Clinical Practice Guidelines: burden or benefit?

AHIA Conference

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NATIONAL BREAST AND OVARIAN CANCER CENTRE

Background

- 1994/5 -Government Inquiry to address inconsistencies in care
- No guidelines existed to inform clinical management
- Large burden of disease - increasing numbers of women diagnosed over time
- Rural, regional and metropolitan medical settings – population density varies widely
- Mixed public and private sector service delivery

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Mission

NBOCC will play a lead role in national cancer control and in improving cancer care, through an evidence-based approach to informing best practice, health systems reform and policy

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“Evidence into Practice”

- **Translation**
- **Implementation**
- **Evaluation**

risk reduction → early detection → diagnosis → medical and supportive care → survivorship → palliative care

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The 'evidence loop'

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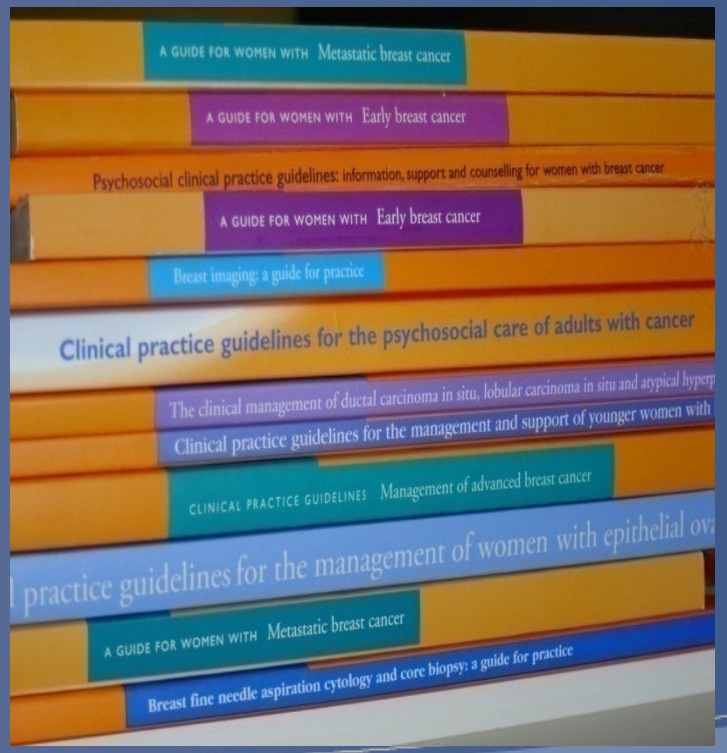
Australian Breast Cancer Guidelines

About 25 Guidelines published by NBOCC since 1995…

Range from early to advanced breast cancer, to psycho-social guidelines, guidelines for aromatase inhibitors to sentinel node biopsy.



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“Guideline” ?.....

- A line drawn or a rope…fixed, to act as a guide
- An indication of a course that should be followed

or

- What policy should be followed

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Aims of Guidelines:

- To assist in clinical decision making by doctors and patients
- To educate all involved in care of patients
- To assess and assure quality of care by recommending a standard of care
- To improve the quality of care and outcomes

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Criticisms of Guidelines:

- *Anti-intellectual*
- *Standardising practice around the average*
- *Prevent discretion in individual cases*
- *Limit clinician freedom and innovation*
- *May increase the risk of litigation*

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Principles

- Guidelines need to be evidence-based
- Guidelines need to be balanced
- Guidelines need to be accepted and respected
- Guidelines need to be used

- **Level I:** systematic review of RCT's
- **Level II:** at least 1 properly designed RCT
- **Level III:** well designed controlled trials
  or
  - well designed case-control study
  or
  - from multiple series
- **Level IV:** opinions of respected authorities, descriptive studies, or reports of expert committees

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Guideline Development Process

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Maintaining Currency

- Ongoing review of specific topics
  - new trials may be underway or longer follow-up required
- Constant review of new published research
  - daily activity by in-house evidence team
- Review should be information & time triggered
  - i.e respond to new information and review every 4yrs
- Horizon scanning
  - emerging areas

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Establishing Guidelines

PROBLEMS

- Expensive
- Time consuming production phase
- Quickly out of date

SOLUTION

- Break up into smaller questions / particular issues
- Web based development and publication

