

THE GUIDELINE UTILIZATION RESOURCE UNIT

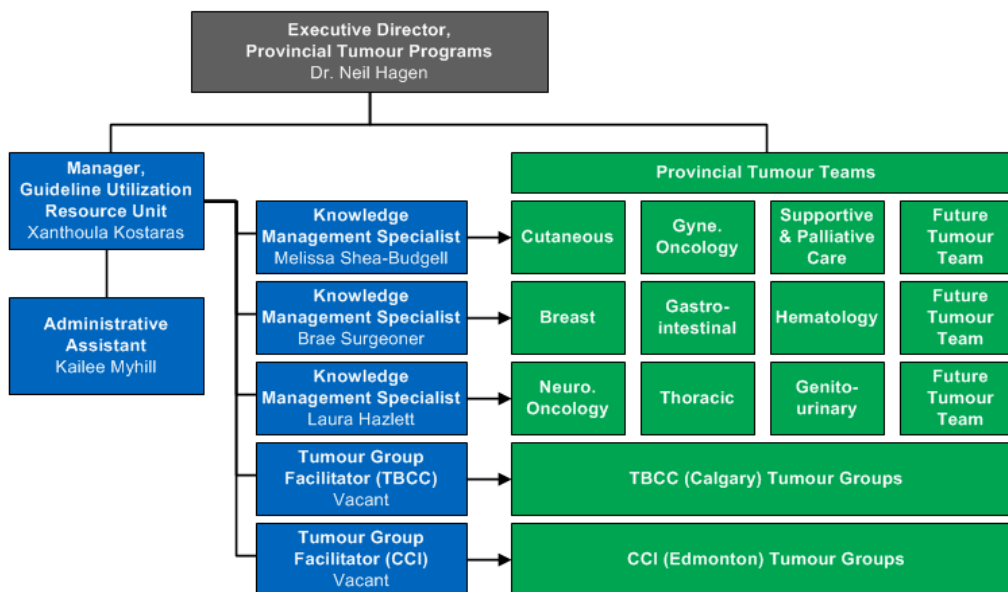
This handbook was developed by the Guideline Utilization Resource Unit (GURU) to outline the process involved in the development of clinical practice guidelines for Alberta Health Services - Cancer Care.

GURU was established in 2006 by the former Alberta Cancer Board, and is supported by Alberta Health Services - Cancer Care. The two main goals of GURU are to support the Provincial Tumour Teams in articulating their best practices related to the diagnosis, staging, treatment, and follow-up of cancer, and to provide family physicians and patients with disease-specific information in a succinct and timely manner. Current work is focused on the first goal: the development of evidence-informed clinical practice guidelines for site-specific cancers.

GURU supports nine Provincial Tumour Teams, which are made up of clinicians, pathologists, nurses, pharmacists, and researchers from across the province of Alberta. At present, GURU's core staff includes three Knowledge Management (KM) Specialists, an Administrative Assistant, the Manager, and the Executive Director of the Provincial Tumour Programs. The KM Specialists develop the evidence base on which the guideline recommendations are based, assist in the formulation of recommendations for the guideline document, oversee the development of the guideline documents, and assist the Tumour Teams during annual meetings to review current and draft guidelines and identify potential new guideline topics. On an *ad hoc* basis, they also develop guideline documents that encompass aspects of cancer care applicable across the tumour teams (e.g. immunization guidelines, supportive care guidelines).

A detailed manual describing timelines and administrative tasks required for the planning of the annual Provincial Tumour Team meetings is available from GURU upon request. Figure 1 illustrates the organizational structure of GURU and lists the nine provincial Tumour Teams which are formally supported by GURU. Three additional Tumour Teams will be supported by GURU, as of spring 2012.

Figure 1. Structure of the Guideline Utilization Resource Unit



GUIDELINE PLANNING

Identification of a New Guideline Topic. The Provincial Tumour Team Lead will solicit, usually at the annual meeting, input from Tumour Team members regarding priorities for new guideline topics. Priorities may be based on burden of disease, new treatment options, variation in practice, and new evidence. The Provincial Tumour Team Lead will make the final decision on which topics will be developed into guidelines. On average, KM Specialists support the development of up to three new guidelines per Tumour Team annually, in addition to updating existing guidelines.

