Complete Summary

GUIDELINE TITLE

Breast cancer in limited-resource countries: early detection and access to care.

BIBLIOGRAPHIC SOURCE(S)

Smith RA, Caleffi M, Albert US, Chen TH, Duffy SW, Franceschi D, Nystrom L. Breast cancer in limited-resource countries: early detection and access to care. Breast J 2006 Jan-Feb;12 Suppl 1:S16-26. [63 references] PubMed

GUIDELINE STATUS

This is the current release of the guideline.

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SCOPE

DISEASE/CONDITION(S)

Breast cancer

GUIDELINE CATEGORY

Diagnosis
Screening

CLINICAL SPECIALTY

Family Practice
Internal Medicine
Nursing
Obstetrics and Gynecology
Oncology

Radiation Oncology
Radiology
Surgery

INTENDED USERS

Advanced Practice Nurses
Allied Health Personnel
Health Care Providers
Hospitals
Nurses
Physician Assistants
Physicians
Public Health Departments

GUIDELINE OBJECTIVE(S)

To develop evidence-based, economically feasible, and culturally appropriate guidelines that can be used in nations with limited health care resources to improve breast cancer early detection and access to care

TARGET POPULATION

- Asymptomatic women in limited-resource countries
- Women in limited-resource countries with signs and symptoms of breast disease
- Women in limited-resource countries with breast cancer

INTERVENTIONS AND PRACTICES CONSIDERED

1. Public education to increase breast cancer awareness, especially awareness about breast cancer survivability
2. Tailored approaches to increase breast cancer awareness that are targeted to specific audiences and that take into account culture, religion, and other factors
3. Clinical breast examination (CBE) training for detecting symptomatic (palpable) breast cancer
4. Opportunistic CBE
5. Breast self examination training
6. Mammography and other imaging-based screening programs for detecting asymptomatic (non-palpable) breast cancer)

MAJOR OUTCOMES CONSIDERED

- Tumor size at diagnosis
- Tumor stage at diagnosis
- Rates of advanced disease
- Breast cancer morbidity and mortality rates
- Breast cancer survival rates

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

The Breast Health Global Initiative (BHGI) 2005 Guideline panel for early detection and access to care relied on the literature review performed for the 2002 BHGI report and conducted a new MEDLINE search under the subject headings "breast awareness," "clinical breast examination," "breast self-examination," and "mammography," limited to the English language, from 2000 to 2005. They also performed an additional PubMed search under the subject headings "breast cancer," "low-resource countries," and "developing countries," also limited to the English language, from 1990 to 2005.

NUMBER OF SOURCE DOCUMENTS

219

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Expert Consensus

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Source documents were circulated among expert consensus panelists prior to Global Summit review; commentary and review collected and collated in conjunction with preparation of consensus documents.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Consensus Statement Preparation

The observations from the 2002 Breast Health Global Initiative (BHGI) Global Summit (see companion document, "Breast Cancer in Limited-Resource Countries: An Overview of the Breast Health Global Initiative 2005 Guidelines" in "Availability of Companion Documents" field) served as the starting point for the 2005 BHGI Global Summit.

The 2002 BHGI guidelines were reexamined, revised, and extended at the 2005 BHGI Global Summit. Twelve national and international groups joined the BHGI as collaborating organizations (See Appendix A of the companion document, "Breast Cancer in Limited-Resource Countries: An Overview of the Breast Health Global Initiative 2005 Guidelines" in "Availability of Companion Documents" field). In addition, to obtain input on international guideline development, the BHGI established affiliations with three World Health Organizations programs: the Cancer Control Programme, Health System Policies and Operations, and the Alliance for Health Policy and Systems Research. The 2005 Global Summit brought together more than 60 international experts from 33 countries of all resource levels. The experts had diverse specialties related to breast care and breast cancer: screening, pathology and cytology, surgery, oncology, radiation therapy, health economics, medical ethics, sociology, and advocacy. The early detection and access to care panel was charged with reviewing, updating, and extending the previously published guidelines on this topic and were asked to prepare a consensus statement summarizing the outcome of their work.