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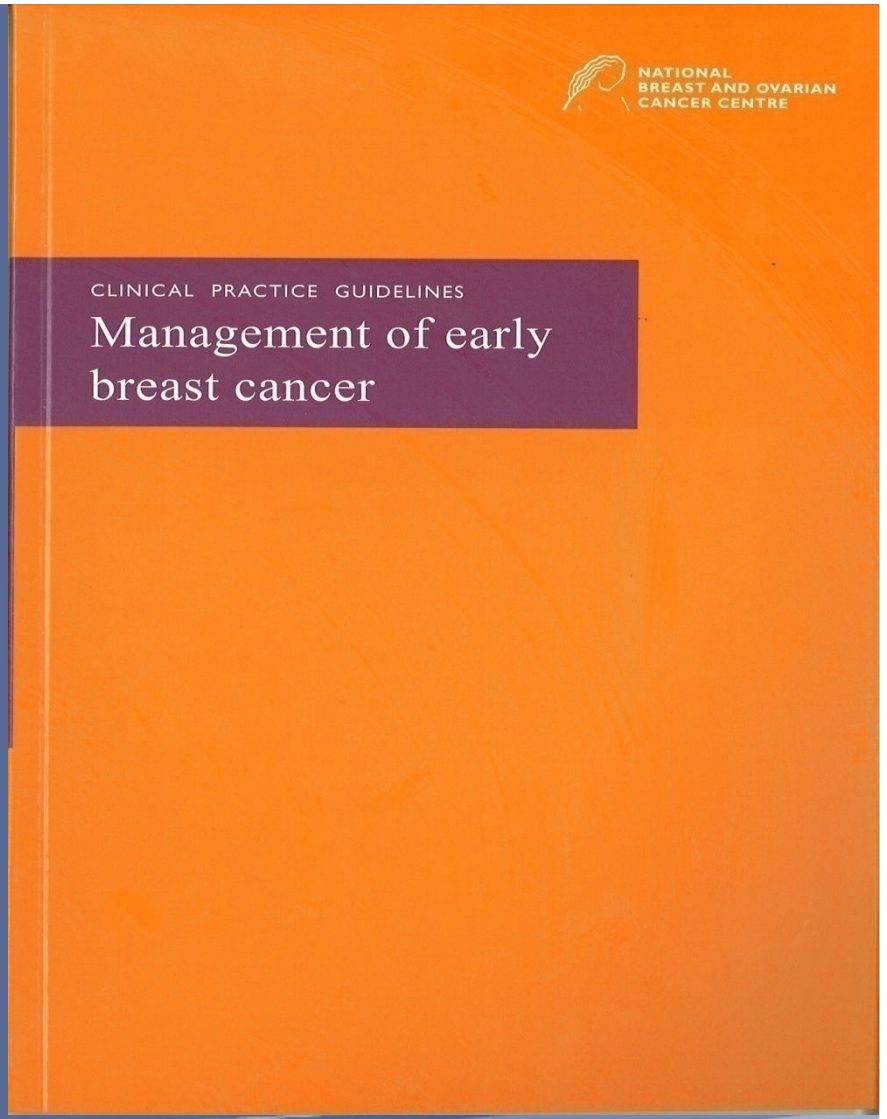
Clinical practice guidelines for the management of early breast cancer

1st edition, 1995
2nd edition, 2001



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NATIONAL BREAST AND OVARIAN CANCER CENTRE
RECOMMENDATIONS FOR USE OF
Sentinel node biopsy
in early (operable) breast cancer
A CLINICAL PRACTICE GUIDELINE DEVELOPED BY NATIONAL BREAST AND OVARIAN CANCER CENTRE® (NBOCC)
PURPOSE
NATIONAL BREAST AND OVARIAN CANCER CENTRE
RECOMMENDATIONS FOR USE OF
Taxane-containing chemotherapy regimens
for the treatment of early (operable) breast cancer
A CLINICAL PRACTICE GUIDELINE DEVELOPED BY NATIONAL BREAST AND OVARIAN CANCER CENTRE (NBOCC)
PURPOSE
NATIONAL BREAST CANCER CENTRE
Incorporating the Ovarian Cancer Program
RECOMMENDATIONS FOR USE OF
Trastuzumab (Herceptin®)
for the treatment of HER2-positive breast cancer
A CLINICAL PRACTICE GUIDELINE DEVELOPED BY THE NATIONAL BREAST CANCER CENTRE (NBCC)
PURPOSE
NATIONAL BREAST CANCER CENTRE
Incorporating the Ovarian Cancer Program
RECOMMENDATIONS FOR
Aromatase inhibitors as adjuvant endocrine therapy
for post-menopausal women with hormone receptor-positive early breast cancer
A CLINICAL PRACTICE GUIDELINE DEVELOPED BY THE NATIONAL BREAST CANCER CENTRE (NBCC)
PURPOSE
BACKGROUND
NATIONAL BREAST AND OVARIAN CANCER CENTRE

Clinical Practice Guidelines for the management of early breast cancer, 2nd edition 2001

