Prepared by:
Australian Safety and Efficacy Register of New Interventional Procedures – Surgical

On behalf of:
The Section of Breast Surgery
And
The Royal Australasian College of Surgeons

With support from:
The Australian Council for Safety and Quality in Health Care

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At its inception the National Breast Cancer Audit (NBCA) was designed as an information tool for breast surgeons who wished to self-audit. However, it was recognised that self-audit was not an adequate means of ensuring high quality breast cancer surgery. The focus of the NBCA subsequently changed to become a full clinical audit where data is collected and surgical practice is assessed against pre-defined standards. Currently 296 surgeons are contributing data to the audit. Participation is a mandatory requirement for full members of the Breast Section.

Substantial progress has been made towards developing and implementing a full clinical audit. The online data entry system was launched in May 2004. Standards for the surgical treatment of breast cancer in Australia were developed and a process for evaluating and reporting surgeons’ results was ratified by RACS Council and endorsed by members of the RACS Breast Section in May 2005. The Breast Section Executive has worked closely with audit staff and committee members to develop a number of quality thresholds against which the audit data can be compared. A document was received by all audit participants describing these quality thresholds. Furthermore, participants received details of a process to be trialled during 2006/7 for surgeons whose results appear to lie outside of these thresholds.

Following the adoption of a Web-based system of data entry in May 2004, the number of breast cancer episodes has risen from 17500 to over 40000. A new web-based system will be introduced in 2006 that will enable surgeons to assess their results compared with the quality thresholds for the 5 key performance indicators.

In 2005, the audit data was interrogated for details about the management of Ductal Carcinoma In-Situ and to provide a “snapshot” of breast cancer surgery and the use of adjuvant therapies for women with early breast cancer. The results were presented at scientific meetings and have been published in scientific peer-reviewed journals. A useful collaboration with the National Breast Cancer Centre was established to enable this important research to come to fruition. In accordance with SQOF funding requirements, State Representatives received reports showing aggregated results for each state. In 2006, the data will be interrogated for issues relating to the management of breast cancer in young women, the elderly and re-excision rates after breast-conserving surgery for invasive/In-situ breast cancer.

It is anticipated that the full-audit cycle will be implemented within the next few years. The success of this process requires the support of all participating surgeons and the RACS. I am particularly grateful for the administrative support provided by Professor Guy Maddern, Mrs Maggi Boult, Ms Sarah Tyson and the Audit staff at ASERNIPS.
Two valuable members of the team, namely Dr Wendy Babidge and Ms Astrid Cuncins-Hearn, have left to pursue new endeavours within the Royal Australasian College of Surgeons and I wish them well. I welcome Dr Tabatha Griffin, Ms Kerin Williams and Ms Claire Miller to the NBCA administration team and am confident that their previous experience will help with the expansion of the audit.

I thank the State Quality Officials Forum for the invaluable financial support provided over the last three years. Although there are significant funding issues in the immediate future, I hope that the various government funding bodies view the NBCA as a priority funding project to ensure high quality surgical care for Australian women with breast cancer.

MR JAMES KOLLIAS               Clinical Director, National Breast Cancer Audit
2. executive summary

Organisation & Governance
The National Breast Cancer Audit is part of the Australian Safety and Efficacy Register of New Interventional Procedures – Surgical (ASERNIP-S) and is overseen by the Research & Audit Division of the Royal Australasian College of Surgeons (RACS).

Governance for the audit is provided by an Audit Clinical Advisory Committee, comprising experts from many areas responsible for the treatment of breast cancer.

Audit mission
- To improve the surgical care and management for all people with early breast cancer in Australia through the careful collection and analysis of audit data and the application of a full cycle of clinical audit.
- To keep up to date with changes in treatment based on available evidence and ensure wide dissemination of this information to practitioners.

Audit progress
During 2005 and early 2006 progress was been made towards the developing of the minimum standards and outlier process. A new Declaration as a Quality Assured Activity (Qualified Privilege) was obtained from the Minister for Health & Ageing. A new online data entry system has also been developed.

Entry of episodes of early breast cancer has increased significantly. In early 2004 there were 17,500 cases. This rose to 30,000 at the time of the last report and is reported here to be over 40,000.

Funding
Funding has been provided by the State Quality Officials Forum through the Australian Council for Safety and Quality in Health Care.
The concept of establishing a compulsory form of accreditation and audit process for the treatment of breast cancer was first expounded in Australia in 1995 by the House of Representatives Standing Committee on Community Affairs. An audit of early breast cancer was subsequently initiated in 1998 under the auspices of the Royal Australasian College of Surgeons. The audit (currently referred to as the National Breast Cancer Audit) has progressed through a number of phases. Starting as a small pilot project for surgeons in Tasmania and South Australia, it now extends to the whole of Australia and New Zealand. Originally devised as a means for surgeons to review their own work, it is being developed into a more transparent audit with results reported to government, hospitals and surgeons.

The overall aim of the audit is:

- To improve the surgical care and management for all people with early breast cancer in Australia through the careful collection and analysis of audit data and the application of a full cycle of clinical audit.

- To keep up to date with changes in treatment based on available evidence and ensure wide dissemination of this information to practitioners.

Much effort has been put into developing the necessary infrastructure to create a fully functional, well respected and useful clinical audit. Evolving issues have included the use of appropriate methods for data collection, ensuring surgeon and stakeholder support, identifying evidence-based benchmarks and developing a process for identifying surgeons who do not meet these benchmarks (known as an outlier process). Together, these will enable a full cycle of quality improvement to take place.

During the last eight years, surgeons have continued to provide a strong support base for the audit despite uncertainty at times about its progress, rationale and funding. This support is of paramount importance as participation in the audit remains semi-voluntary. Full members of the Breast Section are required to participate in the audit; however surgeons can perform breast cancer surgery without becoming members of the Breast Section. The ongoing goodwill of the surgical community is essential to the success of the project.
4. key successes and constraints in developing and maintaining an audit

Key successes
To be regarded as successful an audit must become well recognised as a useful and effective quality improvement tool. Ground breaking areas that the office of the National Breast Cancer Audit has tackled have included the development and implementation of the online data entry system and the development of minimum standards and an outlier system. Ensuring that the audit is backed by robust methodology has been essential to its success.

