



ROYAL AUSTRALASIAN COLLEGE OF SURGEONS

Clinical Quality Registries Project Final report

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Australian Safety and Efficacy Register of New Interventional Procedures – Surgical
of



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Clinical Quality Registries Project

Final report

1. Executive summary

The aim of the Clinical Quality Registries Project was to evaluate the appropriateness of the draft Operating Principles and technical standards document prepared by the Australian Commission on Safety and Quality in Health Care as guidance for future clinical quality registries; this was an opportunity to grow and develop the National Breast Cancer Audit (NBCA), bringing it up to a higher standard of performance that can be sustained in the future. This report contains a summary of the implementation process, including issues encountered, as well as experience-based recommendations for the enhancement of the documentation and implementation of the principles.

The NBCA is confident that the changes implemented as a part of this project have enhanced the audit as a tool for improving and maintaining the quality of care received by early breast cancer patients. The audit currently meets 27 of the 42 draft principles. A further five are in the process of being considered and worked on, four are yet to be considered by audit governance and may involve a significant influx of funding, and three have been partly met to the best of our ability. There are three remaining principles which are either irrelevant to the audit, unfeasible or too difficult to implement.

The major issues encountered with implementation during the project period were: funding uncertainty and lack of funding; a period of transition for the audit as it moves toward becoming a Society of Breast SurgANZ audit; implementation activities which were classed as outside the scope of the audit; the voluntary nature of the audit; delays and incompatible formats from external sources; competing stakeholder priorities; a large governance structure; and an older style website platform.

Overall, it is felt that the draft principles are relevant for clinical quality registries and feasible to implement; however, certain principles may be very difficult to implement, especially for established registries. It is questioned whether following all the principles would be necessary and appropriate for each registry. Also it is noted that the documentation appears biased toward new registries and the potential benefits for major changes in an established registry remains unclear.

The technical standards section of the draft Operating Principles/Standards document lists a generic set of standards without specifying in sufficient detail how these are relevant to an audit or registry environment. The NBCA's IT consultants have advised the audit that the 'required'

elements of the standards list (terminology, data specifications, unique identifiers) should and could be implemented in the next website upgrade. The implementation of any other standards would not be recommended at the current time. This is because the standard did not appear immediately relevant to the audit or would need further development prior to satisfactory implementation.

A clearer and more concise structure is needed for the draft document, with a more explicitly stated purpose. It should be more specific on: what exactly needs to be achieved in order to meet each principle or standard; the potential positive and negative impacts for implementation; and the exceptions where the principle or standard may not be relevant. Cautions on straying from a registry's purpose, recommendations for more outputs to consumers (more than the annual report) and acknowledgement of the use of process measures as proxy outcomes are also recommended additions to the draft document. The document needs to explain what registries gain extrinsically by following the principles, and whether this document could be used as an accreditation tool or could help registries attract funding.

The College has been pleased to be involved in the pilot and sees it as a step forward to improve current registries and to assist new registries to be implemented to a high standard.

2. Introduction

The aim of the Clinical Quality Registries Project was to evaluate the appropriateness of the draft principles and standards document prepared by the Australian Commission on Safety and Quality in Health Care (the Commission) as guidance for future clinical quality registries. From December 2008 to October 2009 the National Breast Cancer Audit (NBCA) has worked towards implementation of changes to the audit to come into line with these principles. The following report provides a detailed evaluation of the principles, with an assessment of the impact of any changes made. It also discusses the relevance of each principle to the specific NBCA environment.

The report goes on to list the problems encountered throughout the implementation and assessment process. It lists any barriers to implementation of the 42 principles, with an indication of how these barriers were overcome or what alternatives to full implementation have been applied in the audit environment. The report also provides recommendations for the final version of the principles and standards document.

3. Background

In 2008 the Australian Commission on Safety and Quality in Health Care, the National Health and Medical Research Council (NHMRC) Centre of Research Excellence in Patient Safety, and

the National E-Health Transition Authority (NEHTA) developed a series of operating principles and technical standards for the establishment and management of Australian Clinical Quality Registries. To date there have been no set standards for the operation of clinical registries. The standardisation proposed by the Commission aims to improve the overall efficiency and function of registries and improve compatibility between registries to aid in future data linkage.

The Commission has engaged the National Breast Cancer Audit (NBCA) and other national registries to test and validate the draft Operating Principles and technical standards. The intention of the NBCA for 2009 was to apply the principles to current operations (where possible), evaluate the practicality of implementing the principles, identify any issues or barriers to implementing the principles and provide recommendations for the final principles and standards to be adopted. This report is the culmination of that process.

