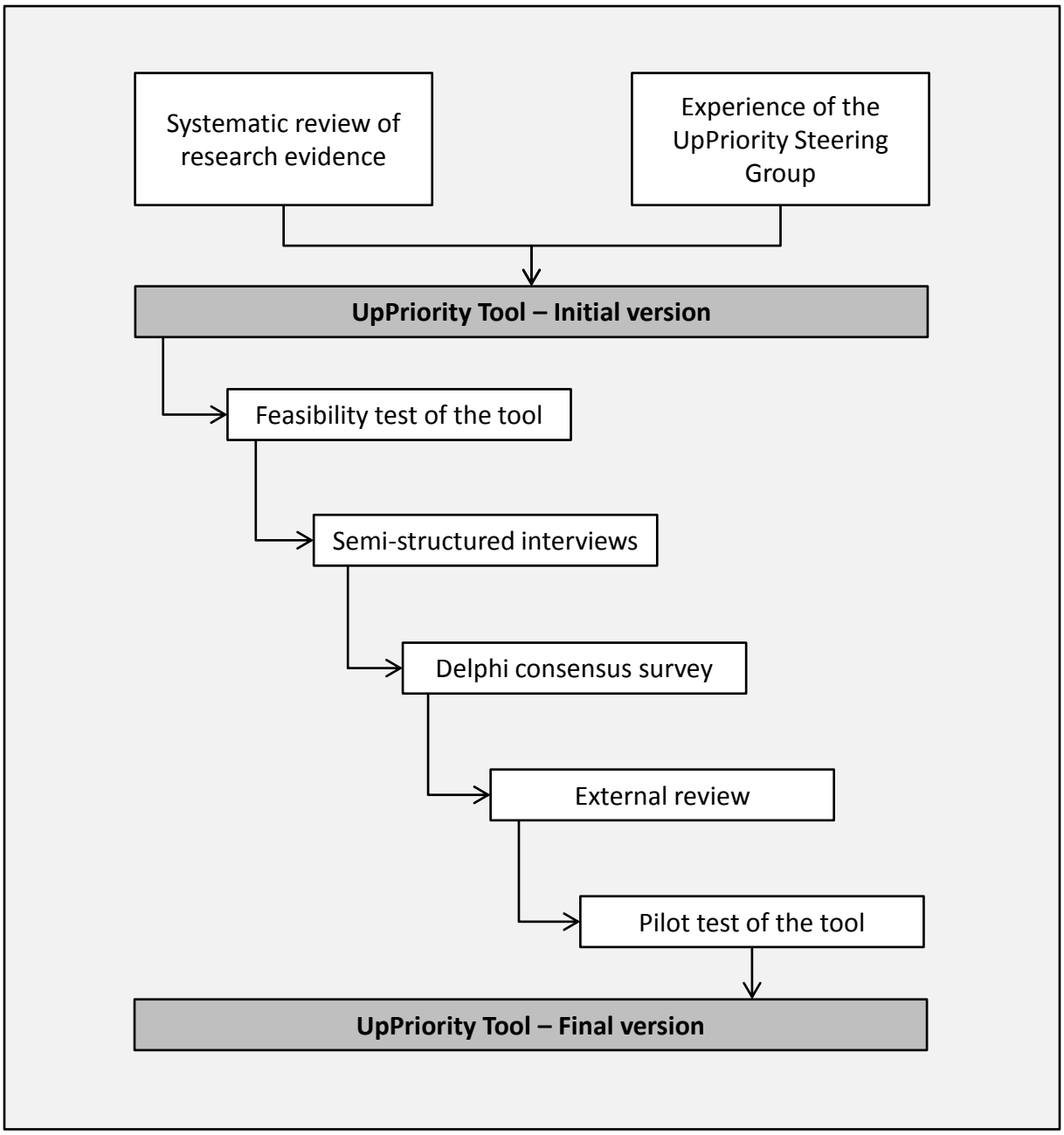
Abbreviations: CG: Clinical guideline; G-I-N: Guidelines International Network; UpSG: UpPriority Steering Group.

Table 2. Study variables in multi-step development process

	Feasibility test	Semi-structured interviews	Delphi consensus survey	External review with clinical guidelines developers	External review with clinical guidelines users	Pilot test
Response rate	X		X	X		X
Characteristics of participants	X	X	X	X	X	X
Characteristics of clinical questions	X					X
Priority scores (single-item and overall-items)	X					X
Characteristics of CG development institution		X	X	X		
Current practices in prioritisation processes		X				
Assessment of the items			X (inclusion)	X (usefulness)		
Assessment of the scores calculation			X	X		
Assessment of the summary report			X	X		
Overall assessment of the tool	X	X	X	X	X	X

Abbreviations: CG: Clinical guideline.

Figure 1. Multi-step development process



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Authors

Martínez García L[1]*, Pardo-Hernandez H[1,2], Niño de Guzman E[1], Superchi C[1], Ballesteros M[1], McFarlane E[3], Penman K[3], Posso M[1], Roqué i Figuls M[1], Sanabria AJ[1], Selva A[4], Vernooij RWM[1], Alonso-Coello P[1,2,5]

Author affiliations

(1) Iberoamerican Cochrane Centre, Biomedical Research Institute Sant Pau (IIB Sant Pau), Barcelona, Spain. (2) CIBER of Epidemiology and Public Health (CIBERESP), Spain. (3) National Institute for Health and Care Excellence, UK. (4) Clinical Epidemiology and Cancer Screening. Corporació Sanitaria Parc Taulí, Sabadell, Spain. (5) Clinical Epidemiology and Biostatistics Department, McMaster University, Hamilton, Canada.

Correspondence

Laura Martínez García. Iberoamerican Cochrane Centre. Hospital de la Santa Creu i Sant Pau, Sant Antoni Maria Claret 167, 08025, Barcelona, Spain. Tel: +34 93 553 78 08. E-mail: laura.martinez.garcia@cochrane.es.

Abstract

Introduction

Due to a continuous emergence of new evidence, clinical guidelines (CGs) require regular surveillance of evidence to maintain their trustworthiness. The updating of CGs is resource-intensive and time-consuming; therefore, updating may include a prioritisation process in order to efficiently ensure recommendations remain up to date. The objective of our project is to develop a pragmatic tool to prioritise clinical questions for updating within a CG.

