Guideline Adaptation:
A Resource Toolkit

| Prepared by the ADAPTE Collaboration 2009
| (www.adapte.org)
| Version 2.0

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The ADAPTE Collaboration

The ADAPTE Collaboration is an international collaboration of researchers, guideline developers, and guideline implementers who aim to promote the development and use of clinical practice guidelines through the adaptation of existing guidelines. The group's main endeavour is to develop and validate a generic adaptation process that will foster valid and high-quality adapted guidelines as well as the users' sense of ownership towards of the adapted guideline.

A more detailed history of the ADAPTE collaboration is provided at the end of the document.

Following the finalization of the ADAPTE Manual and Resource Toolkit and their evaluation, the ADAPTE Collaboration dissolved and transferred the ADAPTE process and its resources to the Guidelines International Network (G-I-N) to facilitate its dissemination.

As of February 2010, G-I-N (www.g-i-n.net) will make this version of the ADAPTE Manual and Resource Toolkit (version 2.0) available for free on its website. G-I-N will establish an Adaptation working group to support groups undertaking or planning to undertake guideline adaptation and to handle further developments and refinements of the ADAPTE Manual and Resource.

Individuals interested in participating in the activities of the adaptation working group should contact the G-I-N Office.

Disclaimer

The ADAPTE process has been thoroughly developed and care has been taken in the preparation of the information contained in this document. Nonetheless, any person seeking to apply or consult this resource toolkit is expected to use independent judgment in his own context. The ADAPTE Collaboration makes no representation or warranties of any kind whatsoever regarding the content or use or application of the ADAPTE process and disclaims any responsibility for the application or use of the manual or resource toolkit in any way.

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ADAPTE Methodology – Recommendations for Use

December 2009

The following recommendations for use of the ADAPTE methodology and resource are based on the results of an evaluation conducted on the draft manual and toolkit. The evaluation consisted of a two part survey: upon requesting the ADAPTE resource, potential users were sent the short version and a survey asking their impressions of the resource, and the proposed process. Upon receipt of the survey by the evaluation team, users were then sent the full resource and another survey. Feedback on the methodology and toolkit was largely positive – potential users felt the process, the modules and the toolkit were clearly laid out and comprehensive[1]. The following are in response to complexity of the process as identified by users:

- Learning Curve: efficient use of any new methodology requires the user to invest time and energy in learning the process until it becomes familiar. Even for guideline developers who will be conversant with many of the steps in this methodology, there are new processes to consider and learn. The first use of the methodology will likely not result in any time savings with respect to overall development time.

- Additional Resources: while the manual describes the adaptation process in some detail, some users, especially those with little guideline development expertise, may wish to consult additional resources. Tool 1 provides a listing of resources that users may find helpful. Users may also consider contacting the G-I-N office to be guided towards other resources.

- Dedicated Project Coordinator: like with de novo guideline development, there is a significant amount of work involved in managing the guideline adaptation process especially for small groups or those with little experience in guideline development. An individual should be identified as responsible for organizing meetings, managing documents, recording decisions and ongoing communication with the panel on the status of the project and remaining work.

- Context of Use – Development versus Implementation: the ADAPTE methodology presented in this manual facilitates the development of a guideline; only a small section towards the end of the manual deals with implementation issues. Thus, use of the ADAPTE methodology outside of a guideline development organization will require early consideration of issues around implementation and adoption of the final product, e.g., available human and material resources, barriers assessments, and strategies for uptake of the new guideline.

Executive Summary

The development and updating of high-quality practice guidelines require substantial resources, and most organisations are under pressure to produce more guidelines in a shorter time with increasingly limited resources. In order to take advantage of existing guidelines and reduce the duplication of effort, guideline adaptation has been proposed as an option for guideline development.

The **ADAPTE process** provides a systematic approach to adapting guidelines produced in one setting for use in a different cultural and organizational context. The process has been designed to ensure that the adapted guideline not only addresses specific health questions relevant to the context of use but also is suited to the needs, priorities, legislation, policies, and resources in the targeted setting. The ADAPTE process has been developed to meet the needs of different user groups, including guideline developers, health care providers, and policy makers at the local, national, and international level, as well as groups with lesser or greater resources interested in developing or implementing guidelines. The process is designed to be flexible, depending on the application. The transparent and explicit reporting of the adaptation process followed will enhance the quality and validity of the adapted guideline.

The adaptation process consists of three main phases (Set-up Phase, Adaptation Phase, and Finalization Phase), each with a set of modules (see Figure on next page).

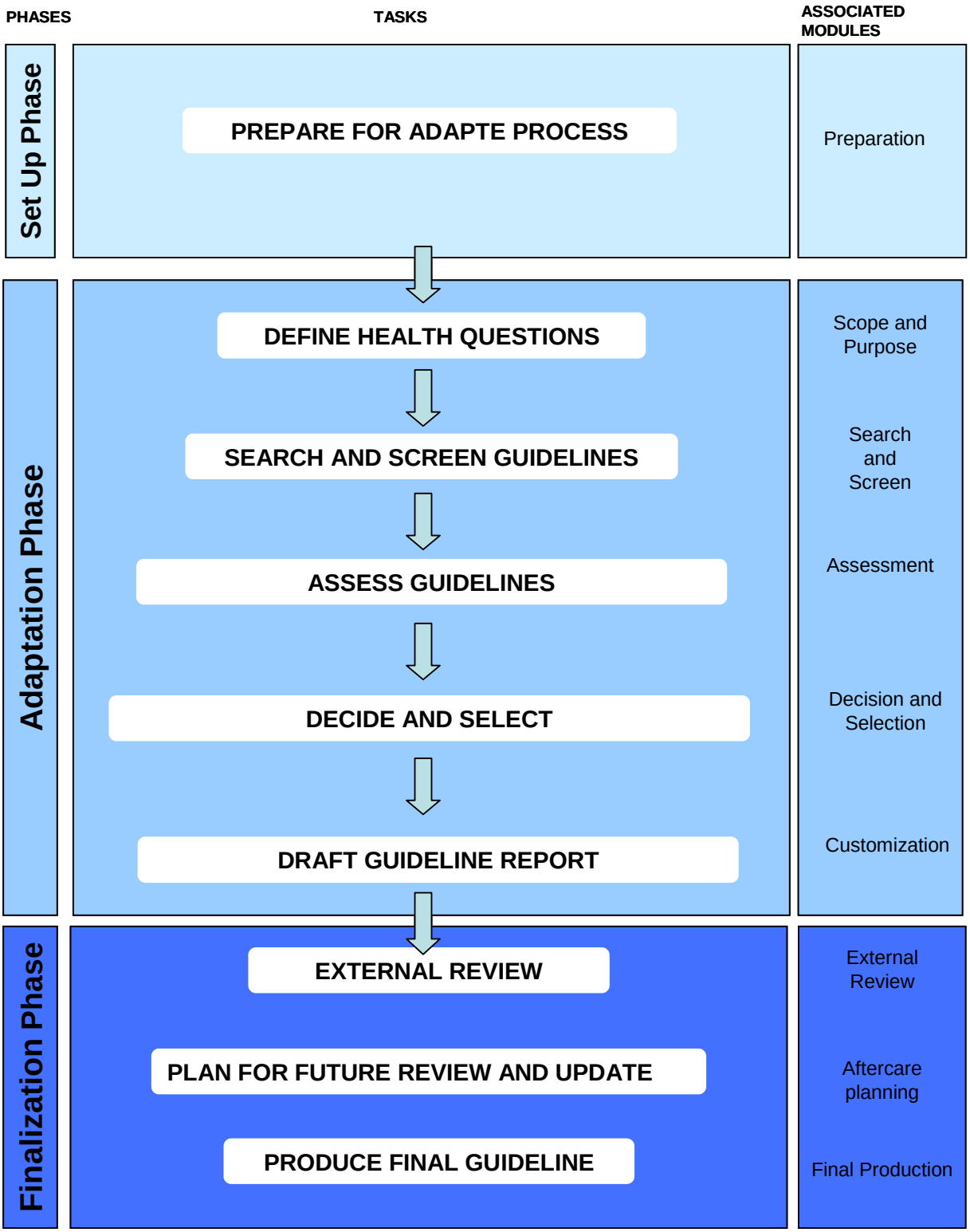
Set-up Phase: Outlines the necessary tasks to be completed prior to beginning the adaptation process (e.g., identifying necessary skills and resources).

Adaptation Phase: Assists users through the process of selecting a topic to identifying specific health questions; searching for and retrieving guidelines; assessing the consistency of the evidence and the guideline quality, currency, content, and applicability; decision making around adaptation; and preparing the draft adapted guideline.

Final Phase: Guides the user through the process of obtaining feedback on the document from stakeholders impacted by the guideline, consulting with the developers of source guidelines used in the adaptation process, establishing a process for the review and updating of the adapted guideline, and creating a final document.

The ADAPTE process is supported by resources, in particular the present resource toolkit and related tools, to facilitate its application. Each module of the resource toolkit provides a detailed description of the steps, the products and deliverables, and the skills and organizational requirements. An example, the adaptation of guidelines for cervical cancer screening, is provided throughout the modules.

Summary of the ADAPTE process



Introduction

The development and updating of high-quality practice guidelines require substantial resources. Most organisations are under pressure to produce more guidelines in a shorter time with increasingly limited resources. While the key methods for guideline development have converged over the years, a large number of organisations worldwide do produce guidelines on the same topic. In order to take advantage of existing guidelines and reduce this duplication of effort, guideline adaptation has been proposed as an option for guideline development (1,2).

However, the cultural and organizational differences between and within countries can lead to legitimate variations in recommendations, even when the evidence base is the same. This means that guidelines produced in one setting may not necessarily be appropriate for another, without careful consideration and/or contextualization. The ADAPTE Collaboration has developed a systematic approach to aid in the adaptation of guidelines and has produced this resource toolkit for that purpose.

Definition of guideline adaptation

The ADAPTE Collaboration defines guideline adaptation as the systematic approach to considering the use and/or modification of (a) guideline(s) produced in one cultural and organizational setting for application in a different context. Adaptation can be used as an alternative to *de novo* guideline development – where guidelines currently exist or for customizing (an) existing guideline(s) to suit the local context.

Aim of guideline adaptation

The overall objective of adaptation is to take advantage of existing guidelines in order to enhance the efficient production and use of high-quality adapted guidelines. The adaptation process described in this resource toolkit has been designed to ensure that the final recommendations address specific health questions relevant to the context of use and address the needs, priorities, legislation, policies, and resources in the target setting, without undermining the validity of the resulting recommendations.

The adaptation process is based on the following core principles

- Respect for the evidence-based principles of guideline development
- Reliable and consistent methods to ensure the quality of the adapted guideline
- Participative approach, involving all key stakeholders, to foster acceptance and ownership of the adapted guideline
- Explicit consideration of context during adaptation to ensure relevance for local practice
- Transparent reporting to promote confidence in the recommendations of the adapted guideline
- Flexible format to accommodate specific needs and circumstances
- Accountability to the primary guideline sources

Outline of adaptation process

The adaptation process consists of three main phases (Set-up Phase, Adaptation Phase, and Finalization Phase), each with a set of modules. Each module includes several steps, products and deliverables, skills and organizational requirements, and tools.

SET-UP PHASE	ADAPTATION PHASE	FINALIZATION PHASE
Preparation Module	Scope and Purpose Module Search and Screen Module Assessment Module Decision and Selection Module Customization Module	External Review and Acknowledgment Module Aftercare Planning Module Final Production Module

Set-up Phase: Outlines the necessary tasks to be completed prior to beginning the adaptation process (e.g., identifying necessary skills and resources) with a first step of determining whether adaptation is feasible. Readers familiar with guideline development will already have experience with these tasks.

Adaptation Phase: Assists users in moving from selecting a topic to identifying specific health questions; searching for and retrieving guidelines; assessing the consistency of the evidence and the guideline quality, currency, content, and applicability; decision making around adaptation; and preparing the draft adapted guideline.

Final Phase: Guides the user through the process of obtaining feedback on the document from stakeholders who will be impacted by the guideline, consulting with the source developers of guidelines used in the adaptation process, establishing a process for the review and updating of the adapted guideline, and creating a final document.

Purpose of this resource toolkit

This resource toolkit provides a practical guide to the adaptation of practice guidelines. The explicit approach described in the resource toolkit is intended to be useful to guideline users and implementers such as local health care authorities and organizations, guideline development organizations, and international health care organizations. The methods aim to suit the needs of a broad range of stakeholders (from novices to those experienced with guideline development and groups with lesser or greater resources).

This resource toolkit is not a guide for developing *de novo* guidelines and does not provide details on guideline dissemination and implementation. Several resource toolkits on these aspects are freely available via the Internet from institutions such as the National Institute for Health and Clinical Excellence (NICE), the Scottish Intercollegiate Guidelines Network (SIGN), the National Health and Medical Research Council (NHMRC), and the New Zealand Guideline Group (NZGG) (see Tool 1 – Guideline Development and Implementation Resources).

Tool 1 – Guideline Development and Implementation Resources

How to use this resource toolkit

The adaptation process described in this resource toolkit has multiple applications. For example, a group may be interested in selecting one specific guideline for adaptation to the local context. Others may want to identify all high-quality guidelines that respond best to the health questions and health care situations of their context and then customize a guideline that meets their needs. In addition, this adaptation process can be applied to guidelines for health promotion, screening, diagnosis, treatment, follow-up, or other interventions in any disease area.

The process is designed to be flexible, depending on the application. Not all modules may be relevant to the users' needs. For example, those wishing to adapt a single guideline will not need to perform a systematic search for all guidelines related to the health question(s) (Adaptation Phase – Search and Screen Module). For those users experienced in guideline development, some of this information will be familiar and may be redundant. However, we suggest that all users read the complete resource toolkit to have a sense of the process from beginning to end.

SET-UP PHASE
1.1 Preparation Module

The Set-up Phase outlines the necessary tasks to be completed prior to beginning the adaptation process (e.g., identifying necessary skills and resources). Readers familiar with guideline development will already have experience with these tasks.

Steps	Products/ Deliverables	Skills and Organizational Requirements	Tools
1. Check whether adaptation is feasible 2. Establish an organizing committee 3. Select a topic 4. Identify skills and resources needed 5. Complete set-up tasks 6. Write protocol	• Organizing committee established • Topic identified • Panel selected • Protocol completed	Clinical expertise Methodological expertise Managerial and administrative skills	Tool 1 – Guideline Development and Implementation Resources Tool 2 – Search Sources and Strategies Tool 3 – Sample Declaration of Conflict of Interest Tool 4 – Consensus Process Resources Tool 5 – Work Plan Example

Step 1. Check whether adaptation is feasible

Even if there are existing guidelines for a specific topic, we suggest checking whether any other guidelines have been produced or are currently being developed on the selected topic by searching the Web sites of guideline clearinghouses and specialty organisations (see Tool 2 – Search Sources and Strategies). In some situations, the decision may be to adapt a specific guideline rather than searching for a larger number of potential source guidelines. If no guidelines related to the topic area exist, a decision will need to be made about whether a guideline should be created *de novo*—for those organizations with the resources to develop guidelines.

Tool 2 – Search Sources and Strategies

Step 2. Establish an organizing committee

An organizing committee should oversee the adaptation process. In the Set-Up Phase, the committee responsibilities will include determining the project scope, organizational and governance structures (e.g., working group or multidisciplinary panel members), terms of reference, and development of an adaptation plan. For the remainder of the document, the term 'panel' will refer to the multidisciplinary group convened for the tasks of the adaptation process. Members of the organizing committee may also be panel members or may solely act to set the process in place.

Step 3. Select a guideline topic

In some cases, the need for a guideline on a particular topic will already have been identified. In other cases, a group may need to select a topic. There are a number of criteria that can be used to identify and prioritize areas for best practice and guideline adaptation (2). For example, these criteria might include:

- The prevalence of the condition
- The existence of underuse, overuse, or misuse of interventions
- The burden associated with the condition (e.g., a system, financial, or patient burden)
- Concerns about practice variation and whether baseline data on current practice is available
- Costs associated with different practice options
- The likelihood that the guideline will be effective in influencing practice
- The potential for improving quality of care and/or patient outcomes (e.g., survival or quality of life)
- The existence of relevant good-quality evidence-based guidelines

Step 4. Identify necessary resources and skills

In addition to ensuring that there are existing guidelines to support adaptation, there need to be sufficient resources to complete the process, resources that include the following:

- Commitment by the panel members to at least one face-to-face meeting and to conference calls
- Commitment by the panel members, outside of meetings, to review all documents
- Coverage of meeting costs
- Possible honorariums for panel members to cover the time spent appraising guidelines
- Availability of project management personnel and administrative support for guideline collection, storage, documentation; and meeting coordination
- Coverage of the costs of implementing the guideline (if relevant)

The credibility of the guideline quality appraisal process rests, in large part, on the credibility of the panel members (3). Who is involved and the skills that they bring to the panel are important. The group should include individuals from among key stakeholders affected by the guideline.

