General

Guideline Title


Bibliographic Source(s)


Guideline Status

Note: This guideline has been updated. The National Guideline Clearinghouse (NGC) is working to update this summary.

Recommendations

Major Recommendations

Note: This guideline has been updated. The National Guideline Clearinghouse (NGC) is working to update this summary. The recommendations that follow are based on the previous version of the guideline.

Definitions for the rating of evidence (High, Intermediate, Low, Insufficient); types of recommendations (Evidence-Based, Formal Consensus, Informal Consensus, No Recommendation); and strength of recommendations (Strong, Moderate, Weak) are provided at the end of the "Major Recommendations" field.

Clinical Question 1

Can Axillary Lymph Node Dissection (ALND) Be Avoided in Patients Who Have Tumor-Free (Negative) Sentinel Lymph Nodes (SLNs)?

Recommendation 1

Clinicians should not recommend ALND for women with early-stage breast cancer who do not have nodal metastases. Type: evidence based; benefits outweigh harms. Evidence quality: strong. Strength of recommendation: high.

Clinical Question 2

Is ALND Necessary for All Patients with Metastatic Findings on Sentinel Node Biopsy (SNB)?

Note: The recommendations in response to this clinical question were split into two separate recommendations. The first recommendation was crafted to reflect the eligibility criteria of Z0011 (women with early-stage breast cancer and one to two SLN metastases, who underwent breast-conserving surgery [BCS] with whole-breast radiotherapy).
Clinical Question 2.1: Is ALND Necessary for All Patients with Metastatic Findings on SNB Planning to Undergo BCS with Whole-Breast Radiotherapy?

Recommendation 2.1

Clinicians should not recommend ALND for women with early-stage breast cancer and one or two SLN metastases who will undergo BCS with conventionally fractionated whole-breast radiotherapy. Type: evidence based; benefits outweigh harms. Evidence quality: strong. Strength of recommendation: high.

Clinical Question 2.2: Is ALND Necessary for All Patients with Metastatic Findings on SNB Who Are Planning to Undergo Mastectomy?

Recommendation 2.2

Clinicians may offer ALND for women with early-stage breast cancer with nodal metastases found on SNB who will undergo mastectomy. Type: evidence based; benefits outweigh harms. Evidence quality: low. Strength of recommendation: weak.

Clinical Question 3

What Is the Role of SNB in Special Circumstances in Clinical Practice?

Note: Because of lack of evidence in many areas, the scope of this section was narrowed to the following circumstances. Recommendations from 2005 are available in Data Supplement 7 (see the "Availability of Companion Documents" field). These recommendations are limited by the insufficiency and paucity of data.

Recommendation 3.1: Multicentric

Clinicians may offer SNB for women who have operable breast cancer and the following circumstance: multicentric tumors. Type: evidence based; benefits outweigh harms. Evidence quality: intermediate. Strength of recommendation: moderate.

Recommendation 3.2: Ductal Carcinoma In Situ

Clinicians may offer SNB for women who have operable breast cancer and the following circumstance: ductal carcinoma in situ (DCIS), when mastectomy is performed. Type: informal consensus; benefits outweigh harms. Evidence quality: insufficient. Strength of recommendation: weak.

Recommendation 3.3: Prior Surgery

Clinicians may offer SNB for women who have operable breast cancer and the following circumstance: prior breast and/or axillary surgery. Type: evidence based; benefits outweigh harms. Evidence quality: intermediate. Strength of recommendation: strong.

Recommendation 3.4: Preoperative/Neoadjuvant Systemic Therapy

Clinicians may offer SNB for women who have operable breast cancer and the following circumstance: preoperative/neoadjuvant systemic therapy (NACT). Type: evidence based; benefits outweigh harms. Evidence quality: intermediate. Strength of recommendation: moderate.

Other Special Circumstances

Recommendation 4.1: Large and Locally Advanced Invasive Tumors (T3/T4)

There are insufficient data to change the 2005 recommendation that clinicians should not perform SNB for women who have early-stage breast cancer and have the following circumstance: large or locally advanced invasive breast cancer (tumor size T3/T4). Type: informal consensus. Evidence quality: insufficient. Strength of recommendation: weak.

Recommendation 4.2

There are insufficient data to change the 2005 recommendation that clinicians should not perform SNB for women who have early-stage breast cancer and have the following circumstance: inflammatory breast cancer. Type: informal consensus. Evidence quality: insufficient. Strength of recommendation: weak.