Whilst developing these processes has been important, the recognition that the whole audit process and methodology for data collection must themselves undergo continuous improvement is also essential to its ongoing success.

It is also essential for the success of a surgical audit that effort is put into developing and maintaining effective lines of communication with key stakeholders, surgeons and the relevant specialty groups. Our relationship with the NBCC and BCNA has been critical, as has the endorsement by the Section of Breast Surgery.

Recognition that an auditing activity is valued by Government is another factor that influences its success. The NBCA has been fortunate to have had this support from the Federal Government thus recognising its role as a tool for improving the quality of surgical treatment of early breast cancer on a national level. Communication with state governments is also vital to inform them of practice measures in their jurisdiction and enables their input to the NBCA initiative. We hope that the provision of information to hospitals will also bring them on board to be partners in this process.

Audit constraints
One of the major constraints for the NBCA has been the failure to obtain long-term funding. This impedes the development of long-term projects. For instance, due to the lack of a cohesive funding structure for 2006 a number of projects have necessarily been put on hold including statistical validation of the outlier process, production of new research papers using audit data, communicating with managers of institutional databases and obtaining data from these sources, evaluating the evidence for the minimum thresholds and the development of new thresholds.

The NBCA has staked a great deal in outlaying resources for the online data entry system. There are a number of very compelling reasons for using such a system, however its utility depends on effective internet access (preferably broadband) and a reasonable level of computer literacy. The former has been a problem for a small number of users, notably rural based surgeons and the latter may be a generational problem which will be overcome with time. Overall the system has
been well received and has been commended by a number of users; however, continued effort will need to be focussed in this area to ensure total success.

A converse of developing strong working relationships with key stakeholders is the damage that can be done by well-placed outspoken critics, especially those with a vested interest in other commercial audit applications. It is not clear how this can be countered other than by continuing to present a quality product.

In order to run a good audit, it is essential to have excellent staff who are trained in a number of specialised areas. To date the NBCA has been exceptionally lucky to have stable and well trained personnel. However it is apparent that staff with skills in this area are often undervalued with the misguided belief that the work can be undertaken by office administrators or untrained personnel. The Australasian Health Research Data Managers Association (AHDMA) has long recognised this problem and has attempted to overcome the lack of recognition in this area.

In addition to trained personnel available to run the audit, success depends strongly on active participation by surgeons. We believe we have been fortunate in this regard due to our partnership with the Section of Breast Surgery but note that the audit is semi-voluntary and unremunerated. These are issues that affect audits in general whereby practitioners are expected to give freely their own time to participate in such initiatives. That is why it is critical to ensure that the activity has significant benefit for participants and that their employees, the hospitals, are made aware of the significant burden placed on their surgeons whilst also recognising the value to their operations of such a quality improvement initiative.
5. project activities

This section reports against project activities outlined in the 2005 “Contract for Services between the Commonwealth of Australia as represented by the Department of Health and Ageing and the Royal Australasian College of Surgeons in relation to services for the National Breast Cancer Audit” (the Contract). An update of activities undertaken since the last progress report is provided in addition to lessons learned and barriers to progress.

Participation in the audit

Participation of surgeons

To ensure participation in the audit was routinely performed by breast surgeons, the Executive of the Breast Section ruled in 2005 that full members of the Breast Section must submit their data to the audit. The Section surveyed their members to ensure accurate membership figures. In February 2006, 266 surgeons were listed as Full Members of the Breast Section; 227 from Australia and 39 from New Zealand.

Currently the breast audit database contains over 40,000 episodes of early breast cancer from 296 surgeons. The location of these surgeons can not be derived from the data in the breast audit database because the hospital field has not been a mandatory data item (although it will be in the new system). However, the audit team have a separate database with contact details for 259 of those surgeons, 214 in Australia and 45 in New Zealand. The locations of the Australian surgeons are shown in Table 1.

Table 1

<table>
<thead>
<tr>
<th>Total number of surgeons contributing to audit in Australia</th>
<th>216</th>
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<tr>
<td>Inner regional Australia</td>
<td>67</td>
</tr>
<tr>
<td>Major cities of Australia</td>
<td>131</td>
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<tr>
<td>Outer regional Australia</td>
<td>14</td>
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<td>Remote Australia</td>
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The locality figures were created by matching the surgeons’ postcodes to the Australian Standard Geographical Classification (ASGC) remoteness classification\(^1\). However, it should be noted that there may be a disparity between the surgeons’ contact address and practice address.

The availability of an accurate membership list for Full Members of the Breast Section has ensured that surgeons can be easily contacted to facilitate appropriate participation.

\(^1\) 2909.0 - Statistical Geography: Volume 3 - Australian Standard Geographical Classification (ASGC) Urban Centres/Localities, 2001
Barriers to increasing participation in the audit

There are several barriers to increasing participation in the audit. These include: engaging surgeons who are not full members of the Breast Section, defining participation, the amount of (unremunerated) time necessary to enter data, understanding and use of technology (eg. the online data entry system), concerns over how the collected information will be used and insufficient access to government data.

Engaging surgeons who are not full members of the Breast Section

A surgeon does not need to be a full member of the Breast Section to perform surgery for breast cancer and participation in the audit is currently voluntary for these surgeons. The precise number of Breast Section members is now known, but no such precise figure is available for non-members. This group would consist mainly of general surgeons, many practicing in a rural setting. It is unlikely that many general surgeons would wish to become a member of the Breast Section if breast surgery is not a major part of their practice. Around 100 non-member surgeons have contributed data to the audit. The only possible way in which the number of surgeons in this group could be accurately obtained would be if there was access to a centralised government resource that recorded procedures for surgeons operating in the public and private sector.