4. Methodology

4.1 Implementation

Phase 1: Awareness of need for transition

In November and December 2008 the initial assessment and prioritising of the project through the project plan was conducted. A projected timeline for reporting and a project plan was created. Areas identified for improvement were data quality assurance, including coverage and completeness, the ability to create effective linkages, the inclusion of outcome data and the output of results.

Phase 2: Plan the transition

A new project officer was appointed to the project in January 2009 to take over from a departing team member. A team was formed to lead and monitor the process, which has met weekly throughout the duration of the project.

Phase 2 involved further prioritising specific changes, researching and assessing the feasibility of suggested changes, and developing plans for moving forward. A rough timeline of expected changes was conceived at this time.

Early discussions with surgeons indicated that further collection of outcome data would be unwelcome and unnecessary, while output for surgeons is constrained by the current data entry and reporting website. Audit management decided to focus on data quality assurance and linkages. Development of complete documentation (policies, procedures), switching to opt-out consent and collection of identified data were also assessed as relevant and feasible to implement for the current project.

Phase 3: Designing necessary changes to the audit

Phase 3 involved developing new documentation, estimating coverage and planning initiatives for increasing coverage, planning for a new data entry website, overhauling the old patient consent process and designing new ways to upload institutional data.

Phase 4: Implementation

The following initiatives were implemented during the project period:

- The new website was trialled and redesigned from the end of 2008 through to March 2009. The site was ready for use by data collectors in March 2009.
- The new opt-out consent system was officially launched to surgeons in June 2009.
- Coverage will be reported in the audit's future annual reports.
- The Coverage Working Party has been working on various strategies for increasing coverage.

Phase 5: Manage performance

The new website and consent system will have to be monitored following the recent upgrades. The audit will also refine the process of data linkage and threshold reporting, taking into account the feedback from initial pilots.

Preparations are underway for a new approach to governance and funding. Oversight and ownership of the audit will move from the Royal Australasian College of Surgeons (the College) to the newly formed Breast Surgeons' Society of Australia and New Zealand (Breast SurgANZ, the Society) before the end of 2009. The College will continue on as data management contractors; however, the change will result in a restructure of the governance and new funding arrangements.

4.2 Assessment

The draft principles have been evaluated throughout the implementation process according to four factors: relevance to the audit, feasibility of implementation, extent of difficulty in implementation (ease), and extent of improvement. These factors have been measured semi-quantitatively by the audit team, with a numerical value assigned to each principle. The factor rating of each principle varies according to the extent of implementation. For example, if the principle was too difficult to implement, there could be no measure of improvement following change as change did not occur. Adding the four values of these factors together gives an overall value for the principle which measures the merit of implementation. The following describes the steps involved in assigning factor values to the principles:

1. In late 2008 the audit team completed an objective comparison of the proposed principles and the current practices of the NBCA. The aim of this comparison was to identify areas of the audit that would need to be improved in order to meet the 42 principles. This list of changes was then examined to ascertain the most important

- changes to be implemented in 2009, and a level of **relevance** was ascribed to each principle as a value out of 10, where 10 is very relevant and 1 is not at all relevant.
2. In early 2009 the audit team developed strategies for the implementation of the proposed changes and assessed the **feasibility** of such changes. Some changes were unable to be implemented due to the structure and purpose of the audit, or external forces, such as funding allowances. The level of feasibility of improving relevant areas based on the requirements of the draft principles has been evaluated as a value out of 10, where 10 is very feasible and 1 is not at all feasible.
 3. As each principle was implemented, the process of change was evaluated and an assessment of the **ease** in meeting the requirements of each principle was produced. Where the changes were unable to be implemented due to external factors (that is, not due to the structure of the audit itself), the audit attempted to ascertain what would be necessary to implement this principle in the future. The extent of difficulty in implementing changes has been assigned as a value out of 10, where 10 is very easy to implement and 1 is very difficult to implement.
 4. Once changes had been implemented, the audit team evaluated the short-term **impact** of the changes on the quality of the audit. Impact was assessed as a value out of 10, where 10 is very improved and 1 is not at all improved. Specific measures of improvement have been documented in the main section of this report, where appropriate.

The results of the assessments of each principle are provided in the main section of the report (section 5). The results are also summarised in Table 2 of Appendix 1.