Updates:

- Recommendations for aromatase inhibitors as adjuvant endocrine therapy for post-menopausal women with hormone receptor-positive early breast cancer – (July 2006)
- Recommendations for use of trastuzumab (Herceptin®) for treatment of HER2-positive breast cancer – (March 2007)
- Recommendations for the use of taxane-containing chemotherapy regimens for treatment of early (operable) breast cancer – (June 2008)
- Recommendations for the use of sentinel node biopsy in the use of early (operable) breast cancer – (June 2008)

NATIONAL BREAST AND OVARIAN CANCER CENTRE

Clinical Practice Guidelines for the management of early breast cancer, 2nd edition 2001

Updates in production:

- Recommendations for staging and managing the axilla in women with early breast cancer
- Recommendations for the follow up of women with early breast cancer

NATIONAL BREAST AND OVARIAN CANCER CENTRE

This document supplements guideline recommendation 9 about axillary node dissection (page 8) and information about sentinel node biopsy (page 57) contained in the NBOCC *Clinical practice guidelines for the management of early breast cancer,* 2nd edition, 2001

NATIONAL BREAST AND OVARIAN CANCER CENTRE

MARCH 2008 | Incorporates published evidence to July 2007

RECOMMENDATIONS FOR USE OF

Sentinel node biopsy

in early (operable) breast cancer

A CLINICAL PRACTICE GUIDELINE DEVELOPED BY NATIONAL BREAST AND OVARIAN CANCER CENTRE* (NBOCC)

This document supplements guideline recommendation 9 about axillary node dissection (page 8) and information about sentinel node biopsy (page 57) contained in the NBCC *Clinical Practice Guideline for the Management of Early Breast Cancer*, 2nd edition 2001.[1]

NBOCC is currently preparing recommendations about staging and management of the axilla in early breast cancer to supplement chapter 4.4 (pages 55–59) of the NBCC *Clinical Practice Guidelines for the Management of Early Breast Cancer,* 2nd edition 2001.[1]

PURPOSE

This guideline includes statements and recommendations based on available, high-level evidence about the use of sentinel node biopsy in women with early (operable) breast cancer. The guideline aims to provide health professionals with information to assist in making management recommendations for improved patient outcomes. NBOCC also develops information specifically for consumers about early breast cancer diagnosis and treatment options.

Endorsed by:

The Royal Australasian College of Physicians

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Statements of evidence

STATEMENTS	LEVEL OF EVIDENCE	& REFERENCE
In women with early (operable) breast cancer :		
The identified trials included patients with unifocal tumours ≤ 3 centimetres in diameter		
Sentinel node biopsy is a suitable alternative to axillary dissection to determine if cancer cells have spread to the lymph nodes	II	Milan ALMANAC SNAC NSABP B-32 Cambridge GIVOM
Sentinel node biopsy is an accurate method of staging the axilla	II	Milan SNAC NSABP B-32 GIVOM
Sentinel node biopsy based treatment is associated with decreased arm morbidity, compared with axillary dissection	II	Milan ALMANAC SNAC Cambridge GIVOM
There are limited trial results to support recommendations for sentinel node biopsy in women with tumours greater than three centimetres in diameter		ALMANAC NSABP B-32
Team, training and experience		
Three trials that required surgeons to be trained and experienced in the sentinel node biopsy technique had lower false-negative rates and higher sensitivity and accuracy than the one trial which did not require surgeons to have formal training or experience		Milan SNAC NSABP B-32 GIVOM
Technique		
Lymphatic mapping using a combination of radioisotope and blue dye may be associated with a higher rate of sentinel node detection[12,13] than blue dye alone and may be associated with improved accuracy[11]	II	Hung Meyer-Rochow Radovanovic
Using blue dye alone or radioisotope alone appears to provide good sentinel node detection and accuracy. However trial data for blue dye alone is limited		Milan GIVOM
Peritumoural, periareolar, intradermal injection sites have all been shown to be effective in detecting the sentinel node in the axilla		FRANSENO DE Povoski