The following skills should be represented on the panel:

- Clinical knowledge in the topic area—knowledge of the issues related to the application of the guideline in local practice and of the latest research in the topic area
- Personal experience with the topic area (e.g., experience gained from living with the disease, having undergone the intervention, or caring for someone with the disease)—to ensure that issues related to patient/consumer needs are discussed and that salient outcomes such as quality of life are considered
- Policy/administrative expertise—to identify the impact of the guideline on an organization and to anticipate resource requirements resulting from implementing the guideline
- Methodological expertise (e.g., health services researchers)—knowledge of research design and knowledge in critical appraisal and guideline appraisal play a role in educating other panel members on issues related to the systematic and rigorous nature of the process and provides a methods resource
- Information retrieval expertise—knowledge of databases and literature searching

- Managerial skills—to manage the timelines of the project, set up meetings and conference calls, and ensure that all documents are circulated to the panel
- Implementation expertise—knowledge of implementation issues, including how to develop a plan for putting the guideline into practice and spearhead the implementation
- Facilitation skills—to help the panel function effectively, ensure all panel members are given opportunities to contribute, and help the panel achieve its aims

A multidisciplinary group is important if the guideline addresses issues that impact several provider groups. The involvement of a mix of disciplines ensures that issues such as those related to the application of the guideline, to the evidence behind the recommendations, and to the impact on patients will all be considered (1,3).

Step 5. Complete tasks for the set-up phase

By the end of this phase, the following items need to be completed or considered:

- Terms of reference: Such terms should be drawn up by either the organizing committee or the panel and could include the scope of the work to be completed, how the membership is constituted, time commitment required and how often the panel should meet. The terms of reference need to be shared with all panel members so that they understand and agree to their involvement in the process.
- Declaration of conflict of interest: ADAPTE encourages all panel members to complete and sign a declaration of conflict of interest. The panel should be aware of the potential bias or vested interests/conflicts of interest of any member who might have been involved in the development of one of the guidelines considered for the adaptation process. Decisions will need to be made as to whether such potential conflicts create a concern or not, and, if they do, how to deal with that concern.

Tool 3 – Sample Declaration of Conflict of Interest

- Consensus process: A decision should be made by the organizing committee or panel as to how the panel will manage decisions (e.g., through either a formal or informal consensus process) and how this process will be reported in the final document.

Tool 4 – Resources on Consensus Processes

- Potential endorsement bodies: The committee should decide whether it would be helpful to have someone or some organization endorse the adapted guideline. If so, they should consider involving a representative of the endorsement body (e.g., hospital administration, professional body, or home care authority) in the process as a member of the panel or as part of the external review process of the draft guideline.
- Guideline authorship: A decision should be made as to who will be responsible for writing the draft adapted guideline and the final report and about the principles of authorship.

  The order of authorship needs to be determined (e.g., name of the member responsible for writing the guideline, name of the chair, and name of the group). Group authorship could also be considered.

- Dissemination and Implementation Strategies: Potential publications should be considered, for example, a publication on the organization's Web site and/or a manuscript submitted to a journal for publication. The eventual implementation of the adapted guideline should be considered throughout the adaptation process, for example, the context of implementation should be taken into account when reviewing possible recommendations. Tool 1 provides a list of available resources that provide good strategies for implementation.

Tool 1 – Guideline Development and Implementation Resources

Step 6. Write adaptation plan

At the completion of the preliminary phase, we recommend that the organizing committee and the panel agree about a plan that outlines the adaptation process to be followed. The formalized plan might include the following headings:

- Introduction
- Topic area
- Panel members, credentials, and declarations of conflicts of interest
- Panel Terms of Reference
- Modules to be followed
- Timeline for completion of the adaptation process and committed target date for completion, including meeting schedule
- Funding source(s)

Throughout the process, each decision taken by the organizing committee and the multidisciplinary panel should be well documented to make the process transparent. A person needs to be identified to manage and communicate this plan to all panel members.

SET-UP PHASE
1.1 Preparation Module

Illustration – Set Up Phase

Cervical cancer screening was selected as a topic for adaptation by a national group. The main reason for choice of this topic was a lack of consistency across the country in terms of how screening was being performed, especially with respect to the screening interval (e.g., intervals between screenings ranged from 1-3 years) and possibly, a potential overuse of resources. An organizing committee was struck to lead the adaptation process; a chair was identified to lead the meetings. Adaptation was chosen over *de novo* development, as the organizing committee was already aware of a number of credible cervical cancer screening guidelines produced by recognized guideline developers and currently in use by practitioners. The committee decided to retrieve as many guidelines as possible as opposed to adapting one guideline.

The chair, with the organizing committee, identified the expertise and skills needed on the panel, including the following: a family physician or general practitioner (1 urban and 1 rural), a nurse or nurse practitioner with experience in cancer screening, a cancer screening expert, a consumer representative, a methodologist, a gynecologic oncologist, a gynecologist, and representatives from professional bodies (a national college of family physicians and a national organization that focuses on developing guidelines for family physicians). The organizing committee was fortunate enough to have access to a resource team who would search for guidelines and retrieve them, calculate the quality scores, assess guideline currency, prepare the recommendations matrices, feed back all data from the assessments and send the draft guideline out for external review and consultation,

Potential panel members were contacted by letter and a follow-up phone call. Their tasks on the panel and total time commitment (Terms of Reference) required were outlined in the letter. Panel members were offered a small honorarium of $50CAD for each guideline that they appraised. Their meeting costs (flights and accommodation) were also covered. Upon agreeing to participate, each panel member signed a declaration of conflict of interest—no conflicts were identified.

The organizing committee prepared a short protocol outlining the process the panel would follow, which included an introduction and rationale for adaptation, the topic area, panel membership, the consensus process to be followed, the modules to be followed, and the funding source. An example of a work plan with timelines is presented in *Tool 5 – Work Plan Example - Cervical Cancer Screening Guidelines Panel.*

Tool 5 – Example of Work Plan –
Cervical Cancer Screening Guidelines Panel

ADAPATION PHASE
2.1 Scope and Purpose Model

The Adaptation Phase assists users through the process of selecting a topic to identifying specific health questions, searching for and retrieving guidelines, assessing the guideline quality, currency, content, consistency and applicability, decision making around adaptation, and preparing the draft adapted guideline.

Steps	Products/ Deliverables	Skills and Organizational Requirements	Tools
7. Determine the health questions	• List of health questions to be included and those that are to be specifically excluded in the projected guideline	Clinical expertise Methodological expertise	Tool 6 – PIPOH

Step 7. Determine the health questions

Once a broad topic area is identified, it is very important to clarify the specific purpose and parameters of the chosen guideline topic by developing a series of structured key questions (4). The definition of a set of clear and focused health questions is an important consideration for successfully completing the adaptation process and will ensure that the final adapted guideline is applicable in the users' context. Conversely, some questions can and should be specifically excluded from the project.

The use of the following five items (PIPOH) will help to define the health questions and cover all relevant aspects:

- The **P**opulation concerned and characteristics of disease or condition
- The **I**ntervention(s) (or diagnostic test, etc.) of interest
- The **P**rofessionals to whom the guideline will be targeted
- The expected **O**utcomes including patient outcomes (e.g., improved disease free survival, improved quality of life); system outcomes (e.g., decrease in practice variation); and/or public health outcomes (e.g., a decrease in cervical cancer incidence)
- The **H**ealth care setting and context in which the guideline is to be implemented

Existing guidelines identified in the preliminary phase may help in defining the health questions. A quick survey of the guideline content may reveal additional health questions.

Tool 6 – PIPOH

ADAPATION PHASE
2.1 Scope and Purpose Model

Illustration – Determining the health question using the PIPOH instrument

The organizing committee used the PIPOH tool to help define their health questions.

Population: They decided that they wanted recommendations that would address average-risk women only (e.g., excluding women who are HIV positive or women with evidence of moderate dysplasia on Pap smear within the last five years). They decided not to specify a starting and finishing age for screening, as they wanted to review what guidelines were recommendations were around different options.

Intervention: The choice of intervention was screening. More specifically, the committee chose to not restrict the guideline search to any particular modality (e.g., conventional cervical cytology or liquid based cytology).
Professionals: Typically, cervical cancer screening is one of the health care manoeuvres performed primarily by family physicians, general practitioners, or nurse practitioners. Thus, the adapted guideline would be designed in consideration of these target groups.

Outcomes and outcome measures: Ideally, the guideline will encourage family physicians and general practitioners to follow the screening interval and screening modality that will be selected as part of the adapted guideline. There is much practice variation across the country, with overtesting of some populations and undertesting of others. The optimal screening interval should result in improved survival against reasonable costs.

Health care setting and context: The organizing committee wanted the guideline to be applicable to primary practice.

Through using the PIPOH, the organizing committee decided on the following clinical question:
What is appropriate cervical cancer screening for average risk women seen in primary care?

Steps	Products/ Deliverables	Skills and Organizational Requirements	Tools
8. Search for guidelines and other relevant documentation 9. Screen retrieved guidelines 10. Reduce total number of guidelines if there are more than can be dealt with by the panel	• Set of potential source guidelines • List of excluded guidelines	Search – Clinical expertise, information retrieval skills Screen – Clinical and methodological expertise	Tool 2 – Search Sources and Strategies Tool 7 – Example Table for Recording the Guideline Characteristics Tool 8 – Example Table for Recording the Clinical Content of Guidelines Tool 9 – AGREE Instrument Tool 10 – AGREE Inter-rater Agreement Spreadsheet and AGREE Score Calculation Spreadsheet

If the panel decides to identify all guidelines related to a topic area, a systematic search needs to be conducted. An initial screening of those guidelines found by the search will eliminate those that are not relevant based on predefined inclusion/exclusion criteria. These decisions need to be documented.

Step 8. Search for guidelines and other relevant documents

Based on the key question(s) defined in the Scope and Purpose Module, a search strategy can be developed and added to the project documentation. Inclusion and exclusion criteria, for example, the year of development, language, and guideline developer group, should be determined a priori (4). The information should guide the search, and an information scientist can be a useful resource to help with designing the strategy. A reasonably comprehensive search for guidelines should be undertaken to identify the most relevant guidelines to consider for adaptation. In some situations, the decision may be to adapt a specific guideline rather than searching for a larger number of potential source guidelines. This decision, as well as the reasons for it, should be clearly stated in the guideline report.

Since guidelines may not be published in journals, and not indexed in bibliographic databases, the search should start in guideline clearinghouses such as the US National Guideline Clearinghouse (www.guideline.gov) and the Guidelines International Network (www.g-i-n.net/) or in country-specific databases. In addition, the Web sites of organisations developing guidelines and of relevant specialty societies should be consulted.

Tool 2 – Search Sources and Strategies

A MEDLINE (www.ncbi.nlm.nih.gov/entrez/query.fcgi) search using a standardised search strategy may yield additional guidelines. Terms to be used include guideline [Publication Type] OR practice guideline [Publication Type] OR recommendation*[Title] OR standard*[Title] OR guideline*[Title], in combination with terms related to the clinical topic.

Internet search engines such as Google, AltaVista, and Yahoo can also be used to locate guidelines. As with other searches, the inclusion and exclusion criteria for the Internet search should be well defined. A recent study has revealed that guidelines posted on the Internet can be of equal or higher quality than guidelines published in the periodical literature (5).

We recommend summarising the following characteristics of the retrieved guidelines in a table:

- Developing organisation/authors
- Date of publication, posting, and release
- Country/language of publication
- Date of posting and/or release
- Dates of the search used by the source guideline developers

Note: A good-quality older guideline could be a good base on which to develop a new guideline. The notion of 'up-to-date' may vary with the clinical or health area; in some areas, best available data are regularly modified, whereas in other areas, new data are rarer [see Assessment Module – Guideline Currency].

Tool 7 – Example Table for Recording the Characteristics of Guidelines

As well as guidelines, an additional search should be conducted to identify any other relevant documents such as recent systematic reviews or health technology assessments reports published since the preparation of the retrieved guidelines. This documentation might be used to confirm whether an update of the evidence is necessary and/or to fill in gaps not covered by retrieved guidelines.

Step 9. Screen retrieved guidelines

The objective of this step is to select guidelines for further appraisal. A preliminary assessment of the health questions covered by the retrieved guidelines should be carried out to eliminate those that are clearly not relevant to the defined key questions. Other criteria such as the guideline publication date should be decided upon in advance by the panel in order to screen out guidelines.

Tool 8 – Example Table for Recording the Clinical Content of Guidelines

In the case where existing guidelines do not cover all the required topic components, the panel will need to make decisions about modifying the scope of their topic, changing their questions to correspond with source guideline questions, modifying the list of health questions, or looking for systematic reviews, health technology assessments reports, or current research articles that would enable them to write their own recommendations for those areas where no

recommendations exist. If some denovo work is required, users may find development manuals such as those produced by the National Institute for Health and Clinical Excellence (NICE), the Scottish Intercollegiate Guidelines Network (SIGN), the National Health and Medical Research Council (NHMRC), and the Canadian Medical Association (CMA) helpful.

For each guideline found, the decision to include or exclude should be recorded, along with the reason(s) for any exclusions.

Step 10. Reduce a large number of retrieved guidelines

If a large number of potentially relevant guidelines are found during the search, the chair and panel must decide whether or not to reduce the number of guidelines, given the potential time and work burden of the appraisal process. Depending on the guideline, the appraisal process might take approximately one and a half hours per guideline, a substantial time commitment if a large number of guidelines must be reviewed (6). If the panel decides to reduce the number of guidelines to be assessed, the criteria for exclusion at this stage must be made explicit.

One way to reduce the number of guidelines for final approval is to use the rigour dimension of the AGREE instrument (see Assessment Module 2.3 – Assess guideline quality) (4).

Tool 9 – AGREE Instrument

Although the AGREE instrument does not provide thresholds for acceptable or unacceptable guidelines based on quality, a comparison of rigour scores across guidelines can provide the panel with information to guide the selection process. For example, the panel could decide on a cut-off point or rank the guidelines, once they see how the guidelines score on rigour (e.g., they may decide that any guideline scoring above 50% on the rigour dimension will be retained). Other options might be to keep all guidelines that score above the median score or all that score above the 60th percentile (4). It should be noted, however, that a poor score might not be sufficient in itself to eliminate a guideline at this stage.

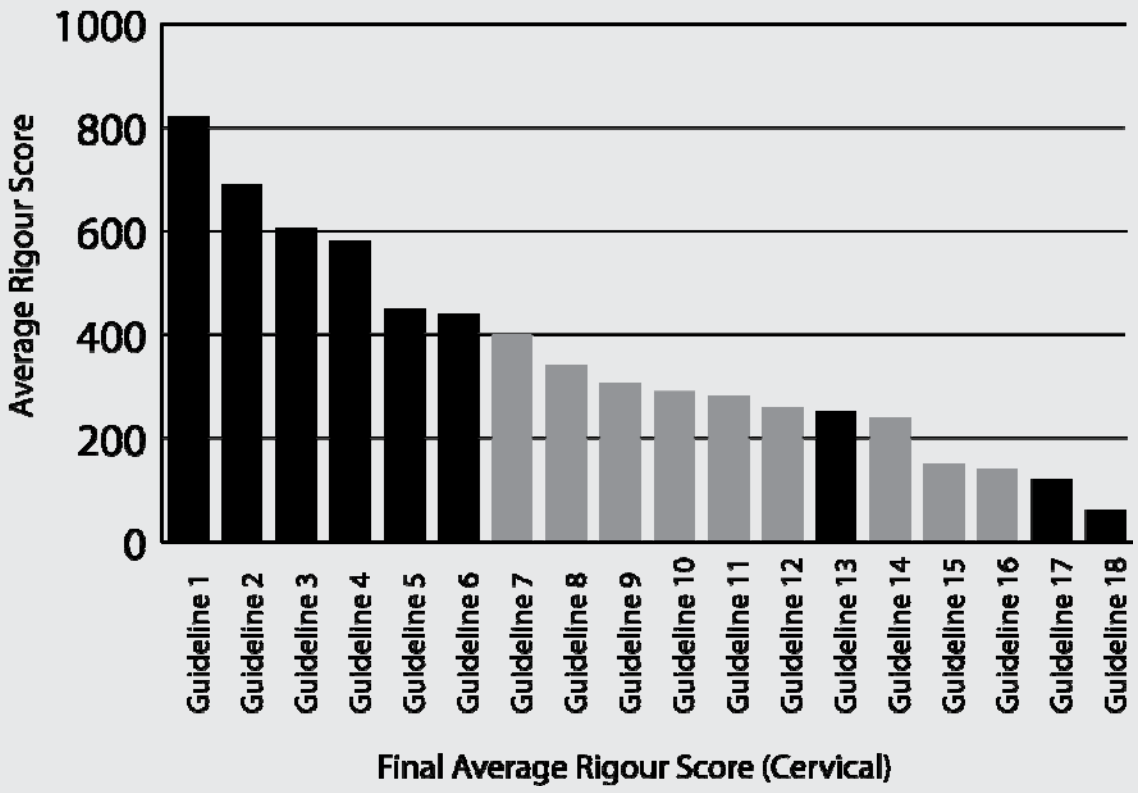
The overall assessment item gives a general indication of whether or not the appraisers consider the guideline to be worth a more detailed assessment. For example, if all the appraisers state that they 'would not recommend' a particular guideline, that guideline could be eliminated from further consideration once the reasons for their decision have been discussed.

The panel may also decide to retain guidelines, based on other merits (e.g., excellent format or the presence of health questions not addressed in the higher quality guidelines). In addition, any member should be allowed to ask the panel to reinclude an eliminated guideline at any time if a good case can be made for its reintroduction (7).

Tool 10 – AGREE Inter-rater Agreement Spreadsheet and AGREE Score Calculation

Illustration – Using the AGREE instrument to reduce a number of guidelines

The guideline search found 18 cervical cancer screening guidelines, which the chair and methodologist felt were too many for the whole panel to review. Four appraisers who were part of the resource team completed the rigour dimension of the AGREE instrument for all 18 guidelines. Upon review, the chair and methodologist decided to keep all guidelines with an average rigour score greater than 40% for appraisal. They also decided to keep three guidelines that scored poorly on the rigour dimension, as they were guidelines created for the panel's health care context and were all well known to panel members. The guidelines kept by the panel are represented by the dark bars on the graph.



