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The GIN-McMaster Guideline Development Checklist (GDC)







Disclosure

- Co-chair GRADE Working Group
- World Health Organization: various committees
- Board of Trustees GIN
- Steering Group Cochrane Collaboration
- No direct financial COI







Today's presentation

- Introduction to the work on the checklist
- The checklist (oon)
- Plans for the checklist







RESEARCH

Guidelines 2.0: systematic development of a comprehensive checklist for a successful guideline enterprise

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ABSTRACT

Background: Although several tools to evaluate the credibility of health care guidelines exist, guidance on practical steps for developing guidelines is lacking. We systematically compiled a comprehensive checklist of items linked to relevant resources and tools that guideline developers could consider, without the expectation that every guideline would address each item.

Methods: We searched data sources, including manuals of international guideline developers, literature on guidelines for guidelines (with a focus on methodology reports from international and national agencies, and professional societies) and recent articles providing systematic guidance. We reviewed these sources in duplicate, extracted items for the checklist using a sensitive approach and developed overarching topics relevant to guidelines. In an iterative

omissions and involved experts in guideline development for revisions and suggestions for items to be added.

Results: We developed a checklist with 18 topics and 146 items and a webpage to facilitate its use by guideline developers. The topics and included items cover all stages of the guideline enterprise, from the planning and formulation of guidelines, to their implementation and evaluation. The final checklist includes links to training materials as well as resources with suggested methodology for applying the items.

Interpretation: The checklist will serve as a resource for guideline developers. Consideration of items on the checklist will support the development, implementation and evaluation of guidelines. We will use crowdsourcing to

Competing interests: None declared. Authors of this manuscript have been involved in the development of various guideline manuals which are referenced in this article.

This article has been peer reviewed.

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Guideline developmen t Process

Eccles et al. Implementation Science 2012, 7:60 http://www.implementationscience.com/content/7/1/6



METHODOLOGY

Open A

Developing clinical practice guidelines: target audiences, identifying topics for guidelines, guideline group composition and functioning a conflicts of interest

Martin P Eccles¹, Jeremy M Grimshaw^{2,3}, Paul Shekelle^{4,5*}, Holger J Schünemann⁶ and Steven Woolf⁷



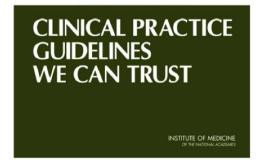
<u>American Thoracic Society Documents</u>

A Guide to Guidelines for Professional Societies and Other Developers of Recommendations

Introduction to Integrating and Coordinating Efforts in COPD Guideline Development. An Official ATS/ERS Workshop Report

Holger J. Schünemann, Mark Woodhead, Antonio Anzueto, A. Sonia Buist, William MacNee,
Klaus F. Rabe, and John Heffner; on behalf of the ATS/ERS Ad Hoc Committee on Integrating
and Coordinating Efforts in COPD Guideline Development

Proc Am Thorac Soc Vol 9, Iss. 5, pp 215–218, Dec 15, 2012



Health Research Policy and Systems





Review

Open Access

Improving the use of research evidence in guideline development: introduction

Andrew D Oxman*1, Atle Fretheim1, Holger J Schünemann2 and SURE3

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Health Research Policy and Systems 2006, 4:13 doi:10.1186/1478-4505-4-13

This article is available from: http://www.health-policy-systems.com/content/4/1/13



Implementing national guideline development programs

- WHO office in Estonia
- MoH in Saudi Arabia
- MoH in Chile
- Professional societies
- DECIDE project





Aim

- Offer a comprehensive toolbox for guideline development, with items linked to relevant resources and other tools
- Not to create a guideline credibility or quality checklist





Methodology

 We used an iterative process that began with 2 of us (H.J.S. and E.A.A.) identifying an initial list of key guideline methodology reports and guidelines for guidelines to review.