STATEMENTS CONTINUED	LEVEL OF EVIDENCE	& REFERENCE
False negative rate		
The false negative rate of sentinel node biopsy decreases and morbidity is minimised if up to three sentinel nodes are removed	II	NSABP B-32 (2007)
The removal of four or more nodes from the axilla does not lower the false negative rate significantly compared with removing up to three nodes		
Pathology		
Detailed, definitive histological assessment (including immunohistochemistry and serial sectioning) of the sentinel node increases the accuracy in the detection of metastatic disease		NBOCC Pathology guidelines
False-negative rates for intraoperative assessment (cytologic methods or frozen section) are high	II	NSABP B-32 GIVOM
Where intraoperative assessment is used, cytologic methods conserve tissue for subsequent detailed histopathological assessment		NBOCC Pathology guidelines
Risk of recurrence		
The long term risk of axillary recurrence following sentinel node biopsy is not known. The duration of follow-up in well-designed randomised control trials is currently limited to six years and to date no increased risk of axillary recurrence has been identified		Milan GIVOM ALMANAC
Adverse events		
Allergic reactions have been reported with the use of blue dye in sentinel node biopsy. These incidences are rare	II	NSABP B-32
Trials did not report on adverse events relating to the dose of radiation to the patient from the use of radioisotope in sentinel node biopsy.		Milan GIVOM ALMANAC SNAC Cambridge
Associated risks of radioisotope use in sentinel node biopsy are minimal and within acceptable limits for patients and staff		MSAC Review
Clinical trials		

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SNB v ALND recommendations (1)

SNB should be offered as a suitable alternative to ALND to patients with: • **unifocal tumours ≤ 3cm and** • **a clinically negative axilla**	II	Milan[2,3] ALMANAC[4] SNAC[6] NSABP B-32[7] Cambridge[8] GIVOM[9,10] ALMANAC[4] NSABP B-32[7]

Tumour sizes varied across the trials. Tumours >3cm in diameter were not well represented in the trial populations.

Detection of the SN

Trial	Successfully mapped SN		Positive SN		Accuracy	False negative rate	Sensitivity	Negative predictive value
	SNB	ALND	SNB	ALND				
Milan			36%	32%	97%	9%	91.2%	95%
ALMANAC	98%		26%	23%				
SNAC	95%	93%	29%	25%		8%	92%	97%
NSABP B-32	97%	97%	26%	26%	97%	10%		96%
Cambridge			34%	26%				
GIVOM	95%	95%	30%	32%	83%	16%	83%	92%

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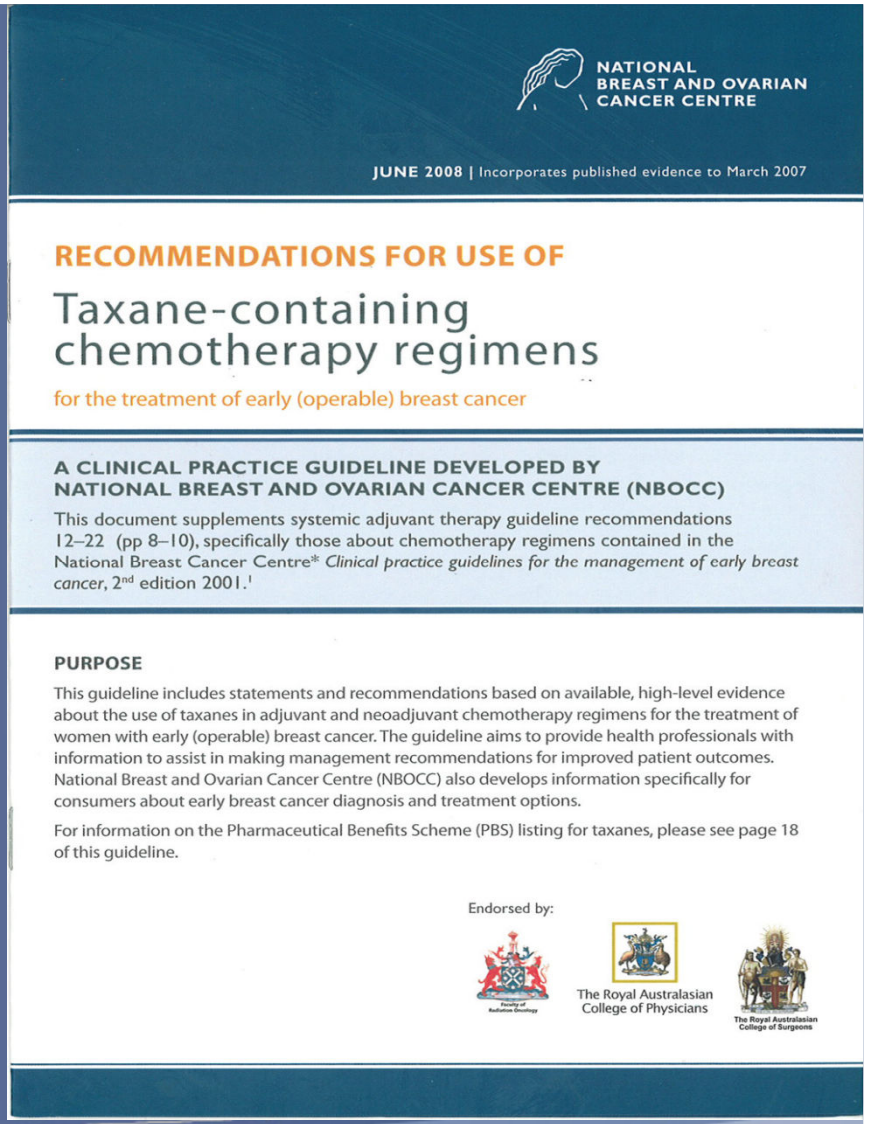
This document supplements systemic adjuvant therapy guideline recommendations 12-22 (pp 8-10), specifically those about chemotherapy regimens contained in the NBOCC *Clinical practice guidelines for the management of early breast cancer,* 2nd edition, 2001