Working Group Assembly and Responsibilities. Normally at the same time that guideline topics are being finalized, the Provincial Tumour Team Lead will identify one or two individuals from the Tumour Team to be the *guideline lead(s)*. If appropriate, the guideline leads will then recruit additional members from the Tumour Team, as needed, to take part in the working group. Clinicians from outside the Tumour Team may also be recruited to the working group, depending on their areas of expertise.

Overall, the working group, with the support and guidance of the KM Specialist, is responsible for developing specific research questions, defining search parameters, interpreting the evidence presented to them in the systematic review, and developing recommendation statements. Any edits to the guideline brought forward upon review by the Tumour Team will be at the discretion of the guideline lead(s); however, publication of the guideline to the Alberta Health Services – Cancer Care website (<http://www.albertahealthservices.ca/cancerguidelines.asp>) is subject to final approval by the Provincial Tumour Team Lead.

Timelines and Expectations. The Provincial Tumour Team Lead is ultimately responsible for ensuring that new guidelines are developed and/or updated in a timely manner. Table 1 summarizes the necessary steps and corresponding responsibilities and timelines.

Table 1. Guideline Development Timelines

Guideline Planning Step	Responsibility	Deadline (respect to Provincial Meeting)
1. Identify guideline topic and working group lead(s)	Prov. Tumour Team Lead	9-12 months prior
2. Recruit working group members (if needed)	Guideline lead(s)	9 months prior
3. Define research question(s), scope, and search parameters at consultation meeting (in person or by telephone)	Guideline lead(s) & GURU (KM Specialist)	9 months prior
4. Conduct literature review; screen results and obtain relevant literature; summarize data in evidence tables; provide to working group	KM Specialist	6 months prior
5. Determine most appropriate guideline development methodology (e.g. adapt, adopt, or <i>de novo</i> synthesis)	Guideline working group	5 months
6. Draft recommendations; get consensus from working group	Guideline working group & KM Specialist	4 months prior
7. Draft guideline document	KM Specialist	3 months prior
8. Review and revise draft guideline document according to working group feedback	Guideline working group & KM Specialist	2 months prior
9. Review draft guideline document and provide any final edits	Guideline lead(s)	1 month prior
10. Circulate draft guideline document to the Provincial Tumour Team	KM Specialist	1-2 weeks prior
11. Review draft guideline document at the Provincial meeting and document all proposed edits	Guideline lead(s) & KM Specialist	Prov. meeting
12. Review and revise draft guideline document; provide any final edits	Guideline lead(s) & KM Specialist	1-4 weeks after
13. Submit final guideline to Provincial Tumour Team Lead for approval to publish to website	KM Specialist on behalf of guideline lead(s)	5 weeks after
14. Approve (with or without changes) guideline	Prov. Tumour Team Lead	6-8 weeks after
15. Publish guideline to website and notify Tumour Team	GURU	8 weeks after

During the initial consultation meeting, the steps in Table 1 will be discussed with the guideline lead(s) and expectations and timelines will be agreed upon or adjusted accordingly. The guideline lead(s) will identify any additional expectations, such as peer-reviewed publication of the guideline. In the event that there is an expectation of guideline publication, an additional discussion regarding authorship, intended journal, scope of the manuscript, etc. will be required.

Deliverables to the Working Group.

Research Questions: Specific research questions to be addressed by the guideline document will be formulated by the guideline lead(s) and KM Specialist using the PICO question format (patient or population, intervention, comparisons, outcomes).¹

Literature Review: The KM Specialist will conduct a literature search using the search parameters identified by the guideline lead(s). The Medline, EMBASE, and Cochrane databases, as well as the National Guidelines Clearinghouse and other relevant clinical practice guideline databases and websites (e.g. National Comprehensive Cancer Network, Scottish Intercollegiate Guideline Network, etc.) will be searched, as appropriate. Occasionally, abstracts on clinical trials presented at conferences such as the American Society for Clinical Oncology will also be included. Generally limits of human studies in the English language will be applied to the search. Further exclusion of studies will depend on the specified outcomes of interest (e.g. response, survival, toxicity, etc.) and relative novelty of the literature. Depending on the availability of well conducted randomized controlled trials and methodologically sound meta-analyses, only the highest level of evidence will be included in the final review. However, for some questions, evidence may be limited to other clinical trials (e.g. not randomized, not well described), cohort studies, case-control studies, and other designs.