Defining participation

It should also be noted that whilst participation in the audit is compulsory for full members of the Breast Section, a working definition of what constitutes participation is still under development.

Unremunerated time needed to participate

Entering data into the audit requires a degree of uninterrupted time. Estimates as to how long it takes to enter one episode vary from 5 to 30 minutes. This will depend on the method used to enter data and the need to use diverse sources of information. The fact that 40,000 episodes have been entered into the audit suggests a reasonable amount of ‘good will’ towards what is essentially an unpaid activity. It is crucial that this good will is maintained and encouraged. In order to achieve this, surgeons should feel that they are obtaining in return something of value that will help them improve their practice. This will be achieved by keeping them fully informed of all new developments and thus engaged in the process of audit development. Tailoring reports that will be of use to surgical practice and developing evidence-based practice guidelines may also be of use. A healthcare system that recognised the benefit of auditing and could ensure that time and resources were made available for this activity should be seen as a high priority.
Use of information technology

Surgeons are encouraged to enter their data into the online data entry system. This system has been fairly slow for some users – specifically those without access to broadband. To overcome this, two strategies will be tested during the next year. The first results from the development of an improved new data entry system which has been engineered to be faster and more responsive. The NBCA is also currently in discussion with the ‘Broadband for Health’ program, part of the Australian government’s HealthConnect Implementation Strategy, in an attempt to secure fast internet access for surgeons, particularly those in rural or remote regions.

In the past, a number of surgeons have continued to use a Microsoft Access database system which had been distributed prior to 2003. During 2005, information was still being received in this format from a number of surgeons; however this version of the Access database did not have two of the most recently introduced data points (e.g. hospital and public or private status of patient). With the development of the new online system, which has incorporated further change in the data points collected, the Access database will no longer be supported. The NBCA called a data moratorium at the end of 2005 and the remaining Access database users were encouraged to consider entering their data using the new online system. For those users without access to fast internet connections, submission of data on paper forms will remain an option.

Concerns over how information will be used

Another continuing barrier to participation is overcoming surgeons’ concerns over how their information will be used (e.g. reporting to bodies such as hospitals and state departments of health). As described previously, surgeons must be reassured that this reporting will be used to effect system changes which are generally beyond his/her control and would be of use to the surgeon. An example of this would be if women treated in rural centres are found to have inadequate access to resources such as breast care nurses or radiologists then hospitals or state departments of health could target resources to improve the system.

Access to Government figures

As described above, if it is possible to access Government figures relating to the number of procedures for early breast cancer being undertaken by hospital and/or surgeon for public and private patients this would provide useful information on which to base decisions on participation quotas for individual surgeons. In 2005 we were advised to obtain permission from State Health representatives in order to obtain access to this information in some form. Originally contact with these representatives was to be undertaken via the Secretariat for the Australian Council for Safety and Quality in Health Care. However, with the closure of this office prior to the launch of the Commission we were provided with contact details for all State Quality Officials. Letters were sent to these representatives, however, only one response was obtained. In view of the dissolution of this group, the timing of our approach was clearly inauspicious and became a major barrier to obtaining access to this information.
**Data transfer from institutional databases**

The requirement to augment the data in the NBCA database by transferring data from other institutional databases is outlined in the Contract. This is an important strategy towards improving participation and avoiding double data entry. A survey conducted by the NBCA found 74 data institutions that claimed to be collecting data for early breast cancer treatment performed at one or more hospitals.

In 2005, the NBCA received data from seven data institutions. Three submitted data using the old Access database and hence their fields and data format were compatible with the main audit database (although they did not include more recent data fields such as hospital and public/private status of patient). These three institutions included data from a total of 18 surgeons and the information was easily added to the database.

Three other data institutions submitted data that required major transformation into the NBCA format in order to upload it into the database. These three institutions included data for a total of 19 surgeons (and 2605 episodes of early breast cancer treatment).

One additional institution sent in data that could not be transformed into the NBCA format due to the provision of inadequate information. This included data on 1804 cases from seven surgeons. The NBCA is still in discussions with this institution about this.

Recruiting data institutions to submit data to the NBCA is a substantial task, in both size and complexity. It requires the full evaluation of the following issues for any given institution:

- Do any, or all, of the surgeons from the institution independently submit their data to the audit?
- What data fields are captured in the institutional database and do they correspond to those required for the NBCA?
- Can information be released from the institution to the NBCA (i.e. have patients consented to this and has the process been approved by the hospital ethics committee)?

Once these issues have been resolved, the process of entering/importing the data from an institution can be time consuming and requires skilled personnel. It is necessary to carefully crosscheck all the data with the most recent version of the NBCA data dictionary to ensure compliance. Whilst a few institutional datasets have been modelled on the RACS dataset, most institutions have developed their own. This latter scenario usually means that transformations are required to get the data into the appropriate format and decisions as to whether there is sufficient information available in the institutional database to warrant its inclusion. In addition, institutions that have been based on the RACS breast audit will now need to change their data fields to realign them with the new online system.
The issue of using institutional data is extremely important but very resource intensive. With insufficient ongoing funding for the audit this project will not be supported. It is estimated that to undertake the project adequately, one full time position for one year would be required.

**Reportage**

This section details the provision of information about the audit to surgeons and other stakeholders as well describing the use of audit data to further the understanding of the treatment of early breast cancer.

**Provision of information to surgeons and other stakeholders**

**Surgeons**

Awareness of the audit is critical to its success. During 2005 the following efforts were put into ensuring that surgeons performing breast cancer were made aware of the audit. Firstly, the audit was promoted at the Royal Australasian College of Surgeons (RACS) Annual Scientific Congress in May 2005, both in conference presentations and via an information stand. Secondly, an informative article was prepared for “Surgical News”, a publication received by all Fellows of RACS. Thirdly, letters were sent to full members of the Breast Section regarding the progress of the audit and a bi-annual newsletter has been implemented. Lastly, an article was prepared for circulation in the Rural Surgeons Newsletter.