Panel cochairs were asked to create a program whereby their expert panel could produce consensus guidelines. The cochairs were responsible for drafting the agenda for the panel's conference day and for organizing and executing the writing of the panel's consensus statement. The panel held one full-day meeting, with a morning session consisting of plenary presentations on topics selected by the cochairs (see Appendix E of the companion document, "Breast Cancer in Limited-Resource Countries: An Overview of the Breast Health Global Initiative 2005 Guidelines" in "Availability of Companion Documents" field) and an afternoon session consisting of discussion and debate among panelists regarding the content of their consensus statement. In addition, to reinforce the aim of the guidelines and to describe the diverse settings in which they might be used, each day began with a presentation by a breast cancer advocate from a limited-resource country to summarize the personal experience of women facing breast cancer in her country.

The panel was also asked to develop checklists for the various interventions. For each intervention, these checklists would describe the strengths, limitations, and necessary resources needed to apply that intervention in the area of early detection and diagnosis. Finally, the panel was asked to identify areas where evidence is lacking and research is needed to better inform future iterations of the guidelines.

The panel's discussion and debate was recorded and transcribed, and the transcript was used as the basis for writing each consensus statement. Panel discussion was directed at creating stratification tables, to describe how resources should be allocated based on the definitions of country resources defined as basic, limited, enhanced, and maximal. Panel cochairs coordinated the writing of the statement, sections of which were coauthored by participating panelists.

Individual Statement Preparation

Some morning plenary speakers were invited to submit manuscripts specific to their presentations to be published along with the consensus statements. In these instances, the supporting material was deemed to be vital to an understanding of the overall guideline recommendations for limited-resource countries, but too lengthy and detailed to be fully included within the consensus statement.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

Published cost analyses were reviewed in the preparation of this guideline.

METHOD OF GUIDELINE VALIDATION

Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Consensus Statement Review

Consensus statement drafts were reviewed and edited by all coauthors of each statement. The final draft, including resolution of disagreements among coauthors, was the responsibility of the panel cochairs.

The consensus statements were then compared centrally for internal consistency in stratification by a subset of coauthors. Differences among panel recommendations were reviewed with panel cochairs and language was adopted to minimize the level of perceived inconsistencies. In cases where resources were definitively stratified differently by the consensus panels, the panel recommendations were maintained in the tables, and instead, the nature of the differences are summarized, explained, and discussed in the companion document, "Breast cancer in limited-resource countries: an overview of the Breast Health Global Initiative 2005 Guidelines" (see "Availability of Companion Documents" field).

Individual Statement Selection and Review

In lieu of the standard external peer-review process, submitted individual statements underwent a special internal review process, reflecting the unique structure and goals of the Breast Health Global Initiative (BHGI) program. All individual statement submissions were reviewed by panel cochairs and selected internal BHGI nonauthor reviewers. Individual statements that did not address issues specific to limited-resource countries were referred for journal submission outside of the BHGI guidelines. Some individual statements that developed individual topics of a more limited scope relevant to limited-resource countries were incorporated into guideline consensus articles. Individual statements that were accepted for publication were determined by the cochairs, internal BHGI

reviewers, and the BHGI director to have specific merit in support of the consensus guidelines.

After final acceptance, all individual statements were coordinated with the consensus guideline statements for internal referencing as data in one or multiple consensus statements. The combination of consensus and individual statements represents a complete BHGI guideline compendium, which is the final work product of the 2005 Global Summit.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

To encourage a consistent approach to the discussion and the guidelines, the panel was asked to stratify health care resources relevant to their assigned areas into one of four levels (Basic, Limited, Enhanced, and Maximal). Definitions for the levels are provided at the end of the "Major Recommendations" field. Each successive resource level subsumes the recommendations for the previous resource level (e.g., basic breast health awareness is recommended at all levels).

Summary of Recommendations

The following table summarizes some of the recommendations made by the panel.