Methods and analysis

To develop the tool, we will use the results and conclusions of a systematic review of methodological research on prioritisation processes for updating and will adopt a methodological approach we have successfully implemented in a previous experience.

We will perform a multi-step process including 1) generation of an initial version of the tool, 2) optimisation of the tool (feasibility test of the tool, semi-structured interviews, Delphi consensus survey, external review by CG methodologists and users, and pilot test of the tool), and 3) approval of the final version of the tool.

At each step of the process, we will, 1) calculate absolute frequencies and proportions (quantitative data), 2) use content analysis to summarise and draw conclusions (qualitative data), and 3) draft a final report, discuss results, and refine the previous versions of the tool. Finally, we will calculate intraclass coefficients (ICC) with 95% confidence intervals (CI) for each item and overall as indicators of agreement among reviewers.

Ethics and dissemination

We have obtained a waiver of approval from the Clinical Research Ethics Committee at the Hospital de la Santa Creu i Sant Pau (Barcelona). The results of the study will be published in peer-reviewed journal and communicated to interested stakeholders.

The tool could support the standardisation of prioritisation processes for updating CGs, and therefore have important implications for a more efficient use of resources in the CG field.

Keywords

Clinical guidelines, evidence-based medicine, methodology, updating, prioritisation.

Word count

Abstract	297
Manuscript	2918

Strengths and limitations

- To develop the tool, we will use the results and conclusions of a systematic review of methodological research on prioritisation processes for updating.
- We will adopt a methodological approach we have successfully implemented in a previous experience.
- We will collect views from CG developers (semi-structured interviews and external reviews), CG methodological experts (Delphi consensus survey), and CG users (semi-structured interviews); these will allow us to pool different stakeholders' opinions about CG updating prioritisation processes.
- The principal limitation of the study is that we will not perform a formal validation of the tool.

Introduction

Clinical guidelines (CGs) are "statements that include recommendations intended to optimise patient care that are informed by systematic reviews (SRs) of evidence and an assessment of the benefits and harms of alternative care options" [1]. Due to a continuous emergence of new evidence [2, 3], CGs require regular surveillance of evidence to maintain their trustworthiness [4, 5].

Several studies have assessed length of time that CGs and their recommendations remain valid [4 - 8]. Based on this evidence, most CG developers have adopted updating strategies based on predetermined timeframes [9].

An updating strategy involves different processes including the identification of new evidence; the assessment of the impact of new evidence on the current CG recommendations and whether an update is required; and the update of the CG if needed [9, 10]. The updating of CGs is resource-intensive and time-consuming [11]. In the current context of restricted resources, there is a growing interest in approaches that support decision-making for updating CGs [12].

We define the prioritisation process for updating of CGs as the methodology used to determine which CGs should be prioritised in order to ensure that resources are invested in updating the topics that are most relevant to different stakeholders [12]. The prioritisation process includes two main stages 1) assessment of CGs using prioritisation criteria (e.g. availability of new evidence, clinical relevance, or users' interest), and 2) classification of CGs in groups according to priority for updating (e.g. high, medium or low relevance for updating) [12].

Different prioritisation processes could be implemented at different time points within an updating strategy. For example, a prioritisation process could be implemented to identify the CGs in greatest need of update (prioritisation across available CGs) [13, 14] or to identify the clinical questions in greatest need of update within a prioritised CG (prioritisation within a CG) [15, 16].

Until now, there is wide variability and suboptimal reporting of the methods used to develop and implement processes to prioritise updating of CGs [12].

Aims and objectives

Primary objective

- To develop a pragmatic tool to prioritise clinical questions for updating within a CG.

Secondary objectives

- To identify the most important items required to prioritise clinical questions for updating within a CG.
- To describe each item, establish a rating scale of items, and provides a guidance on how to rate them.
- To develop guidance on how to calculate and present priority scores to support decision-making for updating clinical questions within a CG.

Methods and analysis

To develop the UpPriority Tool, we will use the results and conclusions of a systematic review of methodological research on prioritisation processes for updating [12] and will adopt a methodological approach we have successfully implemented in a previous experience [17]. We will perform a multi-step process including 1) generation of an initial version of the tool, 2) optimisation of the tool (feasibility test of the tool, semi-structured interviews, Delphi consensus survey, external review by CG methodologists and users, and pilot test of the tool), and 3) approval of the final version of the tool (table 1, figure 1).

Table 1. Characteristics of the multi-step development process

	Generation of the initial version	Optimisation of the tool						Approval of the final version
		Feasibility test	Semi-structured interviews	Delphi consensus survey	External review with clinical guidelines developers	External review with clinical guidelines users	Pilot test	
Objective	To develop the initial version of the tool	To explore the feasibility of the tool	To identify current practices in prioritisation processes for updating CGs	To reach a consensus about the included items of the tool	To assess the usefulness* and understanding of each item of the tool	To assess the usefulness* and understanding of each item of the tool	To explore the inter-observer reliability of the final version of the tool	To approve the final version of the tool
Methods	Informal discussion	Methodological survey	Semi-structured interviews	Delphi consensus survey	Survey	Semi-structured interviews	Methodological survey	Informal discussion
Population	UpSG	CG	CG developers	CG methodological experts from G-I-N Updating Guidelines Working Group	CG developers from G-I-N community	CG users	CG	UpSG
Sample size	-	Convenience sample	Sampling saturation	20 - 30 participants	>250 organisations and individual members	Sampling saturation	Convenience sample	-
Main outcome	-	– Time to apply the tool	– Participants' experiences with prioritisation processes for updating CGs	– Items considered important to prioritise clinical questions for updating within a CG	– Usefulness* rating for each item of the tool	– Participants' views of prioritisation processes for updating CGs with the tool	– Intraclass coefficient with 95% confidence interval	-

Abbreviations: CG: Clinical guideline; G-I-N: Guidelines International Network; UpSG: UpPriority Steering Group.

*Usefulness: "The extent to which a product can be used by specified users to achieve specified goals with effectiveness, efficiency and satisfaction in a specified context of use" [18].