The online data entry system provides surgeons with a method for downloading (into an Excel spreadsheet) all of their patient data that has been entered into the audit. This is useful for surgeons who wish to analyse their own data or create a hospital / clinic resource. This latter could be achieved if several surgeons at a clinic wanted to review their data – each could download their spreadsheet and a master spreadsheet could be created.

Alternatively, “graphical series” reports are available for download. These automatically calculate the surgeon’s results for a number of parameters and present them along with the aggregated results for the audit for the following items.

- Margins of clearance after complete local excision (CLE)
- Surgical interventions
- Tamoxifen prescription
- Women receiving Tamoxifen by age group
- Operations after CLE

The new online system also includes two new reports: the first provides the surgeon with a précis of his/her practice data and the second provides a case summary which can be inserted into the patients’ notes (Appendix 1).
Other audit stakeholders

Audit stakeholders include the Australian Government Department of Health and Ageing, State Departments of Health, hospitals, peak breast cancer organisations and consumer groups.

Reports which provide details of audit results will be prepared for the State government representatives and hospitals. The information contained in these reports was intended to be developed according to the stated requirements of the State representative group, the State Quality Officials Forum (SQOF). However, barriers to the preparation of these reports stem from the changing nature of this group as the Australian Council for Safety and Quality in Health Care moves towards becoming a Commission. SQOF representatives were provided with a copy of the audit data dictionary in order to apprise them of the information available and asked to inform the NBCA what information they would like to see included. Only one response was received and this did not address the information available, but referred to other government figures not presently available to the NBCA. As a consequence, reports will be prepared based on the prototype circulated in 2005.

The National Breast Cancer Council is a key breast cancer organisation and information has been made available to them via participation in the governance of the audit, through a presentation about the breast audit at their offices in Sydney and via a joint initiative to publish audit data during 2005.

Engagement of consumers has also been sought through the Breast Cancer Network Australia. Ultimately women will be advised to seek treatment by surgeons who are full members of the Breast Section. This will be undertaken once the Breast Section has finalised the working definition of what constitutes participation in the audit. Reports concerning the breast audit are available for consumers from the RACS website, however, information has not yet been targeted directly at this group of stakeholders. Information for the BCNA Newsletter, The Beacon, was submitted, but not published.

Reportage of audit data

A number of papers and posters concerning the audit were presented at the RACS Annual Scientific Congress (ASC) in May 2005. An information booth was also staffed by a member of the audit team for the duration of the congress.

To improve our dissemination strategy, a number of publications have been prepared for publication in a peer-reviewed journal. The NBCC financially supported and provided input during their production. These were prepared for publication during 2005 and to date, one has been accepted for publication by the Australian and New Zealand Journal of Surgery and the second is awaiting an editorial decision. A third article was published in this journal in October 2005.
A substantial list of potential research publications was developed in 2005 (Appendix 2). Some of these could be written using the audit data as it is, others would depend on the addition and collection of new data items. It is unlikely that this aspect of the audit will progress during 2006 given the lack of sufficient funding.

A list of audit presentations and publications for 2005 is shown below:

**Presentations**


Publications


Submitted for publication


Ethics, Privacy and Qualified Privilege

The NBCA obtained ethics approval for the activity through the RACS ethics committee, initially in 1998 and more recently in 2004.

Patient data entered into the audit does not include identifiers such as patient name, address or Medicare number.

Whilst the audit provides a means of assessing surgical treatment par excellence, the lack of personal identifiers prevents it being an outcomes audit. Although the Privacy Laws serve as a deterrent against the collection of personal identifiers thus ensuring higher level of privacy for the individual, this prevents information in the audit being cross-checked against the National Death Index or other national reporting methods for cancer and thus limits its use as a tool for evaluating effects of surgical treatment on outcomes such as survival.

Qualified Privilege was last obtained in 2005 for the NBCA. Although this cover lasts for five years, a new application will be submitted in the near future to determine whether provision of information to relevant hospitals can be undertaken if a surgeon appears to be underperforming. At the present time, reporting is limited within the RACS to the Breast Section.
Governance

The governance infrastructure for the audit is shown below:

![Governance Structure of the National Breast Cancer Audit](image)

*Fig. 1  Governance Structure of the National Breast Cancer Audit*

Governance had previously included an audit technical advisory committee (ATAC). However, as technical issues have lessened, the ATAC was dissolved and a number of members were co-opted into the ACAC.

There are two working parties that meet to develop minimum standards and the outlier process, and these two working parties report to ACAC.

The current membership of the audit clinical advisory committee (ACAC), minimum standards working party and the outliers working party is provided in Appendix 3.
Use of national audits and registers to drive clinical quality improvement

The overall aim of the National Breast Cancer Audit is:

- To improve the surgical care and management for all people with early breast cancer in Australia through the careful collection and analysis of audit data and the application of a full cycle of clinical audit.
- To keep up to date with changes in treatment based on available evidence and ensure wide dissemination of this information to practitioners.

The ability to improve the quality of clinical care is dependent on a number of factors: the ability to clearly define the type of care that is under observation, the development of evidence-based or universally accepted standards of care in this area, statistically meaningful measures of the care available, reliable methodology to identify areas requiring quality improvement, effective dissemination of information and the means to affect change.

There are a number of tools that are used in areas of healthcare to drive quality improvement including Total Quality Management (TCM) and Continuous Quality Improvement (CQI). TQM is sometimes used synonymously with CQI but generally refers to an organisation-wide application of improvement principals, which can be used to create a supportive environment for CQI activities to operate. Audits and feedback can be considered as part of the CQI armamentarium along with educational meetings, distribution of educational materials, outreach visits, use of local opinion leaders etc.

