



Tool: Development process and structure of a clinical guideline

Note: This document is provided for information purposes only. Health professional associations making use of this resource should revise and modify it for use in their specific circumstances.

Clinical practice guidelines are systematically developed documents to assist practitioners and patients and their families in the decision of appropriate health care for specific clinical conditions and/or circumstances.¹ In the field of reproductive, maternal and newborn health, they are used to promote standards of practice and improve health care by:

- Describing appropriate care based on the best available scientific evidence and broad consensus;
- Reducing inappropriate variation in practice;
- Providing a more rational basis for referral;
- Providing focus for continuing medical education;
- Promoting efficient use of resources;
- Acting as a focus for quality control, including audit;
- Highlighting shortcomings of existing literature and making suggestions for appropriate future research.²

In medico-legal situations, these documents may also be used to review the issue at hand and establish standards from which to evaluate proper management of care.

The process for development, update, dissemination and evaluation of clinical practice guidelines vary from country to country. In some countries, their development and dissemination are led by health professional associations; in others their development is led by the Ministry of Health and/or other stakeholders in the field such as international health organisations or NGOs active in the field.

Clinical Guideline Development Process

Whether developed by a health professional association or other stakeholders, the clinical guideline development process is more or less the same. It includes the following steps:

- Identify the need for and the scope of the guideline

To consider:

- Is it a matter of reviewing or updating an existing guideline or developing a new one?
- Is it in response to a developing situation or scenario that would assist health professionals in patient care (e.g. HINI in pregnancy, management of post partum hemorrhage)?
- Who will be the audience (e.g. health professionals in primary, secondary or tertiary level of care)?

- Establish a committee to develop the guideline

To consider:

- Who should lead the development of this guideline and be principal author(s)?

Tips for adapting existing clinical guidelines to middle- and lower-resource settings

Developing clinical guidelines can be costly and time consuming. In light of the increasing number of evidence-based clinical guidelines disseminated by leaders in the field, adapting a pre-existing clinical guideline to the local context may be a more suitable option for middle- and lower-resource countries. To be successful, the adaptation process should be systematic and transparent and should include an assessment in terms of the clinical guideline's quality, currency, content, adaptability, etc.

The following are a selection of resources to assist in adapting current and valid clinical guidelines to lower settings:

- *Development of RCOG Green-top Guidelines: consensus methods for adaptation of Green-top Guidelines* [Clinical governance advice no 1d]. 2nd ed. London: Royal College of Obstetricians and Gynaecologists; 2010. Available: <http://www.rcog.org.uk/files/rcog-corp/CGA1dConsensusMethods.pdf>.
- Fervers B, Burgers JS, Haugh MC, Latreille J, Mlika-Cabanne N, Paquet L, et al. Adaptation of clinical guidelines: literature review and proposition for a framework and procedure. *Int J Qual Health Care* 2006;18(3):167-76. Available: <http://intqhc.oxfordjournals.org/content/18/3/167.full.pdf>.
- ADAPTE Collaboration. *The ADAPTE process: resource toolkit for guideline adaptation*. Version 2.0. Berlin: Guideline International Network; 2009. Available: http://www.g-i-n.net/document-store/adapte-resource-toolkit-guideline-adaptation-version-2/at_download/file.

- Who else should be involved in the development process?
- Who will endorse the guideline and thus should be involved in or kept informed of its development?
- What will be the committee's terms of reference?

➤ Obtain scientific evidence and review it (*See Tool 6.6*)

To consider:

- Are there similar guidelines available in other countries?
- Has a systematic review been performed on the topic (e.g. the Cochrane Data Base of Systematic Reviews)?
- Is a literature review on the subject matter available?
- What is the best available evidence on the subject matter (e.g. are there randomized control trials available and are their results applicable)?

➤ Draft the guideline (see table below)

To consider:

- Has an outline of the document been developed, taking into account the scope?
- Has the material to be developed been divided among principal authors?
- What is the timeline for completing the draft guideline (this should be defined in the committee's Terms of Reference)?
- What resources are available to facilitate the process?

➤ Have the guideline reviewed

To consider:

- Are other subject matter experts available to help with the review?
- Are experts from other specialties required (e.g. pediatricians, anesthesiologists)?
- Would the guideline be of interest to other associations? Could these associations be invited to review and possibly endorse the guideline?
- How will the recommendations and comments made during the review be integrated into the guideline?

➤ Approval of the guideline

To consider:

- If appropriate, what other stakeholders could endorse the guideline and facilitate its adoption into practice?

