



encouraged to develop advance directives with their patients during routine visits, free from the pressures of the acute care setting.

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Breast cancer guidelines

All physicians will be grateful to Dr. Maurice McGregor and his many colleagues on the Steering Committee on Clinical Practice Guidelines for the Care and Treatment of Breast Cancer for their prodigious effort in producing the supplement “Clinical practice guidelines for the care and treatment of breast cancer: a Canadian consensus document” (*CMAJ* 1998;158[3 Suppl]:S1-83). My remarks should be considered a part of the refinement process that now begins.

Page S5, in guideline 1, “The palpable breast lump: information and recommendations to assist decision-making when a breast lump is detected” (*CMAJ* 1998;158[3 Suppl]:S3-8), emphasizes that physicians can often distinguish, by clinical examination, benign from malignant breast lumps and that practice improves performance. Unfortunately, “often”

is not good enough for Canadian women. The clinical examination can never reach the level of accuracy of the gold standard, excisional biopsy. Timely access to excisional biopsy is available to everyone in Canada, with the possible exception of those living in remote communities.

Canadian women will accept nothing less than the gold standard. Canadian physicians and surgeons should insist on the same and may be penalized if they provide anything less.¹

Somewhere on page S5 the following message should be prominently displayed: “Any clinically palpable lump (mass lesion) that is solid on aspiration must ultimately be proven to be cancer or not cancer by excisional biopsy.” This recommendation applies to all lumps, even apparently typical fibroadenomas in adolescents and women in their early 20s, because breast cancer does occur — if only rarely — in these age groups. Excisional biopsy could save many physicians and patients a lot of grief.

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I read with interest the consensus guideline “Investigation of lesions detected by mammography” (*CMAJ* 1998;158[3 Suppl]:S9-14). I was involved in the peer review of this document and raised certain concerns at that time. Although the authors addressed some of my comments, a few problems have remained unanswered.

- On page S11 it is stated that “[i]n all but completely straightforward cases . . . the opinion should be ob-

tained of a second radiologist who is also experienced in mammographic interpretation (level V evidence [i.e., opinion of the guideline authors]).” There are no studies to support any benefit from such an approach. I remember that the Canadian National Breast Screening Study (NBSS) followed such a policy, but in my own experience, 2 cases that I identified and that were not confirmed by another radiologist were found to be cancer at the next screening. The authors allude to 2 references,^{1,2} both of which apply to double reading of *all* cases, not only the doubtful ones. I am certain that the routine checking of only doubtful mammograms by a second experienced radiologist will decrease the breast cancer detection rate, even though it may cut back on recalls.

- In the section on the report of mammographic work-up (p. S11), 4 categories of risk stratification are presented. It is stated that the classification is similar to that of the American College of Radiology (ACR). However, the ACR classification has 5 categories, category 1 representing normal results. Eliminating the “normal” category changes the risk value of the others: category 3 in the ACR classification signifies probably benign lesions, whereas here it refers to probably malignant lesions. Given that the ACR system is an internationally accepted categorization, it is confusing and possibly dangerous to change the numeric assignment of the categories.
- The discussion of attribution of a numeric percentage risk within categories is confusing. Page S11 states that the percentage has “no precise quantitative meaning and is intended only to give meaning to the expressions ‘low,’ ‘intermediate’ and ‘high’ risk,” yet on page S12 for category 3 abnormalities it is stated that to perform a biopsy,



“the estimated risk of malignancy should be at least 2%.” In other words, if the estimated risk is 1%, a biopsy should not be performed, but if the risk is 2%, the procedure should be done. However, it is probably impossible to determine a 1% increment of risk from mammographic results.

- Finally, on page S12 under category 3 abnormalities it is stated that “[i]n the case of a suspected papillary lesion, the patient should also be referred for open surgical biopsy because of the difficulty in pathologically interpreting the core specimen (level V evidence).” This recommendation is not supported by any published literature. It may be true that there are more important lesions that should not undergo core biopsy. Parker and Jobe, the pioneers of breast core biopsy, stated that the only patients for whom they do not routinely request core biopsy are those suspected of having radial scar.³ They also stated that core biopsy of granular or cotton ball calcifications is controversial because they are a marker of diffuse disease (benign or malignant).

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[The chair of the Steering Committee responds:]

On behalf of the Steering Committee I thank these contributors for their suggestions. The following comments are my own.

I do not think that Dr. Leo Mahoney and the Steering Committee disagree, although we have not used the words Mahoney suggests. The guidelines say that “once a lump or suspicious change in breast texture is discovered, it is necessary to establish whether it is malignant or not” and “a clinically suspicious lump requires further investigation” [emphasis added]. However, “the principle is to establish a reliable diagnosis using the minimum of procedures.” We surely should not have recourse to excisional biopsy in the absence of suspicion.

Many of the suggestions made by Dr. Rasuli in his review of an earlier draft of one of the guidelines were incorporated. Some of his points, the remaining problems to which he

refers, are valid but debatable and were not incorporated. This situation is inherent in a consensus document. Level V evidence is, by definition, the unsupported opinion of the authors.

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Updating the insulin lispro file

I suspect that a delay between the time of writing and the date of publication of the article “Insulin lispro (Humalog), the first marketed insulin analogue: indications, contraindications and need for further study” (*CMAJ* 1998;158[4]:506-11), by Drs. Anuradha L. Puttagunta and Ellen L. Toth, may be responsible for the inclusion of only studies published up to 1996. However, more recent studies have addressed a number of the questions raised in that article.

The efficacy of insulin lispro in improving the levels of hemoglobin A_{1c} (HgbA_{1c}) has been demonstrated recently; the analogue is particularly effective when the basal insulin and the meal plan are adjusted. Ebeling and associates¹ reported that when

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