# Introduction

## The Steering Committee on Clinical Practice Guidelines for the Care and Treatment of Breast Cancer

Clinical practice guidelines are "systemically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances" (Institute of Medicine).[1]

## Objectives

There is considerable variation in the way in which patients with breast cancer are treated across Canada.[2,3] However, evidence has shown that guidelines can improve the consistency of care.[4] Although some variations in clinical practice may reflect reasonable differences in judgement, other differences may be outside the accepted norms of good practice. Regardless of the reason, variations in practice can be a source of anxiety to patients. In November 1993 the National Forum on Breast Cancer identified a need for better definition of the limits within which treatment decisions should normally vary. These guidelines are an attempt to respond to this need. They are, therefore, directed to physicians who are responsible for advising and caring for patients with breast cancer.

Also articulated at the National Forum on Breast Cancer was the need for patients with breast cancer to be empowered to make their own decisions as much as possible. Accordingly, these guidelines are also directed to the patients themselves. Because the guidelines are sometimes technical and detailed, each one is accompanied by a patient's version. These simpler versions are not comprehensive guides to the management of breast cancer but are readable summaries of the information in each of the principal guideline documents. They are intended to facilitate and enlighten the discussions between patients and their physicians that must precede every clinical decision. Some more comprehensive guides for the lay person on the treatment of breast cancer are listed on page S82.

It should be noted that these guidelines are not the only "correct" approach to the diagnosis and treatment of breast cancer; decisions made outside these limits may sometimes be necessary in specific clinical situations. However, they do reflect a wide consensus regarding the range of treatment options considered acceptable according to current evidence. Thus, whenever recommendations are made outside this range, it would be reasonable to expect that they be justified.

As far as possible, the suggested guidelines are evidence-based. The evidence supporting each guideline statement is cited, along with a number representing its evaluation according to the criteria listed on page S2. For those recommendations for which experimental evidence is lacking, conclusions were drawn from the considered opinion of authorities based on their experience, background knowledge and judgement. The method used in developing these guidelines was designed to ensure that, as far as possible, the judgements reflect a consensus of those concerned with breast cancer treatment in Canada.

## Method

To arrive at a Canadian consensus on these issues, the guidelines were developed as outlined below.

- A Steering Committee on Clinical Practice Guidelines for the Care and Treatment of Breast Cancer was convened by Health Canada based on nominations from provincial and national health agencies. The individuals nominated to the Steering Committee and the agencies that nominated them are listed on page S83.
- The Steering Committee developed a list of 10 topics for which guidelines were most needed. Authors for each topic were selected and requested to draft evidence-based guidelines.
- Each of the draft guidelines underwent repeated cycles of criticism, review and revision by a writing committee comprising 5 to 8 members of the Steering Committee, by 2 to 5 external primary reviewers with special expertise in the particular topic, and by the Steering Committee as a whole.

***Special Supplement***

*See page S83 for a list of the members of the Steering Committee and a full list of names and nominating organizations*

- The resulting draft documents were distributed to secondary reviewers consisting of surgical, medical and radiation oncologists, radiologists, nurses, family physicians and breast cancer survivors selected from across Canada. After further revisions the final drafts were approved by the Steering Committee. In total, each guideline topic went through 20 to 40 cycles of review and revision.

## Authorship

Throughout the process of developing the guidelines, difficult issues were resolved by discussion among members of the Steering Committee until consensus was achieved. The final document reflects a substantial consensus of all who contributed to its preparation. Their names are listed with each guideline. Although this document reflects the generous participation of these and many other individuals, **the Steering Committee is the author of record of these guidelines and, as such, is wholly responsible for their content.**

## Publication date

The process described above took approximately 2 years to complete. During this time much new information was incorporated; however, from the moment of publication these guidelines will need continuing, regular revision. It has been recommended by the Steering Committee that this process be carried out at least every 2 years. It is important for readers to check the completion date of any guideline they are reading to make certain that it is reasonably up to date.

## Gender

Both men and women are subject to breast cancer and, with a few obvious exceptions, these guidelines apply equally to both sexes. However, because women are far more frequently affected, the patients referred to in this document are presumed to be female.

## Acknowledgements

In addition to the contributors listed in each guideline, all have profited from the invaluable assistance and unwavering patience of Ms. B. Nugent (typing, layout, indexing) and of Dr. C. Archer (reference-checking and proofreading in French and English). Their contributions are gratefully acknowledged.

## References

1. Field MJ, Lohr KM, editors. *Guidelines for clinical practice. From development to use.* Washington: National Academy Press; 1992.
2. Goel V, Olivotto I, Hislop TG, Sawka C, Coldman A, Holowaty EJ, et al. Patterns of initial management of node-negative breast cancer in two Canadian provinces. *Can Med Assoc J* 1997;156:25-35.
3. Iscoe NA, Goel V, Wu K, Fehringer G, Holowaty EJ, Naylor DC. Variation in breast cancer surgery in Ontario. *Can Med Assoc J* 1994;150:345-52.
4. Sawka C, Olivotto I, Coldman A, Goel V, Holowaty E, Hislop TG, et al. The association between population-based treatment guidelines and adjuvant therapy for node-negative breast cancer. *Br J Cancer* 1997;75:1534-42.

# Levels of evidence

The evidence cited in the guidelines has been classified as accurately as possible into 5 levels.

**Level I evidence** is based on randomized, controlled trials (or meta-analysis of such trials) of adequate size to ensure a low risk of incorporating false-positive or false-negative results.

**Level II evidence** is based on randomized, controlled trials that are too small to provide level I evidence. These may show either positive trends that are not statistically significant or no trends and are associated with a high risk of false-negative results.

**Level III evidence** is based on nonrandomized, controlled or cohort studies, case series, case-controlled studies or cross-sectional studies.

**Level IV evidence** is based on the opinion of respected authorities or that of expert committees as indicated in published consensus conferences or guidelines.

**Level V evidence** expresses the opinion of those individuals who have written and reviewed these guidelines, based on their experience, knowledge of the relevant literature and discussion with their peers.

These 5 levels of evidence do not directly describe the quality or credibility of evidence. Rather, they indicate the nature of the evidence being used. In general, a randomized, controlled trial has the greatest credibility (level I); however, it may have defects that diminish its value, and these should be noted. Evidence that is based on too few observations to give a statistically significant result is classified as level II. In general, level III studies carry less credibility than level I or II studies, but credibility is increased when consistent results are obtained from several level III studies carried out at different times and in different places.

Decisions must often be made in the absence of published evidence. In these situations it is necessary to use the opinion of experts based on their knowledge and clinical experience. All such evidence is classified as "opinion" (levels IV and V). Distinction is made between the published opinion of authorities (level IV) and the opinion of those who have contributed to these guidelines (level V). However, it should be noted that by the time level V evidence has gone through the exhaustive consensus-building process used in the preparation of these guidelines, it has achieved a level of credibility that is at least equivalent to level IV evidence.