➤ Disseminate the guideline

To consider:

- How will the guideline be presented to government, health professionals, public and other stakeholders?
- Are there opportunities to disseminate the guideline to association members during CME activities (e.g. Scientific Congress, workshop, lunch and learn, etc.)?

➤ Evaluate the guideline

To consider:

- How has the guideline affected outcomes of improved patient care?
- Are there simple audit methodologies that can be used to evaluate the guideline?

Types of clinical guideline documents³

Document type	Main leads	Content focus	Objectives	Target audience	Structure	Examples
Consensus statements	<ul style="list-style-type: none"> *Standing committees of professional associations *Advisory group, usually multidisciplinary *Representatives of other organisations if written as a co-sponsored statement 	Current and/or controversial clinical subject matter being actively debated by peers	<ul style="list-style-type: none"> *Provide information and evaluate new and/or developing treatment and technical procedures; *Review clinical management; *Provide direction/guidance on rapidly changing body of evidence; *Improve quality of care and patient safety; *Promote the efficient use of health care resources. 	Health care practitioners and health care organisations	Less structure, usually provides recommendations	FIGO document on task shifting (in development)
Clinical practice guidelines	<ul style="list-style-type: none"> *Principal author(s) *Standing committees of professional health associations 	Clinical care practice issues	<ul style="list-style-type: none"> *Improve quality of care; *Promote patient safety; *Decrease adverse events or clinical errors; *Promote efficient use of healthcare resources. 	Health care practitioners and healthcare organisations	Structured format that includes an abstract, recommendations with quality of evidence and classification of recommendations and references	FIGO Clinical Practice Guideline on Induction of Labour
Policy statements	<ul style="list-style-type: none"> *Governing body of a health professional association 	Training issues, clinical practice environment,	<ul style="list-style-type: none"> *Stimulate change in legislation and/or governance; *Strengthen advocacy 	National/provincial	Recommendations with quality of evidence and classification of	FIGO document on

Document type	Main leads	Content focus	Objectives	Target audience	Structure	Examples
		access to care and social issues such as violence against women or services to adolescents	efforts aimed at promoting improved health care policies.	governments, health care organisations or other stakeholders	recommendations	bribery and corruption
Technical updates	*Principal author(s) *Standing committees of professional health associations	Current and/or controversial clinical subject matter being actively debated by peers	*Provide information and evaluate new and/or developing treatment and technical procedures; * Review clinical management; *Provide direction/guidance on rapidly changing body of evidence; *Improve quality of care and patient safety; * Promote efficient use of healthcare resources.	Healthcare practitioners and health care organisations	Structured format, although less rigorous than a clinical guideline, that includes summary statements with quality of evidence	Usage of misoprostol in clinical settings

Structure of a Clinical Guideline³

The following provides a template for the standard structure of a clinical guideline and tips for the development process. It was adapted from the structure used by the Society of Obstetricians and Gynaecologists of Canada to develop their guidelines.

Structure	Suggestions/Examples
Title	Create a guideline title that is concise and that clearly reflects its content
Short paragraph outlining the type of guideline and who developed and approved it	<p><u>Example:</u></p> <p>This (<i>type of guideline: Clinical Practice Guideline, Consensus, Policy Statement, Technical Update or Committee Opinion</i>) has been prepared by the (<i>name of committee or group</i>), reviewed (<i>if applicable</i>) by (<i>name of committee or group, including other endorsing organisations/associations</i>) and approved by (<i>other organisation if applicable i.e. joint guideline</i>) and by the Board/Executive Committee (<i>and Council if applicable</i>) of (<i>name of the professional health association or other authority giving the final approval</i>).</p>
Principal author(s)	<p>Principal authors are those who have written the guideline or contributed significantly to its revision. All persons designated as authors should qualify for authorship, and all those who qualify should be listed. The following conditions must be met to qualify for Principal Authorship credit:</p> <ul style="list-style-type: none"> (a) substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data; or (b) substantial contributions to drafting or revising the article; or (c) final approval of the version to be published with the understanding that the only changes that can be made are in the case of error or omission (strictly what's said, not how it's said); and (d) must be a member of the health professional association that is leading the process. <p>Acquisition of funding, the collection of data, or general supervision of the research group, do not justify Principal Authorship.</p> <p>Authors are listed:</p>