Generation of the initial version of the tool

- **Objective:** To develop the initial version of the tool (items, scoring calculation, and summary report).
- **Methods:** The UpSG will participate in informal discussion and will approve the initial version of the tool.
- **Population:** UpSG.

Optimisation of the tool

1. Feasibility test of the tool

- **Objective:** To explore the feasibility and refine the initial version of the tool.
- **Methods:** Methodological survey.
- **Population:** A CG developed within the Spanish National Health System Clinical Guideline Program, published within the last two years, and with <50 clinical questions.
- **Sample size:** Convenience sample [19].
- **Data collection:** Two reviewers from the original Guideline Development Group (GDG) and two reviewers from the UpSG will apply the initial version of the tool. We will use online software to design the survey and collect responses (www.digestepiclin.com). The survey will be available online for one month; weekly email reminders will be sent to participants in order to increase participation.
- **Main outcome:** Time to apply the tool.
- **Other variables:** Response rate, characteristics of participants and workplace, characteristics of clinical questions, priority scores (single-item and overall-items), and overall assessment of the tool (table 2).
- **Data analysis:** For quantitative data, we will calculate absolute frequencies and proportions. For qualitative data, we will use content analysis to summarise and draw conclusions (atlasti.com) [20]. Questionnaires with no response in over 20% of the items will be withdrawn. We will draft a final report, discuss results, and refine the initial version of the tool with the UpSG.

Table 2. Study variables in multi-step development process

	Feasibility test	Semi-structured interviews	Delphi consensus survey	External review with clinical guidelines developers	External review with clinical guidelines users	Pilot test
Response rate	X		X	X		X
Characteristics of participants and workplace	X	X	X	X	X	X
Characteristics of clinical questions	X					X
Priority scores	X					X
Current practices in prioritisation processes for updating CGs		X				
Assessment of each item		X	X (inclusion and understanding)	X (usefulness and understanding)	X (usefulness and understanding)	
Assessment of the scores calculation		X	X	X	X	
Assessment of the summary report		X	X	X	X	
Overall assessment of the tool	X	X	X	X	X	X

Abbreviations: CG: Clinical guideline.

2. Semi-structured interviews

- **Objective:** To identify current practices in prioritisation processes for updating CGs and to refine the initial version of the tool.
- **Methods:** Semi-structured interviews (face-to-face, telephone or Internet).
- **Population:** CG developers that 1) have experience in CG development and/or updating (defined as having participated in GDG and/or Guideline Updating Group [GUG] at least once in the past year), and 2) are fluent in English or Spanish. We will identify participants with the help of the UpSG. When someone does not respond or cannot participate, another contributor will be recruited.
- **Sample size:** We will recruit participants and collect data until information becomes repetitive and no new information emerges (sampling saturation) [21, 22].
- **Data collection:** We will design an interview script to conduct the interviews. Interviews will be audiotaped and transcribed.
- **Main outcome:** Participants' experiences with prioritisation processes for updating CGs.
- **Other variables:** Characteristics of participants and workplace, current practices in prioritisation processes for updating CGs, assessment of each item, assessment of the scoring calculation, assessment of the summary report, and overall assessment of the tool (table 2).
- **Data analysis:** For quantitative data, we will calculate absolute frequencies and proportions. For qualitative data, we will use content analysis to summarise and draw conclusions (atlasti.com) [20]. We will draft a final report, discuss results, and refine the initial version of the tool with the UpSG.

3. Delphi consensus survey

- **Objective**: To reach a consensus about the included items and refine the initial version of the tool.
- **Methods**: Delphi consensus survey. Using a seven point Likert scale (one meaning strongly disagree and seven meaning strongly agree) [23], we will ask participants to rate whether each item should be included in the tool and its clarity. We will calculate the median score for inclusion of each item and will

classify them as 1) excluded (median score of 0 - 3 points), 2) review, modify and retest (median score of 4 - 5 points or with substantial comments), and 3) included (median score of 6 to 7 points and without substantial comments). We will conduct additional Delphi rounds until consensus for inclusion or exclusion is reached and no more relevant comments were provided (two or three rounds, as needed).

- **Population:** CG methodological experts that 1) have methodological experience in CGs development and/or updating (defined as having participated in a CG technical team at least once in the past year and/or in methodological research), and 2) are fluent in English or Spanish. We will identify participants by contacting professionals associated with the Guidelines International Network (G-I-N) Updating Guidelines Working Group (http://www.g-i-n.net/working-groups/updating-guidelines) or authors of methodological research.
- **Sample size:** 20 - 30 participants [24].
- **Data collection:** We will use online software to design the survey and collect responses (www.digestepiclin.com). The survey will be available online for one month; weekly email reminders will be sent to participants in order to increase participation.
- **Main outcome:** Items considered important to prioritise clinical questions for updating within a CG.
- **Other variables (per round):** Characteristics of participants and workplace, assessment of each item (inclusion and understanding), assessment of the scoring calculation, assessment of the summary report, and overall assessment of the tool (table 2).
- **Data analysis:** For quantitative data, we will calculate absolute frequencies and proportions. For qualitative data, we will use content analysis to summarise and draw conclusions (atlasti.com) [20]. Questionnaires with no response in over 20% of the items will be withdrawn. We will draft a final report, discuss results, and refine the initial version of the tool with the UpSG.

4. External review

4.1. External review with clinical guidelines developers

- **Objective**: To assess the usefulness and understanding of each item and refine the initial version of the tool.
- **Methods**: Survey.
- **Population:** CG developers that 1) have experience in CG development/updating (defined as having participated in GDG and/or GUG at least once in the past year), and 2) are fluent in English or Spanish. We will identify participants by contacting professionals associated with the G-I-N community (http://www.g-i-n.net).
- **Sample size:** More than 250 organisations and individual members from the G-I-N community (http://www.g-i-n.net/membership/members-around-the-world).
- **Data collection:** We will use online software to design the survey and collect responses (www.digestepiclin.com). The survey will be available online for one month; weekly email reminders will be sent to participants in order to increase participation.
- **Main outcome:** Usefulness rating for each item of the tool.
- **Other variables:** Characteristics of participants and workplace, assessment of each item (usefulness and understanding), assessment of the scoring calculation, assessment of the summary report, and overall assessment of the tool (table 2).
- **Data analysis:** For quantitative data, we will calculate absolute frequencies and proportions. For qualitative data, we will use content analysis to summarise and draw conclusions (atlasti.com) [20]. Questionnaires with no response in over 20% of the items will be withdrawn. We will draft a final report, discuss results, and refine the initial version of the tool with the UpSG.