NATIONAL BREAST AND OVARIAN CANCER CENTRE

JUNE 2008 | Incorporates published evidence to March 2007

RECOMMENDATIONS FOR USE OF

Taxane-containing chemotherapy regimens

for the treatment of early (operable) breast cancer

A CLINICAL PRACTICE GUIDELINE DEVELOPED BY NATIONAL BREAST AND OVARIAN CANCER CENTRE (NBOCC)

This document supplements systemic adjuvant therapy guideline recommendations 12–22 (pp 8–10), specifically those about chemotherapy regimens contained in the National Breast Cancer Centre* *Clinical practice guidelines for the management of early breast cancer*, 2nd edition 2001.[1]

PURPOSE

This guideline includes statements and recommendations based on available, high-level evidence about the use of taxanes in adjuvant and neoadjuvant chemotherapy regimens for the treatment of women with early (operable) breast cancer. The guideline aims to provide health professionals with information to assist in making management recommendations for improved patient outcomes. National Breast and Ovarian Cancer Centre (NBOCC) also develops information specifically for consumers about early breast cancer diagnosis and treatment options.

For information on the Pharmaceutical Benefits Scheme (PBS) listing for taxanes, please see page 18 of this guideline.

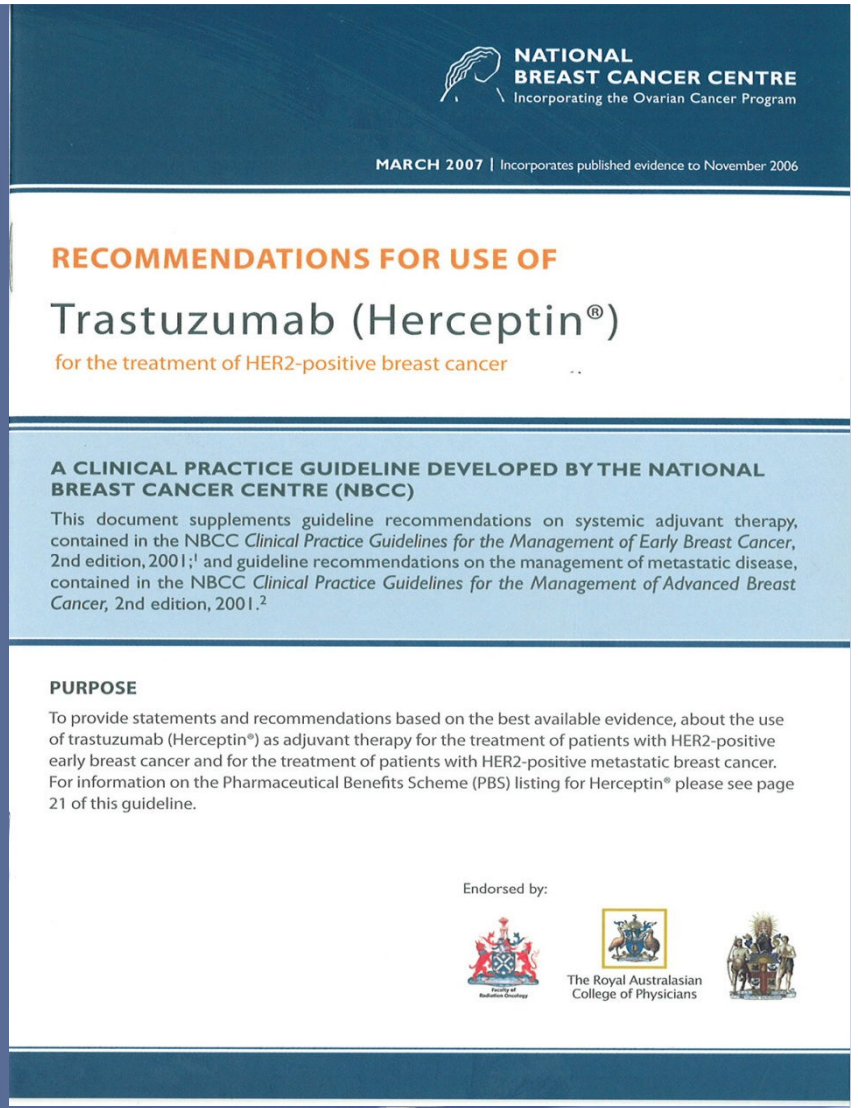
Endorsed by:

The Royal Australasian College of Physicians

The Royal Australasian College of Surgeons

NATIONAL BREAST AND OVARIAN CANCER CENTRE

This document supplements guideline recommendations on systemic adjuvant therapy, contained in the NBOCC *Clinical practice guidelines for the management of early breast cancer,* 2nd edition, 2001



NATIONAL BREAST CANCER CENTRE
Incorporating the Ovarian Cancer Program

MARCH 2007 | Incorporates published evidence to November 2006

RECOMMENDATIONS FOR USE OF

Trastuzumab (Herceptin®)

for the treatment of HER2-positive breast cancer

A CLINICAL PRACTICE GUIDELINE DEVELOPED BY THE NATIONAL BREAST CANCER CENTRE (NBCC)

This document supplements guideline recommendations on systemic adjuvant therapy, contained in the NBCC *Clinical Practice Guidelines for the Management of Early Breast Cancer*, 2nd edition, 2001;[1] and guideline recommendations on the management of metastatic disease, contained in the NBCC *Clinical Practice Guidelines for the Management of Advanced Breast Cancer,* 2nd edition, 2001.[2]

PURPOSE

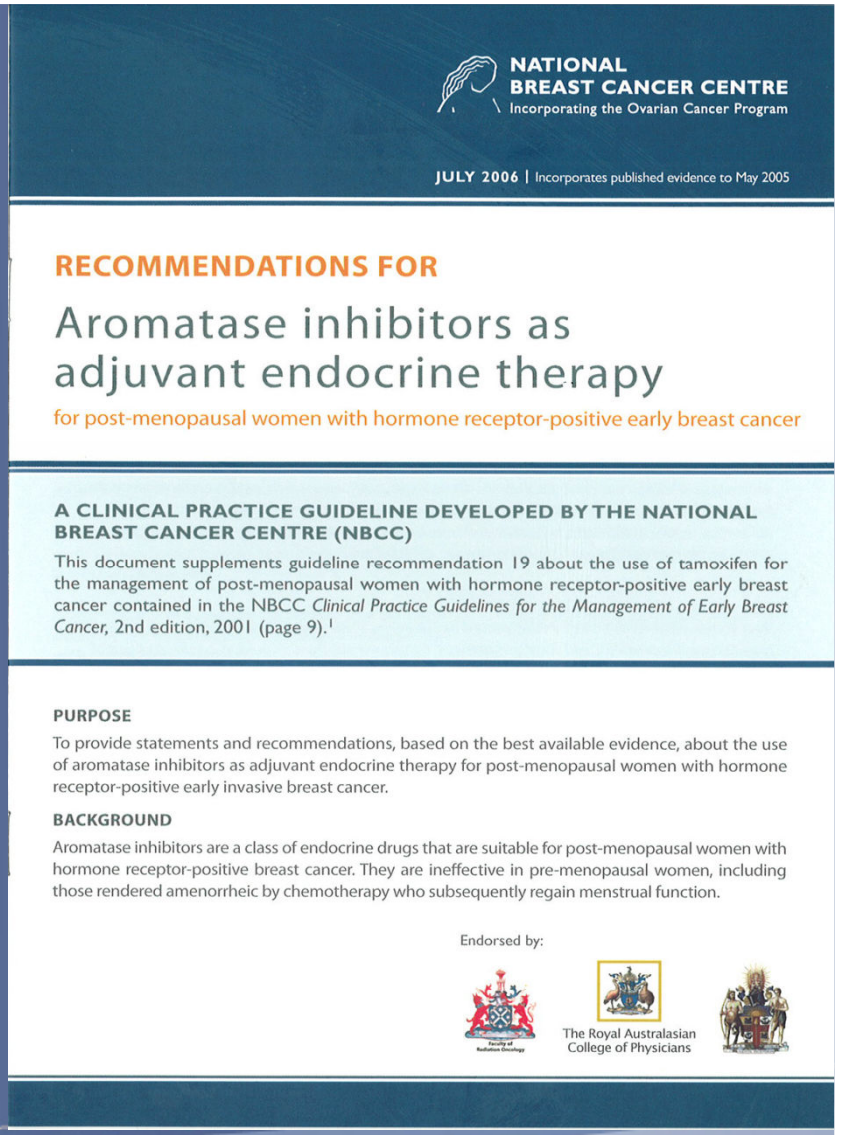
To provide statements and recommendations based on the best available evidence, about the use of trastuzumab (Herceptin®) as adjuvant therapy for the treatment of patients with HER2-positive early breast cancer and for the treatment of patients with HER2-positive metastatic breast cancer. For information on the Pharmaceutical Benefits Scheme (PBS) listing for Herceptin® please see page 21 of this guideline.