Recommendation 4.3

There are insufficient data to change the 2005 recommendation that clinicians should not perform SNB for women who have early-stage breast cancer and the following circumstance: DCIS, when BCS is planned. Type: informal consensus. Evidence quality: insufficient. Strength of recommendation: strong.
Recommendation 4.4

There are insufficient data to change the 2005 recommendation that clinicians should not perform SNB for women who have early-stage breast cancer and have the following circumstance: pregnancy. Type: informal consensus. Evidence quality: insufficient. Strength of recommendation: weak.

Definitions:

Guide for Rating of Evidence

<table>
<thead>
<tr>
<th>Rating for Strength of Evidence</th>
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<tr>
<td>High</td>
<td>High confidence that the available evidence reflects the true magnitude and direction of the net effect (i.e., balance of benefits versus harms) and further research is very unlikely to change either the magnitude or direction of this net effect.</td>
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<tr>
<td>Intermediate</td>
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<td>Low</td>
<td>Low confidence that the available evidence reflects the true magnitude and direction of the net effect. Further research may change either the magnitude and/or direction this net effect.</td>
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<td>Insufficient</td>
<td>Evidence is insufficient to discern the true magnitude and direction of the net effect. Further research may better inform the topic. The use of the consensus opinion of experts is reasonable to inform outcomes related to the topic.</td>
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Guide for Types of Recommendations

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<td>Evidence-Based</td>
<td>There was sufficient evidence from published studies to inform a recommendation to guide clinical practice.</td>
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<td>Formal Consensus</td>
<td>The available evidence was deemed insufficient to inform a recommendation to guide clinical practice. Therefore, the expert Panel used a formal consensus process to reach this recommendation, which is considered the best current guidance for practice. The Panel may choose to provide a rating for the strength of the recommendation (i.e., “strong,” &quot;moderate,” or &quot;weak”). The results of the formal consensus process are summarized in the guideline and reported in an online data supplement (see the “Availability of Companion Documents” field.</td>
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<td>Informal Consensus</td>
<td>The available evidence was deemed insufficient to inform a recommendation to guide clinical practice. The recommendation is considered the best current guidance for practice, based on informal consensus of the expert Panel. The Panel agreed that a formal consensus process was not necessary for reasons described in the literature review and discussion. The Panel may choose to provide a rating for the strength of the recommendation (i.e., “strong,” &quot;moderate,” or &quot;weak”).</td>
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<tr>
<td>No Recommendation</td>
<td>There is insufficient evidence, confidence, or agreement to provide a recommendation to guide clinical practice at this time. The Panel deemed the available evidence as insufficient and concluded it was unlikely that a formal consensus process would achieve the level of agreement needed for a recommendation.</td>
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<td>There is high confidence that the recommendation reflects best practice. This is based on: a) strong evidence for a true net effect (e.g., benefits exceed harms); b) consistent results, with no or minor exceptions; c) minor or no concerns about study quality; and/or d) the extent of panelists’ agreement. Other compelling considerations (discussed in the guideline’s literature review and analyses) may also warrant a strong recommendation.</td>
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<td>Moderate</td>
<td>There is moderate confidence that the recommendation reflects best practice. This is based on: a) good evidence for a true net effect (e.g., benefits exceed harms); b) consistent results, with minor and/or few exceptions; c) minor and/or few concerns about study quality; and/or d) the extent of panelists’ agreement. Other compelling considerations (discussed in the guideline’s literature review and analyses) may also warrant a moderate recommendation.</td>
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There is some confidence that the recommendation offers the best current guidance for practice. This is based on: a) limited evidence for a true net effect (e.g., benefits exceed harms); b) consistent results, but with important exceptions; c) concerns about study quality; and/or d) the extent of panelists’ agreement. Other considerations (discussed in the guideline’s literature review and analyses) may also warrant a weak recommendation.

Clinical Algorithm(s)
None provided

Scope

Disease/Condition(s)
Early-stage breast cancer

Guideline Category
Evaluation
Management
Risk Assessment

Clinical Specialty
Oncology
Pathology
Radiation Oncology
Surgery

Intended Users
Advanced Practice Nurses
Allied Health Personnel
Nurses
Patients
Physician Assistants
Physicians

Guideline Objective(s)
To provide evidence-based recommendations to practicing oncologists, surgeons, and radiation therapy clinicians to update the 2005 clinical practice guideline on the use of sentinel node biopsy (SNB) for patients with early-stage breast cancer

Target Population
Patients with early-stage breast cancer

Interventions and Practices Considered

1. Sentinel node biopsy (SNB) for operable breast cancer in the following circumstances:
   - Multicentric tumors
   - Ductal carcinoma in situ (DCIS)
   - Prior breast and/or axillary surgery
   - Preoperative/neoadjuvant systemic therapy