Resource Allocation for Early Detection and Access to Care

Level of Resources	Detection Method(s)	Evaluation Goal
Basic	Breast health awareness (education ± self-examination) Clinical breast examination (CBE) (clinician education)	Baseline and repeated survey
Limited	Targeted outreach/education encouraging CBE for at-risk groups Diagnostic ultrasound ± diagnostic mammography	Downstaging of symptomatic disease
Enhanced	Diagnostic mammography Opportunistic mammography screening	Opportunistic screening of asymptomatic patients
Maximal	Population-based mammographic screening Other imaging technologies as appropriate: high-risk groups, unique imaging challenges	Population-based screening of asymptomatic patients

Breast Awareness

Timely diagnosis of symptomatic disease relies on breast health awareness in the potential patient population and in primary health care professionals, and thus increased breast health awareness is a key element of interventions at all resource levels. Although awareness is an elusive concept, it clearly has great potential for improving the outcome of breast cancer patients. It is important to be mindful that the great majority of women in the world in whom breast cancer is diagnosed each year are symptomatic at the time of diagnosis, and that the majority of women in the world do not have access to screening mammography. Thus, based on the observation of the association between tumor size and prognosis, it should be clear that the goal of earlier detection is not simply the goal of detecting a greater proportion of breast cancers when they are asymptomatic, but also downsizing symptomatic breast cancers as well.

An important aspect of awareness is dissemination of the knowledge that breast cancer is not rapidly fatal if diagnosed early and in many cases is "curable." In the 1970s and 1980s, the majority of women who developed breast cancer died from the disease. With earlier stages at presentation and better treatment, this is no longer the case. It is clear from the very advanced stage at presentation in some low-resource countries that diagnosis is often delayed in patients who must have been aware of symptoms for some time. Fear of diagnosis, among other factors, is a major contributor to the very advanced stage of disease in many countries, and in fact, this is a global phenomenon not restricted to only limited resource areas. However, avoidance of diagnosis is mitigated in developed countries by the fact that public education about the importance of early detection has been prevalent for decades, access to care is greater, and most women are acquainted with long-term survivors of breast cancer and are less deterred from seeking consultation when symptoms occur. Insofar as this greater responsiveness has evolved over many years, it seems reasonable to speculate that a public education strategy that emphasizes the survivability of breast cancer and uses surviving breast cancer patients will be productive in this effort.

The association between knowledge of surviving patients and greater acceptability of diagnosis may have a synergistic, cumulative effect. Knowledge of long-term survivors may stimulate early consultation for symptoms, which may lead to an earlier average stage at presentation, resulting in turn in more long-term survivors. It is concluded that enhanced awareness has considerable potential for improving the stage at presentation and therefore survival. How to engender that awareness among health care workers as well as the general public and on which particular facets of breast disease to focus are priorities for evaluation, both globally and in local settings.

Clinical Breast Examination

An important feature of health care provider education is training in the clinical breast examination (CBE) procedure. CBE training is necessary as a key contributor to prompt diagnosis of symptomatic disease. CBE is likely to be of use in the early diagnosis of disease that is asymptomatic (i.e., unknown to the patient) in areas where mammographic screening is unavailable. Although this examination may not be able to detect the very small tumors that can be seen only on mammography, it has the potential to improve the situation wherein the majority of tumors diagnosed are at stage III or IV.

Even though there is still no direct randomized trial evidence that regular, high-quality screening CBE confers an advantage over no CBE, or even the more common, cursory, low-quality CBE received by most women today, such an advantage cannot be ruled out. However, the evidence to date indicates that for a program of CBE to be successful, barriers at every step of the continuum of the screening process will need to be identified, understood, monitored, and overcome.

At the most basic level, competent CBE should be available to women with breast symptoms. Once access is in place, there also may be a role for opportunistic screening; that is, screening that takes place on the occasion of health care encounters for other reasons. This does not mean that at every visit to a primary care provider CBE should take place or be offered. Rather it means that the provider chooses appropriate occasions for CBE based on the nature of the consultation, the state of the health and mind of the patient, and the time since the last CBE. This is similar to the opportunistic CBE and mammographic screening currently taking place in parts of North America and Europe. The occasion of CBE also provides an opportunity for a care provider to discuss early signs and symptoms of breast cancer, and to stress the importance of immediately reporting breast changes to their provider. If the patient is interested in conducting periodic breast self examination (BSE), during CBE, information and instruction about BSE can be provided and the patient's technique can be reviewed.