Box 1: Sources for data extraction

Guideline development manuals

North America

- American Academy of Otolaryngology Head and Neck Surgery Clinical Practice Guideline Development Manual, third edition, 2013⁵⁶
- American College of Cardiology American Heart Association Task Force on Practice Guidelines Methodology Manual and Policies, 2010,³² and supplementary documents⁵⁸⁻⁶⁰
- Canadian Task Force on Preventive Health Care Procedure Manual, 2011³³
- Cancer Care Ontario Program in Evidence-Based Care Handbook, 2012,³⁴ and supplementary documents^{61,62}
- US Centers for Disease Control and Prevention (CDC) Guidelines and Recommendations: a CDC Primer, 2012³⁵
- Transparency Matters: Kaiser Permanente's National Guideline Program Methodological Processes, 2012³⁶
- US Preventive Services Task Force Procedure Manual, 2008³⁷

Europe

- Estonian Handbook for Guidelines Development, 2011²⁰
- European Society of Cardiology Recommendations for Guidelines Production, 2010⁴¹
- National Institute for Health and Care Excellence Guidelines Manual, 2012,⁴² and supplementary documents⁶³⁻⁶⁵
- SIGN (Scottish Intercollegiate Guidelines Network) 50: a Guideline Developer's Handbook, 201143
- Spain Ministry of Health Development of Clinical Practice Guidelines in the National Health System: Methodological Manual, 2007⁴⁴
- World Health Organization Handbook for Guideline Development, 2012⁴⁵

South America

- Argentina National Academy of Medicine Guide to Adaptation of Clinical Practice Guidelines, 2008³⁸
- Colombia Ministry of Health and Social Security Methodological Guide for Developing Integrated Care Guidelines in the Colombian System of Health and Social Security, 2010³⁹
- Peru Ministry of Health Technical Standards for the Development of Clinical Practice Guidelines, 2006⁴⁰

Australasia

- National Health and Medical Research Council (NHMRC) Procedures and Requirements for Meeting the 2011 NHMRC Standard for Clinical Practice Guidelines, 2011, 66 and supplementary document 66
- New Zealand Guidelines Group Handbook for the Preparation of Explicit Evidence-Based Clinical Practice Guidelines, 2001⁴⁷

Guideline methodology reports

- The ADAPTE process: resource toolkit for guideline adaptation, 2009⁵⁷
- AGREE II: advancing guideline development, reporting and evaluation in health care, 2010^{1,67,68}
- Methodology for the development of antithrombotic therapy and prevention of thrombosis quidelines: antithrombotic therapy and prevention of thrombosis, 9th edition, 2012⁵
- Conference on Guideline Standardization: Standardized Reporting of Clinical Practice Guidelines, 2003^{23,69}
- Guidelines International Network: Toward International Standards for Clinical Practice Guidelines, 2012²
- Health Research Policy and Systems Series: Improving the Use of Research Evidence in Guideline Development, 2006^{6,70-85}
- Implementation Science Series: Developing Clinical Practice Guidelines, 2012⁷⁻⁹
- Institute of Medicine: Clinical Practice Guidelines We Can Trust, 2011³
- Proceedings of the American Thoracic Society Series: a Guide to Guidelines for Professional Societies and Other Developers of Recommendations, 2012^{11,86–99}

Note: AGREE = Appraisal of Guidelines, Research and Evaluation.





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Methodology

- Searched manuals of international guideline developers, guidelines for guidelines literature
- Reviewed sources in duplicate, extracted items using a sensitive approach and developed overarching topics
- Reviewed items for duplication and omissions using an iterative process and input from experts in guideline development
- Developed a conceptual framework for the processes in guideline development