ADAPATION PHASE
2.3 Assessment Module

Steps	Products/ Deliverables	Skills and Organizational Requirements	Tools
11. Assess guideline quality 12. Assess guideline currency 13. Assess guideline content 14. Assess guideline consistency (search and selection of studies, links between evidence and recommendations) 15. Assess acceptability/ applicability of the recommendations	• AGREE scores • Summary of currency evaluation • Recommendations matrices • Summary of search and selection evaluation • Summary of consistency between evidence, interpretations, and resulting recommendations • Evaluation of applicability/ acceptability	Clinical expertise Methodological expertise Information retrieval skills	Tool 9 - AGREE Instrument Tool 10 – AGREE Inter-rater Agreement and Score Spreadsheets Tool 11 – Sample Currency Survey Tool 12 – Sample Recommendations Matrix Tool 13 – Table of Criteria for Assessing the Quality of Study Search and Selection Tool 14 – Table for Recording Evaluations of Consistency between Evidence, Its Interpretations, and Recommendations Tool 15 – Worksheet – Acceptability/Applicability

The assessment of selected guidelines can take a multidimensional approach—an evaluation of the quality, currency, content, consistency, and acceptability/applicability of the guideline recommendations. The evaluation of these different aspects will provide the basis for making an informed and transparent decision about which source guidelines are relevant and for identifying which recommendations can be adapted. There is no evidence related to any of the assessments to support or refute thresholds standards. The panel needs to decide which assessments to prioritize or what they might accept as thresholds. The choice of assessments will be based on decisions informed by elements such as the context, the health questions, the available evidence, and the resources of the group. Panels can be flexible in deciding which assessments will be undertaken and the order in which they will be implemented; however, the order decided upon by the panel should be outlined in the final document. Each of the assessments is described below.

Step 11. Assess guideline quality

The AGREE instrument

The Appraisal of Guidelines Research & Evaluation (AGREE) Instrument (www.agreetrust.org) provides a framework for assessing the quality of clinical practice guidelines. The 23 items in the AGREE Instrument assess the methods used for developing the guideline and the quality of the reporting. An overall assessment item allows appraisers to make a judgement on the quality of the guideline as a whole, as to whether they would 'strongly recommend,' 'recommend with alterations,' 'would not recommend,' or are 'unsure' about recommending the guideline. The instrument does not assess the clinical content of the recommendations. The instructions in the introduction of the instrument should be read carefully before starting the appraisal. A training resource toolkit is available on the AGREE Web site (www.agreetrust.org).

Tool 9 – AGREE Instrument

Guideline Appraisal Training: Practice Set

If the panel members are unfamiliar with the AGREE instrument, we recommend using one of the guidelines as a training exercise. The members would individually score the training guideline and would then have a short meeting to discuss any questions about the scoring, the dimensions, and so on. The AGREE instrument uses a four-point scale. Where users differ more than one point on any item, there should be a discussion to clarify discrepancies such as differing interpretations of the evaluation criteria or of the guidelines, different values, and so on. Often, the case arises where one member was unable to find a description in the guideline of the item in question and another member is able to point out the location in the text. The training exercise provides members with practice in using the instrument itself and also some indication of how guidelines might be organized.

Main appraisal

Each panel member should receive the AGREE instrument, a copy of the selected guidelines, and any supporting material related to the guidelines.

If possible, there are benefits to having all members of the panel appraise the guidelines to be discussed (2), including the following:

- The appraisal gives all members an in-depth understanding of the content of each guideline and, therefore, generates a more informed discussion.
- It has an educative value as panel members will gain greater awareness of various aspects of guideline structure and content, including what constitutes a good quality document.
- A review of the quality scores can identify where there is a lack of agreement on scoring specific items and will become part of the consensus discussion.
- Overall quality scores from all members can increase reliability when ranking the guidelines,

It may be impractical from a resource or time perspective to have all panel members rate all of the guidelines. Should this be the case, the AGREE training resource toolkit recommends that, with respect to improving the reliability of the AGREE instrument, each guideline should be appraised by at least two and preferably four appraisers.

The scores on the completed AGREE instruments are calculated and can be entered into a spreadsheet. The formulas for calculating the scores are described in the AGREE instrument instructions. The scores can be transferred into a graphical format that makes it easy to compare guidelines on various dimensions.

Tool 10 – AGREE Inter-rater Agreement Spreadsheet and AGREE Score Calculation

How the scores can be used

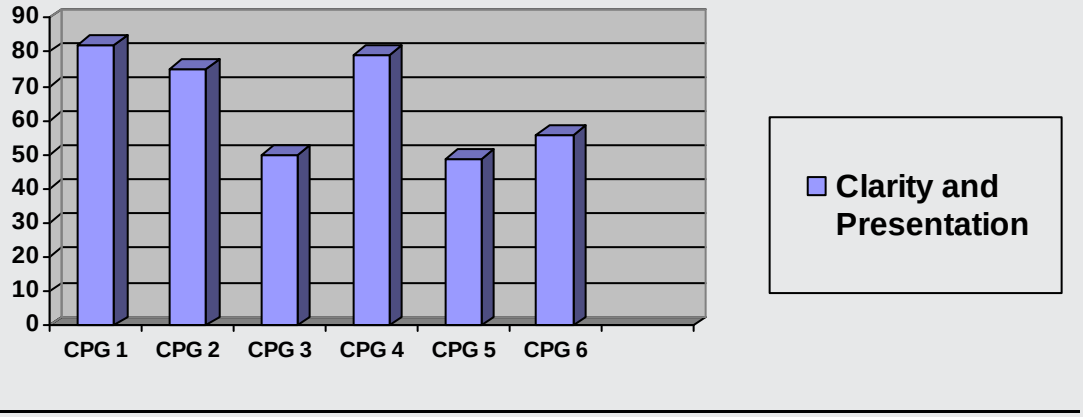
The AGREE scores provide a sense of the quality of some aspects of the guideline and how well they were reported. They can be used as one element in the decision-making process around whether or not to adapt a specific guideline. These scores are helpful in decision making, particularly the domain "*Rigour of Development*," for instance, if the panel has decided to

consider only rigorously developed guidelines. The panel might also be interested in considering guidelines with other merits such as an ideal format or the inclusion of recommendations highly relevant to their local condition and that other guidelines do not include. A poor AGREE score may not be sufficient in itself for eliminating a guideline.

The raw AGREE scores can be used to show rater agreement and disagreement on the various items of the AGREE instrument. All scores of 1 or 2 (strongly disagree or disagree) can be highlighted in one colour or texture, and all scores of 3 or 4 (agree or strongly agree) can be highlighted in another. AGREE items that have equal amounts of each colour and/or texture would be areas for discussion as that situation means that one half of the panel differs from should be held to clarify the source of the differences. As well, intraclass correlations (ICC) (7) could be calculated to give a numerical value of appraiser variability.

The graphical representation of how guidelines compare on the various AGREE dimensions provides a simple and clear measure of comparison. Large differences in the scores for the same dimension across different guidelines can act as a discussion point.

Illustration – Graphical representation of the AGREE domain clarity and presentation scores for cervical cancer screening guidelines



Step 12. Assess guideline currency

Research on the validity of practice guidelines has shown that the evidence supporting guidelines in fields that are rapidly evolving may be outdated in as little as three years, depending on the research activity in the field (8,9). As a result, it is important to assess whether the guidelines are adequately current for the adaptation process. The publication date of the guideline, or the dates/period covered by the literature, should be reviewed to ascertain whether the most current evidence has been included (4) Some developers publish this information in the guideline itself or on their Web sites, for example, the Cancer Care Ontario (www.cancercare.on.ca) and the Scottish Intercollegiate Guidelines Network (www.sign.ac.uk).

If you suspect that a guideline is out of date, there are following updating options:

- Consult with an expert well versed in the field and conduct a rapid review of the literature.
- Contact the guideline developer for further information on currency. A short survey of the guideline developers can ascertain whether there is a more recent version of the guideline, whether the developer intends to update the guideline in the future, and whether the developer is aware of any new evidence that might affect the guideline recommendations (9).
- Perform a literature search of Web sites most likely to provide up-to-date information, in particular, systematic reviews, and contact experts in the field regarding the state of knowledge in a content area.
- Verify whether alerts on an intervention have been released by a monitoring agency such as the Federal Drug Agency (USA) (www.fda.gov/) or the European Monitoring Center for Drugs and Drug Addiction (www.emcdda.eu.int).

If the source guidelines or guidelines are of good quality but the literature is not up-to-date, the literature or evidence must be updated.

If the panel learns that a guideline developer is aware of new evidence that could affect the recommendations or that the developer will be changing a guideline's recommendations substantially, based on new evidence, the panel will need to make some decisions about whether or not to use the guideline in the adaptation process, and will need to document these decisions. A number of the recommendations might possibly be unaffected by the new evidence and portions of the guideline could be retained for adaptation. The panel, however, will need to decide whether to update any recommendations affected by the new evidence, write them *de novo*, or wait for the release of the updated guideline.

Tool 11 – Sample Currency Survey

Step 13. Assess guideline content

Matrices are tables of recommendations drawn from the guidelines under review, although they also might include recommendations from systematic reviews or health technology assessments. We recommend that a clinician who specializes in the topic produce or review the matrices to ensure that no recommendation has been taken out of context. Matrices are most useful in those applications where more than one source guideline is under consideration (1,2).

Illustration – Results of the currency survey

Four of the seven cervical cancer screening guidelines had been published in the previous year. Of the other three, one was published in 1993, one in 1995, and one in 1998. Only the source guideline published in 1993 was under consideration for updating, but at the time of the guideline adaptation, the developer had not yet begun the update. The adaptation panel decided that, even though the recommendations in the 1993 guideline were still clinically relevant (in some cases, the levels of evidence for them had actually increased since the guideline was developed), because the guideline had not been updated for ten years (which they considered too long a period, especially in light of other more recent guidelines), they eliminated it from further consideration.

The matrices can be used by the panel for decision making in a number of ways:

- Where similar recommendations from various guidelines are grouped together, recommendations can be easily compared to see whether they are similar or different, and if different, how they differ.
- The matrices help the group identify all recommendations with strong evidence.
- The matrices help the panel compare wording of recommendations.
- The matrices can provide a basis for a discussion about the clinical relevance of each recommendation.

The recommendations matrices can be presented in two different formats, 1) recommendations grouped by guideline and 2) recommendations grouped by similarity (e.g., all the recommendations on the starting age for cervical cancer screening are grouped together).

Create recommendations matrices

The matrices list the recommendations down the left column and the name of the source guideline across the top. Guidelines could be ordered across the top by date, for example, the most recent in the first column, the second most recent in the second, and so on. They may also be ordered by quality scores on the AGREE instrument, based on particular dimensions. For example, the guideline rating highest on the rigour dimension might be listed first (along with its date) and so on. Other information provided could be how each guideline rated on the overall assessment of the AGREE instrument (e.g., how many rated the guideline as 'strongly recommend,' how many as 'recommend with modifications,' how many as 'would not recommend,' and how many as 'unsure') (1,2).

The levels of evidence associated with the recommendations can be placed within each cell. The difficulty with using levels of evidence is that there is no common classification system, and thus, one must either devise some broad generic system and reclassify each level from the source guideline or provide a guide as to each developer's definitions of their levels of evidence. Another difficulty is that some developers do not attach levels of evidence to their recommendations. However, if the panel has already completed the assessments related to guideline consistency (Tools 13 and 14), then they might reclassify the levels of evidence for each recommendation, using their own system.

Instead of using the levels of evidence, the actual type of study data supporting the recommendation could be listed (e.g., six randomized controlled trials or expert opinion).

Another option would be to put in the evaluations of consistency (as described in the section "Assess guideline consistency" below) associated with each recommendation. If electronic matrices are created, a hyperlink could take the reader to a summary of the evidence.

Tool 12 – Sample Recommendations Matrices

Illustration – A portion of the recommendation matrix for cervical cancer screening recommendations

(Guidelines arranged from left to right by date. Rigour scores, overall quality assessment ratings, and levels of evidence included.)

Cervical Cancer Screening Recommendation – Grouped by Recommendation	Guideline 1 2003	Guideline 2 2003	Guideline 3 2002	Guideline 4 1998	Guideline 5 1995	Guideline 6 1993
AGREE Rigour scores	67.62	84.92	69.39	39.68	53.75	69.23
Overall quality assessment	Strongly recommend (4 raters) Recommend with alterations (2 raters)	Strongly recommend (3 raters) Recommend with alterations (2 raters)	Strongly recommend (5 raters) Would not recommend (1 rater)	Recommend with alterations (4 raters) Would not recommend (1 rater)	Strongly recommend (4 raters) Recommend with alterations (7 raters) Would not recommend (1 rater)	Strongly recommend (1 rater) Recommend with alterations (2 raters) Would not recommend (3 raters) Unsure (1 rater)
Screening onset						
Begin screening with onset of sexual activity					*Level II	
Begin screening 3 years after onset of vaginal intercourse and no later than 21 years of age	Level II	Level II				
Begin screening at age 20 for women who have had sexual intercourse					Level III	
Frequency of screening						
Screen annually with conventional cervical cytology smears		Level II				
Screen initially with 2 smears 1 year apart, if these smears are satisfactory then rescreen every 3 years					Level III	
Screen every 3 years for women with normal smear results, repeat in 1 year if the smear is the first smear of if the previous smear was 5 or more years ago	Level I			Level II		

*** Levels of evidence listed by the guideline developers were reclassified into a system for comparison within the matrix.**

Step 14. Assess guideline consistency

The assessment of the consistency of the guideline includes the following three evaluations:

- Search strategy and selection of evidence supporting the recommendations
- Consistency between the selected evidence and how developers summarize and interpret this evidence
- Consistency between the interpretation of the evidence and the recommendations

In performing these evaluations, the panel will need to review the source guidelines thoroughly. The evaluations will help identify any recommendations in the source guidelines that do not follow directly from the evidence; panel members can then determine whether they will eliminate those recommendations from further consideration.

The evaluations are time consuming, require a thorough review of each source guideline by individuals with methodological and clinical expertise, and may require the gathering of original evidence supporting the interpretations and recommendations in the guideline. However, they provide appraisers with a sense of confidence that the source guideline was developed rigorously, and that there is consistency between the evidence, its interpretation, and the recommendations.

Evaluate search strategy and selection of evidence

The type and quality of the evidence on which recommendations are based can vary, depending on the exact health question addressed and when and how the search for evidence was performed. The period covered by the search and the use of inclusion/exclusion criteria such as language can often explain this variation. An evaluation of the source guideline's search strategy and the selection of evidence used to support the recommendations will determine whether the guideline developers systematically searched for and selected relevant evidence and systematically extracted relevant data. The evaluation should include assessing the relevance and exhaustiveness of the databases searched, the search strategies used (e.g., keywords, dates, and languages), the methods and criteria used to select the references, and how many references were identified, included and excluded.

Tool 13 – Table of Criteria for Assessing the Quality of Study Search and Selection

Evaluate consistency between selected evidence, its interpretation, and resulting recommendations

An evidence-based guideline consists of three main components, the evidence generated via the systematic review on which the source guideline is based, the interpretation of that evidence within the health care context and the developers' experience, and the guideline recommendations that take into account the local situation and values (10). An evaluation of the consistency between these three components examines the quantity and quality of the selected evidence as well as the consistency of results and determines whether the interpretation of the evidence flows from the selected evidence and whether the recommendations are also consistent with the selected evidence. This evaluation will be facilitated by having access to the evidence tables. If these are not included in the published guideline, we recommend that the developers of the source guideline(s) be contacted. With respect to the recommendations, in the case where evidence is weak or non-existent, the basis for the resulting recommendation should be explicitly

indicated in the source guideline (e.g., based on expert consensus by the guideline development panel).

There are a number of questions to be considered in conducting this evaluation:

- Are the consistency and clinical relevance of primary study results reported or discussed?
- Is the clinical and methodological heterogeneity of studies reported or discussed?
- Were the recommendations supported by the conclusions of the critical appraisal of the studies? If not, are there other reasons explicitly presented?
- Is the method for indicating the level of evidence adequately described?
- Is this method used correctly, i.e. is the level of evidence attributed to the recommendation justified?
- Were the patients and interventions in the studies analysed judged to be sufficiently comparable to those targeted by the recommendations?
- Has the balance between risks and benefits been correctly taken into consideration?
- Was a formal process used to define the recommendations?

Tool 14 – Table for Recording Evaluations of Consistency between Evidence, Its Interpretation and Recommendations

Step 15. Assess acceptability and applicability of the recommendations

There are a number of terms that can be used to describe whether a recommendation will be used in practice. Acceptability, feasibility, implementability, and applicability all have slightly different meanings but in essence describe 1) whether the recommendation should put it into practice (acceptability) and 2) whether an organization or group is able to put the recommendation into practice (applicability).

The applicability of a guideline's recommendations in the target context and the degree to which a guideline will need adaptation depends on the differences in the cultural and organizational context, including the availability of health services, expertise, and resources and the organization of health services, as well as population characteristics, beliefs, and value judgments. These context variables are particularly important when adapting guidelines for culturally sensitive interventions or technological innovations.