Once CBE is readily available as a clinical resource, a limited-resource area may consider formal programs of screening for as yet undetected symptomatic breast cancer using CBE. The efficacy of CBE as a stand-alone screening tool is not yet established. The current state of knowledge about the efficacy of CBE programs implies that the introduction of any program of CBE needs to be subjected to thorough evaluation, and this in turn implies that regions with such programs should have systems in place to enable the identification of deaths in patients with breast cancer. In addition, to facilitate evaluation early in the program, before large numbers of deaths have been observed, information on disease stage should be available.

It cannot be too strongly emphasized that a fundamental part of any strategy to reduce mortality and morbidity from breast cancer in limited-resource areas, whether it includes CBE screening or not, is the means to monitor that strategy and to identify and correct failures. Thus, a basic component of any formal program of CBE should include identification of deaths in breast cancer cases as well as routine staging of breast.

Formal Breast Self Examination

Although breast self examination (BSE) cannot be positively recommended on the basis of current evidence, the guideline developers would not actively discourage its use either. BSE instruction may have the greatest value not so much in stimulating regular self examinations, but rather simply in promoting greater awareness of breast symptoms. Because there is not yet an evidence base for its efficiency, any BSE program should be rigorously evaluated, both in terms of deaths in patients with breast cancer and in terms of stage of disease. The

program must be bale to identify deaths in patients and to ascertain the stage of disease at diagnosis.

Mammography

At the present time, mammographic screening is the gold standard for early detection of breast cancer, and regions with enhanced resources should aspire to provide access.

The panel advises against new randomized controlled trials of breast cancer screening with an emphasis on efficacy as part of a strategy for introducing mammography in populations in which mammography currently is not available. There is little reason to question the value of early detection with mammography in population settings where it has not yet been introduced, and considerations about the implementation of mammographic screening should be limited to whether a mammographic screening program would be cost effective and whether high quality would be sustained. In the United States, Europe, and elsewhere, strong quality assurance programs have been developed to ensure that the technical quality of mammography is high. The implementation of mammographic screening must be accompanied by strong quality assurance programs that include regular assessments of quality control, and medical audits and feedback to interpreting physicians and radiologic technologists.

Social and Cultural Considerations

A variety of barriers to awareness, seeking and obtaining care, and responsiveness to screening are evident in the literature and were identified during the 2002 Global Summit: fatalism, inability to act without husband's permission, fear of casting stigma on one's daughters, fear of being ostracized, fear of contagion, reticence, language barriers (e.g., the absence of a word for cancer in some languages), preference for traditional healers, and others. These barriers fall into two general groups: those that can be addressed with education and those that need to be addressed with tailored approaches that take into account culture, religion, and other factors. In both instances, and likely in every setting, tailored approaches will need to be directed toward women, health care workers, and others in the community. Some tailored approaches other than those directed toward women may include soliciting the help of respected leaders (e.g., rabbis for ultraorthodox Jewish women, or sheiks for Muslim women) and outreach to men in strong, patriarchal societies, or traditional healers.

Although only a limited number of examples are presented in the original guideline document, the discussion during the 2005 Global Summit led to the conclusion that a narrow education/clinical response approach to breast cancer that neglects an understanding of potentially powerful barriers is a strategy that increases the likelihood of program failure. It may also lead to the mistaken impression that the key elements of an intervention were unsuccessful, when in fact, the intervention would have worked quite well, but was not sufficient alone to overcome neglected or unforeseen social and cultural barriers to earlier detection and care.

A key barrier to address is the perception that breast cancer is universally fatal. In countries with a lower incidence of the disease, predominately late stage at

presentation, and demographic or geographic barriers, most women may not know of any breast cancer survivors. Yet patients with breast cancer can play a vital role in awareness and screening programs. By sharing their experiences, they can provide information about barriers and help remove taboos surrounding the disease. Advocacy groups can greatly influence the knowledge, attitudes, and behavior of the public, as well as the political process and resources available for breast cancer.