4.2. External review with clinical guidelines users

- **Objective**: To assess the usefulness and understanding of each item and refine the initial version of the tool.
- **Methods**: Semi-structured interviews (face-to-face, telephone or Internet).
- **Population:** CG users (defined as healthcare professionals that use CGs on a regular basis) who are fluent in English or Spanish. We will identify participants with the help of the UpSG. When someone does not respond or cannot participate, a new contributor will be recruited.

- **Sample size:** We will recruit participants and collect data until information becomes repetitive and no new information emerges (sampling saturation) [21, 22].
- **Data collection:** We will design an interview script to conduct the interviews. Interviews will be audiotaped and transcribed.
- **Main outcome:** Participants' views of prioritisation processes for updating CGs with the tool.
- **Other variables:** Characteristics of participants and workplace, assessment of each item (usefulness and understanding), assessment of the scoring calculation, assessment of the summary report, and overall assessment of the tool (table 2).
- **Data analysis:** For quantitative data, we will calculate absolute frequencies and proportions. For qualitative data, we will use content analysis to summarise and draw conclusions (atlasti.com) [20]. We will draft a final report, discuss results, and refine the initial version of the tool with the UpSG.

5. Pilot test of the tool

- **Objective:** To explore the inter-observer reliability of the final version of the tool and refine the initial version of the tool.
- **Methods:** Methodological survey.
- **Population:** A CG developed within the Spanish National Health System Clinical Guideline Program, published within the last two years, and with <50 clinical questions.
- **Sample size:** Convenience sample; the results of the pilot test will inform the sample size calculation for a subsequent main study [25].
- **Data collection:** Two reviewers from the original GDG and two reviewers from the UpSG will apply the initial version of the tool. We will use online software to design the survey and collect responses (www.digestepiclin.com). The survey will be available online for one month; weekly email reminders will be sent to participants in order to increase participation.
- **Main outcome:** Intraclass coefficient (ICC) with 95% confidence interval (CI) for each item and overall.

- **Other variables:** Response rate, characteristics of participants and workplace, characteristics of clinical questions, and priority scores (single-item), and overall assessment of the tool (table 2).
- **Data analysis:** For quantitative data, we will calculate absolute frequencies and proportions. For qualitative data, we will use content analysis to summarise and draw conclusions (atlasti.com) [20]. Questionnaires with no response in over 20% of the items will be withdrawn. We will calculate the ICC with 95% CI for each item and overall as an indicator of agreement among reviewers. According to the scale proposed by Landis and Koch, the degree of agreement between 0.00 and 0.20 is poor, from 0.21 to 0.40 is fair, from 0.41 to 0.60 is moderate, from 0.61 to 0.80 is substantial, and from 0.81 to 1.00 is almost perfect [26]. We will draft a final report, discuss results, and refine the initial version of the tool with the UpSG.

Approval of the final version of the tool

- **Objective:** To approve the final version of the tool (items, scoring calculation, and summary report).
- **Methods:** The UpSG will participate in informal discussion and will approve the final version of the tool.
- **Population:** UpSG.

Ethics and dissemination

We have obtained a waiver of approval from the Clinical Research Ethics Committee at the Hospital de la Santa Creu i Sant Pau (Barcelona), since this study will not involve patients or biological samples.

The results of the study will be published in peer-reviewed journal and communicated to interested stakeholders (for example, via international conferences, electronic bulletin, or web site).

We will develop the UpPriority tool through a comprehensive development process, including the use of previous methodological evidence [12, 17], feasibility testing of the tool, and engagement of the international CG community (semi-structured

interviews, Delphi consensus survey, and external review), and finally a pilot testing of the tool.

Previous SRs on CG updating strategies found limited evidence on processes that could inform the decision of which CGs should be prioritised for updating [9, 10, 27]. There are, nevertheless, new studies that underscore the relevance of the prioritisation process in CG updating [13, 28], coinciding with a growing interest among developers to shift from developing to updating CGs [29].

We recently systematically reviewed the available evidence on strategies to prioritise the updating of SRs, health technology assessments (HTAs), and CGs [12]. We observed that there is wide variability and suboptimal reporting of the methods used to develop and implement such prioritisation processes. Therefore, developers may have difficulties selecting and implementing a prioritisation method to optimise the updating process of CGs.

Agbassi et al. 2014 implemented an annual step-by-step prioritisation process of CGs for updating [13]. The authors reviewed CGs using two questionnaires; the process requires evidence search, evidence review, and review approval [13]. We will build our proposal on this process while addressing some of its shortcomings. Following a comprehensive development process, we will develop a pragmatic survey based tool that will likely be less resource-intensive and time-consuming compared to formal approaches (based on step-by-step algorithm that generally includes literature searches). We will also publish detailed and explicit guidance to allow developers to implement the tool in their institutions and to adapt it, if needed, to their specific circumstances.

We expect to develop a pragmatic tool (items, scoring calculation, and summary report) that will be applicable to all clinical questions within a CG and should be easy to uptake by CG developers. The UpPriority Tool could support the standardisation of prioritisation processes for updating CGs, and therefore have important implications for a more efficient use of resources in the CG field.

Abbreviations

CG: Clinical Guideline; GDG: Guideline Development Group; G-I-N: Guidelines International Network; GUG: Guideline Updating Group; UpSG: UpPriority Steering Group.

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Authors' contributions

LMG and PAC participated in the conception of the study. All authors participated in the design. LMG, HPH, ENG and CS drafted a first version of the protocol. All authors participated revising it critically for important intellectual content and have given final approval of the version to be published.

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Competing interests

None declared.