	<ul style="list-style-type: none"> - in the order that was mutually agreed to and do not necessarily have to be in alphabetical order - by first and last names and initials as indicated by the author (authors with fairly common names need to use initials to help narrow PubMed searches) - with mention of degrees and/or accreditations (MD, RN, RM) - with city and province of the academic address <p>Example: <i>given name, initial, family name, MD, city, province</i></p>
Name of the Committee and its members	If the guideline is developed by a specific committee or group that is well established (i.e. a standing committee of a health professional association), the name of the committee and its members should be included.
Special contributor(s)	Special contributors are those who have significantly contributed to the paper, but who are not to be listed as Principal Authors and are not Committee members.
Disclosure statements	<p>To ensure the highest integrity, and hence public confidence, health professional associations and others should require that all involved in the development of a clinical guideline agree to disclose any circumstances which could give rise to a potential conflict of interest (i.e. any interest which may affect, or may reasonably be perceived to affect, the expert's objectivity and independence). All should agree to disclose any financial, professional or other interest relevant to the subject of the work and any interest that could be significantly affected by the outcome of the work in a Declaration of Interest (DOI) Form.</p> <p>Circumstances which could give rise to a potential conflict of interest include:</p> <ul style="list-style-type: none"> - <u>Intellectual property rights</u> that might be enhanced or diminished by the outcome of the article (either directly or through immediate family); - <u>Financial relationships</u> with a commercial entity or other organisation with an interest related to the subject of the article, for example through employment, consultancies, research support, investment interests, honoraria (either directly or through

	<p>immediate family);</p> <ul style="list-style-type: none"> - <u>Public statements</u> in which an expert opinion, testimony or defence has been given related to the subject of the article; - Relationships with the <u>competitor of a product</u> mentioned in article, for example through employment or having privileged access to proprietary information; - <u>Any other aspect</u> that might be perceived as affecting the expert's objectivity and independence.
Disclaimer	<p><u>Example:</u></p> <p>This document reflects emerging clinical and scientific advances as of the date issued and is subject to change. The information should not be construed as dictating an exclusive course of treatment or procedure to be followed. Local institutions can dictate amendments to these opinions. Amendments should be well documented if modified at the local level. None of the content may be reproduced in any form without prior written permission of the (name of the professional health association or other authority giving the final approval).</p>
<p>Abstract</p> <ul style="list-style-type: none"> ○ Objective ○ Options ○ Outcomes 	<p>Objective: the primary objective of the document, including the health problem and the targeted patients, providers, and settings, as applicable.</p> <p><i><u>Example:</u> This guideline reviews the evidence relating to the potential benefits of the vaginal hysterectomy (VH) and supracervical hysterectomy (SCH) versus total abdominal hysterectomy (TAH) with respect to post-operative sexual function, urinary function, and peri- and post-operative complications. Laparoscopic options are not included in this guideline.</i></p> <p>Options: the clinical practice options considered in the document.</p> <p><i><u>Example:</u> Women considering hysterectomy for benign disease can be given the option of retaining the cervix or proceeding with a total hysterectomy.</i></p>

	<p>Outcomes: significant health and economic outcomes considered in comparing alternative practices.</p> <p><i>Example: The outcomes measured are post-operative sexual function and urinary function, and peri- and post-operative complications.</i></p>		
<p>Evidence</p>	<p><u>Example:</u></p> <p>Published literature was retrieved through searches of PubMed or MEDLINE, CINAHL, and The Cochrane Library in (<i>insert date</i>) using appropriately controlled vocabulary (e.g. <i>insert MeSH</i>) and keywords (e.g. <i>insert key words</i>). Results were restricted to systematic reviews, randomized control trials/controlled clinical trials, and observational studies. There were no date or language restrictions (this statement will need to be adapted to each guideline). Searches were updated on a regular basis and were incorporated into the guideline document up until (<i>insert date</i>). Grey (unpublished) literature was identified through searching the websites of health technology assessment (HTA) agencies, clinical practice guideline collections, clinical trial registries, and from national and international medical specialty societies.</p>		
<p>Values</p> <p>(Note: Although the example provided makes use of the Canadian Task Force on Preventive Health Care’s criteria, users of this tool may consider using the Grading Recommendations Assessments, Development and Evaluation (GRADE) system. For more information, see: http://www.gradeworkinggroup.org/index.htm)</p>	<p>Disclosure of how values were assigned to potential outcomes of practice options and of who participated in the value assignment process.</p> <p><i>Example: The quality of evidence was rated using the criteria described in the Report of the Canadian Task Force on Preventive Health Care.</i></p> <hr/> <p><i>Table 1: Key to evidence statements and grading of recommendations, using the ranking of the Canadian Task Force on Preventative Health Care</i></p> <table border="1" data-bbox="781 1545 1393 1598"> <tr> <td data-bbox="781 1545 1094 1598">Quality of Evidence Assessment*</td> <td data-bbox="1094 1545 1393 1598">Classification of Recommendations‡</td> </tr> </table>	Quality of Evidence Assessment*	Classification of Recommendations‡
Quality of Evidence Assessment*	Classification of Recommendations‡		

