Complete Summary

GUIDELINE TITLE

Early detection of breast cancer.

BIBLIOGRAPHIC SOURCE(S)

Royal New Zealand College of General Practitioners. Early detection of breast cancer. Wellington (New Zealand): Royal New Zealand College of General Practitioners; 1999. 61 p. [176 references]

COMPLETE SUMMARY CONTENT

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SCOPE

DISEASE/CONDITION(S)

Breast cancer

GUIDELINE CATEGORY

Diagnosis
Risk Assessment
Screening

CLINICAL SPECIALTY

Family Practice

INTENDED USERS

Advanced Practice Nurses
Nurses
Physicians

GUIDELINE OBJECTIVE(S)

- To help primary care providers provide consistent advice to women about the risk factors for and the early detection and diagnosis of breast cancer
- To provide information about cultural considerations for Maori, which may be useful for improving the service effectiveness that primary care providers can offer

TARGET POPULATION

Asymptomatic and symptomatic women

- Women in New Zealand aged 50-74 years without symptoms suggestive of breast cancer
- High-risk asymptomatic women in New Zealand aged 40 and over
- Women in New Zealand with symptoms suggestive of breast cancer
- Maori women

INTERVENTIONS AND PRACTICES CONSIDERED

Risk Assessment

1. Identify risk factors for developing breast cancer, such as gender, age, family history, medical history, radiation exposure
2. Genetic testing for BRCA 1 and 2 genes

Screening

1. Mammography alone or with clinical breast examination (CBE)
2. Breast self examination (BSE)

Diagnosis

1. The triple test: clinical breast examination (CBE), diagnostic mammography, fine needle aspiration biopsy (FNAB)
2. Diagnostic ultrasound
3. Core biopsy
4. Other diagnostic modalities, such as radioisotope scintimammography, colour doppler and magnetic resonance mammography

MAJOR OUTCOMES CONSIDERED

- Risk of developing breast cancer (breast cancer morbidity)
- Breast cancer mortality
- Clinical performance characteristics of screening tests (sensitivity, specificity)

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Systematic literature reviews were conducted twice during guideline development by different individuals (July 1996-November 1998):

- The early detection and diagnosis of breast cancer, 1996, Drs. Pullon and McLeod
- The early detection and diagnosis of breast cancer, an update, 1999, New Zealand Health Technology Assessment Unit.

The Australian National Breast Cancer Centre Guidelines were also used in part as seeding guidelines:

- Current best advice about familial aspects of breast cancer. A guide for general practitioners, 1997.
- Guideline for the investigation of breast symptoms, 1997.

NUMBER OF SOURCE DOCUMENTS

Not stated

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

I Evidence obtained from systematic review of all relevant randomised controlled trials (RCTs).

II Evidence obtained from at least one properly designed RCT.

III-1 Evidence obtained from well designed controlled trials without randomisation.

III-2 Evidence obtained from well designed cohort or case controlled analytic studies, preferably from more than one centre or research group.

III-3 Evidence obtained from multiple time-series with or without the intervention. Dramatic results in uncontrolled experiments such as the introduction of penicillin treatment in the 1940s could be regarded as this type of evidence.

IV-1 Evidence from descriptive studies including case series, case reports and cross-sectional studies.

IV-2 Published policies, recommendations or opinions of recognised experts, organisations, or learned colleagues. Including endorsement of Level IV-3 evidence by recognised bodies.

IV-3 Consensus opinion of the working party not endorsed formally by recognised bodies.

N/A Not applicable - not possible to apply a level of evidence.

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not applicable

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

These guidelines were developed through systematic literature review and the consensus of a broad-based, multi-disciplinary group including both professional and consumer perspectives.

August 1998

The development group met and progressed the draft guidelines using the systematic review.

The Australian National Breast Cancer Centre Guidelines were also used in part as seeding guidelines. The draft was subsequently reviewed in further face-to-face meetings and teleconference.

November 1998

An additional literature review to cover the period subsequent to the initial review (1996-1999) was contracted to the New Zealand Health Technology Assessment Unit. The working group incorporated the update literature review and further reviewed the draft guidelines.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

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

A Maori general practitioner and a Health Funding Authority (HFA) representative served as reviewers.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Levels of evidence (I-IV, N/A) for recommendations are defined at the end of the Major Recommendation field.

Specific Risk Factors

It is important for primary care providers to provide accurate and understandable information to women about breast cancer risk care. They should be able to give a woman requesting risk assessment her absolute risk, not just her relative risk.

For the majority of risk factors there are no practical preventative strategies.

The most important risk factors for developing breast cancer are female gender and increasing age.

