

The National Breast Cancer *Audit*

Process for managing outliers in breast cancer surgery



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Prepared by:

Australian Safety & Efficacy Register of
New Interventional Procedures – Surgical

On behalf of:

The Section of Breast Surgery
and
The Royal Australasian College of Surgeons



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Introduction

The purpose of this document is to describe the process that has been developed to identify and manage surgeons who are shown to be outliers in the surgical treatment of early breast cancer.

The National Breast Cancer Audit (NBCA) collects data from surgeons in Australia and New Zealand on the treatment of early breast cancer. An audit clinical advisory committee (ACAC) oversees the audit and has established two subcommittees to enable the NBCA to become a fully functioning clinical audit according to the definition provided by the National Institute of Clinical Excellence (UK). One subcommittee has overseen the development of quality thresholds and the second has evaluated ways of identifying and managing outliers. The development of quality thresholds is critical to the process of identifying outliers as it provides a yardstick against which surgical treatment can be measured. The aim is to develop standards for treatment modalities which are supported by good quality evidence and expert consensus. The outlier process provides a framework for applying the quality thresholds to individual surgical practice. The outlier process is not intended to be punitive, rather to be informative and educative to ensure the treatment of early breast cancer in Australia and New Zealand is of the highest possible quality.

Adequate dissemination of information to surgeons will be of high priority to ensure that the process of using quality thresholds in clinical audit is well understood.

Abbreviations

ACAC	Audit Clinical Advisory Committee
BCS	Breast Conserving Surgery
DCIS	Ductal carcinoma in situ
NBCA	National Breast Cancer Audit
RACS	Royal Australasian College of Surgeons

Development of quality thresholds

In order to develop quality thresholds it was first necessary to identify key issues surrounding the surgical treatment of early breast cancer. From each key issue an indicator was developed and, from the indicator, a value for each quality threshold could be derived.

A **key issue** is defined as:

A clinical practice agreed by the current evidence base and/ or expert consensus to result in better clinical management of patients with early breast cancer.

An example of a **key issue** is as follows:

“Women with early breast cancer should be prescribed tamoxifen where appropriate.”

An example of an **indicator** is as follows:

“The percentage of suitable women prescribed tamoxifen”

The values for each **quality threshold** were derived from these quantifiable indicators.

The minimum standards subcommittee identified six key issues which had well defined, unambiguous indicators (see Table 1).

Table 1: Key Issues and Indicators

	Key Issue	Indicator
1	Referral for radiotherapy after BCS for invasive cancer and DCIS	Percentage of invasive cancer patients referred for radiotherapy after BCS Percentage of DCIS patients referred for radiotherapy after BCS
2	Offering or prescribing hormonal treatment for oestrogen receptor positive tumours	Percentage of patients referred or prescribed hormonal treatment for oestrogen receptor positive tumours
3	Axillary staging for invasive cancers	Percentage of invasive cancer patients undergoing axillary surgery
4	No axillary surgery for DCIS patients	Percentage of DCIS patients undergoing axillary surgery
5	Clear margins for BCS in both invasive cancers and DCIS	Percentage of invasive cancer patients with clear margins Percentage of DCIS patients with clear margins
6	Offering BCS to women with apparent unifocal lesions on pre-operative assessment	Percentage of patients with unifocal tumours who received BCS

At the present time, the audit does not address the last key issue/ indicator (offering BCS to women with apparent unifocal lesions on pre-operative assessment).

Quality thresholds have been developed for the other five key issues / indicators based on expert consensus and an evaluation of the clinical data entered into the audit; these are shown in Table 2.

Table 2: Quality thresholds

	Description	Quality threshold
1	Percentage of patients with invasive cancer treated with breast conserving surgery who were referred for or prescribed radiotherapy	=85%
2	The percentage of patients referred for or prescribed hormonal treatment for oestrogen positive tumours	=85%
3	The percentage of patients undergoing axillary surgery for invasive cancer	=90%
4	The percentage of DCIS patients undergoing no axillary surgery	=90%
5	The percentage of invasive cancer patients with clear margins	=95%

The NBCA has established a working relationship with the National Breast Cancer Centre in Sydney, to facilitate the process of reviewing the evidence-base for important key issues where the current evidence-base is poor.