2. Axillary lymph node dissection (ALND) for women with early-stage breast cancer with nodal metastases found on SNB who will receive mastectomy

Note: The following interventions were considered but not recommended or there was insufficient evidence to make a recommendation:

ALND for women with early-stage breast cancer who
   - Do not have nodal metastases
   - Have one or two SLN metastases who will receive breast-conserving surgery (BCS) with conventionally fractionated whole-breast radiotherapy

SNB for operable breast cancer in the following circumstances:
   - Large or locally advanced invasive breast cancers
   - Inflammatory breast cancer
   - DCIS when breast-conserving surgery is planned
   - Pregnancy

Major Outcomes Considered

Clinical outcomes
   - Recurrence: axillary, locoregional, all; time-to-recurrence; factors related to recurrence (e.g., patient characteristics only in those randomized to no axillary lymph node dissection [ALND])
   - Metastases
   - Mortality: all-cause and breast cancer-specific
   - Number of nodes
   - Complications/morbidity: incidence/rates of lymphedema, etc.

Performance outcomes: percentage of patients for whom sentinel node biopsy (SNB) is successful

Methodology

Methods Used to Collect/Select the Evidence

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

Literature Search Strategy

PubMed and the Cochrane Collaboration Library electronic databases were searched from February 2004 to January 2013 for evidence reporting on outcomes of interest. Further details on the search strategy are provided in Data Supplements 3 and 4 (see the "Availability of Companion Documents" field).

Inclusion and Exclusion Criteria

Articles were selected for inclusion in the systematic review of the evidence if they met the following criteria:
Population: women with early-stage breast cancer.

For Clinical Questions 1 and 2, fully published or recent meeting presentations of English-language reports of phase III randomized clinical trials (RCTs) or rigorously conducted systematic reviews or meta-analyses. Trials with a population of women with early breast cancer that compared sentinel node biopsy (SNB) with the standard treatment of axillary lymph node dissection (ALND); this included studies comparing SNB alone with SNB plus ALND, for those patients with negative sentinel lymph nodes (SLNs).

For special circumstances, prospective comparative cohort trials were accepted (criteria listed in Data Supplement 8 [see the "Availability of Companion Documents" field]).

Articles were excluded from the systematic review if they were: (1) meeting abstracts not subsequently published in peer-reviewed journals; (2) editorials, commentaries, letters, news articles, case reports, or narrative reviews; and (3) published in a language other than English.

Number of Source Documents

39 papers from 22 studies met selection criteria and underwent data extraction

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

Guide for Rating of Evidence

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Methods Used to Analyze the Evidence

Systematic Review with Evidence Tables

Description of the Methods Used to Analyze the Evidence

Data Extraction

Literature search results were reviewed and deemed appropriate for full text review by two American Society of Clinical Oncology (ASCO) staff members in consultation with the Update Committee Co-Chairs. Data were extracted by two reviewers and subsequently checked for accuracy through an audit of the data by another ASCO staff member. Disagreements were resolved through discussion and consultation with the Co-Chairs if necessary.

Methods Used to Formulate the Recommendations

Expert Consensus
Description of Methods Used to Formulate the Recommendations

Update Committee Composition

The American Society of Clinical Oncology (ASCO) Clinical Practice Guidelines Committee convened an Update Committee with multidisciplinary representation in medical oncology, nuclear and radiation oncology, surgical oncology, pathology, community oncology, patient/advocacy representation, and guideline implementation. The Update Committee was led by two Co-Chairs who had primary responsibility for the development and timely completion of the guideline. For this guideline, the Co-chairs selected additional members from the Update Committee to form a Writing Group to assist in the development and review of the guideline drafts.

Guideline Development Process

The Update Committee met on several occasions and corresponded frequently through email; progress on guideline development was driven primarily by the Update Committee along with ASCO staff. The purpose of the Committee meetings was for members to contribute content, provide critical review, interpret evidence, and finalize the guideline recommendations based upon the consideration of the evidence.

Development of Recommendations

The guideline recommendations were crafted, in part, using the GuideLines Into DEcision Support (GLIDES) methodology and accompanying BRIDGE-Wiz™ software. This method helps guideline panels systematically develop clear, translatable, and implementable recommendations using natural language, based on the evidence and assessment of its quality to increase usability for end users. The process incorporates distilling the actions involved, identifying who will carry them out, to whom, under what circumstances, and clarifying if and how end users can carry out the actions consistently. This process helps the Panel focus the discussion, avoid using unnecessary and/or ambiguous language and clearly state its intentions.