Figures

- Figure 1. Multi-step development process

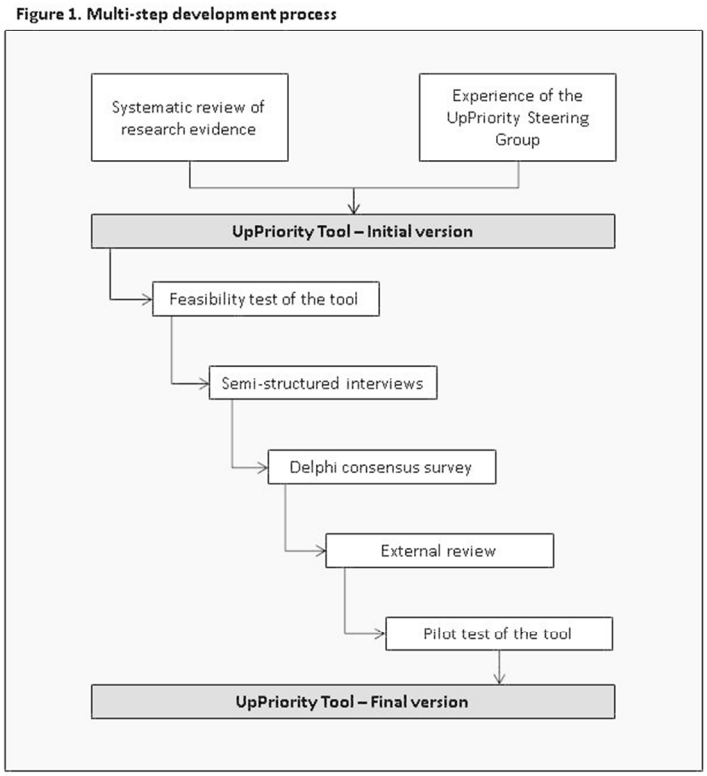

Figure 1. Multi-step development process

60x88mm (300 x 300 DPI)

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Development of a prioritisation tool for the updating of clinical guideline questions: the UpPriority Tool protocol

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Development of a prioritisation tool for the updating of clinical guideline questions: the UpPriority Tool protocol

Authors

Martínez García L[1]*, Pardo-Hernandez H[1,2], Niño de Guzman E[1], Superchi C[1], Ballesteros M[1], McFarlane E[3], Penman K[3], Posso M[1], Roqué i Figuls M[1], Sanabria AJ[1], Selva A[4], Vernooij RWM[1], Alonso-Coello P[1,2,5]

Author affiliations

(1) Iberoamerican Cochrane Centre, Biomedical Research Institute Sant Pau (IIB Sant Pau), Barcelona, Spain. (2) CIBER of Epidemiology and Public Health (CIBERESP), Spain. (3) National Institute for Health and Care Excellence, UK. (4) Clinical Epidemiology and Cancer Screening. Corporació Sanitaria Parc Taulí, Sabadell, Spain. (5) Clinical Epidemiology and Biostatistics Department, McMaster University, Hamilton, Canada.

Correspondence

Laura Martínez García. Iberoamerican Cochrane Centre. Hospital de la Santa Creu i Sant Pau, Sant Antoni Maria Claret 167, 08025, Barcelona, Spain. Tel: +34 93 553 78 08. E-mail: laura.martinez.garcia@cochrane.es.

Abstract

Introduction

Due to a continuous emergence of new evidence, clinical guidelines (CGs) require regular surveillance of evidence to maintain their trustworthiness. The updating of CGs is resource-intensive and time-consuming; therefore, updating may include a prioritisation process in order to efficiently ensure recommendations remain up to date. The objective of our project is to develop a pragmatic tool to prioritise clinical questions for updating within a CG.

Methods and analysis

To develop the tool, we will use the results and conclusions of a systematic review of methodological research on prioritisation processes for updating and will adopt a methodological approach we have successfully implemented in a previous experience.

We will perform a multi-step process including 1) generation of an initial version of the tool, 2) optimisation of the tool (feasibility test of the tool, semi-structured interviews, Delphi consensus survey, external review by CG methodologists and users, and pilot test of the tool), and 3) approval of the final version of the tool.

At each step of the process, we will, 1) calculate absolute frequencies and proportions (quantitative data), 2) use content analysis to summarise and draw conclusions (qualitative data), and 3) draft a final report, discuss results, and refine the previous versions of the tool. Finally, we will calculate intraclass coefficients (ICC) with 95% confidence intervals (CI) for each item and overall as indicators of agreement among reviewers.

Ethics and dissemination

We have obtained a waiver of approval from the Clinical Research Ethics Committee at the Hospital de la Santa Creu i Sant Pau (Barcelona). The results of the study will be published in peer-reviewed journal and communicated to interested stakeholders.

The tool could support the standardisation of prioritisation processes for updating CGs, and therefore have important implications for a more efficient use of resources in the CG field.

Keywords

Clinical guidelines, evidence-based medicine, methodology, updating, prioritisation.

Word count

Abstract	297
Manuscript	3071

Strengths and limitations

- To develop the tool, we will use the results and conclusions of a systematic review of methodological research on prioritisation processes for updating.
- We will adopt a methodological approach we have successfully implemented in a previous experience.
- We will collect views from CG developers (semi-structured interviews and external reviews), CG methodological experts (Delphi consensus survey), and CG users (semi-structured interviews); these will allow us to pool different stakeholders' opinions about CG updating prioritisation processes.
- The principal limitation of the study is that we will not perform a formal validation of the tool.

Introduction

Clinical guidelines (CGs) are "statements that include recommendations intended to optimise patient care that are informed by systematic reviews (SRs) of evidence and an assessment of the benefits and harms of alternative care options" [1]. Due to a continuous emergence of new evidence [2, 3], CGs require regular surveillance of evidence to maintain their trustworthiness [4, 5].

Several studies have assessed length of time that CGs and their recommendations remain valid [4 - 8]. Based on this evidence, most CG developers have adopted updating strategies based on predetermined timeframes [9].

An updating strategy involves different processes including the identification of new evidence; the assessment of the impact of new evidence on the current CG recommendations and whether an update is required; and the update of the CG if needed [9, 10]. The updating of CGs is resource-intensive and time-consuming [11]. In the current context of restricted resources, there is a growing interest in approaches that support decision-making for updating CGs [12].