5. Implementation outcomes and assessment of operating principles

5.1 Attributes

S5-P1: CLEAR AND PRECISELY DEFINED PURPOSE (currently met)

Relevance = 10; Feasibility = 10; Ease = 9; Impact = 10; Overall value = 39/40

The NBCA considers Principle 1 to be the most important principle in the draft document. The audit was conceived to answer an already established problem and so had a purpose from the beginning. This is the recommended course for all registries. If there is no clearly established purpose, there should be no registry and the other principles will be redundant. The cost of establishing and maintaining an effective audit or registry is high, and a clear, precisely-defined purpose is needed to justify the audit's existence.

In 1995, the House of Representatives Standing Committee on Community Affairs recommended that the Royal Australasian College of Surgeons (the College) establish a compulsory form of accreditation and audit process for surgeons performing breast cancer surgery. The NBCA was conceived in response to this recommendation. The audit's original

purpose was to provide a benchmarking tool for the College Breast Section members to self-audit their practice. The information collected allowed surgeons to compare their own practices with the aggregated practice profile of their Australasian peers. In 2003 the emphasis began to shift toward providing a full clinical audit cycle to better ensure the high quality of care in breast cancer surgery in Australia and New Zealand. A Clinical Advisory Committee (now called the Steering Committee) was formed at this time to provide guidance on clinical aspects of the audit and comprised a diverse range of experts. Key to fulfilling the new purpose of the audit was the setting of threshold values (see section 5 Principle 36 for more details on this process) and establishment of an adequate outliers process (see S5-P28). The role of the audit is to evaluate results of data collection in the light of these thresholds and provide feedback to surgeons.

The clearly defined purpose has impacted on the audit in four important ways. Firstly it provides the scope and goals of the audit. If the audit did not have a purpose it would not achieve any improvements in quality of care because it would not have a clear idea of what it is trying to achieve. Secondly, the clear purpose of the audit is one of the reasons for such high support from surgeons in the field. If surgeons did not see a benefit for themselves, the profession, or the patients, they would not contribute data to the audit. Thirdly, the clear purpose also attracts a lot of support from other stakeholders, such as consumer groups or research organisations as they can see value in the audit. Lastly, a clear purpose aids the audit in attracting funding. Without a clear purpose, the audit would not be able to argue its case.

The NBCA suggests that Principle 1 also include a caution about straying too far from the original purpose. A purpose may evolve and change as a registry (in this case, audit) continues; however, a registry should avoid expanding its activities too far outside of this purpose. Expanding audit activities outside of its purpose may invalidate the purpose and therefore devalue the registry. That is, if a registry collects a large amount of data that is not needed to fulfil its purpose, stakeholders may come to believe that the registry is no longer fulfilling the original purpose, but moving into another area. This issue is referred to as 'scope creep' in the draft principles document, and will impact on coverage if it entails a large increase in participants' effort for little perceived value. Currently 'scope creep' is mentioned in the introduction to the draft document only and not mentioned under Principle 1.

S5-P2: CORE DATA COLLECTION OF ESSENTIAL ELEMENTS (currently met)

Relevance = 10; Feasibility = 9; Ease = 8; Impact = 7; Overall value = 34/40

The NBCA believes that defining a 'core' data collection should be a key goal of any registry. The audit developed this list of core data items into a minimum dataset (MDS). A minimum dataset was considered necessary to improve participation in the audit by decreasing the burden of data collection. The decrease in time taken for data entry through use of the MDS form should also lead to less 'batch' loading, that is, waiting until there are enough forms for data entry to be 'worthwhile'. Less batch loading will mean an improvement in timeliness of data

entry. A one page form that contains only 'essential' items should also lead to an improvement in the completeness of these fields as surgeons will be more aware of what is considered 'essential'.

Surgeons were asked to voice concerns with their experience of data entry and output from the NBCA at the Section of Breast Surgery Annual Meeting in May 2007. One of the main concerns raised by surgeons was the complexity and time required for data entry, both in terms of extracting data from case records and transcribing into the online system. At that time, the audit consisted of five pages of data, 86 separate items with 328 options, including different questions for invasive tumours and ductal carcinoma in situ tumours – a very complicated dataset. Many surgeons found that contributing data to the audit required employing a data entry officer or use of their administrative staff, at a cost to them. One of the main concerns when the audit was first conceived was keeping the process as simple as possible. Surgeons felt that the audit had strayed from this original ideal.