Rating Scheme for the Strength of the Recommendations

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Rating for Strength of Recommendation

**Guideline's literature review and analyses** may also warrant a strong recommendation.

- **Strong**
  - There is moderate confidence that the recommendation reflects best practice. This is based on: a) good evidence for a true net effect (e.g., benefits exceed harms); b) consistent results, with minor and/or few exceptions; c) minor and/or few concerns about study quality; and/or d) the extent of panelists' agreement. Other compelling considerations (discussed in the guideline's literature review and analyses) may also warrant a moderate recommendation.

- **Weak**
  - There is some confidence that the recommendation offers the best current guidance for practice. This is based on: a) limited evidence for a true net effect (e.g., benefits exceed harms); b) consistent results, but with important exceptions; c) concerns about study quality; and/or d) the extent of panelists' agreement. Other considerations (discussed in the guideline's literature review and analyses) may also warrant a weak recommendation.

Cost Analysis

A formal cost analysis was not performed and published cost analyses were not reviewed.

Method of Guideline Validation

- External Peer Review
- Internal Peer Review

Description of Method of Guideline Validation

All members of the Update Committee participated in the preparation of the draft guideline document, which was then disseminated for external review and submitted to the Journal of Clinical Oncology (JCO) for peer review and publication. All ASCO guidelines are reviewed and approved by the American Society of Clinical Oncology (ASCO) Clinical Practice Guideline Committee prior to publication.

The Clinical Practice Guideline Committee approved this guideline update on November 19, 2013.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The type of supporting evidence is identified and graded for each recommendation (see the "Major Recommendations" field).

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

- Appropriate use of sentinel node biopsy (SNB) in patients with early-stage breast cancer

Potential Harms

- Adverse events associated with sentinel node biopsy (SNB) and axillary lymph node dissection (ALND) include lymphedema, infections, seroma, and neurologic and sensory deficits, including paresthesia and shoulder pain and/or impairment of motion.
- False-negative results

Qualifying Statements
Qualifying Statements

- The Clinical Practice Guidelines and other guidance published herein are provided by the American Society of Clinical Oncology (ASCO) to assist providers in clinical decision making. The information herein should not be relied on as being complete or accurate, nor should it be considered as inclusive of all proper treatments or methods of care or as a statement of the standard of care. With the rapid development of scientific knowledge, new evidence may emerge between the time information is developed and when it is published or read. The information is not continually updated and may not reflect the most recent evidence. The information addresses only the topics specifically identified therein and is not applicable to other interventions, diseases, or stages of diseases. This information does not mandate any particular course of medical care. Furthermore, the information is not intended to substitute for the independent professional judgment of the treating provider, because the information does not account for individual variation among patients. Recommendations reflect high, moderate, or low confidence that the recommendation reflects the net effect of a given course of action. The use of words like must, must not, should, and should not indicates that a course of action is recommended or not recommended for either most or many patients, but there is latitude for the treating physician to select other courses of action in individual cases. In all cases, the selected course of action should be considered by the treating provider in the context of treating the individual patient. Use of the information is voluntary. ASCO provides this information on an as-is basis and makes no warranty, express or implied, regarding the information. ASCO specifically disclaims any warranties of merchantability or fitness for a particular use or purpose. ASCO assumes no responsibility for any injury or damage to persons or property arising out of or related to any use of this information or for any errors or omissions.

- Clinicians may perform sentinel node biopsy (SNB) for ductal carcinoma in situ (DCIS) diagnosed by minimally invasive breast biopsy: one, when mastectomy is planned, because this precludes subsequent SNB at a second operation; two, when physical examination or imaging shows a mass lesion highly suggestive of invasive cancer; or three, the area of DCIS by imaging is large (≥5 cm). SNB may be offered before or after neoadjuvant systemic therapy (NACT), but the procedure seems less accurate after NACT. This update deleted a recommendation for patients having undergone prior nononcologic breast surgery or axillary surgery because of insufficient data to inform a recommendation.

Implementation of the Guideline

Description of Implementation Strategy

American Society of Clinical Oncology (ASCO) guidelines are developed to be implemented in a variety of health settings. Barriers to implementation and application of the guideline recommendations include the need to increase awareness among front-line practitioners and cancer survivors and also the need to provide adequate services in the face of limited resources. The guideline Bottom Line was designed to facilitate implementation of recommendations. This guideline will be distributed widely through the ASCO Practice Guideline Implementation Network and other ASCO communications. ASCO guidelines are posted on the ASCO Web site and most often published in *Journal of Clinical Oncology* (JCO) and *Journal of Oncology Practice*.