We define the prioritisation process for updating of CGs as the methodology used to determine which CGs should be prioritised in order to ensure that resources are invested in updating the topics that are most relevant to different stakeholders [12]. The prioritisation process includes two main stages 1) assessment of CGs using prioritisation criteria (e.g. availability of new evidence, clinical relevance, or users' interest), and 2) classification of CGs in groups according to priority for updating (e.g. high, medium or low relevance for updating) [12].

Different prioritisation processes could be implemented at different time points within an updating strategy. For example, a prioritisation process could be implemented to identify the CGs in greatest need of update (prioritisation across available CGs) [13, 14] or to identify the clinical questions in greatest need of update within a prioritised CG (prioritisation within a CG) [15, 16].

Until now, there is wide variability and suboptimal reporting of the methods used to develop and implement processes to prioritise updating of CGs [12].

Aims and objectives

Primary objective

- To develop a pragmatic tool to prioritise clinical questions for updating within a CG.

Secondary objectives

- To identify the most important items required to prioritise clinical questions for updating within a CG.
- To describe each item, establish a rating scale of items, and provides a guidance on how to rate them.
- To develop guidance on how to calculate and present priority scores to support decision-making for updating clinical questions within a CG.

Methods and analysis

To develop the UpPriority Tool, we will use the results and conclusions of a systematic review of methodological research on prioritisation processes for updating [12] and will adopt a methodological approach we have successfully implemented in a previous experience [17]. We will perform a multi-step process including 1) generation of an initial version of the tool, 2) optimisation of the tool (feasibility test of the tool, semi-structured interviews, Delphi consensus survey, external review by CG methodologists and users, and pilot test of the tool), and 3) approval of the final version of the tool (table 1, figure 1).

Table 1. Characteristics of the multi-step development process

	Generation of the initial version	Optimisation of the tool						Approval of the final version
		Feasibility test	Semi-structured interviews	Delphi consensus survey	External review with clinical guidelines developers	External review with clinical guidelines users	Pilot test	
Objective	To develop the initial version of the tool	To explore the feasibility of the tool	To identify current practices in prioritisation processes for updating CGs	To reach a consensus about the included items of the tool	To assess the usefulness* and understanding of each item of the tool	To assess the usefulness* and understanding of each item of the tool	To explore the inter-observer reliability of the final version of the tool	To approve the final version of the tool
Study design	-	Methodological survey	Semi-structured interviews	Delphi consensus survey	Survey	Semi-structured interviews	Methodological survey	-
Participants	UpSG	CG	CG developers	CG methodological experts from G-I-N Updating Guidelines Working Group	CG developers from G-I-N community	CG users	CG	UpSG
Main outcome	-	– Time to apply the tool	– Participants' experiences with prioritisation processes for updating CGs	– Items considered important to prioritise clinical questions for updating within a CG	– Usefulness* rating for each item of the tool	– Participants' views of prioritisation processes for updating CGs with the tool	– Intraclass coefficient with 95% confidence interval	-
Study size	-	Convenience sample	Sampling saturation	20 - 30 participants	>250 organisations and individual members	Sampling saturation	Convenience sample	-

Abbreviations: CG: Clinical guideline; G-I-N: Guidelines International Network; UpSG: UpPriority Steering Group.

*Usefulness: "The extent to which a product can be used by specified users to achieve specified goals with effectiveness, efficiency and satisfaction in a specified context of use" [18].

Generation of the initial version of the tool

- **Objective:** To develop the initial version of the tool (items, scoring calculation, and summary report).
- **Method:** The UpSG will participate in informal discussion and will approve the initial version of the tool.
- **Participants:** UpSG.

Optimisation of the tool

1. Feasibility test of the tool

- **Objective:** To explore the feasibility and refine the initial version of the tool.
- **Study design:** Methodological survey.
- **Participants:** A CG developed within the Spanish National Health System Clinical Guideline Program, published within the last two years, and with <50 clinical questions.
- **Main outcome:** Time to apply the tool.
- **Other variables:** Response rate, characteristics of participants and workplace, characteristics of clinical questions, priority scores (single-item and overall-items), and overall assessment of the tool (table 2).
- **Data collection:** Two reviewers from the original Guideline Development Group (GDG) and two reviewers from the UpSG will apply the initial version of the tool. We will use online software to design the survey and collect responses (www.digestepiclin.com).
- **Bias:** To minimise non-response bias, the survey will be available online for one month; weekly email reminders will be sent to reviewers. To minimise observer bias, two reviewers from outside the UpSG will apply the tool.
- **Study size:** Convenience sample [19].
- **Data analysis:** For quantitative data, we will calculate absolute frequencies and proportions. For qualitative data, we will use content analysis to summarise and draw conclusions (atlasti.com) [20]. Questionnaires with no response in over 20% of the items will be withdrawn. We will draft a final report, discuss results, and refine the initial version of the tool with the UpSG.

Table 2. Study variables in multi-step development process

	Feasibility test	Semi-structured interviews	Delphi consensus survey	External review with clinical guidelines developers	External review with clinical guidelines users	Pilot test
Response rate	X		X	X		X
Characteristics of participants and workplace	X	X	X	X	X	X
Characteristics of clinical questions	X					X
Priority scores	X					X
Current practices in prioritisation processes for updating CGs		X				
Assessment of each item		X	X (inclusion and understanding)	X (usefulness and understanding)	X (usefulness and understanding)	
Assessment of the scores calculation		X	X	X	X	
Assessment of the summary report		X	X	X	X	
Overall assessment of the tool	X	X	X	X	X	X

Abbreviations: CG: Clinical guideline.

2. Semi-structured interviews

- **Objective:** To identify current practices in prioritisation processes for updating CGs and to refine the initial version of the tool.
- **Study design:** Semi-structured interviews (face-to-face, telephone or Internet).
- **Participants:** CG developers that 1) have experience in CG development and/or updating (defined as having participated in GDG and/or Guideline Updating Group [GUG] at least once in the past year), and 2) are fluent in English or Spanish. We will identify participants with the help of the UpSG. When someone does not respond or cannot participate, another contributor will be recruited.
- **Main outcome:** Participants' experiences with prioritisation processes for updating CGs.
- **Other variables:** Characteristics of participants and workplace, current practices in prioritisation processes for updating CGs, assessment of each item, assessment of the scoring calculation, assessment of the summary report, and overall assessment of the tool (table 2).
- **Data collection:** Interviews will be audiotaped and transcribed (each interview will last approximately one hour).
- **Bias:** To minimise interviewer bias, semi-structured interviews will be conducted using an interview guide.
- **Study size:** We will recruit participants and collect data until information becomes repetitive and no new information emerges (sampling saturation) [21, 22].
- **Data analysis:** For quantitative data, we will calculate absolute frequencies and proportions. For qualitative data, we will use content analysis to summarise and draw conclusions (atlasti.com) [20]. We will draft a final report, discuss results, and refine the initial version of the tool with the UpSG.