To allay surgeons' concerns, significant time and resources went into the development of a minimum dataset to decrease the burden of collection for surgeons while still collecting enough information for assessment of key quality performance indicators. The MDS was developed in conjunction with the steering committee and in consultation with surgeons. In 2008 the MDS was officially introduced as an option, via a paper form. The surgeons could then transcribe this data into the online, long version of the data entry website or send the paper forms into the NBCA office. In late March 2009 the MDS was officially launched on the data entry website. The updated website provides surgeons with the option of filling in all information fields (long form) or only filling in the core data elements required for calculating the quality thresholds (MDS form). The surgeons can also switch between views if they want to fill in the core values and then add extra information included in the long form.

There has been a general positive response from surgeons on the implementation of the MDS and short form. These responses have shown that most surgeons prefer the shorter form, which in hard copy fits onto one page and displays online as a single scrolling page. This is much easier to navigate than the long form. However, following its implementation, some issues associated with shortening the dataset have arisen. For example, some surgeons believe additional items should have been included in the MDS (laterality for example), and some usability issues have been highlighted. These issues can be reviewed in the future. The MDS is a collection of items essential for performance calculations. If surgeons wish to include extra information, they can switch to the long form.

Analysing data collected and entered after the MDS short form was available online shows that over 50% of entries completed MDS questions only (see Figure 6 in Appendix 3). It also showed that, on average, these cases were entered 51 days closer to surgery than cases which included items outside the MDS but included in the full dataset (referred to as MDS+). MDS-only cases were recorded 9.5 months (282 days) after surgery on average compared with 11 months

(333 days) for MDS+ cases. Each year there will be old datasets added to the database, through institutional data uploads, for example. These records are important for research and historical purposes but tend to skew the average timeliness figures up. It may be more useful then to look at the median value. The median value for MDS-only cases was 6 months (188 days) and for MDS+ cases it was 3 months (97 days).

The audit team have postulated two theories on why the MDS+ median timeliness figures would be lower than the MDS-only median. Firstly, surgeons often collect data on paper forms and later transcribe them into the data entry system. The paper MDS forms had been distributed approximately 6-9 months prior to the MDS short form being available online. Cases older than this would have had to be recorded on the long form. This means that 'older' cases would include more than MDS when transcribed into the data entry system. These cases would be outliers and would have more effect on an average than on a median. Secondly, some surgeons have indicated a period of waiting for the MDS to be implemented in the online system before inputting data. This implies that the time between surgery and data entry was lengthened only because the MDS short form option was not available. In future MDS-only data should therefore be entered in less than the 6 month median. The median time to data entry was already lower in June and July compared with April and May (see figure 9 in Appendix 3).

In terms of completeness, 80% of MDS-only invasive cases completed every question on the MDS short form compared with 57% of cases completing all MDS points on the MDS+ (see figure 7 in Appendix 3). As stated elsewhere (see S5-P10 & S6-P10), the questions on completeness of margins are problematic with 84% of MDS-only cases completing at least one of the two margin questions and 75% of MDS+ cases completing at least one of the two margin questions. Histological grade and presence of necrosis was also lower than expected for DCIS MDS cases. These problems warrant further investigation by audit governance.

Analysis also shows that the number of case submissions increased around the time of MDS implementation online (note that this was also near the deadline for data submission from previous year – see figure 2 in Appendix 2). Submissions were lower than previous years in the months prior to MDS online implementation. The NBCA team believe this is due to surgeons holding back data until the new MDS online system was up and running.

The draft Operating Principles and Technical Standards document states that core data items should be based on the essential elements needed to fulfil the registry's purpose. It also lists what these elements are, in general. This list includes identifying information, risk adjustment factors and outcome data. It is the NBCA's contention that core data will be different depending on the purpose of the registry and there will be exceptions for each of these elements. The NBCA suggests that the Operating Principles document should include information on some of these exceptions. It is important that a registry have a core data collection, but this collection must be based on what is necessary to fulfil the registry's original purpose, rather than what 'should' be collected in a registry.

S5-P3: SYSTEMATIC DATA COLLECTION AT ALL CONTRIBUTING SITES

(cannot be implemented fully)

Relevance = 9; Feasibility = 4; Ease = NA; Impact = NA; Overall value = 13/40

For accurate results and meaningful benchmarking, collectors should be recording the same data and collecting the data in the same way. If this is not the case, comparison between data collectors may be called into question.

When the audit was piloted back in 1998, one of the main goals was to establish a standard template for the collection of clinical data for patient diagnosis, pathology, surgical interventions and adjuvant therapies. Currently, data for the audit is extracted from medical records and pathology reports by data collectors and is captured in one of three ways: data is entered straight into the data entry website; data is entered onto a paper form and then transcribed into the data entry website; or data is entered into another collection database and either uploaded to the NBCA database or physically transcribed from printed output of the other database (the NBCA refers to data uploaded or transcribed from another database as 'institutional data').