Assessing whether a recommendation is acceptable and/or applicable or not is done by discussing each recommendation in light of the following questions:

- Does the population described for eligibility match the population to which the recommendation is targeted in the local setting (acceptable)?
- Does the intervention meet patient views and preferences in the context of use (acceptable)?
- Are the intervention and/or equipment available in the context of use (applicable)?
- Is the necessary expertise (knowledge and skills) available in the context of use (applicable)?
- Are there any constraints, organisational barriers, legislation, policies, and/or resources in the health care setting of use that would impede the implementation of the recommendation (applicable)?

- Is the recommendation compatible with the culture and values in the setting where it is to be used (acceptable and applicable)?
- Does the benefit to be gained from implementing this recommendation make it worth implementing (acceptable)?

These questions can be proposed to the panel by the chair as each recommendation is being considered. Another way to address these questions is through an assessment form. Panel members might be asked to answer these questions at the same time as they are appraising the guidelines using the AGREE instrument. Results could then be fed back to the panel at the beginning of the meeting.

Tool 15 – Worksheet – Acceptability/applicability

ADAPATION PHASE
2.4 Decision and Selection Module

Steps	Products/ Deliverables	Skills and Organizational Requirements	Tools
16. Review assessments to aid in decision making 17. Select between guidelines and recommendations to create an adapted guideline	• Decision made on the content of the final document	Clinical expertise Methodological expertise Facilitation skills (Chair)	See Table for a list of all resources available to the panel

Step 16. Review assessments

The results of the assessment module provide an explicit basis for informed and transparent decision making around the selection and modifications of source guidelines. At the panel meeting, members will be presented with a number of documents that summarize the results of the assessment module (see Table). Some of the assessments relate to the consistency of the source evidence with the interpretations and the recommendations, some relate to the guideline as a whole, and some relate to the recommendations.

Table. Available assessments and their possible use by the panel

Assessments Related to Quality	Possible Use
Overall AGREE assessment	Can be used as a starting point for elimination of those guidelines that most members "would not recommend."
Raw AGREE scores	Used to assess rater agreement and ensure that the panelists' scores are reliable. Can be used to show where there are major differences among panel members on various items of the dimensions of the AGREE instrument. Can be used to promote consensus by highlighting areas of disagreement in perceptions of the guideline.
Summary AGREE dimension graphs	Can be used to show how one guideline rates on each of the six AGREE domains or how all of the guidelines compare on each of the various AGREE domains.
Assessments Related to Quality	**Possible Use**
Results of the currency assessment (Tool 11)	Can be used to eliminate any guidelines that are out of date or that will soon undergo a major revision. Can also be used to define where updates are needed.
Assessments Related to Quality	**Possible Use**
Recommendations matrices (Tool 12)	Can be used to easily compare recommendations from all of the potential guidelines with respect to content and wording and level of evidence, if included.

Supporting material (e.g., systematic reviews, health technology assessments, articles)	Can be used to provide more information on certain topic areas, to fill in gaps not covered by recommendations, to update recommendations, or to confirm the accuracy of evidence supporting the recommendations.
Assessments related to source evidence and guidelines	**Possible use**
Results of the evaluation of the search strategy and selection of evidence (Tool 13)	Provides an indication for each guideline of the comprehensiveness of the search strategy and the evidence selected.
Results of the evaluation of consistency between evidence and its interpretation and between the interpretation and recommendations (Tool 14)	Provides an indication of whether there are inconsistencies with the guideline developers' interpretation of the evidence and its translation into recommendations within a guideline or between guidelines.
Assessment related to applicability	**Possible Use**
Results of the applicability evaluation (Tool 15)	Can be used to decide if the recommendations are applicable, can be implemented in the user's context, and are worth implementing

Step 17. Select between guidelines and recommendations to create an adapted guideline

The chair should assist the panel in following the consensus process they had previously decided upon. The steps followed in coming to group consensus, or not reaching any consensus, **must** be recorded. The chair and the group and/or panel need to pay careful attention to any new evidence brought to the panel during the discussion to determine if any of the recommendations are affected by this evidence. Any modifications to the recommendations must be carefully documented and the evidence supporting the modification provided, along with supporting references. This is a meeting best held face-to-face. Good facilitation skills are needed by the chair to ensure that all members have an opportunity to present their views.

Decision making and selection occurs around the following five options:

1) **REJECT the whole guideline:** After reviewing all of the assessments, the panel decides to reject the complete guideline. The decision should be based on how the panel weighs the assessments (e.g., poor AGREE scores, guideline is out-of-date, or the recommendations do not apply to the panel's context).
2) **ACCEPT a whole guideline and all of its recommendations**: After reviewing all of the assessments, the panel accepts the guideline as is.
3) **ACCEPT the evidence summary of the guideline:** After reviewing all of the assessments, the panel decides to accept the description of the evidence (or parts of it) but to reject the interpretation of the evidence and the recommendations.
4) **ACCEPT specific recommendations:** After reviewing the recommendations from the guideline or guidelines, the panel decides which recommendations to accept and which to reject (e.g., those recommendations needing major modification would be rejected), which may be from one or more guidelines.
5) **MODIFY specific recommendations:** After reviewing the recommendations from the guideline or guidelines, the panel decides which are acceptable but need to

be modified (e.g., new data may be added to the original recommendation or the wording might be changed to better reflect the panel's context).

Caution: Care must always be taken when modifying existing guidelines and/or recommendations not to change the recommendations to such an extent that they are no longer in keeping with the evidence upon which they should be based.

Based on the above decisions, the panel can create an adapted guideline acceptable for their context that addresses all of their health questions.

Illustration – Decision making process followed by the cervical cancer screening panel

Process	Action
1. Panel decides to begin by seeing if they can eliminate guidelines that members would not recommend. Reviewed overall assessment scores – 'strongly recommend' category. Began with those that had '0' in strongly recommend category. Those who did recommend 'with alterations' were asked to discuss their decisions.	Guideline 5 and 7 are eliminated – not screening guidelines
2. Continue to use overall assessment scores to look at next poorest scoring guideline – '1' strongly recommend, '2' recommend with alterations, '3' would not recommend, '4' unsure. Asked member who 'strongly recommended' to discuss decision.	Guideline 4 is eliminated - outdated
3. Review information from the currency survey	Panel notes also that Guideline 3 is outdated – removed from further consideration
4. Begin discussion of top three choices (*based on their AGREE scores).*	Temporarily put aside Guideline 6 as group doesn't have enough information about developer and conflict of interest
5. Decide to look at the individual recommendations of the top three guidelines. Discuss Guideline 1.	Accept all five recommendations of Guideline 1 after discussion.
6. Discuss Guideline 2.	Panel decides that they can not agree with annual screening, did not find rationale for why 70 years was selected as a stopping age for screening.
7. Go on to discuss Guideline 6. Importance of guideline needing to address practice reality is discussed.	Panel feels Guideline 6 is too lengthy for busy family physicians and merely repackages recommendations from other developers. Also concern that they are sponsored by US State health plans.
8. Panel decides to go through Guideline 1 to see if can accept in entirety.	Consensus to accept as is and group provides rationale.
9. Decides to look at Guideline 2 and Guideline 6 to see if they can be accepted in entirety as well.	Decide that cannot accept either as is.
10. Discussion on target population.	Group decides that source guidelines only cover average-risk population. Decides to 'park' high-risk population – need more information and/or comprehensive list of relevant guidelines.
11. Consensus achieved.	Panel agrees to accept Guideline 1 in its current form.

Steps	Products/ Deliverables	Skills and Organizational Requirements	Tools
18. Prepare a document that respects the needs of the end users and provides a detailed transparent explanation of the process	• Draft guideline document	Knowledge of clinical practice and local context Editorial skills Design skills	Tool 16 – Checklist of Adapted Guideline Content

Step 18. Prepare draft adapted guideline

Once the panel has reached a decision on the content of the adapted guideline, a draft document will be produced that should include details on the process followed. A suggested template for the format of the guideline is presented in Tool 16.

Tool 16 – Checklist of Adapted Guideline Content

The template includes the following sections:

1. Overview material:
   - structured abstract that includes the guideline's release date and print and electronic sources
   - name and institutional affiliation of adaptation panel
2. Introduction and background
3. Scope and purpose
4. Target audience of the guideline
5. Target population
6. Health questions
7. Recommendations:
   - risks and benefits associated with the recommendations
   - specific circumstances under which to perform recommendations
   - strength of recommendations based on stated recommendation grading criteria (if used)
8. Supporting evidence and information for the recommendations:
   - panel rationale behind the recommendations
   - presentation of additional evidence and/or the results of the updating process
   - how and why existing recommendations were modified

9. External Review and Consultation Process (to be discussed in next section)
    - who was asked to review the guideline
    - what process was followed
    - discussion of feedback and what was incorporated into the final document
10. Plan for scheduled review and update (to be discussed in next section)
11. Algorithm or summary document
12. Implementation considerations
13. Glossary (for unfamiliar terms)
14. References of all material used in creating the guideline
15. Acknowledgment of source guideline developers and permission granted (where necessary)
16. List of panel members and their credentials, declaration of conflicts of interest
17. List of funding source(s)
18. Appendix describing adaptation process:
    - guideline search and retrieval including the list of guidelines identified and whether they were included or excluded and why
    - guideline assessment including which assessments were undertaken and in which order, and a summary of results for each assessment (including AGREE domain scores)
    - decision process followed by panel
    - results and decisions of each evaluation

Two key and common defining elements of the guideline format, regardless of the model used, should be the transparency and explicitness of the process (i.e., sufficient detail so that the methodology could be reproduced and potential adopters are confident that the process used to adapt the guideline was rigorous and thorough) and the appropriate referencing and acknowledgement of intellectual credits to the source documents.

FINALIZATION PHASE
3.1 External Review and Acknowledgement Module

The Finalization Phase guides the user through the process of obtaining feedback on the document from stakeholders impacted by the guideline, consulting with the developers of source guidelines used in the adaptation process, establishing a process for the review and updating of the adapted guideline, and creating a final document.

Steps	Products/ Deliverables	Skills and Organizational Requirements	Tools
19. External review by target users 20. Consult with relevant endorsement bodies 21. Consult with developers of source guidelines 22. Acknowledge source documents	• Feedback from external review incorporated into guideline • Approval by endorsing body(ies) • Feedback from source guideline developers incorporated into guideline	Managerial and administrative skills	Tool 17 – Samples of External Review Surveys

Step 19. External review - target audience of the guideline

Once the panel has decided on the adaptation of their guideline, the next step is to send the adapted guideline to those who will be affected by its uptake (i.e., the users, including any practitioners who would use the guideline in practice or any patient affected by the guideline). Users also include, for example, policy makers, decision makers, organization representatives, and managers. Different questions might need to be asked of each group. The external review should ask questions about whether the users approve of the draft guideline, what its strengths and weaknesses are, and what requires modification. In addition, users might be asked questions around their confidence in the adaptation process, whether they would use the guideline in their practice, and how it would impact or change their current practice or routines. Users, administrators, and managers might be asked about the acceptability of the guideline for the organization and about the resource implications. A structured questionnaire is helpful for this step (11).

Tool 17 – Samples of External Review Surveys

The purpose of this external review is to (1,2):

- Foster ownership and commitment of intended users toward the guideline
- Ensure that those most likely to use the guidelines will have the opportunity to review the guideline and provide feedback. This will help identify any areas not covered by the guideline, ensure that the recommendations are clear and applicable, and give an idea of the potential acceptance by the relevant uptake group.
- Allow managers and policy makers to consider the resources and other impacts of the guidelines and begin preparing for implementation
- Act as the first dissemination of the adapted guideline

FINALIZATION PHASE
3.1 External Review and Acknowledgement Module

The external review should ask questions about whether the reviewers approve of the draft guideline, what its strengths and weaknesses are, and what requires modification.

Electronic media can be used to collect any comments. All feedback received should be documented and discussed by panel and any changes made to the adapted guideline should be described. If the panel decides not to modify the guideline, regardless of the feedback received, this should also be documented, as well as the reasons for this decision.

Step 20. Consult with endorsement bodies

In order to help with widespread implementation, we recommend that the adapted guideline be formally endorsed by professional body(ies) or organization(s) most closely connected to the guideline topic (e.g., a national college of family physicians might endorse guidelines related to primary care) (2). The endorsement of a guideline by relevant professional organizations has been shown to enhance the acceptability of a guideline to the organization's members (12). Endorsement can be a simple recognition by the organization of the relevance of the guideline to its members or a more formal process to implement the adapted guideline as policy within the organization. For example, a hospital endorsing a guideline to be implemented in one of its departments might commit resources to support the guideline, including any additional staff training that might be needed and so on. An organization with a nationally distributed membership might, among various dissemination options, provide the guideline as a resource to its members or post it on its Web site.

Step 21. Consult with source guideline developers

The draft guideline may be sent for feedback to any guideline developers whose recommendations have been used in the draft guideline, particularly in the case where changes have been made to the original recommendations.

Step 22. Acknowledge source documents

All documents used in the creation of the draft guideline should be referenced in the final document. The panel will need to determine whether they need to seek permission to use any guideline or guideline recommendation used in the adapted guideline. Requirements to seek permission should be available as part of the guideline document under a copyright clause. Information on sources, required permissions, and agreements should be kept in the project documentation.

FINALIZATION PHASE
3.1 External Review and Acknowledgement Module

Illustration – Process of external review of the cervical cancer screening guideline

The draft cervical cancer screening guideline was sent to family physicians/general practitioners for external review. In selecting the sample for review, the organizing committee attempted to select practitioners from across the county and working in both urban and rural practices. Practitioners were sent the draft guideline along with a short survey of questions about, for example, the practitioner's confidence in the process, the applicability of the guideline to the practitioner's patients and practice context, and whether the practitioner would use the guideline in practice. Practitioners were asked to provide feedback on the guideline itself, and in particular, the recommendations and the panel's rationale for the recommendations. Feedback from practitioners was summarized and presented in a separate section of the guideline document labeled External Review. A response to the feedback by the panel was included. The places where the feedback was used to alter the draft guideline were clearly indicated.

The organizing committee decided to send a copy of the adapted guideline to the source developer for feedback (after completing their assessments, the panel decided that they would endorse one guideline without modification).

Endorsement by the national college of family physicians was tentatively agreed upon prior to beginning the adaptation process. A member of the college sat as a panel member throughout the process. Once the adapted guideline was finalized, it was submitted to the college for review and official approval. The college of family physicians then posted the guideline on their Web site, and profiled the guideline at their annual conference.

Steps	Products/ Deliverables	Skills and Organizational Requirements	Tools
23. Plan for aftercare of the adapted guideline Consult with relevant endorsement bodies	• Plan for review and updates	Clinical expertise Methodological expertise Information retrieval skills	Tool 18 – Report on the updating process

Step 23. Plan for aftercare of the adapted guideline

Guideline updating requires a two-stage process, identifying new evidence and determining whether that new evidence warrants an update (8,9). New evidence might be identified through a focused literature review and/or through consultation with experts. Whether new evidence requires a guideline update depends on how extensively it impacts on the guideline's recommendations (e.g., resource changes, outcome changes, technology changes, changes in existing benefits and harms, or changes in values related to outcomes). The extent of the update will depend on the results of the review, either to:

- discontinue use of the guideline;
- discontinue/withdraw some of the recommendations but not the entire guideline;
- redo the systematic review; or
- rewrite only those recommendations needing an update as long as the validity of the guideline is not compromised.

A review date should be decided upon, along with a process for dealing with reviewing the adapted guideline. Decisions about which review date to choose might be based upon when the source guidelines from which recommendations were selected are updated or expire, or a choice of a set period (e.g., there is some evidence that guidelines might be outdated in as little as three to four years after their release (8). If the evidence in the adapted guideline has not been updated earlier on in the ADAPTE process (e.g., if the panel does not have the resources to do so), the challenge inherent in an adapted guideline made up of recommendations from a number of source guidelines is that each of the source guidelines may become outdated at different times.

The panel needs to decide who will undertake the initial search for new evidence at the scheduled review date. Depending on the extent of the update needed, the designated individual(s) will need to make decisions on what expertise and resources would be required and whether the process is feasible.

Depending on the extent of change, the updated guideline should be sent to a group of experts, stakeholders, and policy makers for external review. Feedback on the updated guideline should be incorporated in the final document.

Tool 18 – Report on Results of Updating Process

Illustration – Development of an updating plan

The chair of the organizing committee offered to take overall responsibility for deciding when a review and update of the adapted guideline might be necessary. He asked that those members of the panel with the relevant expertise assist with the actual work of update and review when the time comes.

As the adapted guideline is only based on one guideline, the panel decided that the chair should keep in touch with the source guideline developers and monitor when they propose to review the evidence behind the source guideline and/or make substantive changes. The chair asked the resource team to monitor publication of new systematic reviews or health technology assessments reports particularly those related to changes in technology.

A plan for review was written up and put into the final adapted guideline.

FINALIZATION PHASE
3.3 Final Production Module

Steps	Products/ Deliverables	Skills and Organizational Requirements	Tools
24. Produce high quality final guideline	• Final guideline document • Summary document and tools for application, e.g., patient information material	Editorial skills Design skills	

Step 24. Produce final guidance document

Implementation plans and customizing the adapted guideline are part of the adaptation process that occurs, or should occur, at the local level. At this level, the clinical implications and organizational and cultural context are fully understood, and the adapted guideline can be customized appropriately to take into account these considerations.