	<p>I: Evidence obtained from at least one properly randomized controlled trial</p> <p>II-1: Evidence from well-designed controlled trials without randomization</p> <p>II-2: Evidence from well-designed cohort (prospective or retrospective) or case-control studies, preferably from more than one centre or research group</p> <p>II-3: Evidence obtained from comparisons between times or places with or without the intervention. Dramatic results in uncontrolled experiments (such as the results of treatment with penicillin in the 1940s) could also be included in this category</p> <p>III: Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees</p> <p>A. There is good evidence to recommend the clinical preventive action</p> <p>B. There is fair evidence to recommend the clinical preventive action</p> <p>C. The existing evidence is conflicting and does not allow to make a recommendation for or against use of the clinical preventive action; however, other factors may influence decision-making</p> <p>D. There is fair evidence to recommend against the clinical preventive action</p> <p>E. There is good evidence to recommend against the clinical preventive action</p> <p>L. There is insufficient evidence (in quantity or quality) to make a recommendation; however, other factors may influence decision-making</p> <p><small>* The quality of evidence reported in these guidelines has been adapted from The Evaluation of Evidence criteria described in the Canadian Task Force on Preventive Health Care. †Recommendations included in these guidelines have been adapted from the Classification of recommendations criteria described in The Canadian Task Force on Preventive Health Care.</small></p>
Benefits, harms and costs	The type and magnitude of benefits, harms and costs to patients expected from implementation of the clinical guideline by a health care facility.
Validation	Report of any external reviews, comparisons with other documents, or clinical testing of the use of the guideline document.
Sponsors	Disclosure of the person(s) who developed, funded, or endorsed the document.
Keywords	3 to 10 keywords or short phrases which will assist in cross-indexing the document (preferably some MeSH terms, which are available at http://www.ncbi.nlm.nih.gov/sites/entrez?db=mesh)
Recommendations and/or summary statements	In this example, the recommendations and/or summary statements make use of the <u>Quality of Evidence Assessment</u> ranking used by the Quality of Evidence Assessment and/or the Classification of Recommendations of the Canadian Task Force on Preventive Health Care.

<p>(Note: Although the example provided makes use of the Canadian Task Force on Preventive Health Care's criteria, users of this tool may consider using the Grading Recommendations Assessments, Development and Evaluation (GRADE) system. For more information, see: http://www.gradeworkinggroup.org/index.htm)</p>	<p><u>Example of summary statement:</u> <i>A comparison of women who were diagnosed antenatally and those who were not shows respective neonatal survival rates of 97% and 44%, and neonatal blood transfusion rates of 3.4% and 58.5%, respectively. Vasa previa can be diagnosed antenatally, using combined abdominal and transvaginal ultrasound and colour flow mapping; however, many cases are not diagnosed, and not making such a diagnosis is still acceptable. Even under the best circumstances the false positive rate is extremely low (II-2).</i></p>
<p>Introduction</p>	<p>The introduction states the guideline's purpose and summarizes relevant background information. It should not be longer than one to two double-spaced manuscript pages. It is best to avoid subheadings within the introduction.</p> <p>The introduction is often the best place in which to reference the Quality of Evidence Assessment and Classifications of Recommendations.</p>
<p>Main content</p>	<p>Use headings and subheadings to reflect the progression of logic or the flow of thought. If photographic images, figures and table designs are used, these elements should complement rather than duplicate information found within the text. Tables should be complete enough to be understood without continual reference to the text, but contain only the data needed for the reader's understanding. Remember, it is the responsibility of the author(s) to obtain permission to reproduce any material that has been previously published or is copyrighted or registered, including tables that bear the statement "adapted from."</p>
<p>Conclusion/Summary</p>	<p>Authors should provide a brief conclusion to summarize the document. References do not belong in the conclusion.</p>
<p>Recommendations</p>	<p>The recommendations used in the abstract portion of the document are repeated at the end of the main section, just before the references.</p>
<p>References</p>	<p>It is the responsibility of the author(s) to verify the accuracy of references against the original documents. In the bio-medical/clinical field, the NLM style of citation is preferred. For more info, see: http://www.ncbi.nlm.nih.gov/books/NBK7256/.</p>

BIBLIOGRAPHY

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2. Clinical practice guidelines. Open Clinical; 2012. Available: <http://www.openclinical.org/guidelines.html>.
3. *SOGC guidelines: information and development manual*. Ottawa: Society of Obstetricians and Gynaecologists of Canada; 2011. Available: <http://www.sogc.org/guidelines/documents/manGuideInfoDevelopManual.pdf>