The newly updated data entry portal mirrors the paper data entry forms to ensure that both paper and online data collectors are measuring and recording the same data in the same way. Unfortunately, the NBCA has no control over the methods and depth of data collection at an institutional level. Ignoring this large data pool would mean a significant limitation in coverage for the audit. Many surgeons consider re-entering the same data into the NBCA database as 'double data entry' and are unwilling to make this extra effort. Principle 13 of the draft Operating Principles also advocates use of existing data sources where possible. Adhering to Principle 13 may conflict with adhering to Principle 3. Perhaps a caution should be added to the document under Principle 3, or Principle 3 could be reworded or made clearer to take this into account.

The audit's current position is to ensure the standardisation of data collected specifically for the audit and to translate institutional data into the standard audit format during transfer into the database. Although the NBCA has been successful in linking certain institutional datasets (Auckland, Perth, Melbourne), we have had trouble with others due to incongruent datasets. If the format of the original data is sufficiently different to the format of NBCA data specifications, such that it can't be mapped, or there are too few similar items and the MDS cannot be adequately completed, it may mean that data is missing in the final record or is not meaningful enough to be worth pursuing.

Following the commencement of this project, the NBOCC have published guidelines for Breast Cancer Specific Data Items for Clinical Data Registration.¹ These guidelines were ascertained in conjunction with the NBCA dataset. It will be the aim of the NBCA to encourage institutions to comply with the current recommended dataset guidelines which will bring them in line with the

NBCA. In the meantime, procedures have been formulated on institutional data entry and uploading, explicitly listing the rules which apply to translating the format of this data.

The NBCA considers that Principle 3 is a good ideal; however, in reality, if data is used from external sources, the method of collection may differ slightly from the registry's collection methods. This will mean a decision must be made as to whether this data is compatible with the registry's data format. Registries should not be so restrictive that they reject existing data based on minor differences. So although the audit supports this principle as an ideal, the principle may need to take into account that compromises may be required for a fuller coverage of cases.

S5-P4: EPIDEMIOLOGICALLY SOUND DATA (currently met)

Relevance = 10; Feasibility = 9; Ease = 7; Impact = 8; Overall value = 34/40

The audit supports Principle 4, as it is important for data to be accurate, objective and comparable. If measures are subjective, it cannot be guaranteed that all surgeons will be measuring the item in the same way. If surgeons are not measuring the item in the same way, it becomes difficult to compare results across surgeons.

The NBCA has attempted to include only epidemiologically sound data in its dataset through intense consultation with epidemiologists, surgeons, consumer representatives and other stakeholder groups throughout the life of the audit. This consultation includes feedback on the original dataset from data collectors during the 12-month pilot study in 1998 as well as continual review by audit governance and key stakeholders. Including only sound data items in the dataset ensures that the data is meaningful for audit and research purposes, and assures surgeons that data collection is a valuable use of their time.

S5-P5: OUTCOMES PROPERLY ASCERTAINED (currently met)

Relevance = 8; Feasibility = 6; Ease = 6; Impact = 7; Overall value = 27/40

For the purposes of the NBCA, the direct measurement of patient outcome, and the assessment of surgeon performance against this outcome, is problematic. Survival from breast cancer, the ultimate patient outcome, can be valuable for general research purposes; however, it is dependent on a large number of factors that are not directly related to a surgeon's actions at the point of care. This leads to problems at the individual surgeon assessment level. Although survival data is now available for the audit through linkage with the Australian Institute of Health and Welfare's (AIHW) National Death Index (NDI), this information is not considered essential for audit function and will not be used for surgeon assessment. The 'outcome' measured by the audit is surgeon adherence to the key guiding principles for early breast cancer and DCIS treatment, which have been set by the Steering Committee and are based on the National Breast and Ovarian Cancer Centre (NBOCC) Clinical Management Guidelines (CMG).^{2,3}

As mentioned above, the NBCA trialled a linkage with the National Death Index (NDI) in 2008 to ascertain the ease of gaining patient outcome data for research purposes (see S5-P14 for information on the success of this initiative). The addition of NDI information to the audit data will not affect reporting to surgeons or outlier management. The NDI information will be used for research purposes only.