Given the multidisciplinary care discussed in this guideline and the importance of sharing the update with the many relevant stakeholders, it is suggested that community oncologists, surgical oncologists, and radiation oncologists as well as patient navigators and academic, community, and hospital-based cancer centers consider these guidelines. In addition, given that the majority of US cancer programs have cancer tumor boards or continuing medical education activities that include the many clinicians treating breast cancer, the Panel encourages those programs to distribute and stimulate discussion of this guideline update. In expanding outreach of ASCO guidelines through the national tumor board system, the Panel hopes to speed the sharing of this update as well as to stimulate coordinated multidisciplinary care decisions among medical oncologists, radiation oncologists, and surgical oncologists as well as patients, their advocates, and cancer program leaders. The American College of Surgeons, which accredits most U.S. cancer programs, has included review of National Comprehensive Cancer Network guidelines for the diagnosis and treatment of cancer as quality measures in the past few years. Discussion of including ASCO guidelines and updates as part of this process would further increase the review and discussion of ASCO guidelines and likely speed the uptake of newly evaluated studies and guideline updates that can improve the quality of cancer care for patients.

For additional information on the ASCO implementation strategy, please see the ASCO Web site.

Implementation Tools

Patient Resources
Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need
Getting Better
Living with Illness

IOM Domain
Effectiveness
Patient-centeredness

Identifying Information and Availability

Bibliographic Source(s)


Adaptation
Not applicable: The guideline was not adapted from another source.

Date Released
2005 Oct 20 (revised 2014 May 1)

Guideline Developer(s)
American Society of Clinical Oncology - Medical Specialty Society

Source(s) of Funding
American Society of Clinical Oncology

Guideline Committee
Composition of Group That Authored the Guideline

Update Committee Members: Gary H. Lyman, MD, MPH, FASCO (Co-chair), Fred Hutchinson Cancer Research Center, University of Washington, Seattle, WA; Armando E. Giuliano, MD (Co-chair), John Wayne Cancer Institute, Cedars-Sinai Medical Center, Los Angeles, CA; Al B. Benson III, MD, Northwestern University, Chicago, IL; Linda Bossman, MD, FACP, Wilshire Oncology Medical Group, Rancho Cucamonga, CA; Harold J. Burstein, MD, PhD, Dana-Farber Cancer Institute, Boston, MA; Hiram S. Cody III, MD, Memorial Sloan Kettering Cancer Center, New York, NY; Stephen B. Edge, MD, Baptist Cancer Center, Memphis, TN; James A. Hayman, MD, University of Michigan, Ann Arbor, MI; Lisa A. Newman, MD, MPH, University of Michigan, Ann Arbor, MI; Cheryl L. Perkins, MD, RPH, Dallas, TX; Donald A. Podoloff, MD, University of Texas MD Anderson Cancer Center, Houston, TX; Roderick R. Turner, MD, John Wayne Cancer Institute, Santa Monica, CA; Donald L. Weaver, MD, University of Vermont College of Medicine and Vermont Cancer Center, Burlington, VT

Financial Disclosures/Conflicts of Interest

The Update Committee was assembled in accordance with the American Society of Clinical Oncology (ASCO) Conflicts of Interest Management Procedures for Clinical Practice Guidelines (i.e., Procedures, summarized at http://www.asco.org/rwc). Members of the committee completed the ASCO disclosure form, which requires disclosure of financial and other interests that are relevant to the subject matter of the guideline, including relationships with commercial entities that are reasonably likely to experience direct regulatory or commercial impact as a result of promulgation of the guideline. Categories for disclosure include employment relationships, consulting arrangements, stock ownership, honoraria, research funding, and expert testimony. In accordance with the Procedures, the majority of the members of the committee did not disclose any such relationships.

The author(s) indicated no potential conflicts of interest.

Guideline Status

Note: This guideline has been updated. The National Guideline Clearinghouse (NGC) is working to update this summary.

Guideline Availability

The updated guideline is available from the Journal of Clinical Oncology Web site.

Print copies: Available from American Society of Clinical Oncology, Cancer Policy and Clinical Affairs, 2318 Mill Rd, Suite 800, Alexandria, VA 22314; E-mail: guidelines@asco.org.

Availability of Companion Documents

The following are available:

Patient Resources

The following is available:


Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

NGC Status

This NGC summary was completed by ECRI on November 18, 2005. The information was verified by the guideline developer on December 1, 2005. This summary was updated by ECRI Institute on June 9, 2014.

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