A final guideline product that is short, clear and unambiguous has been shown to make new guidelines more acceptable to physicians (aspects that are also applicable to adapted guidelines) (1,13). Algorithms or care pathways, checklists, and patient information material are desirable. How a document is formatted may modify the way a message is conveyed. The adapted guideline needs to be formatted for its intended group. While the implementation of research findings should be considered in producing the final document (e.g., recommending physician and patient reminder systems in those clinical areas where they have been shown to be effective), there are also a number of implementation resources available to assist in ensuring that the guideline is used in practice (see Tool 1).

The final product might be reviewed using the AGREE instrument (6) as a checklist to assess how the adapted guideline rates with respect to quality criteria.

Illustration – Format of the final guideline document

The final version of the adapted guideline was formatted to take into account the preferences of family physicians. A one-page summary of the recommendations prefaced the main document. As it has been shown that reminders targeted at both the practitioner and the patient improve screening rates, the panel decided to produce a patient brochure that echoed the recommendations of the adapted guideline. The patient brochure was translated into the languages of those populations in that locale that are traditionally underscreened, e.g., immigrant populations.

Glossary

Acceptability

Acceptability is defined as the extent to which the users are likely to adopt (see the term adoption below) a recommendation, based on internal qualities such as clarity, comprehensiveness, and logical reasoning and on external factors such as the burden imposed on the process and system of care, patient and providers attitudes and beliefs, and patients needs, expectations, and preferences.

Adapted from: Shiffman R, Dixon J, Brandt C, Essaihi A, Hsiao A, Michel G, et al. The GuideLine Implementability Appraisal (GLIA): development of an instrument to identify obstacles to guideline development. BMC Med Inform Decis Mak. 2005;5:23.

Adaptation

Adaptation of guidelines is the systematic approach to considering the use and/or modification of (a) guideline(s) produced in one cultural and organizational setting for application in a different context. Adaptation can be used as an alternative to *de novo* guideline development or for customizing (an) existing guideline(s) to suit the local context.

Adoption

Adoption of a guideline is the acceptance of a guideline as a whole after the assessment of its quality, currency, and content. When health care providers (or other users of recommendations) adopt a guideline, they feel committed to change their practices in accordance with the recommendations of the guideline.

Adapted from: Davis DA and Taylor-Vaisey A. Translating guidelines into practice. A systematic review of theoretic concepts, practical experience and research evidence in the adoption of clinical practice guidelines. Can Med Assoc J. 1997;157:408-16.

Applicability

Applicability is defined as the extent to which the users are able to put a recommendation into practice, based on internal qualities such as a clearly defined eligible patient population that matches the population to which the intervention is targeted in the local setting and external factors such as the availability of the necessary knowledge, skills, provider time, staff, equipment, and other resources.

Applicability is sometimes taken as a synonym for feasibility:

- Feasibility of the acquisition of necessary skills and knowledge
- Feasibility of the necessary increase in provider time, staff, equipment, and so on.

Adapted from: Shiffman R, Dixon J, Brandt C, Essaihi A, Hsiao A, Michel G, et al. The GuideLine Implementability Appraisal (GLIA): development of an instrument to identify obstacles to guideline development. BMC Med Inform Decis Mak. 2005;5:23.

Culture

Culture represents the norms and values of a specific group, community, or population.

Diffusion

Diffusion is a passive means of transferring knowledge; it is not directed towards a target audience. An example of diffusion is the publication of articles in medical journals.

Lomas J. Diffusion, dissemination and implementation: who should do what? In: Warren K, Mosteller F editors., Annals of the New York Academy of Sciences: Doing more good than harm: the evaluation of health care interventions. Vol. 703. New York: New York Academy of Sciences; 1993.

Dissemination

Dissemination is more active than diffusion in that it targets a specific audience and involves tailoring the information for that audience. Examples of dissemination strategies include targeted mailings, presentations, and press conferences.

Lomas J. Diffusion, dissemination and implementation: who should do what? In: Warren K, Mosteller F editors., Annals of the New York Academy of Sciences: Doing more good than harm: the evaluation of health care interventions. Vol. 703. New York: New York Academy of Sciences; 1993.

Evidence-based principles

Evidence-based medicine has been defined as "the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients. The practice of evidence based medicine means integrating individual clinical expertise with the best available external clinical evidence from systematic research."

Sackett DL, Rosenberg WM, Gray JA, Haynes RB, Richardson WS. "Evidence Based Medicine: What It Is and What It Isn't," BMJ 1996;312:71-2.

Evidence tables

Evidence tables are summaries of the most salient information from studies identified in the systematic review. The elements of evidence tables are dependent on the types of information in studies related to a particular topic but might include information such as the article reference, the study type (e.g., randomized controlled trial or cohort), the number of patients and their characteristics, and the intervention, comparison arms, outcome measures, and effect sizes.

Scottish Intercollegiate Guidelines Network. SIGN 50: A guideline developer's handbook. 2001 [updated 2004 May]. Available from: *www.sign.ac.uk/guidelines/fulltext/50/index.html*

Guideline or Practice guideline

"Systematically developed statements about specific health problems, intended to assist practitioners and patients in making decisions about appropriate health care."

Adapted from: Field MJ, Lohr KN Editors; Committee on Clinical Practice Guidelines, Institute of Medicine. Guidelines for clinical practice: from development to use. Washington (DC): National Academy Press; 1992.

Guideline consistency

Agreement between the evidence and the recommendations, based on the:

- comprehensiveness of the study search and selection process,
- coherence between the results of the studies and their interpretation by the guideline authors, and
- transparency between this interpretation and the recommendations.

Guideline content

In this document, guideline content refers to the recommendations in the source guidelines.

Guideline currency

A guideline may be considered up to date "when [no] new information on interventions, outcomes, and performance justifies updating [it]."
Shekelle P, Eccles MP, Grimshaw JM, Woolf SH. When should guidelines be updated? BMJ. 2001;323:155-7.

Guideline quality

"By quality of clinical practice guidelines we mean the confidence that the potential biases of guideline development have been addressed adequately and that the recommendations are both internally and externally valid, and are feasible for practice. This process involves taking into account the benefits, harms and costs of the recommendations, as well as the practical issues attached to them. Therefore, the assessment [of quality] includes judgements about the methods used for developing the guidelines, the content of the final recommendations, and the factors linked to their uptake."
The AGREE Collaboration. Appraisal of Guidelines for Research and Evaluation (AGREE) Instrument.2001 Sep. Available from: www.agreetrust.org

Guideline topic

In this document, the topic refers to the theme of the guideline, as described in the guideline title, for a targeted population (disease and patients) and intervention. The purpose, the audience, and the setting intended for the guideline, although not necessarily explicitly stated in the title, are also part of the topic. A guideline on a given topic may contain more than one health question.

Health question

The health question is a precisely described health issue (e.g., clinical, professional practice or public health) relating to the topic of the guideline. A recommendation (and supporting evidence) is developed for each question. A guideline may include one or more questions.

Implementation

"Implementation includes methods to promote the uptake of research findings into routine healthcare in both clinical and policy contexts and hence to improve the quality and effectiveness of healthcare. It includes the study of influences on healthcare professional and organisational behaviour."
Adapted from : Implementation Science. www.implementationscience.com/info/about/.

Intraclass correlations

Intraclass correlations provide a measurement of the extent to which two or more raters agree when rating the same set of things. The intraclass correlation is a reliability index and is typically a ratio of the variance of interest over the sum of the variance of interest plus error.
Shrout P, Fleiss J. Intraclass correlations: uses in assessing rater reliability. Psychol Bull. 1979;86(2):420-8.

Recommendation

"Any statement that promote or advocate a particular course of action in clinical care."
Burgers JS. Quality of clinical practice guidelines [thesis]. Nijmegen: UMC St. Radboud; 2002.

Stakeholder

"A stakeholder is an individual, group and/or organization with a vested interest in your decision to implement a guideline. Stakeholders include individuals or groups who will be directly or indirectly affected by the implementation of a guideline."
Registered Nurses Association of Ontario). Toolkit: implementation of clinical practice guidelines. Toronto, Canada: Registered Nurses Association of Ontario; 2002.

Source Guideline

In this document, source guidelines refer to those guidelines selected to undergo assessments of quality, currency, content, consistency, and acceptability/applicability and upon which an adapted guideline may be based.

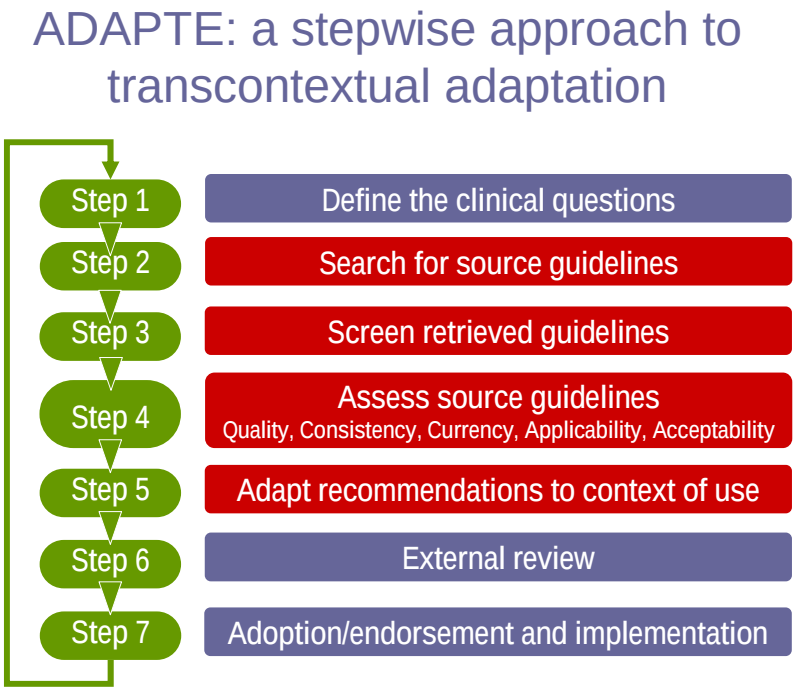
Detailed history of the ADAPTE collaboration

The ADAPTE Collaboration is an international collaboration of guideline developers, researchers, and clinicians who aim to promote the development and use of clinical practice guidelines through the adaptation of existing guidelines (14, 15). The ADAPTE Collaboration is born of two independent groups focussing on guideline adaptation, the ADAPTE group and the Practice Guideline Evaluation and Adaptation Cycle (PGEAC) group. Based on the similarity of their concepts and underlying principles and their commonality in process, the two groups decided to join forces and become the current ADAPTE Collaboration. At the 2005 Guidelines International Meeting in Lyon, Béatrice Fervers and Ian Graham, representing both groups, presented a plenary session on guideline adaptation that demonstrated the compatibility of the two approaches
http://www.g-i-n.net/index.cfm?fuseaction=news&fusesubaction=article&documentid=60&articleID=146.

The ADAPTE group
The ADAPTE group was initiated during a collaborative project involving the French National Federation of Comprehensive Cancer Centres (FNCLCC) and the Department of Cancer Control of the Québec Ministry of Health and Social Services. The initial aim of the project was the adaptation of cancer guidelines developed in France (Standards, Options, Recommendations [SOR - www.fnclcc.fr/sor.htm]) to the context of cancer care in Québec. To achieve this aim and in response to the increasing interest in guideline adaptation, the group developed a structured framework for the adaptation of clinical practice guidelines as an alternative to *de novo* guideline development (5) (see next page for a graphic representation of the framework). The framework builds on the observation that cultural and organisational differences between and within countries can lead to legitimate variations in recommendations, even when the evidence base is the same. The adaptation of guidelines produced in one cultural and organizational setting for use in another has been called “trans-contextual adaptation.”

The process development was based on the expertise of the Group members and their experiences in different contexts with guideline development and adaptation. The former group involved guideline developers, clinicians, and health services researchers from France (FNCLCC and the French National Authority for Health [HAS]), Canada (Department of Cancer Control Québec), Switzerland (Health Care Evaluation Unit and Clinical Epidemiology Centre (IUSMP); University of Lausanne), and the Netherlands (Dutch Institute for Healthcare Improvement CBO).

The ADAPTE process respects evidence-based principles for guideline development and takes into consideration the organisational and cultural context to ensure relevance for local practice. The framework has received input from the scientific board of the SOR programme and a group of 16 oncologists and pharmacists from Québec and has been modified to reflect these comments. The SOR programme and the HAS in France started using the process, and initial experience within the SOR programme showed that guideline adaptation might lead to a reduced length of time for guideline development and that experts appreciated using the process.

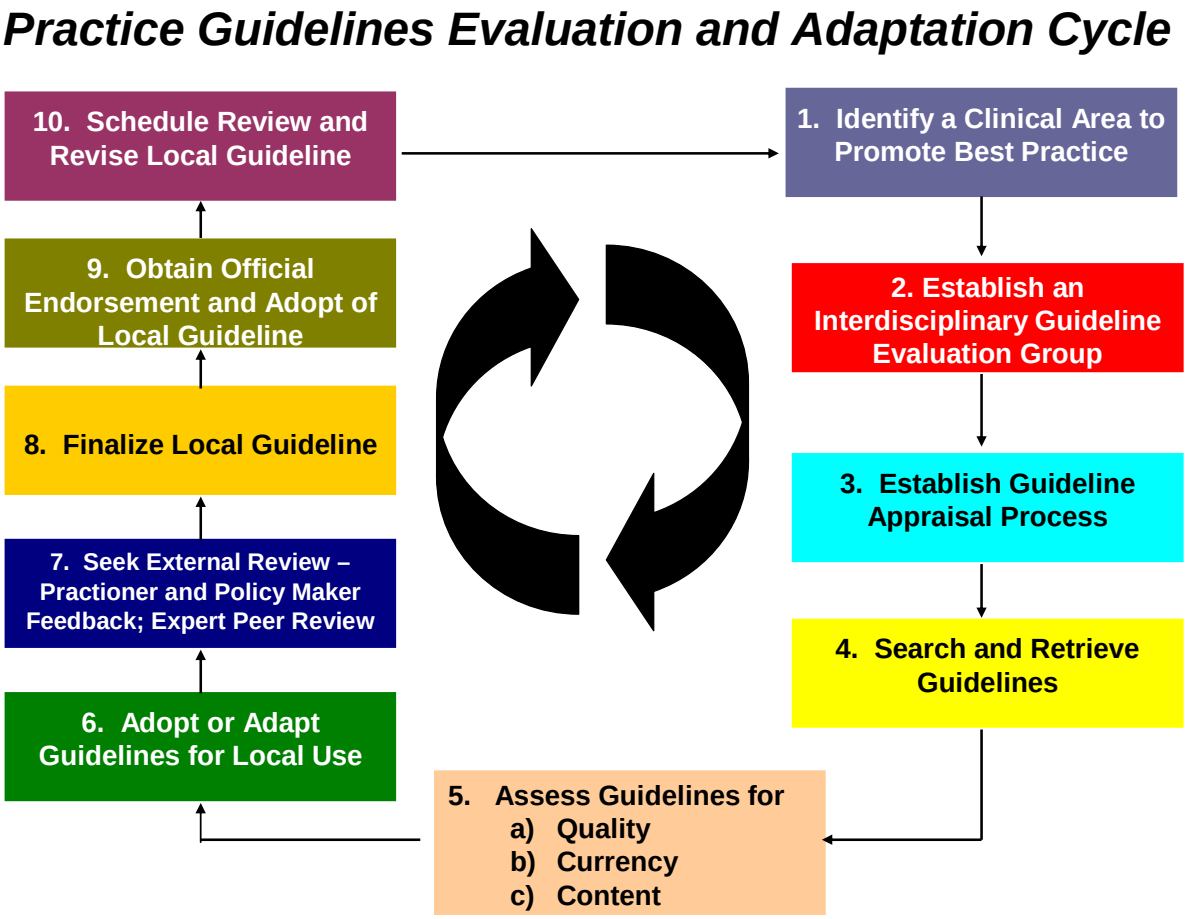


Practice Guideline Evaluation and Adaptation Cycle (PGEAC)

Graham and Harrison initially developed the Practice Guideline Evaluation and Adaptation Cycle (PGEAC) for a project that involved creating a regional protocol for the community care of leg ulcers (16,17). The interdisciplinary group that they were working with did not have the resources to develop a clinical practice guideline from inception but wanted to be evidence based in their approach, and so they elected to adapt existing guidelines for local use. The steps used by the PGAEC (see next page for a graphic representation) were intended to guide the process of adapting guidelines and to ensure the adaptation process was as pragmatic and rigorous as possible. Each step of the cycle was based on existing research, when available. A number of groups have since used the framework to adapt guidelines for local, regional, and national use. The Department of Obstetrics at the Ottawa Hospital has used it to develop its protocol for the management of the second stage of labour (18). Nurses have used the framework to adapt gestational diabetes guidelines to the local context of aboriginal peoples (Fairleigh et al, under review). The PGEAC has influenced the guideline development process adopted by the Registered Nurses Association of Ontario (1,19). The framework has also been used by the Stroke Canada Optimization of Rehabilitation through Evidence (SCORE) Project to develop recommendations for upper and lower extremities and risk assessment post-stroke (20).

The PGEAC has also been the focus of a study funded by the Canadian Institutes of Health Research. This study involved forming national panels and studying their use of the PGEAC for developing recommendations for two cancer screening practices (Zitzelsberger and Graham, unpublished). The framework has also been used by the Canadian Strategy for Cancer Control Clinical Practice Guideline Action Group to produce guidance on the management of painful bony metastases (21). In addition, in collaboration with the Canadian Strategy for Cancer Control, the Society of Gynecologic Oncologists of Canada has used the process to develop recommendations for the treatment of ovarian cancer (13). All of these experiences with the PGEAC were used to further refine the framework (2,4). In addition to being positively received in the practice community (22), the PGEAC was recently validated by a pre-post study of the implementation of a community care leg ulcer protocol (23,24) . The study revealed that,

following implementation of the adapted protocol, healing rates increased from 23% in the pre-implementation period to 59% in the post-implementation period.