In alignment with Principle 1, the outcomes pertinent to a registry will be defined by its intended purpose. The NBCA dataset concentrates on surgeon performance outcomes. Surgeons are encouraged to wait until their provision of care to breast cancer patients is at an end before entering data. This is to ensure that what is recorded is final data, including the final margin after surgeries, as well as adjuvant therapy information.

Principles 5, 6, 17 and 37 all assume that patient outcome data is collected. Perhaps there could be a mention in the Operating Principles document that 'outcome' refers to the main quality measurables of the registry rather than patient outcomes. The burden of collecting follow-up data for the audit to determine outcomes is too great for surgeons. The NBCA has therefore developed surrogate measures of performance which would translate to better outcomes. This data is easier to gather and monitor and is based on existing evidence. The audit would support Principle 5 if this was taken into account.

S5-P6: BURDEN AND COST OF COLLECTION CONSIDERED (currently met)

Relevance = 8; Feasibility = 9; Ease = 7; Impact = 7; Overall value = 31/40

The NBCA believes it is important to consider the burden and cost of collecting any and all data before inclusion in the dataset. A new registry must consider the minimum number of items that can be collected while fulfilling its main purpose. If data collection is burdensome for collectors, it may result in decreased coverage or completeness as eligible collectors will be hesitant in participating, will not send in all their cases, or will not fill out the entire form. Established registries should also consider the burden and cost of collecting before including additional data items in an established dataset. Again, if the collecting becomes too burdensome it will lose collectors.

The burden of collecting patient outcome data has been considered by the NBCA and pronounced too high for surgeons. The audit currently collects reoperation and, optionally, follow-up information. Although the audit's optional follow-up does collect information on lymphoedema, disease status and survival, extending the dataset to include other adverse events or enforcing follow-up as compulsory was considered 'scope creep'. It would create additional work for data collectors and transcribers without adding sufficient benefit as patient outcome is not included in benchmark figures, as well as being potentially unattainable information for the surgeon due to the tendency for patients to have their primary care

transferred to other specialties. Ultimate patient outcomes will be collected through linkage with the NDI.

The burden of data collection and data entry in general has been a focus of the NBCA for some time, and in response to this issue the audit has developed a minimum dataset which provides faster and easier data entry for surgeons. The audit also supports data collectors via an email and telephone helpdesk and provides each surgeon with a data entry user guide and data dictionary. Work is underway on a cost effective and flexible method of uploading data from other sources so that surgeons are not burdened with 'double data entry' (see S5-P13).

This principle assumes that outcome data is collected. The audit does not measure outcome directly, but uses process of care measures as surrogate measures of outcome. Because of this, the audit has considered the burden of *all* data collection in responding to this principle. It is unclear whether this is appropriate as the draft document does not account for registries using process measures as proxies for outcomes. The recommendation of the NBCA is to make it clearer how this principle relates to registries using process of care measures as outcome proxies. For example, if patient outcome measurement has been considered and dismissed, has this principle been met? If process measures are outcome proxies, do these registries need to consider the burden of collecting process measures to fulfil this principle? Are these registries exempt from this principle if they do not collect patient outcome?

The NBCA also rates the consideration of burden and cost of data collection to be an important issue for a registry at all times, rather than just a consideration in determining when to collect outcome data. A well-run registry with a clearly defined and useful purpose will provide many benefits to participants in terms of feedback, status and data management. A new registry needs to be careful in how it deals with things like scope creep, outliers management and the burden of data collection to ensure stakeholder buy-in. As the registry grows in profile and provides more benefits for users, a power shift may occur whereby the registry gains more power in determining the requirements being set for participants. However, the registry must still ensure that the benefits of participation outweigh the burden. The NBCA recommends that Principle 6 be rewritten to take into account the burden of data collection in general, or that this become a principle of its own.

S5-P7: COMPLETE COLLECTION FROM ENTIRE ELIGIBLE POPULATION (cannot be implemented)

Relevance =8; Feasibility = 2; Ease = NA; Impact = NA; Overall value = 10/40

The NBCA considers coverage an important issue for clinical quality registries which focus on improving quality of care. Improving quality of care is an extension of the original purpose of the audit, which was to provide a self-auditing tool for participating surgeons. To extend the audit in this way, it is essential to gain as much data as possible, with no bias in terms of who is

contributing data or from where. This will ensure the audit data is representative of the quality of care received in both Australia and New Zealand.