3. Delphi consensus survey

- **Objective**: To reach a consensus about the included items and refine the initial version of the tool.
- **Study design**: Delphi consensus survey.

Before the first Delphi round, we will provide the results of previous methodological research to Delphi panel members.

In the first Delphi round, we will ask participants to rate whether each item should be included in the tool and its clarity using a seven point Likert scale (one meaning strongly disagree and seven meaning strongly agree) [23]. We will calculate the median score for inclusion of each item and will classify them as 1) excluded (median score of 0 - 3 points), 2) review, modify and retest (median score of 4 - 5 points or with substantial comments), and 3) included (median score of 6 to 7 points and without substantial comments).

After each Delphi round, we will provide feedback to Delphi panel members (all responses will be anonymised prior to circulation). We will conduct additional Delphi rounds until consensus for inclusion or exclusion is reached and no more relevant comments were provided (two or three rounds, as needed).

- **Participants:** CG methodological experts that 1) have methodological experience in CGs development and/or updating (defined as having participated in a CG technical team at least once in the past year and/or in methodological research), and 2) are fluent in English or Spanish. We will identify participants by contacting professionals associated with the Guidelines International Network (G-I-N) Updating Guidelines Working Group (http://www.g-i-n.net/working-groups/updating-guidelines) or authors of methodological research. Non-responders will not be invited to subsequent rounds.
- **Main outcome:** Items considered important to prioritise clinical questions for updating within a CG.
- **Other variables (per round):** Characteristics of participants and workplace, assessment of each item (inclusion and understanding), assessment of the scoring calculation, assessment of the summary report, and overall assessment of the tool (table 2).
- **Data collection:** We will use online software to design the survey and collect responses (www.digestepiclin.com).
- **Bias:** To minimise selection bias of Delphi panel members, all G-I-N Updating Guidelines Working Group members will be invited to participate. To minimise

non-response bias, the survey will be available online for one month; weekly email reminders will be sent to reviewers.

- **Study size:** 20 - 30 participants [24].
- **Data analysis:** For quantitative data, we will calculate absolute frequencies and proportions. For qualitative data, we will use content analysis to summarise and draw conclusions (atlasti.com) [20]. Questionnaires with no response in over 20% of the items will be withdrawn. We will draft a final report, discuss results, and refine the initial version of the tool with the UpSG.

4. External review

4.1. External review with clinical guidelines developers

- **Objective**: To assess the usefulness and understanding of each item and refine the initial version of the tool.
- **Study design**: Survey.
- **Participants:** CG developers that 1) have experience in CG development/updating (defined as having participated in GDG and/or GUG at least once in the past year), and 2) are fluent in English or Spanish. We will identify participants by contacting professionals associated with the G-I-N community (http://www.g-i-n.net).
- **Main outcome:** Usefulness rating for each item of the tool.
- **Other variables:** Characteristics of participants and workplace, assessment of each item (usefulness and understanding), assessment of the scoring calculation, assessment of the summary report, and overall assessment of the tool (table 2).
- **Data collection:** We will use online software to design the survey and collect responses (www.digestepiclin.com).
- **Bias:** To minimise selection bias of survey participants, all G-I-N members will be invited to participate. To minimise non-response bias, the survey will be available online for one month; weekly email reminders will be sent to reviewers. Furthermore, the questionnaire will be pilot tested to improve wording and layout.
- **Study size:** More than 250 organisations and individual members from the G-I-N community (http://www.g-i-n.net/membership/members-around-the-world).

- **Data analysis:** For quantitative data, we will calculate absolute frequencies and proportions. For qualitative data, we will use content analysis to summarise and draw conclusions (atlasti.com) [20]. Questionnaires with no response in over 20% of the items will be withdrawn. We will draft a final report, discuss results, and refine the initial version of the tool with the UpSG.

4.2. External review with clinical guidelines users

- **Objective**: To assess the usefulness and understanding of each item and refine the initial version of the tool.
- **Study design**: Semi-structured interviews (face-to-face, telephone or Internet).
- **Participants:** CG users (defined as healthcare professionals that use CGs on a regular basis) who are fluent in English or Spanish. We will identify participants with the help of the UpSG. When someone does not respond or cannot participate, a new contributor will be recruited.
- **Main outcome:** Participants' views of prioritisation processes for updating CGs with the tool.
- **Other variables:** Characteristics of participants and workplace, assessment of each item (usefulness and understanding), assessment of the scoring calculation, assessment of the summary report, and overall assessment of the tool (table 2).
- **Data collection:** Interviews will be audiotaped and transcribed (each interview will last approximately one hour).
- **Bias:** To minimise interviewer bias, semi-structured interviews will be conducted using an interview guide.
- **Study size:** We will recruit participants and collect data until information becomes repetitive and no new information emerges (sampling saturation) [21, 22].
- **Data analysis:** For quantitative data, we will calculate absolute frequencies and proportions. For qualitative data, we will use content analysis to summarise and draw conclusions (atlasti.com) [20]. We will draft a final report, discuss results, and refine the initial version of the tool with the UpSG.