When planning awareness programs, guidelines should address who will be the target for the awareness messages. Targeting messages to a specific population is essential to avoid overloading the system. For example, failing to target a breast awareness message might result in many adolescent women presenting with breast pain, which would drain the resources available to identify older women with breast cancer.

The panel strongly encourages the contribution and perspective of medical anthropology and medical sociology, and the application of these perspectives and methodologies to the understanding of the local situation will be helpful in clarifying barriers. In all regions, it is likely that there are factors other than, or in addition to, lack of awareness that explain why women typically present with late-stage breast cancer.

Resource Stratification Definitions

Basic level: Core resources or fundamental services absolutely necessary for any breast health care system to function. By definition, a health care system lacking any basic-level resource would be unable to provide breast cancer care to its patient population. Basic-level services are typically applied in a single clinical interaction.

Limited level: Second-tier resources or services that produce major improvements in outcome, such as increased survival, but which are attainable with limited financial means and modest infrastructure. Limited-level services may involve single or multiple clinical interactions.

Enhanced level: Third-tier resources or services that are optional but important. Enhanced-level resources may produce minor improvements in outcome but increase the number and quality of therapeutic options and patient choice.

Maximal level: High-level resources or services that may be used in some high-resource countries, but nonetheless should be considered lower priority than those in the basic, limited, or enhanced categories on the basis of cost or impracticality for limited-resource environments. In order to be useful, maximal-level resources typically depend on the existence and functionality of all lower-level resources.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is not specifically stated for each recommendation.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

- Improved early detection of breast cancer in limited-resource countries
- Improved access to breast cancer care in limited-resource countries
- Improved breast cancer morbidity and mortality in limited-resource countries

POTENTIAL HARMS

Not stated

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

See the original guideline document and companion document, "Breast Cancer in Limited-Resource Countries: Health Care Systems and Public Policy" (see "Availability of Companion Documents" field) for implementation strategies.

IMPLEMENTATION TOOLS

Quick Reference Guides/Physician Guides

For information about availability, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better
Living with Illness
Staying Healthy

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Smith RA, Caleffi M, Albert US, Chen TH, Duffy SW, Franceschi D, Nystrom L. Breast cancer in limited-resource countries: early detection and access to care. Breast J 2006 Jan-Feb;12 Suppl 1:S16-26. [63 references] PubMed

ADAPTATION

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

DATE RELEASED

2006 Jan

GUIDELINE DEVELOPER(S)

Breast Health Global Initiative - Professional Association
Fred Hutchinson Cancer Research Center - Private Nonprofit Research Organization
Susan G. Komen Breast Cancer Foundation - Private Nonprofit Research Organization

SOURCE(S) OF FUNDING

Breast Health Global Initiative

GUIDELINE COMMITTEE

Global Summit Early Detection and Access to Care Panel

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from the Fred Hutchinson Cancer Research Center Web site.

Print copies: Available from Robert A. Smith, PhD, Director of Cancer Screening, American Cancer Society, 1599 Clifton Rd. NE, Atlanta, GA 30329, USA; E-mail: Robert.Smith@cancer.org.

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- Breast cancer in limited resource countries: an overview of the breast health global initiative 2005 guidelines. Breast J 2006 Jan-Feb;12 Suppl 1:S3-15. Available in Portable Document Format (PDF) from the Fred Hutchinson Cancer Research Center Web site.
- Breast cancer in limited-resource countries: health care systems and public policy. Breast J 2006 Jan-Feb;12 Suppl 1:S54-69. Available in Portable Document Format (PDF) from the Fred Hutchinson Cancer Research Center Web site.
- The Breast Health Global Initiative (BHGI) resource-stratified matrix guidelines. Breast J 2006 Jan-Feb;12 Suppl 1:S117-20. Available in Portable Document Format (PDF) from the Fred Hutchinson Cancer Research Center Web site.

Print copies: Available from Benjamin O. Anderson, MD, Department of Surgery, Box 356410, University of Washington, Seattle, WA 98195, USA, or e-mail: banderso@u.washington.edu.

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI on July 27, 2006. The information was verified by the guideline developer on August 28, 2006.

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