Additional key issues and indicators

In addition to the key issues and indicators shown in Table 1, a further list of key issues was identified as clearly being important to current good clinical practice. This list is more problematic either because the indicator is difficult to quantify or the current evidence-base is not strong. Table 3 shows these key issues:

Table 3: Key issues and indicators - under development

Key issue	Indicator under development	New data item(s) required?
Referral to Medical Oncologist for moderate/high risk cases	Percentage of patients with intermediate or high risk of recurrence, who are referred to a medical oncologist	Was this woman referred to medical oncologist <input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Not available
Referral to a breast care nurse before surgery	Percentage of patients having contact with a breast care nurse between being informed of a diagnosis and having definitive surgery	Was this woman referred to a breast care nurse prior to surgery? <input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Not available
Referral to Radiation Oncologist for high risk cases after mastectomy	Percentage of patients with intermediate or high risk of recurrence after mastectomy, who are referred to a radiation oncologist	The definition of 'high risk' patients is under review.
Multidisciplinary care management of patients	Percentage of patients with evidence of multidisciplinary care team management discussion having taken place as defined by an agreed local protocol	What method of multidisciplinary care was used in treating this patient? <input type="radio"/> None <input type="radio"/> Individual practitioner model <input type="radio"/> Forum minus breast care nurse and allied health professionals <input type="radio"/> Full forum including breast care nurse and allied health professionals <input type="radio"/> Other

For mastectomy patients, discussion of reconstruction occurring prior to mastectomy	No indicator proposed at present	Under discussion.
Screening of women for likely depression/psychosocial morbidity and referral to appropriate care	No indicator proposed at present	Under discussion.
Provision of suitable information on breast cancer related issues to the patient		<p>Was this patient provided with one or more of the following items?</p> <ul style="list-style-type: none"> ○ Printed information (language and culturally appropriate?) ○ Information on how to access relevant Internet sites (if requested?) ○ Contact details of appropriate support networks (such as the BCNA, state cancer help lines, etc....) ○ Provision of the NBCC document 'A guide for women with early breast cancer' (either by yourself or a staff member?)

Although quality threshold values cannot as yet be derived from these key issues, the literature will continue to be reviewed to ascertain whether any changes in the evidence-base have occurred and where possible data will be collected, with a view to considering their addition as a quality threshold at a later stage.

Outlier process

1. Identification of outliers

Audit staff will review participant's de-identified audit data against the quality thresholds on a six-monthly basis. If a surgeon's results fall outside the quality thresholds a report will be prepared and submitted to the Breast Section Review Group and ACAC. The report will not include the surgeon's name.

2. Assessment of report by Breast Section Review Group

The report will be reviewed by a Breast Section Review Group composed of three surgeons from the Breast Section Executive. The Review Group may request further data analysis from the audit staff at this time. The Review Group will determine whether there is any clear clinical justification for the variation from the quality thresholds, or whether further action is required. The Breast Section Review Group is then required to report their results to the full Executive of the Breast Section.

3. Review of audit results with identified surgeon

Where there appears to be no clear clinical justification for variation from the quality thresholds, the Breast Section Review Group will request the surgeon's identity from the Audit Manager. The surgeon will be identified to one member of the group ideally from another State, who will make contact with the surgeon to discuss his/her results. The identified surgeon will be given adequate time to prepare any relevant material or information prior to the full discussion of audit results, to enable them to justify their practice and to support discussions. The aim of this discussion would be to gain more information about the surgeon's practice and /or to make suggestions for the surgeon to consider which would align their practice more effectively with the quality thresholds. The Review Group member will follow-up the discussion with a letter to the surgeon outlining the outcomes of the meeting. If the results suggest that a change in practice is necessary, the surgeon will also be informed that his / her results will be reassessed. The surgeon has the right to appeal any decision to the Breast Section Executive.

4. Reporting requirements of the Breast Section Executive

For all surgeons whose practice has required investigation by a member of the Breast Section Review Group, a report must be submitted by the Breast Section Executive to the ACAC, informing them that:

- A 'no action' decision has been made with reasons, or
- Dialogue has been established with the surgeon.

5. Ongoing assessment of surgeons where a suggestion has been made for practice change

Where a surgeon's performance has resulted in a recommendation to better align practice with the quality thresholds, that surgeons' audit data will be reviewed again after six months. A report of these findings will be issued to the Breast Section Review Group and to the surgeon. A copy of this will go to ACAC, but will not identify the surgeon. The Breast Section Review Group will ascertain whether any recommended improvements in practice have taken place since the first evaluation. The Breast Section Review Group will inform the Breast Section Executive of their review of practice (i.e. acknowledgment of improvement or requirement for further discussions with surgeon), and undertake further dialogue where necessary. The surgeon will be informed of the results of their review. The Breast Section Executive will report the results back to ACAC.

6. Action to be taken where improvements in practice are not found after an agreed period of time

In the rare event that further action is necessary after either:

- Two six-month review periods or
- The Breast Section Executive forms the view that the surgeon's performance is significantly outside the quality thresholds and /or is posing a significant risk to patient safety to warrant taking action earlier.

The surgeon will have his/her status as a full member of the Breast Section of RACS reviewed, with a possibility of a termination of their full membership status. The RACS Council would be notified if full membership is revoked and could consider further action if it was felt this was warranted. The RACS Council will provide reports to ACAC regarding the outcome of any action that they have taken against a surgeon.