Unlike many hospital, health group, or State-based audits, the NBCA is a national clinical audit. Audit data is used to provide instant feedback to surgeons (passive feedback). The development of benchmarks and an outlier process will be used to target surgeons who are not reaching these standards (active feedback / educational outreach).

Jamtvedt et al undertook a systematic review of the effects of audit and feedback on professional practice and health care outcomes. The study indicated that audit and feedback can be useful with or without educational meetings, peer comparison or other complementary interventions. However the report does recommend that audit and feedback be used where it is likely to effect change, especially when adherence to recommended practice is low.

The NBCA is a large-scale, well supported audit. If the audit has sufficient funding to continue, it will be able to show whether surgeons have changed their practice in line with the recommended benchmarks.

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1 Almaraz 1994 Quality management and the process of change. J Organisational Change Management. 7(2):6-15
**Progress in establishing benchmarks**

The process of establishing standards of care was undertaken by a working party formed from members of the ACAC. The working party based their work on the Australian Guidelines for the treatment of early breast cancer and DCIS management\(^1\). In addition they drew on expert consensus, an evaluation of the evidence supporting each standard and the audit data.

In order to identify quantitative measurements of surgical care it was first necessary to identify the key issues surrounding the surgical treatment of early breast cancer. Each key issue was then evaluated to determine whether a quantifiable indicator could be developed. An example of a key issue and quantifiable indicator are as follows:

**Key issue:**

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

**Indicator:**

“The percentage of suitable women prescribed tamoxifen”

Once an indicator was developed the audit data was analysed to help decide what practical value could be used as a “quality threshold”.

**Quality threshold:**

Definition: “a pragmatic but arbitrary value chosen to represent the provision of good quality care to patients”

Example: the percentage of patients referred for or prescribed hormonal treatment for oestrogen positive tumours should be \(\geq 85\%\)

Following the first round of meetings, five key issues were identified which had well defined, unambiguous indicators, reasonably high-level evidence and which could be evaluated using audit data. These were developed into the quality thresholds shown in the following table.

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These quality thresholds were ratified by the ACAC, the Breast Section and the RACS. Documents outlining the thresholds were circulated to surgeons in June 2005. However, in the process of updating the website and reviewing data points the decision was made to significantly change how margin data is collected. This changeover means that clear margins cannot be calculated using the old data and there will need to be a period of data collection before it can be used as a quality threshold.

The work of establishing quality thresholds is a dynamic and ongoing task. In December 2005, the minimum standards working party met and defined the following terms of reference for the group:

- Review evidence for quality thresholds
- Consider the addition of data points for key issues with well defined indicators
- Determine whether the evidence base has improved for key issues/indicators under review and/or whether there is any practical resolution to quantifying indicators
- Addition of new key issues and indicators

**Evidence-base:** It was recognised by the group that there should be an ongoing effort to seek out high quality evidence on which to base further quality thresholds (and to further support the current thresholds). This process will require a reasonable level of support and can only occur if sufficient resources are available. The group could see the benefits of co-ordinating this activity with those undertaken by the National Breast Cancer Centre.

**Addition of new data points to support key issues:** A number of key issues and indicators had been identified during the first round of meetings, however in some cases the audit did not collect the necessary data. Discussions have continued to determine how these key issues can be

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<th>Description</th>
<th>Quality threshold</th>
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<tbody>
<tr>
<td>1  The percentage of invasive cancer patients with clear margins</td>
<td>≥95%</td>
</tr>
<tr>
<td>2  Percentage of patients with invasive cancer treated with breast conserving surgery who were referred for or prescribed radiotherapy</td>
<td>≥85%</td>
</tr>
<tr>
<td>3  The percentage of patients referred for or prescribed hormonal treatment for oestrogen positive tumours</td>
<td>≥85%</td>
</tr>
<tr>
<td>4  The percentage of patients undergoing axillary surgery for invasive cancer</td>
<td>≥90%</td>
</tr>
<tr>
<td>5  The percentage of DCIS patients who underwent breast conserving surgery undergoing no axillary surgery</td>
<td>≥90%</td>
</tr>
</tbody>
</table>
used and whether well defined, appropriate data items can be added to the database or if the issue can be evaluated through the use of a practice survey. An example of the latter is the use of multidisciplinary care and breast care nurses in a practice. The group believe these issues will be better resolved by survey rather than adding a data point to the audit that would need to be answered each time a new episode of breast cancer is entered.

**New key issues and indictors:** As new information becomes available and changes are made in the treatment of early breast cancer it will be appropriate for the working group to continue with its work of developing new key issues and indicators.
Development of an outlier process

In 2005, a process to describe how the clinical care of patients with early breast cancer would be assessed was developed by a working party of ACAC (the outlier working party). The iterative process of identifying outliers, reporting, reviewing, action and reassessment was ratified at the same time as the quality thresholds. A document outlining the combined information was posted to all full members of the Breast Section and they were asked to consent into this process. To date consent has been received from 90% of the Breast Section members.

Before the outlier process can be implemented, external statistical advice will be sought to develop a robust and transparent process to determine whether or not a surgeon is adequately meeting the quality thresholds. The NBCA has been in contact with statisticians regarding this, and is currently seeking confirmation of continued funding to proceed.

The Breast Audit outlier process was not fully accepted by the funding body and discussions continued after the distribution of the document and consent sheets to surgeons. The main point of contention was the end point of the process (i.e. the limits to reporting the actions of a surgeon). In the circulated document the final stage of the outlier process for a surgeon whose practice had been found to be below standard was that:

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.