Processes

Terminology

Clarification

Description in simple terms





18 guideline topics

Box 2	: Topics included in ch	necklist for guideline development
Topic		Description
	rganization, budget, anning and training	Involves laying out a general but detailed plan describing what is feasible, how it will be achieved and what resources are required to produce and use the guideline. The plan should refer to a specific period and be expressed in formal, measurable terms.
2. Pri	iority setting	Refers to the identification, balancing and ranking of priorities by stakeholders. Priority setting ensures that resources and attention are devoted to those general areas (e.g., chronic obstructive pulmonary disease, diabetes, cardiovascular disease, cancer, prevention) where health care recommendations will provide the greatest benefit to the population, a jurisdiction or a country. A priority-setting approach needs to contribute to future plans while responding to existing, potentially difficult circumstances. 100,101
	uideline group embership	Defines who is involved, in what capacity, and how the members are selected for the guideline development and at other steps of the guideline enterprise.
	tablishing guideline oup processes	Defines the steps to be followed, how those involved will interact and how decisions will be made.
	entifying target audience nd topic selection	Involves describing the potential users or consumers of the guideline and defining the topics to be covered in the guideline (e.g., diagnosis of chronic obstructive pulmonary disease).
	onsumer and stakeholder volvement	Describes how relevant people or groups who are not necessarily members of the panel but are affected by the guideline (e.g., as target audience or users) will be engaged.
	1 (1 1	

Focuses on defining and managing the potential divergence between an individual's interests and his or her professional obligations that could lead to questioning whether the actions or decisions are motivated by gain, such as financial, academic advancement, clinical revenue streams or community standing. Financial or intellectua or other relationships that may affect an individual's or organization's ability to approach a scientific question with an open mind are included.

diagnostic tests and strategies) and outcomes that will be relevant for decision-making (e.g., should test A be used, or should treatments B, C, D or E be used in chronic obstructive pulmonary disease?).





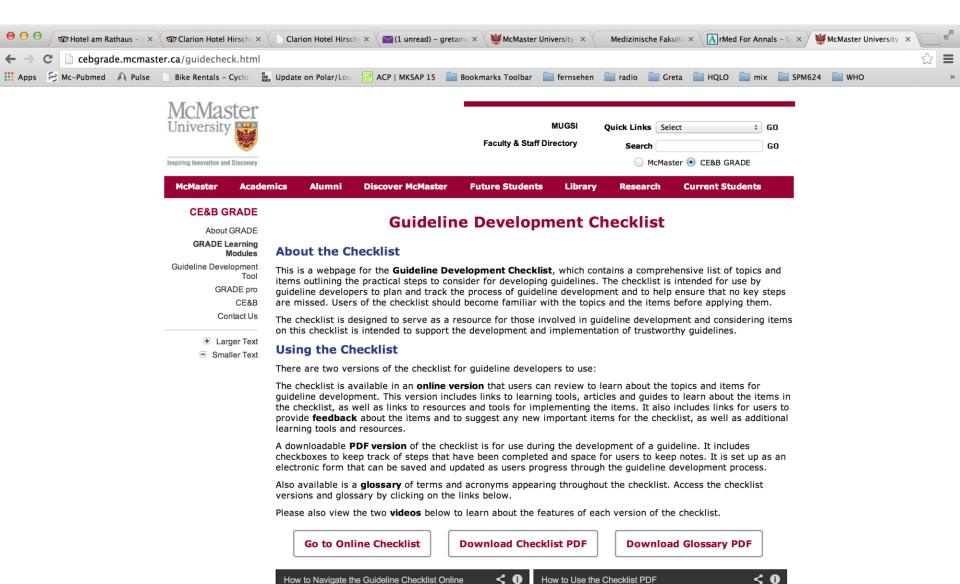