As a voluntary activity, the feasibility of the audit covering the entire eligible population is low. If the entire population is not covered, it is important to ensure that data collected is representative of surgical care for early breast cancer cases in Australia and New Zealand. To ensure that data collected is representative of the population, the audit invites all surgeons performing breast surgery to participate, from Breast Section members who specialise in the area to general surgeons, often practising in rural areas who may only see a couple of breast cancer patients per year. The audit also takes a bi-national approach, aiming to cover all regions, rather than be focused on one area.

In late 2008, the Audit Coverage Working Party was formed to tackle the issue of coverage. As at April 2009, the audit coverage for the period 2000-2006 was less than 50% of all breast cancer cases in Australia and New Zealand. Since 2006, the audit has upgraded the data entry website, implemented a minimum dataset (MDS) and sent invitations to non-participants to consider contributing data, as well as uploading data from various institutions around Australia and New Zealand. All of these should have an effect on coverage. Other initiatives for increasing coverage will be implemented as the audit moves under the umbrella of the newly formed Society of Breast SurgANZ.

Unless a registry is running under legislation which enforces participation, full collection from an entire population is unlikely. It may be better for the Operating Principles to set a parameter for data quality purposes, such as 90% or 95%.

In terms of completeness of cases submitted to the audit, new validation rules implemented during the recent website upgrade have produced increases in the completeness of data entry fields, most noticeably in diagnosis date which is up from 90% complete to 100% complete (it is now a mandatory field). These validation rules include mandatory fields where a record cannot be saved if the field is blank, and incompleteness alerts which alert a data transcriber to blank MDS fields. As already reported (see S5-P2), there are still some concerns over the completion of certain MDS fields, most notably margin measurements. This is an issue that warrants further investigation by the audit Steering Committee. In general, MDS fields are filled in by the majority of data transcribers (over 95%). The completion of the Full Dataset (FDS) is less of a concern for the audit.

The NBCA recommends that Principle 7 be clearer on whether it refers to coverage (that is, covering the complete population of cases), coverage per individual health provider, unit or hospital (i.e. for NBCA, ensuring participating surgeons submit all cases) or completeness of dataset questions for all cases submitted. The principle, as it stands, is slightly vague and appears to be referring to all three. The NBCA questions whether any voluntary registry can gain full coverage of a population or complete data for every case. It recommends setting a high

limit, such as 95%, for coverage and completeness and specifying that completeness refers to completeness of core data items.

Principle 7 also appears to assume that coverage determination and publication would and should be performed by the registry itself. Coverage determination via a third party, such as the Commission, would provide a more transparent and objective evaluation of coverage.

5.2 Data collection

S5-P8: NO IMPACT ON PROVISION OF CARE AND NOT A BURDEN OR COST TO CONSUMERS

(currently met)

Relevance = 8; Feasibility = 9; Ease = 8; Impact = 9; Overall value = 34/40

The purpose of a Clinical Quality Registry is to improve the quality of care received by consumers. If collecting data for the registry negatively impacts on the provision of care, it is in conflict with the ultimate purpose of that registry and careful consideration must be given to whether this collection is necessary. Principle 8 is also important from an ethical standpoint. The Australian *Privacy Act*, 1988 states that the collection of personal information must not be unreasonably intrusive. For these reasons, the NBCA supports Principle 8.

The NBCA is what is referred to in 'The National Statement on Ethical Conduct in Human Research' as negligible risk research.⁴ That means that there is no foreseeable risk of harm or discomfort to the patient. Including data in the audit involves no effort on the part of the patient and does not affect their treatment plan in any way. The burden of data collection rests with the surgeon. Patients will be less likely to opt-out if it is made clear to them that participation will help improve the quality of care in early breast cancer treatment with no effort on their part, or impact on health care received. This is outlined in the NBCA patient information sheet.

S5-P9: DATA COLLECTION AS CLOSE AS POSSIBLE TO POINT OF CARE (cannot be implemented)

Relevance = 6; Feasibility = 5; Ease = 4; Impact = NA; Overall value = 15/40

The NBCA has no measure of the time of data collection, only the time of data submission (see S6-P9). These events may be synonymous or there may be a time lag, depending on the method of data entry. As the NBCA cannot provide a measure of time between care and data collection, timeliness measures are based on time between care and data submission.

Although the NBCA agrees that it would be preferable to have data entered as close as possible to the time of the event, the NBCA is a voluntary audit and as such cannot restrict the time of data entry without heavily impacting on coverage. The timeliness of data entry is also impacted by the wait on pathology results and the completion of treatment. The NBCA believes that

coverage and data completeness are more important to the quality of the audit than timeliness of data entry.