Endorsed by:

The Royal Australasian College of Physicians

NATIONAL BREAST AND OVARIAN CANCER CENTRE

This document supplements guideline recommendation 19 about the use of tamoxifen for the management of post-menopausal women with hormone receptor-positive early breast cancer contained in the NBOCC *Clinical practice guidelines for the management of early breast cancer,* 2nd edition, 2001 (page 9)



NATIONAL BREAST CANCER CENTRE
Incorporating the Ovarian Cancer Program

JULY 2006 | Incorporates published evidence to May 2005

RECOMMENDATIONS FOR

Aromatase inhibitors as adjuvant endocrine therapy

for post-menopausal women with hormone receptor-positive early breast cancer

A CLINICAL PRACTICE GUIDELINE DEVELOPED BY THE NATIONAL BREAST CANCER CENTRE (NBCC)

This document supplements guideline recommendation 19 about the use of tamoxifen for the management of post-menopausal women with hormone receptor-positive early breast cancer contained in the NBCC *Clinical Practice Guidelines for the Management of Early Breast Cancer,* 2nd edition, 2001 (page 9).[1]

PURPOSE

To provide statements and recommendations, based on the best available evidence, about the use of aromatase inhibitors as adjuvant endocrine therapy for post-menopausal women with hormone receptor-positive early invasive breast cancer.

BACKGROUND

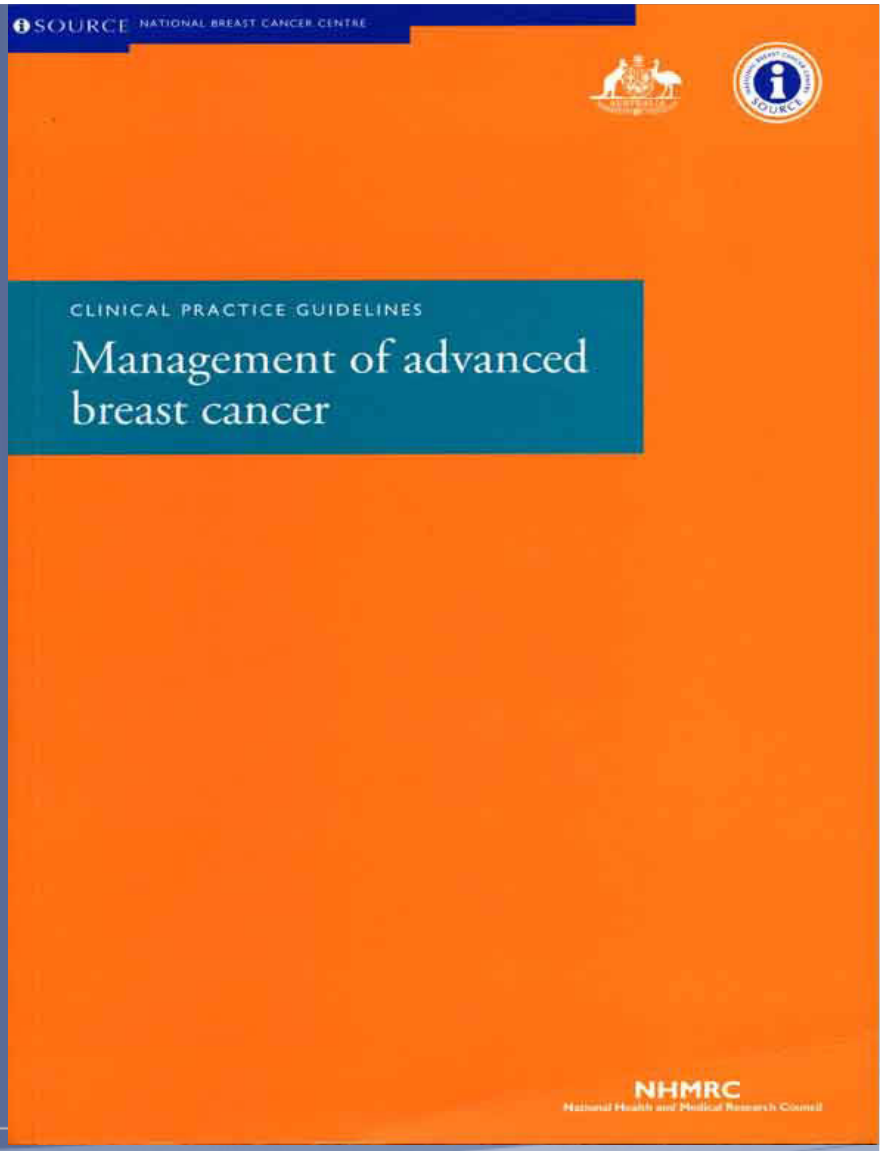
Aromatase inhibitors are a class of endocrine drugs that are suitable for post-menopausal women with hormone receptor-positive breast cancer. They are ineffective in pre-menopausal women, including those rendered amenorrheic by chemotherapy who subsequently regain menstrual function.