The SQOF believed that surgeons in this category should have their results reported to the hospital and possible also relevant medical boards. The RACS has accepted that notification of hospitals is an appropriate end point for surgeons under certain circumstances. However it remains to be seen whether a quality assurance activity with the potential to widely disseminate results will obtain the necessary Qualified Privilege cover. In addition, the trust of surgeons who participate in what is effectively a voluntary unpaid activity must be gained so that they continue to support the audit under these circumstances. Surgeons need to be assured that reporting to hospitals will only ensue as the endpoint of the outliers process, following an inability to improve practice up to the expected standards and following significant input from the practitioner concerned. The onus of detecting surgeons who are engaging in unsafe practices is clearly of enormous importance but is likely to be reflected in a very small number of cases. The most significant quality improvement is likely to come from identifying deficient practice patterns not resulting from inappropriate care by the practitioner but more so the setting that they are working in.
The online data entry system

The first online data entry system was launched to surgeons in May 2004. Since then, a six month post-implementation evaluation was conducted which provided information on the following:

- help desk activities and reported errors
- response time of the online system for entering data and downloading reports
- server down-time (planned and unplanned)
- uptake of users switching to the website (from other methods of data entry)
- feedback on the usability of the online system
- feedback on the relevance of the data points and usefulness of the reports.

The information gained was used to develop an improved online data entry system (Version 2) which is due to be rolled out to users in March 2006. Version 2 has been developed on leading edge software architecture (Microsoft .NET technology) which will provide a number of benefits:

- more powerful and flexible reporting
- greater ease of use, particularly with data entry/editing
- a more resilient system less prone to data corruption
- easier maintenance, operation and management of the system.

The development of the new system, and the feedback received from surgeons prior, provided opportunity to assess the data fields collected by the audit. Several new fields have been incorporated, which include date of diagnosis, use of neo-adjuvant therapy, use of herceptin, more detailed margin information, HER-2 receptor status, referral source, date of discharge and participation in a breast cancer treatment trial. A few items have been removed: TNM staging, dissatisfaction with pathology report, time to detection in preoperative scintigraphy and method/s used for intraoperative lymphatic mapping.

Another new and innovative aspect of Version 2 is the surgeon summary page that will be displayed every time a user logs onto the system. This page will present an overview of the surgeon’s entered cases and will also display the performance of the surgeon in comparison with the evidence-based minimum standards and national results.
Research

A joint application to the Australian Research Council (ARC) Linkage with Flinders University has been successful. The research project, to be led by Professor John Roddieck of Flinders University, will involve using data mining tools to analyse data held by the National Breast Cancer Audit to yield insight into associations and clusters between attributes and attribute-values hidden in the data. The aim of the project will be to use data mining to generate hypotheses and identity previously unknown/unexpected associations. There will also be a possibility to use pattern language techniques to enable translation of attributes to different audit systems. The majority of funding is coming from the Australian Research Council, however ASERNIP-S, the Australian Computer Society and Flinders University are also providing some support.

As described previously, a list of potential research topics for the NBCA has been compiled (Appendix 2). It is hoped that some progress will be made on some of these topics during 2006.
In this section we discuss lessons learned during the continued development and management of the National Breast Cancer Audit (NBCA).

**Lessons learned: Governance**

The NBCA is governed by the Audit Clinical Advisory Committee (ACAC). The ACAC provides the NBCA with a broad expert base of professionals associated with the management and care of breast cancer patients. There is no doubt that this governance has helped define the direction and development of the audit. The treatment of early breast cancer will continue to evolve as new treatment modalities become accepted practice and it is essential that the audit evolves to reflect these changes. One of the main challenges facing ACAC members is to provide strong leadership that effects change when necessary.

A close working relationship exists with the Section of Breast Surgery and it is essential that this is retained for the duration of the audit.

**Lessons learned: Privacy and consent**

In 2005, the NBCA obtained a new Declaration as a Quality Assurance Activity from the Australian Government Minister for Health and Ageing. This Declaration aims to provide protection of NBCA participants from civil proceedings and helps gain and/or maintain the confidence of participants. The new Declaration reflected the necessary changes in reporting resulting from the outlier process. Although the Declaration covers the activity for a period of five years, in 2006 a new application will be sought to cover the more wide-ranging reporting requested by the Australian Council for Safety and Quality in Health Care. It is not yet known whether this will be granted but initial enquiries have suggested that it may be possible. This may be the first case to test such an outlier system regarding the QP legislation.

The NBCA has been in the process of obtaining consent from surgeons who are full members of the Breast Section to participate in the outlier process. Chasing up the non-responders has proven to be a time consuming exercise. Ultimately the Section of Breast Surgery will have to take responsibility for non-responders as these surgeons will not be able to retain their status as full members.
Lessons learned: Data collection

To maintain user confidence, the data items collected for the audit must be unambiguous. This can be achieved in a variety of ways such as providing a detailed data dictionary with clear field definitions, using pull-down onscreen menus, having onscreen prompts and validating data to ensure appropriate responses. This work is ongoing. During 2005 it became apparent that the method of capturing margins data was not sufficient. A surgeons’ working party recommended that the data item be changed to that collected by Breast Screen Aotearoa (NZ). This will be implemented in the upcoming system upgrade, in conjunction with its definition in the data dictionary. A consequence of changing this field will mean that the associated quality threshold can not be cross checked against surgeon data until sufficient new information has been collected.

It became clear that maintaining a Microsoft Access database in addition to the online data entry system was not ideal. The inflexibility of updating the distributed Access databases meant that it was difficult to ensure that users were entering data for the most recently introduced data fields. It is also a time consuming and resource intensive process to transfer the data received in this format into the online system. Surgeons who had continued to use this method of data entry were advised well in advance of the changeover to the new system that it was to be discontinued. As yet, is not clear how many will change over to the online data system and who will use paper data entry forms.

One of the aims of moving to a new online data collection system has been to increase the speed at which data can be entered. This was considered a limiting factor for some surgeons. It awaits to be seen whether this objective will have been met and if so, whether users of paper forms can be convinced to use the system. Without this it will be hard to achieve the efficiencies that derive from surgeons entering their own data and obviating the need to divert audit resources to entering paper-based data.