	<i>3.</i>	of outcomes and interventions, values, preferences and utilities	assess the possible consequences. These include patient, caregiver and health care provider knowledge, attitudes, expectations, moral and ethical values, and beliefs; patient goals for life and health; prior experience with the intervention and the condition; symptom experience (e.g., breathlessness, pain, dyspnea, weight loss); preferences for and importance of desirable and undesirable outcomes; perceived impact of the condition or interventions on quality of life, well-being or satisfaction, and interactions between the work of implementing the intervention, the intervention itself, and other contexts the patient may be experiencing; preferences for alternative courses of action; and preferences relating to communication content and styles, information and involvement in decision-making and care. This can be related to what in the economic literature is considered <i>utilities</i> . An intervention itself can be considered a consequence of a recommendation (e.g., the burden of taking a medication or undergoing surgery) and a level of importance or value is associated with that.	
	10.	Deciding what evidence to include and searching for evidence	Focuses on laying out inclusion and exclusion criteria based on types of evidence (e.g., rigorous research, informally collected), study designs, characteristics of the population, interventions and comparators, and deciding how the evidence will be identified and obtained. It also includes but is not limited to evidence about values and preferences, local data and resources.	
	11.	Summarizing evidence and considering additional	Focuses on presenting evidence in a synthetic format (e.g., tables or brief narratives) to facilitate the development and understanding of recommendations. It also involves identifying and considering additional information	
re in in	sea clud	rch (individual studies a de, but is not limited to ventions, values, prefer	dence one can place in the obtained evidence by transparently evaluating the obtained and across studies) and other evidence applying structured approaches. This may be one of evidence about baseline risk or burden of disease, importance of outcomes and rences and utilities, resource use (cost), estimates of effects and accuracy of diagnostic	
		recommendations and determining their strength	process to integrate the factors that influence a recommendation. Determining the strength of the recommendations refers to judgments about how confident a guideline panel is that the implementation of a recommendation exerts more desirable than undesirable consequences.	
	14.	Wording of recommendations and of considerations about implementation, feasibility and equity	Refers to choosing syntax and formulations that facilitate understanding and implementation of the recommendations. Such wording is connected to considerations about implementation, feasibility and equity, which refer to the guideline panel's considerations about how the recommendation will be used and what impact it may have on the factors described.	
ĺĺ	1.	Departing and pear review	Departing refers to have a guideline will be made public/or, print online). Deer region refers to have the	