Age-related absolute risks of developing breast cancer are:

Age group	25-44	45-54	55-79	Over 80
Five-year absolute risk	Less than 0.5%	0.5%	1-1.5%	1.5-2%

Other Risk Factors

High risk factors	Moderate risk factors
(Relative risk over four times normal for age) • A strong family history (as defined in the guideline) [Level	(Relative risk two to four times normal for age) • A moderate family history of breast cancer (as defined in the

III-2] • Genetic factors (e.g. BRCA1 genes) [Level IV-1] • Previous treatment for childhood cancer or Hodgkin's disease [Level III-2]; children irradiated between the ages of 10 and 16 are at the greatest risk [Level IV-1] • High grade ductal carcinoma-in-situ (DCIS) • Lobular carcinoma-in-situ • Atypical ductal hyperplasia with a family history of breast cancer [Level III-2] • Previous breast cancer, particularly in women under 45 years at age of diagnosis [Level III-2]	guideline) • Previous personal history of breast cancer including DCIS • Previous personal history of ovarian cancer • Gross cystic disease [Level III-2] • Atypical ductal hyperplasia with no family history of breast cancer [Level III-2]

Screening for Breast Cancer

Mammography is the principle screening procedure for breast cancer (in women with no symptoms).

- Clinical breast examination may be used in conjunction with mammography screening. [Level I]
- For women aged 50-74 two-yearly mammography is recommended. [Level I]
- Annual mammography is recommended for higher risk women (as defined in the guideline) over the age of 40. [Level III-2]
- For women aged 40-49 annual routine mammography is not advised unless they are higher risk (as defined in the guideline). [Level I]

Breast Symptoms For Further Investigation [Level IV-1]

Appearance changes	Lumps	Nipple discharge	Breast pain
• Recent nipple changes including nipple retraction or distortion, and	• A palpable lump or a discrete mass in the breast is an indication for further investigation • Asymmetrical	Spontaneous nipple discharge that is not associated with lactation is an indication for further investigation when it is:	• It is important to investigate any woman, especially post-menopausa

eczema that does not respond completely to treatment • Skin dimpling over the breast (peau d'orange)	thickening should be assessed after the next period or four to six weeks later in a woman who is not menstruating	• Unilateral, or • From a single duct, or • Blood stained, or • Associated with other signs and symptoms, or • Occurs in a woman aged over 60 years	l women, with a persistent, localised area of pain • The diagnosis of breast pain requires a careful history, clinical breast examination (CBE) and radiological imaging (where appropriate)

Investigations For Symptomatic Women

The triple test	Clinical breast examination (CBE)
The triple test is the method of choice for diagnosing any palpable abnormalities of the breast. It comprises: 1. Clinical breast examination. 2. Diagnostic (not screening) mammography. 3. Fine needle aspiration biopsy (FNAB). • The triple test is positive if any of its three components is positive (malignant or suspicious). • The triple test is negative only if all three components are negative or benign. • A woman with a positive triple test requires further investigation	• High quality CBE is an important step in primary care. • High quality CBE includes visual inspection, comprehensive coverage of breast tissue, and a reasonable search duration. [Levels II, III-2, and IV-1]

and follow-up.	

Definitions:

Level of Evidence Ratings

I Evidence obtained from systematic review of all relevant randomised controlled trials (RCTs).

II Evidence obtained from at least one properly designed RCT.

III-1 Evidence obtained from well designed controlled trials without randomisation.

III-2 Evidence obtained from well designed cohort or case controlled analytic studies, preferably from more than one centre or research group.

III-3 Evidence obtained from multiple time-series with or without the intervention. Dramatic results in uncontrolled experiments such as the introduction of penicillin treatment in the 1940s could be regarded as this type of evidence.

IV-1 Evidence from descriptive studies including case series, case reports and cross-sectional studies.

<strongiv-2< strong> Published policies, recommendations or opinions of recognised experts, organisations, or learned colleagues. Including endorsement of Level IV-3 evidence by recognised bodies.

IV-3 Consensus opinion of the working party not endorsed formally by recognised bodies.

N/A Not applicable - not possible to apply a level of evidence.

CLINICAL ALGORITHM(S)

Algorithms are provided for (1) women presenting with breast symptoms; (2) women presenting with a nipple discharge; and (3) women with a cyst established by ultrasound.

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

These guidelines were developed through systematic literature review and the consensus of a broad-based, multi-disciplinary group including both professional and consumer perspectives. The type of supporting evidence is identified for each recommendation (refer to "Major Recommendations").

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Breast screening reduces breast cancer mortality by 20% to 38% in women aged between 50 and 64 years. It has been estimated 480 lives could be saved over the first five years if mammography screening is provided to the entire female population aged 50-69.