Lessons learned: Analysis and reporting

One clear criticism of the audit has been the lack of publications obtained from the data. Some effort was put into ameliorating this in 2005; however this required the dedicated resources of audit staff. Effort has been put into encouraging surgeons or other breast cancer professionals to use the data for this purpose but so far no such papers have been completed. The audit has drawn up a substantial list of potential research questions and projects that will be attempted once time, data and resources are available.

In addition to producing publishable articles, analysis and reporting is necessary to produce reports for hospitals and State Departments of Health. This has been difficult during the 2005/6 funding period, most probably due to the changeover of the Australian Council for Safety and Quality in Health Care to the new Commission. The audit was asked to produce reports based upon the wishes of the SQOF members, however to date, this information has not been forthcoming and reports will therefore contain information similar to that contained in the 2005
reports with the addition of reporting on the current quality thresholds. This information in itself may not be as useful as desired if data has been entered into the system without the hospital name. The hospital at which the surgery was performed was added as a new field in 2004, but was not a mandatory data item in the old database. The new system will make fields such as this mandatory for reporting purposes.

**Lessons learned: Timeliness and methods of feedback to participants**

As discussed in Section 5, audits with feedback can be successful tools to affect change. One of the challenges of achieving this is to target the provision of information in a timely but cost effective manner. A number of different strategies to provide feedback are necessary. Not all participants have access to a fast and reliable internet connection, so this method, whilst useful for some, is not universally effective. The NBCA often disseminates information at specialist meetings as it is easier to target the users in these forums. Other methods of providing information include mail-outs, articles in the Surgical News newsletter, articles written for the rural surgeons, placement of reports on the RACS/ASERNIP-S website and journal publications. The help desk also provides an opportunity for participants to obtain information when required. In 2006 a regular newsletter will be posted to full members of the Breast Section. A combination of methods to provide feedback will continue in 2006, with new strategies employed as they become available.

**Lessons learned: Costs, funding options and barriers to obtaining funding**

Audits are traditionally undervalued and under funded. Short-term funding (year-by-year) is problematic as much time and resources is put into the search for ongoing funding. The NBCA has been beset by this problem since its inception. The current contract ends in March 2006 with a short extension until June (possibly with significantly reduced funding). Effort continues to be put into locating ongoing sources of funding which consequently detracts from the work of the audit.

The main cost associated with the NBCA (as for most projects) is salaries. Not surprisingly, the amount of work that can be undertaken is directly proportional to the number of people available to do the work. A large amount of time has been put into the development of the new online system (another major cost) and it is hoped that once this is functioning, less time will need to be spent in this area. It is unlikely however that the new system will be maintenance free and it is also anticipated that once more funding becomes available new reports will need to be developed.

Discussions had also progressed to develop a statistically robust methodology for the outliers process. Lack of ongoing funding and limited resources meant that this project was put on hold. Extra money was made available by the NBCC in 2005 so that research papers using audit data could be prepared. Lack of publications has been a major criticism of the project, however insufficient funding has meant that personnel are not available to do this research.
Lessons learned: Involvement of the public and private sector

The split between the public and private sector in the Australian Health Care system creates a range of problems for any national auditing project. A major problem has been the lack of access to a single national data repository containing information on both systems. Audit staff have not been able to obtain figures relating to the number of separations for procedures for early breast cancer – on a national, state or hospital basis. This information would be useful to determine what percentage of episodes is being captured and to help target efforts in increasing participation.

SQOF members were individually asked for permission to obtain access to this information, but possibly due to changes in responsibility of this committee, only one response was received.

The alternative to obtaining this information from a central data repository would be to request this information from each of the hospitals at which surgery for early breast cancer is performed. This would be a very major undertaking in itself and would require dedicated resources.
7. staff profiles

RACS Research and Audit Director
Dr Wendy Babidge
Dr Babidge was appointed as a Director of the Royal Australasian College of Surgeons (RACS) in June 2005 and is responsible for the areas of research and audit. She oversees the management of the ASERNIP-S program and is ultimately responsible for the administration of the RACS morbidity and mortality audits and the provision of scholarships for surgical research. Another major focus of the Research and Audit Division is to develop a secure web-based logbook system for the purpose of surgical training.
Wendy has an Honours Degree in Biotechnology, a PhD from the University of Adelaide and a Graduate Diploma in Business. Wendy is interested in further developing unique methodologies for the assessment of new and emerging surgical procedures.

ASERNIP-S Surgical Director
Professor Guy Maddern
Professor Maddern (RP Jepson Professor of Surgery, University of Adelaide) was appointed inaugural Surgical Director of ASERNIP-S in October 1997. Since that time Professor Maddern has been involved in developing the ASERNIP-S programme for the Royal Australasian College of Surgeons. Professor Maddern is a practising hepatobiliary surgeon based at The Queen Elizabeth Hospital, Head of the Division of Surgery and Director of the Basil Hetzel Institute for Medical Research in Adelaide.

ASERNIP-S Manager
Kerin Williams
Kerin Williams joined ASERNIP-S in November 2005 as Manager of the ASERNIP-S program. She has a Bachelor of Arts (Psychology, Sociology and Philosophy), Graduate Diploma Social Science, and an Advanced Diploma in Management (Business), has commenced a Master in Public Health/Business Management qualification, and is a Registered Nurse. Kerin has managed State and National projects for the Department of Health and Ageing over the past 10 years in the area of adolescent mental health and suicide prevention. She has recently been employed as Program Manager for the Southern Division of General Practice, and has also managed her own consultancy practice specializing in health and education projects where there is a need to develop multidisciplinary collaborative working relationships.
ASERNIP-S Senior Research Officer (Audit Manager)

Maggi Boult
Maggi Boult has an Honours Degree in Plant Science, a Graduate Diploma in Information Studies and a Diploma in Computer Programming. Maggi has worked extensively in a diverse range of scientific environments and has written computer applications and databases for commercial and scientific use. Maggi joined ASERNIP-S in 1998 and has been involved in a number of research areas. Currently she manages the morbidity audits and is the ASERNIP-S Privacy Officer.