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SET UP PHASE
Preparation Module

Tool 1: Guideline Development and Implementation Resources

Organization Name	URL	Resources/References
National Health and Medical Research Council (Australia)	http://www.nhmrc.gov.au	Handbook series on preparing clinical practice guidelines – 6 toolkits
Scottish Intercollegiate Guidelines Network	http://www.sign.ac.uk	SIGN Guideline Development Handbook: SIGN 50
National Institute for Health and Clinical Excellence (UK)	http://www.nice.org.uk	"Using guidance" – section on implementation How we work – Developing NICE clinical guidelines
French National Authority for Health (HAS)	http://has-sante.fr	Les Recommandations pour la pratique clinique - Bases méthodologiques pour leur réalisation en France Efficacité des méthodes de mise en oeuvre des recommandations médicales
Grading of Recommendations, Assessment, Development and Evaluation (GRADE)	http://www.gradeworkinggroup.org	See the GRADE website for a list of publications and a toolbox
New Zealand Guideline Group	http://www.nzgg.org.nz	Evidence Resources section has resources on developing guidelines, assessing guidelines and tools
Joanna Briggs Institute (JBI)	http://joannabriggs.edu.au/pubs/	FAME system for assigning a level of evidence to conclusions in JBI systematic reviews.
Registered Nurses Association of Ontario	http://www.rnao.org	Registered Nurses Association of Ontario. Toolkit: implementation of clinical practice guidelines. Toronto, Canada: Registered Nurses Association of Ontario; 2002.
NHS Centre for Reviews and Dissemination (UK)	http://www.york.ac.uk/inst/crd/	NHS Centre for Reviews and Dissemination. Getting evidence into practice. Eff Health Care 1999;5 (1):1-16.
DSI Institut for Sundhedsvaesen (Denmark)	http://www.dsi.dk	Thorsen T, Makela M. editors Changing professional practice: theory and practice of clinical guidelines implementation. DSI rapport 99.05. Copenhagen, Denmark: Danish Institute for Health Services Research and Development; 1999.
Veterans Health Administration (USA)	http:/www1.va.gov/health/	Veterans Health Administration. Putting clinical practice guidelines to work in the Department of Veterans Affairs: A guide for action.
Yale University School of Medicine (USA)	http://www.biomedcentral.com/1472-6947/5/23	Shiffman R, Dixon J, Brandt C, Essaihi A, Hsiao A, Michel G, et al. The GuideLine Implementability Appraisal (GLIA): development of an instrument to identify obstacles to guideline development. BMC Med Inform Decis Mak. 2005;5:23.

SET UP PHASE
Preparation Module

Tool 2: Search Sources and Strategies

Sources for existing guidelines

Guideline sources include both print publications and Web sites such as those for guideline clearinghouses and known developers as well as electronic databases, the reference lists in retrieved guidelines (hand searches), and panel members' recommendations.

Increasingly, guideline developers are posting their guidelines directly on the Web. This avoids delays in waiting for journals to publish guidelines, permits the rapid updating of guidelines, and reduces dissemination costs. However, when guidelines are posted directly to the Web, there is a greater chance that they may not be indexed in commonly consulted databases such as MEDLINE.

Guideline clearinghouses and sources for systematic reviews and health technology assessments (list is not exhaustive)

Guideline Internet Sites	URL
National Guidelines Clearinghouse (NGC)	http://www.guideline.gov/
Guidelines International Network (G-I-N)	http://www.g-i-n.net/
Ontario Guidelines Advisory Committee (GAC) Recommended Clinical Practice Guidelines	http://www.gacguidelines.ca
Institute for Clinical Systems Improvement (ICSI)	http://www.icsi.org/knowledge/
National Institute for Clinical Evidence (NICE)	http://www.nice.org.uk/page.aspx?o=ourguidance
New Zealand Guidelines Group	http://www.nzgg.org.nz
Scottish Intercollegiate Guidelines Network (SIGN)	http://www.sign.ac.uk/guidelines/index.html
Canadian Agency for Drugs and Technology in Health	http://www.cadth.ca/
Canadian Medical Association Infobase	http://mdm.ca/cpgsnew/cpgs/index.asp
The Cochrane library	http://www3.interscience.wiley.com/cgi-bin/mrwhome/106568753/HOME
Food and Drug Administration	http://www.fda.gov/cder/guidance/index.htm
Centre for Reviews and Dissemination Health Technology Assessment Database	http://www.york.ac.uk/inst/crd/crddatabases.htm#HTA
Directory of evidence-based information Web sites	http://132.203.128.28/medecine/repertoire/repertoire.asp
Haute Autorité de Santé (HAS)	http://has-sante.fr/anaes/anaesparametrage.nsf/Page?ReadForm&Section=/anaes/SiteWeb.nsf/wRubriquesID/APEH-3YTFUH?OpenDocument&Defaut=y&

SET UP PHASE
Preparation Module

Guideline Internet Sites	URL
CHU de Rouen - Catalogue & Index des Sites Médicaux Francophones (CISMef)	http://doccismef.chu-rouen.fr/servlets/Simple?Mot=recommandations+professionnelles&aff=4&tri=50&datt=1&debut=0&rechercher.x=29&rechercher.y=18
Bibliothèque médicale AF Lemanissier	http://www.bmlweb.org/consensus.html
Direction de la lutte contre le cancer - Ministère de la santé et des services sociaux du Québec	http://www.msss.gouv.qc.ca/sujets/prob_sante/cancer/index.php?id=76,105,0,0,1,0
SOR :Standards, Options et Recommandations	http://www.fnclcc.fr/-sci/sor/index.htm
Registered Nurses Association of Ontario	http://www.rnao.org
Agency for Quality in Medicine	http://www.aezq.de
Finnish Medical Society Duodecim	http://www.kaypahoito.fi
American Society of Clinical Oncology	http://www.asco.org
Cancer Care Ontario Practice Guideline Initiative	http://cancercare.on.ca
National Cancer Institute	http://www.cancer.gov
National Comprehensive Cancer Network	http://www.nccn.org
Agence Française de Securite Sanitaire des Produits de Sante (AFSSAPS)	http://afssaps.sante.fr

Retrieved references can be saved directly into reference software. The search strategy used (e.g., list of sources and terms) and the original locations and/or sources of the guidelines should all be documented.

Choosing inclusion/exclusion criteria for guideline selection

The chair or the panel will need to decide on some initial inclusion/exclusion criteria that will assist in the search and retrieval of guidelines. Some of the criteria that might be used include:

- Selecting only evidence-based guidelines (guideline must include a report on systematic literature searches and explicit links between individual recommendations and their supporting evidence)
- Selecting only national and/or international guidelines
- Specifying a range of dates for publication
- Selecting only those published since an important review was published

SET UP PHASE
Preparation Module

- Selecting peer reviewed publications only
- Selecting guidelines written in a particular language
- Excluding guidelines written by a single author not on behalf of an organization – in order to be valid and comprehensive, a guideline ideally requires multidisciplinary input
- Excluding guidelines published without references – as the panel needs to know whether a thorough literature review was conducted and whether current evidence was used in the preparation of the recommendations

SET UP PHASE
Preparation Module

Tool 3: Sample Declaration of Conflict of Interest

CONFLICT OF INTEREST
DISCLOSURE DECLARATION

NAME _____

NAME OF PANEL _____

DATE _____

The following questions are designed to allow participants in the guideline appraisal group to disclose any real or apparent conflict(s) of interest with respect to their activities in guideline development. Conflicts of interest include the appraisers' participation in the development or endorsement of any of the guidelines that are being reviewed for the purpose of this project. They may also involve relationships with pharmaceutical companies or other corporations whose products or services are related to the guideline topics. Financial interests or relationships requiring disclosure include but are not limited to honoraria, consultancies, employment, or stock ownership.

The intent of the disclosure declaration is to have the participants in guideline appraisal identify any potential conflict(s) in relation to any of the guidelines that are under consideration in order that appraisal group members can form their own judgments, while taking the conflict(s) of interest of other group members into consideration.

Please answer each of the following questions by circling either "NO" or "YES". If you answer "YES" to any question, please describe the nature of the interest and/or relationship, and identify the relevant commercial entity.

1. **PARTICIPATION IN GUIDELINE DEVELOPMENT**
   Have you been involved in the development on any of the guidelines under review (e.g., a member of the guideline development committee)?

   NO YES

   If YES, please identify the guideline and describe your involvement:
   Title of the guideline: _____
   _____
   _____

2. **GUIDELINE ENDORSEMENT**
   Have you directly participated in any processes to formally endorse any of the guidelines under review?

NO YES

If YES, please identify the guideline and describe your involvement:
Title of the guideline:

3. EMPLOYMENT
Are you or have you been employed by a guideline developer or an entity having a commercial interest in any of the guidelines under consideration?

NO YES

If YES, please describe:

4. CONSULTANCY
Have you served as a consultant for any guideline developer or an entity having a commercial interest in any of the guidelines under consideration?

NO YES

If YES, please describe:

5. OWNERSHIP INTERESTS – PART A
Do you have any ownership interests (including stock options) in any entity, the stock of which is not publicly traded, which has a commercial interest in any of guidelines under consideration?

NO YES

If YES, please describe:

6. **OWNERSHIP INTERESTS – PART B**
Do you have any ownership interests (including stock options but excluding indirect investments through mutual funds and the like) valued at $1500 or more in any entity that has a commercial interest in any of the guidelines under consideration?

NO YES

If YES, please describe:

7. **RESEARCH FUNDING**
Are you currently receiving or have you received research funding from any entity that has a commercial interest in any of the guidelines under consideration?

NO YES

If YES, please describe:

8. **HONORARIA**
Have you been paid honoraria or received gifts of value equal to or greater than $3500 per year or $7500 over a three-year period from a guideline developer or an entity having a commercial interest in any of the guidelines under consideration or from the developers of any of the guidelines under consideration?

NO YES

If YES, please describe:

9. OTHER POTENTIAL CONFLICT(S) OF INTEREST

SIGNATURE _____

DATE (Please print) _____

Tool 4: Consensus Process Resources

References

Pagliari C, Grimshaw J. Impact of group structure and process on multidisciplinary evidence-based guideline development: an observational study. J Eval Clin Pract. 2002;8(2):145-53.

Raine R, Sanderson C, Hutchings A, Carter S, Larkin K, Black N. An experimental study of determinants of group judgments in clinical guideline development. Lancet. 2004;364 (9432):429-37.

Hutchings A, Raine R. A systematic review of factors affecting the judgments produced by formal consensus development methods in health care. J Health Serv Res Policy. 2006;11(3):172-9.

SET UP PHASE
Preparation Module

Tool 5: Example of Work Plan – Cervical Cancer Screening Guidelines Panel

Guideline Phases		Tasks	Assigned To	Corresponding Modules	Timeline
Preliminary Phase		• Decide on broad topic area • Assess feasibility of adaptation • Identify needed resources • Establish multidisciplinary panel • Write protocol • Identify endorsing body • Discuss authorship and accountability • Discuss dissemination and implementation	• Organizing committee	Preparation Module	Month 1
Adaptation Phase	Initial Meeting (or conference call)	• Decide on terms of reference/consensus • process • Establish guideline inclusion/exclusion criteria • Help identify key search terms • Help identify key documents/ sources	• Organizing committee • Organizing committee • Resource team • Resource team	Preparation Module	
		• Refine topic area	• Panel	Scope and Purpose Module	
		• Complete guideline search • Narrow list of CPGs (if needed)	• Resource team • Organizing committee/ resource team	Search and Screen Module	

SET UP PHASE
Preparation Module

Guideline Phases		Tasks	Assigned To	Corresponding Modules	Timeline
		• Complete AGREE appraisal • Assess guideline currency • Complete evaluations (literature search and evidence, consistency of evidence and conclusions, conclusions and recommendations) for all recommendations (optional) • Prepare recommendations matrix • Assess acceptability	• Panel • Resource team • Panel member(s) • Resource team plus 1 clinician to review • Panel	Assessment Module	
	Second meeting (face-to-face)	• Review all data • Decide on recommendations for adapted guideline	• Panel	Decision and Selection Module	
Finalization Phase		• Write 1st draft of CPG and/or report on process	• Chair	Customization Module	
	Third meeting (or conference call)	• Approve1st draft by panel	• Panel		
		• Send for external review and consultation • Get formal endorsement	• Resource team • Chair and designated panel member from professional society	External Review Module	
	Fourth meeting (or conference call)	• Discuss feedback from review and consultation	• Panel		
		• Decide on update process	• Panel	Aftercare planning Module	
		• Create final adapted guideline	• Designated author	Final Production Module	

SET UP PHASE
Preparation Module

Guideline Phases		Tasks	Assigned To	Corresponding Modules	Timeline
Implementation Phase		• Consider implementation issues and develop implementation plan	• Panel or implementation group		

ADAPTATION PHASE
Search and Screen Module
Tool 6: PIPOH

(NOTE: This tool was developed specifically for use in the adaptation of oncology guidelines. However, there will be many subtopics within each main item that are relevant to other topics. A generic PIPOH is being developed)

The PIPOH items are:

- **P**atient population (including disease characteristics)
- **I**ntervention (s) of interest
- **P**rofessionals/patients (audience for whom the guideline is prepared)
- **O**utcomes to be taken into consideration (purpose of the guideline)
- **H**ealthcare setting and context

and their parameters, are to be used as prompts in the framing of the topic and health questions to be included or excluded from the guideline project.

For example, guideline developers and/or adapters might decide that a guideline on the general topic of "management of breast cancer" is to be developed. They then have to describe the **p**opulation that the guideline is to discuss, e.g., which cancer stages, age groups, clinical circumstances, genetic considerations, and so forth, are to be included or excluded.

The kind of **i**nterventions to include or exclude are also to be decided, considering the following: Is prevention part of the guideline? Screening? Or should the guideline development team only consider curative and palliative treatments, leaving aside, for other guidelines to discuss, prevention, promotion, diagnosis, and end of life care.

The scope of the guideline also includes other considerations that guideline developers/adapters might want to discuss, including the following: Who is the intended audience of the guideline, **p**rofessional specialties and/or patients? As well, the purpose of the guideline should be defined, asking the question: What **o**utcomes are expected from publishing the guideline? Ideally, outcomes should be defined in a way that provides benchmarks against which the impact of the guideline can be evaluated. Finally, the **h**ealth care setting(s) where the guideline is to be implemented or exert its effects are to be described.

Framing the scope of the guideline as precisely as possible and as early as possible in the process of guideline development or adaptation facilitates the management of the project. The PIPOH checklist has been devised for such a purpose in the field of oncology.

ADAPTATION PHASE
Search and Screen Module
The PIPOH check list for oncology

Each PIPOH item, unless self explanatory, is followed by a brief tutorial.