Endorsed by:

The Royal Australasian College of Physicians

NATIONAL BREAST AND OVARIAN CANCER CENTRE

NBOCC
Clinical practice guidelines for the management of advanced breast cancer,
2nd edition, 2001



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Clinical Practice Guidelines for the management of advanced breast cancer, 2nd edition 2001

Updates:

- Recommendations for use of trastuzumab (Herceptin®) for treatment of HER2-positive breast cancer – (March 2007)

- Recommendations for the use of endocrine therapy for the treatment of hormone receptor-positive advanced breast cancer – (June 2008)

Updates in production:

- Recommendations for the use of chemotherapy for treatment of advanced breast cancer

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What do clinicians think of CPG's

- 153 Surveys of CPGs; 11,611 responses
- Response rate 72%

Overview paper: MJA: 2002;177;502-505

» Helpful resource 75%
» Good educational tool 71%
» Intended to improve quality 70%
» Too rigid 30%
» Reduce physician autonomy 34%
» Increase litigation 41%
» Intended to cut health care costs 52%

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Evaluation

1998 : Greater Western Area of Sydney

- 74% aware of the guidelines
- Only 20% felt guidelines influenced their practice
- BUT 46% agreed they would improve outcomes

Ward J et all MJA 1998;169; 292-293

National Breast Cancer Audit

Key Clinical Indicators: e.g.

- Breast Conservation Rates
- Use of RT after Breast Conservation
- Use of sentinel node biopsy
- Use of Herceptin in Her2+ve breast cancer
- No Axillary Dissection after DCIS excision

NBCA

Proportion of women who had sentinel node biopsy

By location

- 65% major cities
- 54% inner regional
- 47% remote locations

By age

- 57% women under 40 years
- 63%-68% women 40-69 years
- 56% women 70-79 years

By referral source

- 73% women referred through BreastScreen
- 56% women with symptomatic presentation

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Proportion of women who had chemotherapy

- 89% women under 40 years
- 58% women 50-59 years
- 40% women 60-69 years

Proportion of women undergoing breast reconstruction

- 13% major cities
- 5% inner regional
- 2% remote locations

Proportion of women undergoing breast conserving surgery

- 74% BreastScreen referrals
- 56% symptomatic presentations

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Guidelines do make a difference

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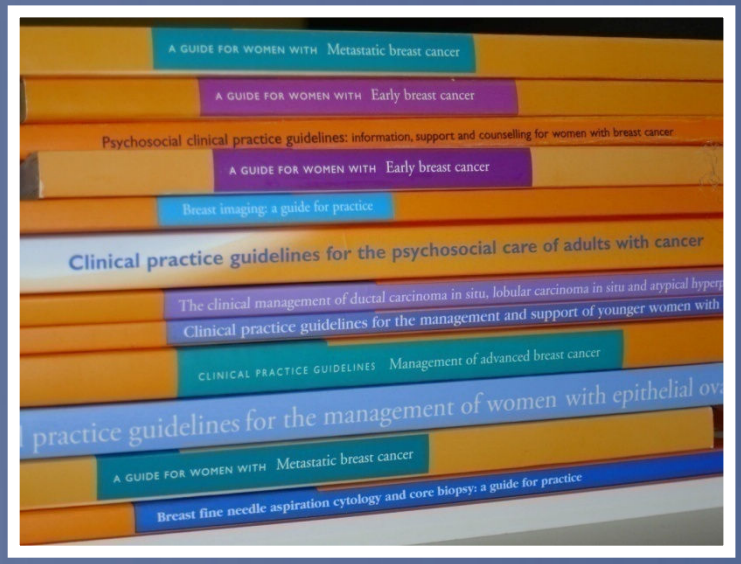
www.nbocc.org.au



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