5. Pilot test of the tool

- **Objective:** To explore the inter-observer reliability of the final version of the tool and refine the initial version of the tool.
- **Study design:** Methodological survey.
- **Participants:** A CG developed within the Spanish National Health System Clinical Guideline Program, published within the last two years, and with <50 clinical questions.
- **Main outcome:** Intraclass coefficient (ICC) with 95% confidence interval (CI) for each item and overall.
- **Other variables:** Response rate, characteristics of participants and workplace, characteristics of clinical questions, and priority scores (single-item), and overall assessment of the tool (table 2).
- **Data collection:** Two reviewers from the original GDG and two reviewers from the UpSG will apply the initial version of the tool. We will use online software to design the survey and collect responses (www.digestepiclin.com).
- **Bias:** To minimise non-response bias, the survey will be available online for one month; weekly email reminders will be sent to reviewers. To minimise observer bias, two reviewers from outside the UpSG will apply the tool.
- **Study size:** Convenience sample; the results of the pilot test will inform the sample size calculation for a subsequent main study [25].
- **Data analysis:** For quantitative data, we will calculate absolute frequencies and proportions. For qualitative data, we will use content analysis to summarise and draw conclusions (atlasti.com) [20]. Questionnaires with no response in over 20% of the items will be withdrawn. We will calculate the ICC with 95% CI for each item and overall as an indicator of agreement among reviewers. According to the scale proposed by Landis and Koch, the degree of agreement between 0.00 and 0.20 is poor, from 0.21 to 0.40 is fair, from 0.41 to 0.60 is moderate, from 0.61 to 0.80 is substantial, and from 0.81 to 1.00 is almost perfect [26]. We will draft a final report, discuss results, and refine the initial version of the tool with the UpSG.

Approval of the final version of the tool

- **Objective:** To approve the final version of the tool (items, scoring calculation, and summary report).
- **Method:** The UpSG will participate in informal discussion and will approve the final version of the tool.
- **Participants:** UpSG.

Ethics and dissemination

We have obtained a waiver of approval from the Clinical Research Ethics Committee at the Hospital de la Santa Creu i Sant Pau (Barcelona, Spain), since this study will not involve patients or biological samples.

The results of the study will be published in peer-reviewed journal and communicated to interested stakeholders (for example, via international conferences, electronic bulletin, or web site).

We will develop the UpPriority tool through a comprehensive development process, including the use of previous methodological evidence [12, 17], feasibility testing of the tool, and engagement of the international CG community (semi-structured interviews, Delphi consensus survey, and external review), and finally a pilot testing of the tool.

Previous SRs on CG updating strategies found limited evidence on processes that could inform the decision of which CGs should be prioritised for updating [9, 10, 27]. There are, nevertheless, new studies that underscore the relevance of the prioritisation process in CG updating [13, 28], coinciding with a growing interest among developers to shift from developing to updating CGs [29].

We recently systematically reviewed the available evidence on strategies to prioritise the updating of SRs, health technology assessments (HTAs), and CGs [12]. We observed that there is wide variability and suboptimal reporting of the methods used to develop and implement such prioritisation processes. Therefore, developers may have difficulties selecting and implementing a prioritisation method to optimise the updating process of CGs.

Agbassi et al. 2014 implemented an annual step-by-step prioritisation process of CGs for updating [13]. The authors reviewed CGs using two questionnaires; the process requires evidence search, evidence review, and review approval [13]. We will build our proposal on this process while addressing some of its shortcomings. Following a comprehensive development process, we will develop a pragmatic survey based tool that will likely be less resource-intensive and time-consuming compared to formal approaches (based on step-by-step algorithm that generally includes literature searches). We will also publish detailed and explicit guidance to allow developers to implement the tool in their institutions and to adapt it, if needed, to their specific circumstances.

We expect to develop a pragmatic tool (items, scoring calculation, and summary report) that will be applicable to all clinical questions within a CG and should be easy to uptake by CG developers. The UpPriority Tool could support the standardisation of prioritisation processes for updating CGs, and therefore have important implications for a more efficient use of resources in the CG field.

Abbreviations

CG: Clinical Guideline; GDG: Guideline Development Group; G-I-N: Guidelines International Network; GUG: Guideline Updating Group; UpSG: UpPriority Steering Group.

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Contributors

LMG and PAC were involved in conception and study design. LMG, HPH, ENG and CS were involved in drafting of the first version of the article. LMG, HPH, ENG, CS, MB, EM, KP, MP, MRF, AJS, AS, RWMV, and PAC were involved in critical revision of the article for important intellectual content. LMG, HPH, ENG, CS, MB, EM, KP, MP, MRF, AJS, AS, RWMV, and PAC were involved in final approval of the article.

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Competing interests

None declared.

Ethics approval

Clinical Research Ethics Committee (Hospital de la Santa Creu i Sant Pau, Barcelona, Spain).

Data sharing statement

Data from the study will be available on request.

Figures

- Figure 1. Multi-step development process

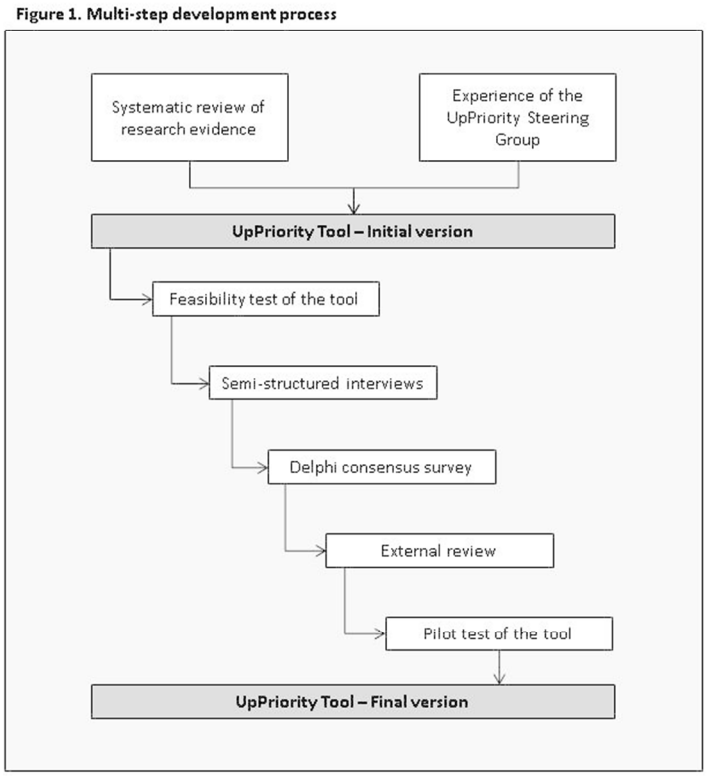

Figure 1. Multi-step development process

60x88mm (300 x 300 DPI)