Screening mammography has a high sensitivity (80-95%) and specificity (93-95%) and both of these measures generally increase with a patient's age. Regular two-yearly screening mammography results in a reduction of breast cancer mortality by approximately 30% for women aged 40-74. Specifically, mortality is reduced 26-34% in women aged over 65 and 20-38% in women aged 50-64 by two-yearly mammography screening.

POTENTIAL HARMS

False positives. These can lead to unnecessary investigations ranging from repeat mammography to ultrasound, fine needle aspiration biopsy (FNAB) and/or biopsy. There is a significant false positive rate for mammography screening (0.9 - 6.5%), which substantially contributes to the costs associated with screening. In New Zealand, the risk of a false positive for a woman at some point during a 20-year screening programme (aged 50-69) has been calculated at 34%.

False negatives. As with any investigation a negative result may occur even though cancer is present. The sensitivity of screening mammography is 86-94% depending on age. Thus the false negative rate is 6-14%.

Over-treatment: There is a potential for a screening programme to detect a cancer in a woman who might never have presented clinically before dying from another cause. Thus screening may increase morbidity while not reducing mortality.

Radiation: There is no clear evidence that accumulated radiation from mammography increases the risk of breast cancer.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

These guidelines are intended to serve as an aid for decision making for both primary care providers and patients. It is important that providers are familiar with how to interpret the data in order to discuss options with patients.

These guidelines are intended to provide guidance to primary care providers. However, the complex nature of breast cancer issues and the inherent variation among patients mean that clinical judgement must still be exercised in applying the guidelines.

Screening mammography for women younger than 50 years is controversial. There are many methodological problems in published studies and meta analysis of this age group. Further study is needed to resolve this issue. Such a trial is underway in the United Kingdom, although it will be a number of years before any definitive results are available.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Staying Healthy

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Royal New Zealand College of General Practitioners. Early detection of breast cancer. Wellington (New Zealand): Royal New Zealand College of General Practitioners; 1999. 61 p. [176 references]

ADAPTATION

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

DATE RELEASED

1999

GUIDELINE DEVELOPER(S)

Royal New Zealand College of General Practitioners - Medical Specialty Society

SOURCE(S) OF FUNDING

Ministry of Health (New Zealand)

GUIDELINE COMMITTEE

Not stated

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

The 1997 development group consisted of a range of experts in the areas of breast cancer and general practice including an epidemiologist and general practitioner who were New Zealand Guidelines Group Fellows, a Cancer Society representative, a pathologist, a breast cancer surgeon, a breast cancer nurse specialist, a radiologist, two practice nurses (one Maori), a Pacific Islands consumer and a consumer representative.

The 1998 development group comprised a general practice researcher, an epidemiologist, a breast cancer surgeon, a radiologist, a breast nurse specialist, a Cancer Society representative, a consumer representative, two practice nurses (one a Maori), a Pacific Islands representative, two general practitioners, and a pathologist.

1997 Work Group Members: Dr Tim Kenealy (RNZCGP project leader); Dr Phil Barham; Nicole Barker; Dr Sue Pullon; Mr John Simpson; Robyn Albertson; Dr Wendy Hadden; Barbara Robson; Elaine Boyd; Dr Tessa Turnbull; Dr Jocelyn Tracey; Dr Diane Kenwright; Dr Debbie McLeod.

1998 Work Group Members: Dr Stuart Foote (RNZCGP project leader and facilitator); Dr Phil Barham; Nicole Barker; Dr Sue Pullon; Mr John Simpson; Robyn Albertson; Dr Wendy Hadden; Barbara Robson; Christine Millar; Dr Tessa Turnbull; Dr Jocelyn Tracey; Dr Diane Kenwright.

Nov 1998 - June 1999 Work Group Members: Dr Jim Vause (RNZCGP joint project leader); Dr Karen Flegg (RNZCGP joint project leader, CEO of the RNZCGP); Dr Bruce Adlam; Cathy Webber; Dr Sue Pullon; Mr John Simpson; Robyn Albertson; Dr Wendy Hadden; Barbara Robson; Christine Millar; Dr Jackie Blue; Dr Ashley Bloomfield.

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

An update is not in progress at this time.

GUIDELINE AVAILABILITY

Electronic copies: Not available at this time.

Print copies: Available from the Royal New Zealand College of General Practitioners, PO Box 10440, Wellington New Zealand.

AVAILABILITY OF COMPANION DOCUMENTS

The following is available:

- Quick reference guide for primary care providers: early detection of breast cancer. Wellington, New Zealand: Royal New Zealand College of General Practitioners, 1999.

Print copies: Available from the Royal New Zealand College of General Practitioners, PO Box 10440, Wellington New Zealand.

PATIENT RESOURCES

None available

NGC STATUS

This summary was completed by ECRI on October 10, 2000. The information was verified by the guideline developer on October 27, 2000.

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