ASERNIP-S Senior Research Officer

Dr Tabatha Griffin
Tabatha Griffin has an Honours Degree in plant and environmental biology and has also completed a PhD at Flinders University specialising in the fields of ecology and entomology. Tabatha joined ASERNIP-S in April 2003 where she was previously involved in conducting systematic literature reviews. She currently manages the National Breast Cancer Audit.

ASERNIP-S Research Officer

Sarah Tyson
Sarah Tyson joined ASERNIP-S as a researcher after operating the RACS Breast Audit as a separate project for four years. She has a science degree from the University of Adelaide majoring in Clinical and Experimental Pharmacology & Toxicology, and Biochemistry. Prior to her appointment Sarah was engaged in several other complex projects in the health and disability sectors.

ASERNIP-S Administrative Assistant

Louise Kennedy
Louise Kennedy joined ASERNIP-S in December 2002, on a part-time basis. She has a Certificate III in Business (Office Administration), and has studied several Information Technology subjects. Louise previously worked in clerical positions for the Commonwealth Public Service. At ASERNIP-S, Louise provides assistance to the administrative officers and audit projects.

ASERNIP-S Project Officer

Claire Miller
Claire Miller joined ASERNIP-S in August 2005. She has a Bachelor of Health Sciences degree, majoring in Public Health and Psychology, from the University of Adelaide. In 2004, she completed an Honours degree in Psychology, with an emphasis on health psychology. Her Honours thesis focused on health behaviours and attitudes around self administered cancer screening techniques. She has also worked in a histopathology and cytopathology laboratory. At ASERNIP-S Claire is working as a project officer and is currently involved with both the National Breast Cancer Audit and the audit of endoluminal repair of Abdominal Aortic Aneurysms.
APPENDIX 1

Surgeon Practice Report and Patient Summary Page

Screenshot of surgeon practice report
(Note: still under development; showing dummy-data)
### Screenshot of patient summary page

(Note: still under development; showing dummy data)
APPENDIX 2

Summary of potential research topics

Research projects - current:
DCIS management practices in Australia and New Zealand
Surgical treatment of younger women
Is the older breast cancer patient being under treated?

Flinders University have won an ARC grant to use data-mining tools tailored for health information to detect underlying patterns in the audit data set. ASERNIP-S is committed to partnering Flinders University in the project for three years.

Future research projects:
Patterns of practice across Australian states
Re-operation rates following initial conservative surgical treatment of early breast cancer
Re-operation rates following mastectomy for early breast cancer
Management of the axilla in early breast cancer
Uptake of herceptin treatment across Australia
Uptake of sentinel node biopsy
“Upstaging” effect of sentinel node biopsy in clinical practice
Analysis of patients who refuse treatment
The influence of caseload on practice
Delivery patterns of tamoxifen (SERMS) – is it being prescribed appropriately?
What axillary sampling techniques are being used for patients with invasive cancers?
Trends in practice over the period of the audit
Rates and patterns of neo-adjuvant therapy
Approaches to multidisciplinary care in surgical setting
Are breast care nurses being included in clinical practice?
Practical statistical approaches to identifying outliers
Updating the evidence and creating quality thresholds
Establishing the clear margin rate after breast conserving surgery for patients with invasive and / or DCIS
Are patients with DCIS undergoing axillary surgery?
Are women who are diagnosed with unifocal lesions on pre-operative assessment being offered breast conserving surgery
Confirmation of the VNPI for DCIS
Australian prognosis calculator
Use of adjuvant systemic therapy according to the VNPI
Analysis of treatment patterns in DCIS patients with a low VNPI score
Pre-mastectomy indicators for the need for post mastectomy radiotherapy
Use of post-mastectomy irradiation in high –risk patients with breast cancer
Factors affecting referral for radiotherapy after breast conserving surgery for invasive and DCIS
Use of radiotherapy after breast conservation for DCIS – implications for VNPI
Correlation between clinical and histological parameters
Re-educative approaches to improving clinical management of early breast cancer
Treatment of early breast cancer in regional and rural settings
Treatment of males with early breast cancer

**Downstream or add-on research projects:**

- The audit collects semi-deidentified patient data, collecting only the first three letter of the surname and the date of birth. A downstream project using data-linkage may be possible, with, for instance, the National Death Index. Statistical advice would be sought as to the reliability of this approach. If valid, the data could be analysed to review survival following different treatment modalities.

- Validation techniques for data in a large national audit will involve research methodology to determine the most appropriate approach to this process.

- The evolution of quality thresholds over time – will they become de-facto clinical practice guidelines?

- Statistical evaluation of audit results to determine whether they can be generalised to the whole population.
<table>
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<th>Membership of NBCA governance committees</th>
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<tr>
<td><strong>Audit clinical advisory committee</strong></td>
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<tr>
<td><strong>Role</strong></td>
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<tr>
<td>Professor Guy Maddern (Chair)</td>
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<tr>
<td>Mr Ian Campbell</td>
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<tr>
<td>Associate Professor John Collins</td>
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<tr>
<td>Dr Ros Drummond</td>
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<td>Mr Jim Kollias</td>
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<td>Mr Peter Malycha</td>
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<td>Mr David Oliver</td>
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<td>Professor Ian Olver</td>
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<td>Mr Chris Pyke</td>
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<td>Mr David Roder</td>
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<td>Ms Janet Rice</td>
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<td>Ms Lyn Swinburne</td>
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<td>Ms Susan Timbs</td>
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<td>Mr David Walters</td>
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<td>Dr Helen Zorbas</td>
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| **Minimum standards working group**      |
| **‘Outliers’ working group**             |
| Mr Jim Kollias (Chair)                   | Associate Professor John Collins (Chair) |
| Mr David Oliver                         | Mr David Oliver              |
| Ms Lyn Swinburne                        | Ms Susan Timbs               |