Evidence Tables: Evidence tables containing the first author, year of publication, patient group/stage of disease, methodology, and main outcomes of interest will be assembled using the studies identified in the literature search. Existing guidelines on the topic will be assessed by the KM Specialist using portions of the Agree II instrument (<http://www.agreetrust.org/instrument.htm>) and those meeting the minimum requirements will be included in the evidence document.² Due to limited resources, GURU does not regularly employ the use of multiple reviewers to rank the level of evidence; rather, the methodology portion of the evidence table contains the pertinent information required for the reader to judge for himself the quality of the studies.

Deciding on a Methodology. The choice to adopt, adapt, or develop de novo guideline recommendations will depend on the questions to be addressed by the guideline and the volume, quality, relevance, and novelty of existing guidelines. If an existing guideline addresses all of the questions of interest, is appropriate for the Alberta context, and is relatively recent (i.e. usually published in the last three to five years), then it may be appropriate to adopt. Otherwise, the evidentiary base of the existing guidelines, updated with any new evidence since the existing guidelines were published, may be the most efficient way to develop new recommendations that address all of the areas of interest.

GUIDELINE DEVELOPMENT

Formulating Recommendations. The working group members formulate the guideline recommendations based on the evidence synthesized by the KM Specialist during the planning process, blended with expert clinical interpretation of the evidence. As detailed above, the working group members may decide to adopt the recommendations of another institution without any revisions, adapt the recommendations of another institution or institutions to better reflect local practices, or develop their own set of recommendations by adapting some, but not all, recommendations from different guidelines.

The degree to which a recommendation is based on expert opinion of the working group and/or the Provincial Tumour Team members will be explicitly stated in the guideline recommendations. Similar to the ASCO methodology for formulating guideline recommendations, GURU does not use formal rating schemes for describing the strength of the recommendations, but rather describes, in conventional and explicit language, the type and quality of the research and existing guidelines that were taken into consideration when formulating the recommendations.³

Drafting the Document. After the working group members have come to a consensus on the guideline recommendations, the KM Specialist will complete a draft version of the guideline document. Guideline manuscripts conform to a standardized format. The KM Specialist will provide working group members with the template for the GURU guideline format, and seek input on the content of specific sections in the template, as necessary.

The sections included in this standardized format include:

- *Background* – a brief description of the rationale for the guideline, burden of the condition, and/or importance of health care intervention
- *Guideline Questions* – lists the clinical questions developed during the planning phase
- *Development* – reviews the specialties and affiliations of the working group members and Provincial Tumour Team, but does not include specific names
- *Search Strategy* – describes the details of the literature search strategy and environmental scan
- *Target Population* – describes the patient population of interest, lists any inclusion/exclusion criteria
- *Recommendations* – provides a summary of the key guidance statements
- *Discussion* – provides a detailed summary of the evidence used to develop each guideline recommendation
- *Glossary of Terms*
- *Dissemination* – describes specific methods that will be used to disseminate and implement the guideline
- *Maintenance* – describes when and how the guideline will be reviewed and updated
- *Conflict of Interest* – provides detailed information on potential conflicts of interest, and states that the guideline developers are satisfied it was created in an unbiased manner
- *References*
- *Appendices*

Guideline Review and Approval. When the draft guideline document has been completed, revised, and reviewed by the KM Specialist and the working group members, it will be sent to all members of the Provincial Tumour Team for review and comment. This step ensures that those intended to use the guideline have the opportunity to review the document and identify potential difficulties for implementation before the guideline is finalized.⁴ Depending on the size of the document, and the number of people it is sent to for review, a deadline of one to two weeks will usually be given to submit any feedback. Ideally, this review will occur prior to the annual Provincial Tumour Team meeting, and a discussion of the proposed edits will take place at the meeting. The working group members will then make final revisions to the document based on the received feedback, as appropriate. Once the guideline is finalized, it will be officially endorsed by the Provincial Tumour Team Lead and the Director of Provincial Clinical Teams.

GUIDELINE DISSEMINATION

Once the guideline document has received official approval from the Tumour Team Lead, it will be posted to the Alberta Health Services website (www.albertahealthservices.ca/cancerguidelines.asp) and notification will be sent via email to all members of the Provincial Tumour Team. A monthly status report, listing all completed and in-progress guidelines, is also sent out by GURU to all interested parties within Alberta Health Services – Cancer Care. Whenever possible, members of the working group will also present the guideline at local tumour group weekly rounds.