Includes integrating, in the process of developing the guidelines, how those affected by its recommendations

9. Considering importance

15. Reporting and peer review Reporting refers to how a guideline will be made public (e.g., print, online). Peer review refers to how the quideline document will be reviewed before its publication and how it can be assessed (e.g., for errors), both internally and externally, by stakeholders who were not members of the guideline development group. 16. Dissemination and Focuses on strategies to make relevant groups aware of the guidelines and to enhance their uptake implementation (e.g., publications and tools such as mobile applications). 17. Evaluation and use Refers to formal and informal strategies that allow judgments about: evaluation of the guidelines as a process and product; evaluation of the use or uptake, or both; and evaluation of impact and whether or not the guideline leads to improvement in patient or population health or other consequences. 18. Updating Refers to how and when a guideline requires revision because of changes in the evidence or other factors that influence the recommendations.

Interactive website cebgrade.mcmaster.ca/guidecheck.html



Please also view the two videos below to learn about the features of each version of the checklist.



The Guideline Development Checklist is officially endorsed by:



Developed in collaboration with:



































Figure 2: An example of a topic from the guideline development checklist and the corresponding items for consideration.

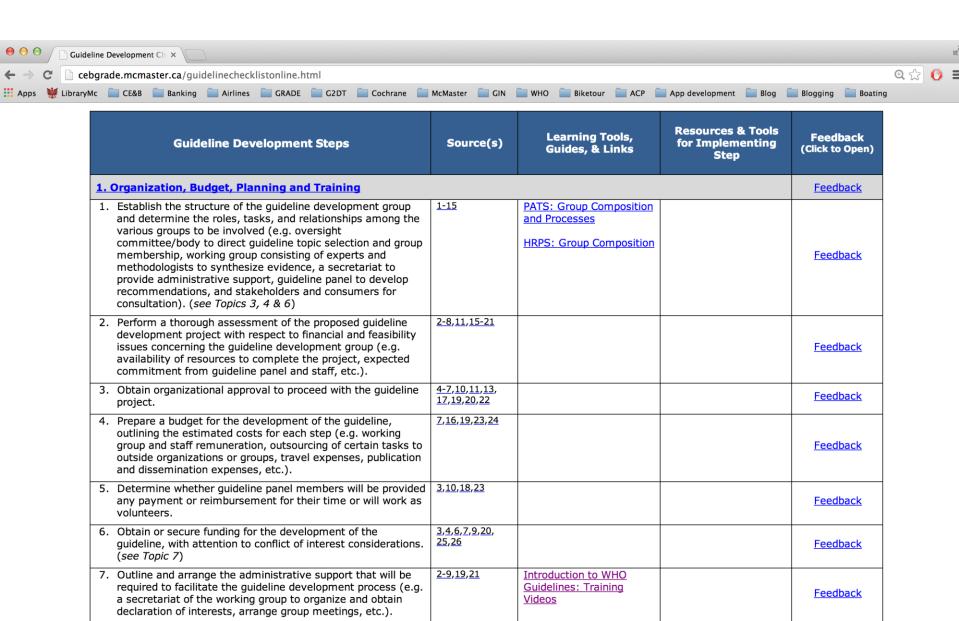
Completed	Not Applicable		Guideline Development Steps	Source(s)
1.0)rgai	nizat	ion, Budget, Planning and Training	
		1.	Establish the structure of the guideline development group and determine the roles, tasks, and relationships among the various groups to be involved (e.g. oversight committee/body to direct guideline topic selection and group membership, working group consisting of experts and methodologists to synthesize evidence, a secretariat to provide administrative support, guideline panel to develop recommendations, and stakeholders and consumers for consultation). (see Topics 3, 4 & 6)	1-15
		2.	Perform a thorough assessment of the proposed guideline development project with respect to financial and feasibility issues concerning the guideline development group (e.g. availability of resources to complete the project, expected commitment from guideline panel and staff, etc.).	2-8,11,15-21
		3.	Obtain organizational approval to proceed with the guideline project.	4-7,10,11,13,17,19,20,22
		4.	Prepare a budget for the development of the guideline, outlining the estimated costs for each step (e.g. working group and staff remuneration, outsourcing of certain tasks to outside organizations or groups, travel expenses, publication and dissemination expenses, etc.).	7,16,19,23,24
		5.	Determine whether guideline panel members will be provided any payment or reimbursement for their time or will work as volunteers.	3,10,18,23
		6.	Obtain or secure funding for the development of the guideline, with attention to conflict of interest considerations. (see Topic 7)	3,4,6,7,9,20,25,26