		Include	Exclude	Details
Population (disease and patients characteristics)	**Site**	☐	☐	
	The majority of guidelines in the cancer field deal with at least one site (breast, colon, lung, etc..). However, guidelines can be produced that concern, for example, supportive treatments, where no specific site needs to be defined.			
	Stage	☐	☐	
	Cancer stages can be described using a systematic terminology like that of the AJCC : Cancer Staging Resource toolkit. Sixth edition. American Joint Committee on Cancer, Greene F.L. *et al.* Eds., Springer – Verlag, New-York, 2002 Some stages could be specifically excluded. For example *in situ* breast cancer			
	Histology.	☐	☐	
	Reference: Fritz A, Percy C, Jack A, Shanmugaratnam K, Sobin L, Parkin DM, Whelan S, editors. International classification of diseases for oncology. 3rd ed.. Geneva, Switzerland: World Health Organization; 2000.			
	Gender	☐	☐	
	Age	☐	☐	
	Clinically relevant examples for oncology : ☐ 0 – 19 ☐ 20 – 49 ☐ 50 – 74 ☐ 75+ ☐ premenopausal ☐ postmenopausal			
	Clinical circumstances	☐	☐	
		☐	☐	
		☐	☐	
	Relevant examples for oncology: ☐ treatment naive ☐ refractory ☐ optimal debulking or not ☐ special physiological status like pregnancy ☐ risk-modifying therapies (e.g., HRT) ☐ high cancer risk group ☐ performance status ☐ comorbidity ☐ neutropenia ☐ hypercalcemia ☐ diagnosis basis (e.g., clinical examination or tests) ☐ previous cancer ☐ complications ☐ study protocol ☐ surgically removable tumour ☐ immunosuppression			
	Genetics	☐	☐	
	Special genotypes (BRCA1 & 2, amplified HER2/*neu*) or phenotypes			
	Psychosocial/cultural	☐	☐	
	For recommendations concerning, for example: targeted supportive interventions screening in specific professional groups populations with a higher risk of cancer (Kaposi) or recommendations in which self-reported symptoms are necessary (e.g., language barriers or education)			

ADAPTATION PHASE
Search and Screen Module

Interventions	**Prevention-promotion**	☐	☐	
	Interventions that aim at modifying risks factors, risk evaluation included. Examples of prevention interventions: ☐ Individual preventive measures ☐ Public health interventions (e.g., heath education or preventive health services) ☐ Environmental interventions ☐ Worksite interventions ☐ Interventions aimed at the organisation of health services			
	Screening	☐	☐	
	Cancer detection in the population, genetic screening, screening processes, mass screening, early diagnosis, etc.			
	Diagnosis	☐	☐	
	Examples: ☐ First evaluation ☐ Physical examination ☐ Tests ☐ Surgery for diagnosis			
	Prognosis	☐	☐	
	E.g., markers			
	Treatment(s)	☐	☐	
		☐	☐	
		☐	☐	
		☐	☐	
	Examples of treatment topics in oncology: ☐ Sequence of treatments ☐ Curative/palliative radiotherapy ☐ Curative/palliative surgery ☐ Curative/palliative hormone treatment ☐ Adjuvant/neo-adjuvant/palliative chemotherapy ☐ Single/multi agent chemotherapy ☐ Chemotherapy + radiotherapy ☐ Prophylactic radiotherapy ☐ Immunotherapy ☐ Novel agents ☐ Treatment choice (comparison) ☐ Treatment duration ☐ Treatment delay			
	Line of treatment	☐	☐	
	☐ **Adjuvant** ☐ **Neo-adjuvant** ☐ **1st treatment of a local recurrence** ☐ **Metastatic 1st line** ☐ Metastatic after the 1st line ☐ Induction ☐ Continuance Example of a guideline that concerns a specific line of treatment: "First-line chemotherapy for postoperative patients with stage II, III or IV epithelial ovarian cancer, fallopian tube cancer, or primary peritoneal cancer," Cancer Care Ontario			
	Response evaluation	☐	☐	
	Examples: ☐ Physical examination ☐ Imaging ☐ Tests ☐ Pathology ☐ Surgery			
	Supportive care	☐	☐	
	Examples: ☐ Symptoms management: nausea/vomiting, fever and chills, bone marrow depression, eye problems, fatigue, hot flushes, neurological problems, stomatitis, pain, distress, etc. ☐ Psychosocial support ☐ Reconstructive surgery ☐ Nursing evaluation ☐ Nursing interventions ☐ Complementary and alternative medicine			
	Follow up	☐	☐	
	Rehabilitation	☐	☐	
	End of life care	☐	☐	
	Genetic counselling	☐	☐	
	Interventions on organisations	☐	☐	

ADAPTATION PHASE
Search and Screen Module

	Examples: ☐ Introducing new processes (ex. decision aids, standards) ☐ Interdisciplinarity ☐ New management approaches ☐ Information technology			

		Include	Exclude	Details
Professionals/Patients: targeted users	**Providers**	☐	☐	
	☐ Hematologists-oncologists ☐ Surgeons- oncologists ☐ Gynecologists-oncologists ☐ Surgeons ☐ Radiation oncologists ☐ Pathologists ☐ General practitioners ☐ Pharmacists ☐ Nurses ☐ Social workers ☐ Physiotherapists ☐ Dentists ☐ Dieticians ☐ Psychologists ☐ Orthodontists			
	Stakeholders	☐	☐	
	☐ Hospital directors ☐ Head nurses ☐ Public health departments ☐ Government ☐ Other organisations			
	Patients	☐	☐	
	Should the guideline explicitly take into account patient preferences, opinions, expectations, and needs (reflected in the composition of the guideline development team)?			
Outcome – purpose of the guideline	**Patients outcomes**			
	☐ Tumour response ☐ Survival ☐ Disease-free survival ☐ Quality of life (e.g., pain control, psychological well being, performance status) ☐ Innocuity ☐ Test precision and reliability ☐ Treatment compliance			
	System outcomes	☐	☐	
	☐ Costs ☐ Decrease in practice variation ☐ Decrease in care system use ☐ Improvements in quality of care indicators (e.g., appropriateness, optimized use, access, efficiency, timeliness, safety, continuity, etc.)			
	Public health outcomes			
	☐ Morbidity ☐ Mortality ☐ Incidence ☐ Prevalence			
Health care setting	**Organisation**	☐	☐	
		☐	☐	
		☐	☐	

	☐ Community hospital ☐ University hospital ☐ In-bed patient ☐ Ambulatory care ☐ Intensive care ☐ Emergency ☐ Cancer center ☐ Primary care ☐ Doctor's office ☐ Community care center ☐ Palliative care ☐ Home care ☐ Long-term care hospital ☐ Local context ☐ Regional context ☐ National context

Other comments

Tool 7: Table for Summarizing Guideline Characteristics

Title	Publisher	Country, language	Publication date	End of search date	Comments
…… ……					
…… ……					
…… ……					
…… ……					
…… ……					
…… ……					
…… ……					

ADAPTATION PHASE
Search and Screen Module
Tool 8: Table for Summarizing Guideline Content

		Actual content of guidelines (CPG) (indicate with ☑ if included in guideline)			
		CPG #1	**CPG #2**	**CPG #3**	**CPG #4**
Health question #1					
Health question #2					
Health question #3					
Health question #4					
Health question #5					
Health question #6					
Population	Insert definition here				
Intervention(s)	Insert definition here				
Professionals/patients	Insert definition here				
Outcome	Insert definition here				
Healthcare setting	Insert definition here				

Population: describe, if not adequately described in any health question discussed in the retrieved guidelines, the characteristics of the disease and patients for which there is to be some discussion (not necessarily a recommendation) in the guideline

Intervention: describe, if not adequately described in any health question discussed in the retrieved guidelines, the intervention(s) to be discussed

Professionals/patients: describe the targeted users of the guideline, e.g., specialists, professionals, and/or patients

Outcome: describe the purpose of the guideline and its objectives and outcome(s) against which an impact can be measured

Healthcare setting: describe the health care setting(s) in which the guideline is to be implemented

ADAPTATION PHASE
Search and Screen Module/ Assessment Module

Tool 9: AGREE Instrument

Available free of charge for download at www.agreetrust.org

The AGREE Instrument - short appraisal form

SCOPE AND PURPOSE

1. The overall objective(s) of the guideline is(are) specifically described.	Strongly Agree	4	3	2	1	Strongly Disagree
2. The clinical question(s) covered by the guideline is(are) specifically described.	Strongly Agree	4	3	2	1	Strongly Disagree
3. The patients to whom the guideline is meant to apply are specifically described.	Strongly Agree	4	3	2	1	Strongly Disagree

STAKEHOLDER INVOLVEMENT

4. The guideline development group includes individuals from all the relevant disciplines or stakeholders.	Strongly Agree	4	3	2	1	Strongly Disagree
5. The patients' views and preferences have been sought.	Strongly Agree	4	3	2	1	Strongly Disagree
6. The target users of the guideline are clearly defined.	Strongly Agree	4	3	2	1	Strongly Disagree
7. The guideline has been piloted among target users.	Strongly Agree	4	3	2	1	Strongly Disagree

METHODOLOGY

8. Systematic methods were used to search for evidence.	Strongly Agree	4	3	2	1	Strongly Disagree
9. The criteria for selecting the evidence are clearly described.	Strongly Agree	4	3	2	1	Strongly Disagree
10. The methods used for formulating the recommendations are clearly described.	Strongly Agree	4	3	2	1	Strongly Disagree
11. The health benefits, side effects and risks have been considered in formulating the recommendations.	Strongly Agree	4	3	2	1	Strongly Disagree
12. There is an explicit link between the recommendations and the supporting evidence.	Strongly Agree	4	3	2	1	Strongly Disagree
13. The guideline has been externally reviewed by experts prior to publication.	Strongly Agree	4	3	2	1	Strongly Disagree

ADAPTATION PHASE
Search and Screen Module/ Assessment Module

14. A procedure for updating the guideline is provided.	Strongly Agree	4	3	2	1	Strongly Disagree

CLARITY AND PRESENTATION

15. The recommendations are specific and unambiguous.	Strongly Agree	4	3	2	1	Strongly Disagree
16. The different options for management of the condition are clearly presented.	Strongly Agree	4	3	2	1	Strongly Disagree
17. Key recommendations are easily identifiable.	Strongly Agree	4	3	2	1	Strongly Disagree
18. The guideline is supported with tools for application.	Strongly Agree	4	3	2	1	Strongly Disagree

APPLICABILITY

19. The potential organisational barriers in applying the guideline have been discussed.	Strongly Agree	4	3	2	1	Strongly Disagree
20. The potential costs implications of applying the recommendations have been considered.	Strongly Agree	4	3	2	1	Strongly Disagree
21. The guideline presents key review criteria for monitoring and/or audit purposes.	Strongly Agree	4	3	2	1	Strongly Disagree

METHODOLOGY

22. The guideline is editorially independent from the funding body.	Strongly Agree	4	3	2	1	Strongly Disagree
23. Conflicts of interest of guideline development members have been recorded.	Strongly Agree	4	3	2	1	Strongly Disagree

OVERALL ASSESSMENT

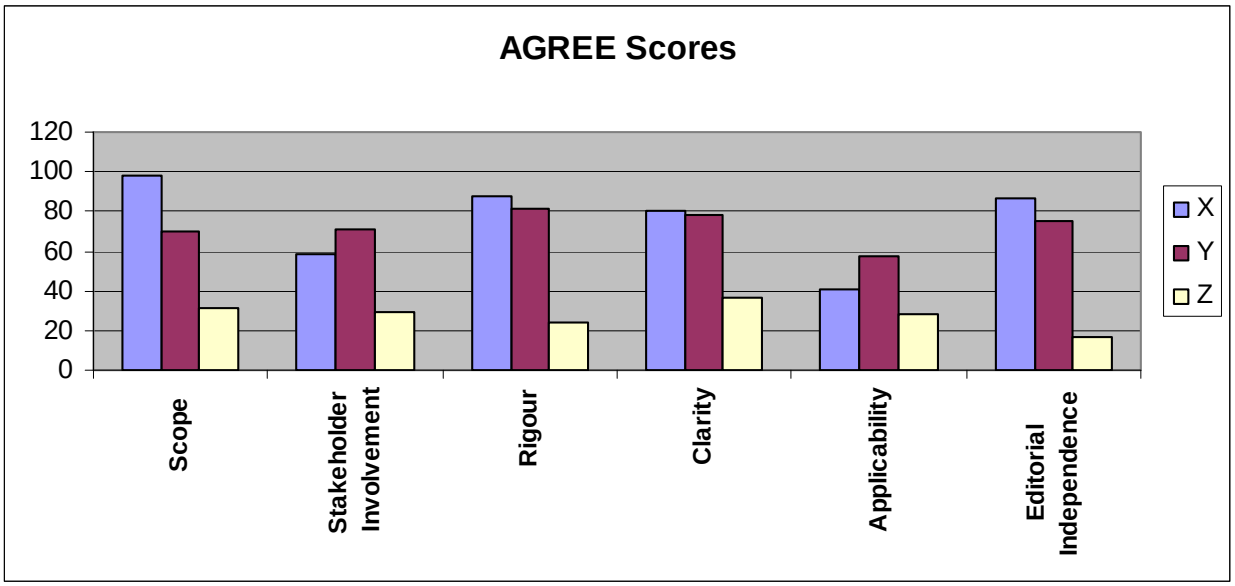
Would you recommend this guideline for use in practice?

Strongly recommend	
Recommend (with provisos or alterations)	
Would not recommend	
Unsure	

ADAPTATION PHASE
Search and Screen Module/ Assessment Module

Tool 10: AGREE Inter-rater Agreement Spreadsheet and AGREE Score Calculation Spreadsheet

Excel sheets will eventually be made available on the ADAPTE Web site at www.adapte.org. Meanwhile, here is an example of a graph produced from the results of the assessment of three guidelines (X, Y, and Z) by six assessors, using the AGREE instrument, and entered into a Microsoft® Excel* spreadsheet.



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ADAPTATION PHASE
Search and Screen Module/ Assessment Module

Tool 11: Sample Currency Survey of Guideline Developers

	Yes	No
Are you aware of any new evidence relevant to this clinical practice guidelines statement?		
If so, please provide a reference for this new evidence.		
Is there any new evidence to invalidate any of the recommendations comprising the guideline?		
If so, please indicate which recommendation(s) are in need of updating, and provide the reference for this new evidence.		
Are there any plans to update the guideline in the near future?		
If so, when?		
When was the clinical practice guideline last updated? **What is the citation for the latest version?**		

Tool 12: Sample Recommendation Matrix

The following is an example of a recommendation matrix created for the creation of a guideline on systemic therapy for recurrent ovarian cancer using the adaptation process.

ADAPTATION PHASE
Assessment Module

Recommendations Matrix – Recurrent Ovarian Cancer – Systemic Therapy

	CCO Recurrent Ovarian* (Draft guideline)	SIGN Epithelial Ovarian (Guideline)	BC Cancer (Management guidelines)	NHMRC (Guideline)	NICE (Technology Appraisal)
Context: Clinical trials Individual assessment Role of chemotherapy Quality of life	*The body of evidence that informs clinical recommendations is sparse and incomplete; thus, all pts with recurrences are encouraged to participate in clinical trials. (Level 3, Recommendation C)* *Each pt needs to be assessed individually to determine optimal therapy for her in terms of recurrence, sensitivity to platinum, and toxicity. (Level 3, Recommendation C)* *Women may repeatedly be considered platinum-sensitive and may benefit from more than one line of therapy. (Level 2, Recommendation B)*	*Pt care should be discussed within the multidisciplinary team, and where possible, pts should be entered into appropriate clinical trials. (Good practice point)* Chemotherapy for recurrent ovarian cancer should be regarded as palliative in intent and should be reserved for symptomatic recurrence of disease. (B) Women should be given accurate information on their likely response to chemotherapy, including adverse effects, so that they can make an informed decision about whether or not to proceed with trt. (D) The impact of chemotherapy toxicities on patients' QOL must be balanced against their anticipated response to trt. (D)			**Note: the tech appraisal only reviewed paclitaxel, PLDH, and topotecan* *Within the recommendations, the choice of trt for second-line or subsequent chemotherapy should be made after discussion between the responsible clinician and the pt about the risks and benefits of the options available*

Regular text = Recommendation in guideline Italicized text = qualifying statement or trt option in a document other than a CPG

	CCO	SIGN	BC Cancer	NHMRC	NICE	NCCN	NCI PDQ
Patients with platinum-sensitive recurrences							
Combination therapy	Combination chemotherapy is preferred over single-agent chemotherapy. Either paclitaxel/carboplatin or gemcitabine/carboplatin is favoured over carboplatin alone in terms of overall survival and response rate. (Level 1, Recommendation A)	Symptomatic platinum-sensitive cancer recurrence can be treated with further platinum and paclitaxel. (B) *Cautious clinical judgement should be used when considering the use of platinum and paclitaxel in pts with symptomatic platinum-sensitive cancer recurrence after a trt-free interval of 6-12 mths. (gd practice pt)*			*Paclitaxel in combination with a platinum-based compound (carboplatin or cisplatin) is recommended as an option for second-line (or subsequent) trt of women with platinum-sensitive or partially platinum-sensitive advanced cancer, except in women allergic to platinum-based compounds.*	*Recent evidence suggests that combination chemotherapy may be superior to single-agent therapy in this situation, although sequential therapy may provide the same results. Alternatively, pts can be treated with single agent taxane or platinum and then crossed over to the other agent as dictated by clinical response.*	*Carboplatin + paclitaxel resulted in progression-free survival (Level of evidence 1iiA)*

	CCO	SIGN	BC Cancer	NHMRC	NICE	NCCN	NCI PDQ
Patients with platinum-sensitive recurrences							
Single-agent recommendations (platinum compound)	If combination therapy is not indicated, it is the opinion of the Gynecology Cancer DSG that a single platinum compound (i.e., carboplatin) is preferred over a non-platinum compound. (Level 3, Recommendation B)		If pts have shown a high-quality and long-lasting response to initial platinum-based trt, then carboplatin can be used with a good chance of secondary response.	Retreat with carboplatin (Level of evidence IV). *Principle of therapy for relapsed disease should be that the potential utility of single agent carboplatin should be exhausted before moving on to other agents.*	*PLDH is recommended as an option for the second line (or subsequent) trt of women with partially platinum-sensitive, platinum-resistant or platinum-refractory advanced cancer and for women who are allergic to platinum-based compounds.*	*For stage III and IV patients with partial responses, recurrence regimens include single-agent therapy or a combination of a taxane and a platinum, recurrence chemotherapy, or IP therapy.*	Retreatment with cisplatin or carboplatin should be considered.
Other agent recommendations	If a platinum compound is not indicated, then it is the opinion of the Gynecology Cancer DSG that trt decisions should be based on toxicity and ease of administration information. (Level 3, Recommendation C) *Only one comparative randomized trial in the sensitive group has compared two non-platinum compounds (PLD vs. topotecan). Neither compound has been compared to carboplatin.(Level 1, Recommendation B)*						

	CCO	SIGN	BC Cancer	NHMRC	NICE	NCCN	NCI
Patients with platinum-resistant recurrences							
Paclitaxel	There is no evidence to support or refute the use of more than one line of chemotherapy in patients with platinum-resistant recurrences. (Level 3, Recommendation C)	*The optimal agents in platinum-resistant disease have yet to be defined, and trt should be based on specialist judgement. (gd practice pt)*	Pts with progressive platinum-refractory ovarian cancer may benefit from taxol if this agent was not a component of primary trt.	*An argument can be made for not considering further treatment.* *In patients with relapsed ovarian cancer, QOL must be a major component of assessment.*	*Single-agent paclitaxel is recommended as an option for the second line (or subsequent) trt of women with platinum-refractory or platinum-resistant advanced cancer or for women who are allergic to platinum-based compounds.* *PLDH(see above)* *Topotecan is recommended as an option for second-line (or subsequent) trt only for those women with platinum-refractory or platinum-resistant advanced cancer or those who are allergic to platinum-based compounds for whom PLDH and single-agent paclitaxel are considered inappropriate.*	*Supportive care OR recurrence regimen (see next page)*	*Trt with paclitaxel should be considered*
Topotecan	Options include non-platinum drugs such as topotecan and doxorubicin. (Level 3, Recommendation B)						

	CCO	SIGN	BC Cancer	NHMRC	NICE	NCCN	NCI
Salvage chemotherapy and other options		Tamoxifen should be considered in pts for wh om chemotherapy is not appropriate. (C)	Taxol is not indicated for those with asymptomatic and/or non-progressive disease following conventional therapy or those with bowel obstructions or a marked impairment of performance status. Other drugs potentially effective in this situation are oral etoposide, gemcitabine, topotecan, and vinorelbine.	*In trt of ovarian cancer no longer sensitive to platinum, topotecan and PLDH have some efficacy in terms of response rate and survival times.* *Tamoxifen can be considered where chemotherapy is inappropriate*		*Acceptable recurrence modalities:* *tamoxifen* *oral etoposide* *vinorelbine* *paclitaxel* *docetaxel* *topotecan* *altretamine* *PLDH* *carboplatin* *cisplatin* *oxaliplatin* *gemcitabine* *cyclophosphamide* *melphalan* *radiation therapy* *Pts who progress on 2 consecutive single-agent regimens without evidence of clinical benefit are unlikely to benefit from additional chemotherapy and may be offered best supportive care or clinical trial.*	*PLD, topotecan, PLD and topotecan, gemcitabine, fluorouracil and leucovorin, tamoxifen, etoposide, ifosfamide, HMM, capecitabine – all have shown activity in refractory ovarian cancer* *Secondary cytoreduction – no studies to show survival advantage.* *Surgical intervention may improve QOL when disease-related symptoms can be abrogated.*

Abbreviations: BC Cancer = British Columbia Cancer Agency; CCO = Cancer Care Ontario; Chemo = chemotherapy; CPG = clinical practice guideline; DSG=disease site group; Gd practice pt = good practice point; HMM = Altretamine; IP = intraperitoneal; Mths = months; NCCN = National Comprehensive Cancer Network; NCI = National Cancer Institute; NHMRC = National Health and Medical Research Council; NICE = National Institute for Clinical Evidence; PLDH=pegylated liposomal doxorubicin hydrochloride; Pts=patients; QOL=quality of life; SIGN = Scottish Intercollegiate Guidelines Network; Tech = technical; Trt = treatment; Vs, = versus.