Dissemination may also include publication of the guideline document or portions of it, in a peer-reviewed medical journal. The decision to pursue publication, and the commitments of the interested authors should be clearly documented during the guideline planning process.

GUIDELINE MAINTENANCE

Ideally, all guidelines would be reviewed on an annual basis, during the Provincial Tumour Team meetings. However, due to limited resources, it may be necessary to prioritize those guidelines most in need of review. In most cases, this will include guidelines for which there is a high likelihood of new evidence.

The KM Specialist will consult with the Provincial Tumour Team Lead to ensure that the questions of interest are still

relevant and the likelihood of major revisions to the recommendations, themselves, is low. The Provincial Tumour Team Lead will identify a guideline lead, if the original lead(s) are not available. The KM Specialist will then conduct a literature review and provide updated evidence tables to the guideline lead(s), who will then review the evidence and make any necessary changes. While minor changes may not require internal review, most often the updated document will be circulated for review by the Tumour Team before being submitted to the Provincial Tumour Team Lead for final approval. Once approved, the guideline document will be published to the website. In the event that there is a lot of new evidence or evidence that may change the scope or utility of the guideline entirely, a new guideline document may be warranted, using the guideline development principles described earlier.

REFERENCES

1. Richardson WS, Wilson MC, Nishikawa J, Hayward RS. The well-built clinical question: a key to evidence-based decisions. *ACP J Club* 1995 Nov-Dec;123(3):A12-3.
2. The AGREE Collaboration, Cluzeau FA, Burgers JS, Brouwers M, Grol R, Mäkelä M, Littlejohns P, Grimshaw J, Hunt C. Development and validation of an international appraisal instrument for assessing the quality of clinical practice guidelines: the AGREE project. *Qual Saf Health Care* 2003;12(1):18-23.
3. American Society of Clinical Oncology. Guideline Procedures Manual, Expert Panel Version 3.0. December 2008. Available at: [http://www.asco.org/ASCO/Downloads/Cancer%20Policy%20and%20Clinical%20Affairs/Clinical%20Affairs%20\(derivative%20products\)/Methodology%20Manual%2012.17.08-FINAL.pdf](http://www.asco.org/ASCO/Downloads/Cancer%20Policy%20and%20Clinical%20Affairs/Clinical%20Affairs%20(derivative%20products)/Methodology%20Manual%2012.17.08-FINAL.pdf) Accessed: May 27, 2010
4. Graham ID, Harrison MB. Evaluation and adaptation of clinical practice guidelines. *Evidence Based Nurs* 2005 Jul;8:68-72.

ADDITIONAL RESOURCES

Handbooks and Manuals:

Davis D, Goldman J, Palda VA. Handbook on clinical practice guidelines. Ottawa: Canadian Medical Association, 2007. Available at: <http://www.cma.ca/handbook.pdf> Accessed: June 1, 2010

Cancer Care Ontario Program in Evidence-Based Care. Program in evidence-based care handbook, 2009. Available at: <http://www.cancercare.on.ca/common/pages/UserFile.aspx?fileId=50876> Accessed: May 27, 2010

Higgins JPT, Green S (Editors). Cochrane Handbook for Systematic Reviews of Interventions Version 5.0.2 [updated September 2009]. The Cochrane Collaboration, 2008. Available at: <http://www.cochrane-handbook.org/> Accessed: May 27, 2010

National Institute for Health and Clinical Excellence. The guidelines manual. London: National Institute for Health and Clinical Excellence, January 2009. Available at: http://www.nice.org.uk/media/5F2/44/The_guidelines_manual_2009_-_All_chapters.pdf Accessed: May 27, 2010

Articles of Interest:

Murphy MK, Black NA, Lamping DL, McKee CM, Sanderson CFB, Askham J, et al. Consensus development methods, and their use in clinical guideline development. *Health Technol Assess* 1998;2(3).

Turner T, Misso M, Harris C, Green S. Development of evidence-based clinical practice guidelines (CPGs): comparing approaches. *Implementation Science* 2008;3:45. Available at: <http://www.implementationscience.com/content/3/1/45> Accessed: May 27, 2010