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A	В	D	E	F
Completed	Not Applicable	Guideline Development Steps	Responsible?	Decision
2 1. Organiza	tion, Budge	t, Planning and Training		
3		 Establish the structure of the guideline development group and determine the roles, tasks, and relationships among the various groups to be involved (e.g. oversight committee/body to direct guideline topic selection and group membership, working group consisting of experts and methodologists to synthesize evidence, a secretariat to provide administrative support, guideline panel to develop recommendations, and stakeholders and consumers for consultation). (see Topics 3, 4 & 6) Perform a thorough assessment of the proposed guideline development project with respect to financial and feasibility 		
4		issues concerning the guideline development group (e.g. availability of resources to complete the project, expected commitment from guideline panel and staff, etc.).		
5		Obtain organizational approval to proceed with the guideline project.		
6		4. Prepare a budget for the development of the guideline, outlining the estimated costs for each step (e.g. working group and staff remuneration, outsourcing of certain tasks to outside organizations or groups, travel expenses, publication and dissemination expenses, etc.).		
7	х	Determine whether guideline panel members will be provided any payment or reimbursement for their time or will work as volunteers.		
0		6. Obtain or secure funding for the development of the guideline, with attention to conflict of interest considerations. (see		
0		Topic 7) 7. Outline and arrange the administrative support that will be required to facilitate the guideline development process (e.g. a		
9		secretariat of the working group to organize and obtain declaration of interests, arrange group meetings, etc.).		
10		 Plan and prepare for training and support that will be required for those involved in the guideline development process (e.g. conflict of interest related education or training for guideline panel members, teaching sessions for patients to be involved in the guideline group, etc.). (see Topics 4 & 6) 		
11		9. Set a timeline for the completion of the guideline and target dates for the completion of milestones in the guideline development process.		
12		10. Determine what, if any, legal considerations are relevant for the planned guideline (e.g. reimbursement policies for orphan drugs).		
		11. Prepare a protocol for the entire guideline that can be completed as the project progresses in order to keep the guideline		
		development group on track, including an outline of the overall goals and objectives for the guideline, the timeline, task assignments, steps that will require documentation of decisions, and the proposed methodology for all steps (i.e. those		
		covered in this checklist, for example the methods for forming the guideline group, selection of topics to be covered in		
13 14 2. Priority S	Sotting	guideline, consensus methods, consultation methods, evidence search and selection methods, etc.).		
Z. Filolity 8	Jetung	1. Decide on a process for priority setting of guideline topics needed and who will be responsible for directing the process		
15	х	(e.g. priorities set by oversight committee at headquarters of sponsoring organization, priorities referred by government ministries of health or by professional societies).		
16	x	Apply a systematic and transparent process with specific criteria for the proposal of a guideline topic during priority setting (e.g. high prevalence and burden of disease, avoidable mortality and morbidity, high cost, emerging diseases or setting to the property of the propert		
17	х	emerging care options, variation in clinical practice, rapidly changing evidence, etc.). 3. Involve appropriate stakeholders in the priority setting process and guideline topic selection (e.g. clinicians, professional societies, policymakers, payers, the public). (see Topic 6)		
18		 Consider and decide how different perspectives about the importance and resources required for implementing the guideline recommendations will be considered (e.g. patients, payers, clinicians, public health programs). (see Topic 11) 		
x		5. Search for any existing up-to-date guidelines covering the proposed topic and assess their credibility (e.g. AGREE II). Determine whether existing guideline(s) can be adapted or if a completely new guideline should be developed. (see also Topic 10).		
		Discuss the need or opportunity to partner with other organizations that develop guidelines to determine whether a		
20	4 -> -> -	GDC Checklist Time schedule +		
CONTROL SECTION 1				





ARE YOU DRUI	VK2
YES	VIV.
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Next steps









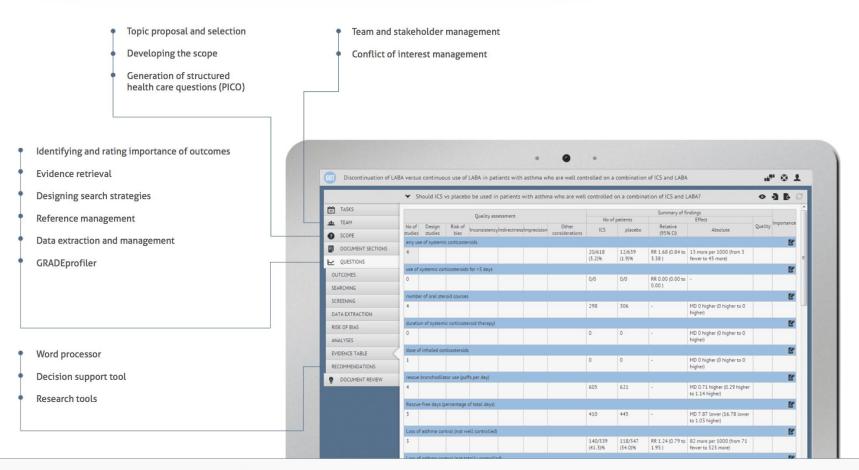


- Explicit use in real guidelines
 - Two ongoing projects
- Identify time/resource intensive items
- Tools
 - Integration with guideline development tool
 (GDT) guidelinedevelopment.org





The modules will include among others:



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Guidelines...

"Guidelines are recommendations intended to <u>assist</u> providers and recipients of health care and other stakeholders to make <u>informed</u> <u>decisions</u>."

WHO 2003, 2007