Recommendations Matrix – Recurrent Ovarian Cancer

Definitions of Platinum Sensitive and Platinum Resistant as used in the resources

Platinum Sensitive
CCO – relapse after 6 months
SIGN – relapse after 6 months
BC Cancer Agency – relapse after 12 months
NHMRC – relapse after 6 months
NICE – relapse after 6+ months
NCI – relapse after 5-12 months minimum
NCCN – complete remission and relapse 6+ months after starting chemo

Platinum Resistant
CCO – no response to initial platinum-based chemo, complete or partial response followed by progression while still on chemo, response then relapse 6 months after stop of chemo
SIGN – treatment-free interval less than 6 months
BC Cancer – less than complete clinical response, 6 months or less interval between treatment and relapse
NHMRC – patients who do not respond to initial therapy or who progress during initial chemo
NICE – Resistant = relapse within 6 months of completion of initial platinum-based chemo/ Refractory = no response to initial platinum-based chemo
NCI – progression of disease while on platinum-based regimen or recurrence shortly after completion of regimen
NCCN – progression or stable disease on primary chemo or complete remission and relapse less than 6 months after stopping chemo

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ADAPTATION PHASE
Customization Module

Tool 13: Evaluation Sheet – Search and Selection of Evidence

	Guideline #1			Guideline #2		
	Yes	**Unsure**	**No**	**Yes**	**Unsure**	**No**
Overall, was the search for evidence comprehensive?	○	○	○	○	○	○
The authors had a clearly focused question (population, intervention, outcome)	○	○	○	○	○	○
Appropriate databases were searched for source guidelines	○	○	○	○	○	○
Internet sites were searched for source guidelines	○	○	○	○	○	○
Years covered in search	○	○	○	○	○	○
Languages covered in search	○	○	○	○	○	○
Keywords used	○	○	○	○	○	○
Combinations of keywords	○	○	○	○	○	○
Detailed search strategies are provided with the guideline	○	○	○	○	○	○
Snowball methods were used	○	○	○	○	○	○
A hand search of the reference lists was completed	○	○	○	○	○	○
Local experts and/or societies were asked for guideline recommendations	○	○	○	○	○	○

ADAPTATION PHASE
Customization Module

	Guideline #1			Guideline #2		
	Yes	**Unsure**	**No**	**Yes**	**Unsure**	**No**
Overall, was bias in the selection of articles avoided?	○	○	○	○	○	○
Inclusion and exclusion criteria reported	○	○	○	○	○	○
The number of persons who selected and analysed the data is documented	○	○	○	○	○	○
The procedure to solve disagreement is described	○	○	○	○	○	○
The number of references analysed is documented	○	○	○	○	○	○
The number of excluded references is documented	○	○	○	○	○	○
The reasons for excluding references are given	○	○	○	○	○	○
The criteria for inclusion and exclusion are clinically and methodologically valid	○	○	○	○	○	○
The reasons for exclusion conform to the selection and exclusion criteria	○	○		○	○	○
The process for selection of evidence is adequately described	○	○	○	○	○	○
	Comments			**Comments**		

ADAPTATION PHASE
Customization Module

Tool 14: Evaluation Sheet – Scientific Validity of Guidelines (Consistency between Evidence, Its Interpretation and Recommendations)

Health question 1	Guideline #1			Guideline #2		
	Yes	**Unsure**	**No**	**Yes**	**Unsure**	**No**
Overall, the evidence was valid	○	○	○	○	○	○
Given the search strategy, the risk that relevant evidence has been missed is low	○	○	○	○	○	○
The criteria for selecting the evidence is explicit	○	○	○	○	○	○
Settings and protocols of selected studies fit with the health question	○	○	○	○	○	○
Outcomes were clinically sound (e.g., duration of disease-free survival might be considered too weak as evidence compared to overall survival)	○	○	○	○	○	○
The criteria used for assessing the quality and validity of the selected studies are adequately reported (type of studies, randomization methods, patient retention in groups etc.)	○	○	○	○	○	○
The risk that biased evidence has been reported is low	○	○	○	○	○	○
The outcomes were considered clinically sound (e.g., duration of disease free survival might be considered too weak as evidence compared to overall survival)	○	○	○	○	○	○
When a meta-analysis was performed, statistical analyses were appropriate. Sensitivity analysis and test of heterogeneity was performed	○	○	○	○	○	○

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Customization Module

Health question 1	Guideline #1			Guideline #2		
	Yes	Unsure	No	Yes	Unsure	No
Coherence between the evidence and recommendations	○	○	○	○	○	○
The evidence was direct. Patients and interventions included in the studies were comparable to those targeted by the recommendation	○	○	○	○	○	○
Conclusions were supported by data and/or the analysis; results were consistent from study to study. When inconsistencies existed in data, considered judgment was applied and reported.	○	○	○	○	○	○
The conclusions are clinically relevant. (Statistical significance is not always equal to clinical significance)	○	○	○	○	○	○
The conclusions derived from data point to effectiveness/ineffectiveness of the intervention and the recommendation is written accordingly	○	○	○	○	○	○
There is some justification to recommend/not recommend the intervention even though the evidence is weak	○	○	○	○	○	○
The hierarchy of strength of evidence is adequately described	○	○	○	○	○	○
Overall, the scientific quality of this recommendation does not present risks of bias	○	○	○	○	○	○
The strength of evidence attributed to the recommendation is adequately described and justified	○	○	○	○	○	○
Risks and benefits have been weighed	○	○	○	○	○	○
	Comments			Comments		

(Process is repeated as needed for additional health questions)

ADAPTATION PHASE
Customization Module

Tool 15: Evaluation sheet – Acceptability/Applicability

Health question 1	Guideline #1			Guideline #2		
	Yes	**Unsure**	**No**	**Yes**	**Unsure**	**No**
Overall, the recommendation is acceptable	○	○	○	○	○	○
The strength of evidence and the magnitude of effect adequately support the grade of the recommendation	○	○	○	○	○	○
There is sufficient benefit of the intervention, compared with other available management	○	○	○	○	○	○
The recommendation is compatible with the culture and values in the setting where it is to be used	○	○	○	○	○	○
	Comments			**Comments**		
	Yes	**Unsure**	**No**	**Yes**	**Unsure**	**No**
Overall, the recommendation is applicable	○	○	○	○	○	○
The intervention is applicable to the patients in the context of use	○	○	○	○	○	○
The intervention/equipment is available in the context of use	○	○	○	○	○	○
The necessary expertise is available in the context of use	○	○	○	○	○	○
There are no constraints, legislation, policies, or resources in the health care setting of use that would impede the implementation of the recommendation	○	○	○	○	○	○
	Comments			**Comments**		

(Process is repeated as needed for additional health questions)

ADAPTATION PHASE
Customization Module

Tool 16: Checklist of Adapted Guideline Content

Guideline section	When to be completed/ Completed
1. Overview material • Structured abstract including: o Guideline's release date o Status (original, adapted, revised, updated) o Print and electronic sources • Adapter and source guideline developer	
2. Introduction and background	
3. Scope and purpose	
4. Target audience of the guideline	
5. Health questions	
6. Recommendations • Risks and benefits associated with the recommendations • Specific circumstances under which to perform the recommendation • Strength of recommendation (if assigned)	
7. Supporting evidence and information for the recommendations • Panel rationale behind the recommendations • Presentation of additional evidence • How and why existing recommendations were modified	
8. External review and consultation process • Who was asked to review the guideline • What process was followed • Discussion of feedback • Feedback incorporated into the final document	
9. Plan for scheduled review and update	
10. Algorithm or summary document	
11. Implementation considerations	
12. Glossary (for unfamiliar terms)	
13. References of all material used in creating the guideline	
14. Acknowledgment of source guideline developers and permission granted (where necessary)	
15. List of panel members and their credentials, declaration of conflicts of interest	
16. List of funding sources	
17. Appendix describing adaptation process including: • Guideline search and retrieval including list of guidelines and whether they were included/excluded, with rationale • Guideline assessments including a summary of results for each assessment (including AGREE domain scores) • Decision process followed by panel • Results and decisions of each evaluation	

FINALIZATION PHASE
External Review and Acknowledgement Module

Tool 17: Sample External Review Surveys

The following are examples of external review surveys used to gather feedback from practitioners on an adapted guideline.

Cervical Cancer Screening Guidelines Appraisal Project
Family Physician (FP) Survey

Yrs as a FP/GP:_____ **Gender**: F ❍ M ❍
Practice setting: Rural ❍ Urban ❍ Group ❍ Individual ❍

Which cervical cancer screening guideline do you currently follow:
Health Canada ❍ Canadian Task Force on Preventive Health Care ❍
American Cancer Society ❍ US Preventive Services Task Force ❍
Other ❍ Please indicate which: _____
Provincial guidelines ❍ Please indicate which:_____
Not Sure ❍

For each item, please check off the box that most adequately reflects your opinion.	Strongly Agree				Strongly Disagree
Current use of clinical practice guidelines (CPGs)	1	2	3	4	5
I receive CPGs on cervical screening from a variety of sources	❍	❍	❍	❍	❍
I receive CPGs on cervical screening that contradict one another	❍	❍	❍	❍	❍
Contradictory CPGs make it difficult to decide which to use	❍	❍	❍	❍	❍
Panel process and consensus statement					
The cervical cancer screening panel is credible	❍	❍	❍	❍	❍
The consensus statement made by the panel is reasonable	❍	❍	❍	❍	❍
The consensus statement may have been influenced by vested interests	❍	❍	❍	❍	❍
The process used by the panel to come to consensus is credible	❍	❍	❍	❍	❍
If I agreed with the recommendations, I would use a guideline that was developed outside of Canada	❍	❍	❍	❍	❍
The consensus statement is applicable to the majority of female patients in my practice	❍	❍	❍	❍	❍
Following this consensus statement would not require major changes to my practice	❍	❍	❍	❍	❍
This consensus statement is likely to be used by most of my colleagues	❍	❍	❍	❍	❍
This consensus statement is flexible enough to allow for clinical judgment	❍	❍	❍	❍	❍
If the Canadian College of Family Physicians endorsed this consensus statement, I would be more likely to follow it	❍	❍	❍	❍	❍
If the Canadian Strategy for Cancer Control endorsed this consensus statement, I would be more likely to follow it	❍	❍	❍	❍	❍
I would find it useful to have access to quality systematic appraisals of existing CPGs for topics related to family practice	❍	❍	❍	❍	❍

I would *accept* the consensus statement made by this expert panel:
Absolutely ❍ With modifications ❍ I reject the consensus statement ❍

I would *follow* the consensus statement made by this expert panel:
Very likely ❍ Somewhat likely ❍ Not at all likely ❍

Comments:
_____
_____

All information you provide will remain CONFIDENTIAL. Results of the survey will only be presented in aggregate form and your name will not appear on any reports.

FINALIZATION PHASE
Aftercare Planning Module
Practitioner Feedback Survey

PRACTICE GUIDELINES INITIATIVE
CANCER CARE ONTARIO'S PROGRAM IN EVIDENCE-BASED CARE
PRACTITIONER FEEDBACK
http://www.cancercare.on.ca/ccopgi/

DRAFT PRACTICE GUIDELINE REPORT #

For each item, please check off the box that most adequately reflects your opinion.

1. Are you responsible for the care of patients for whom this draft guideline report is relevant? This may include the referral, diagnosis, treatment, or follow-up of patients.	☐ yes	☐ no	☐ unsure
If you answered "*No*" or "*Unsure*", please return this questionnaire to the address on the reverse side. If you answered "*Yes*", please answer the questions below and return to the address on the reverse side.			

	strongly agree		neither agree or disagree		strongly disagree
2. The rationale for developing a guideline, as stated in the "*Choice of Topic*" section of this draft report, is clear.	☐	☐	☐	☐	☐
3. There is a need for a guideline on this topic.	☐	☐	☐	☐	☐
4. The literature search is relevant and complete (e.g., no key trials were missed nor any included that should not have been) in this draft guideline.	☐	☐	☐	☐	☐
5. I agree with the methodology used to summarize the evidence included in this draft guideline.	☐	☐	☐	☐	☐
6. The results of the trials described in this draft guideline are interpreted according to my understanding of the data.	☐	☐	☐	☐	☐
7. The draft recommendations in this report are clear.	☐	☐	☐	☐	☐
8. I agree with the draft recommendations as stated.	☐	☐	☐	☐	☐
9. The draft recommendations are suitable for the patients for whom they are intended.	☐	☐	☐	☐	☐
10. The draft recommendations are too rigid to apply to individual patients.	☐	☐	☐	☐	☐
11. When applied, the draft recommendations will produce more benefits for patients than harms.	☐	☐	☐	☐	☐
12. The draft guideline report presents options that will be acceptable to patients.	☐	☐	☐	☐	☐
13. To apply the draft recommendations will require reorganization of services/care in my practice setting.	☐	☐	☐	☐	☐
14. To apply the draft recommendations will be technically challenging.	☐	☐	☐	☐	☐
15. The draft recommendations are too expensive to apply.	☐	☐	☐	☐	☐
16. The draft recommendations are likely to be supported by a majority of my colleagues.	☐	☐	☐	☐	☐
17. If I follow the draft recommendations, the expected effects on patient outcomes will be obvious.	☐	☐	☐	☐	☐
18. The draft recommendations reflect a more effective approach for improving patient outcomes than is current usual practice. (if they are the same as current practice, please tick NA). *NA* ☐	☐	☐	☐	☐	☐

FINALIZATION PHASE
Aftercare Planning Module

19. When applied, the draft recommendations will result in better use of resources than current usual practice (if they are the same as current practice, please tick NA). *NA* ☐	☐	☐	☐	☐	☐
20. I would feel comfortable if my patients received the care recommended in the draft guideline.	☐	☐	☐	☐	☐
21. This draft report should be approved as a practice guideline.	☐	☐	☐	☐	☐
	not at all likely		unsure	very	likely
22. If this draft report were to be approved as a practice guideline, how likely would you be to make use of it in your own practice?	☐	☐	☐	☐	☐
23. If this draft report were to be approved as a practice guideline, how likely would you be to apply the recommendations to your patients?	☐	☐	☐	☐	☐

COMMENTS ABOUT THE DRAFT PRACTICE GUIDELINE REPORT

Thank you for taking time to respond.
Please visit our Web site for access to the most up-to-date versions of all completed clinical practice guideline and evidence summary reports.

http://www.cancercare.on.ca/access_PEBC.htm

The Practitioner Feedback Survey is based on the following reference: Brouwers MC, Graham ID, Hanna SE, Cameron DA, Browman GP. Clinicians' assessments of practice guidelines in oncology: the CAPGO survey**.** Int J Technol Assess Health Care. 2004 Fall;20(4):421-6. (Cancer Care Ontario, Hamilton, Canada. mbrouwer@mcmaster.ca)

Tool 18: Table for Reporting on Results of Update Process

Health question	Recommendation in original guideline(s)	End date of literature search	New evidence (references)	Final recommendation	Comments
Q 1					
Q 2					
Q 3					
Q 4					
Q 5					
Q n					