The audit has attempted to control the timeliness of data entry in two ways. Firstly, the data entry website allows real-time data collection so that surgeons can input data at the time of consultation, or soon after. Secondly, the audit asks data collectors to have all of their data for a particular year in by 30 April the next year. This time limit was set by the Steering Committee in the early days of the audit to allow some flexibility in data entry for collectors while ensuring the data was reasonably complete and representative for data analysis. As stated above, however, the audit is a voluntary activity and must still accept data after this period or risk losing data. There are also issues with institutional data as there have been long delays in gaining and successfully importing data from external sources (see S5-P13 and S6-P13). The surgeons should still be able to input data into their own institutional system in a timely manner; however, the audit does not record time of data collection, only time entered into the audit database. Looking at data entered in 2009, the time taken between surgery and data entry has been approximately 10 months (or 307 days) on average. Each year there will be old datasets added to the database, through institutional data uploads for example. These records are important for research and historical purposes but tend to skew the average timeliness figures. It may be more useful then to look at the median value which is approximately 4.5 months (134 days). See Figures 4 and 5 in Appendix 2 of this report for more information on the timeliness of NBCA data entry. These charts show that timeliness of submission has generally improved in 2009, as the average prior to 2009 was approximately 12-13 months between surgery and data submission and the median was approximately 5.5 to 6 months.

Calculations based on 2007 and 2008 cases estimate that 83% of the year's data collected by the audit is submitted by 30 April of the next year. For a visual representation of the number of cases entered before and after 30 April see figure 3 in Appendix 2.

Principle 9 could be improved by clarification of what constitutes 'as close as possible'. Decisions about breast cancer care or the ascertainment of that care may not be possible until after discussions between disciplines are made or after the treatment has actually started. In breast cancer management this may take several months. As such, the time of data entry for various data registries will vary according to outcome measures. It may not be possible therefore to give a definitive time limit for data collection due to the diverse nature of Australian registries; however, the NBCA recommends the Operating Principles at least contain advice on how to determine the optimal time limit for any given registry. It is also unclear whether all registry data must be in by a certain time to meet this principle or whether registries should aim to collect a high percentage of data (85-90%) by that time.

The audit agrees that timeliness is an important concept to be addressed by registries; however, many registries cannot directly control or measure the time of data collection (that is,

when the data is collected from case notes and recorded on paper or entered directly into the database). Timely data collection may then be an issue controlled by data contributors. It was the NBCA's understanding that the principles document was aimed at registry managers rather than data contributors. The NBCA considers it unlikely that data contributors will familiarise themselves with the operating principles. That being the case, the principle could be reworded to say that the role of the registry staff is to convey the importance of timely data collection to their users and promote a culture of timeliness, so that any errors are easier to identify and fix. The NBCA would support a principle that concentrates on issues that are in the power of registry managers or governance to control.

S5-P10: UNIFORMLY AND EASILY ACCESSIBLE FROM DATA SOURCE

(cannot be implemented fully)

Relevance = 7; Feasibility = 6; Ease = 4; Impact = NA; Overall value = 17/40

If core elements of the dataset are not easily accessible it creates a burden on data collectors who need to acquire this information. This could lead to a drop in coverage for voluntary registries, such as the NBCA, as participants may decide that the return on this effort is not worth the inconvenience. It could also lead to incomplete data if the information could not be accessed.

Most information required for the NBCA dataset can be recorded straight from the patient notes of the surgeon; however, surgeons can often be constrained by what is provided to them in pathology reports. For example, new pathology reporting guidelines for breast cancer were released by the NBOCC in 2008, including a new synoptic report, which suggests providing a measurement for a single 'closest margin'.⁵ Widespread uptake of the synoptic report format by pathologists over time will create problems for NBCA data collectors, as the NBCA dataset requires measurements for both circumferential and vertical margins. The NBCA does not have control over this source data. The issue will need to be monitored closely to ensure that the quality of the NBCA data is not compromised.

The NBCA considers Principle 10 to be a good ideal; however, in reality there may be cases where exceptions need to be made. Perhaps the principle could be reworded to say that inclusion of items that are not easily accessible to participants must be carefully considered, with perceived benefits weighed against foreseeable negative implications and the likelihood of access for collectors.

S5-P11: STANDARD DEFINITIONS, TERMINOLOGIES AND SPECIFICATIONS USED

(cannot be implemented fully)

Relevance = 7; Feasibility = 3; Ease = NA; Impact = NA; Overall value = 10/40

The NBCA considers it important to standardise definitions, terminology and format of recording, both internally amongst different data collectors and more broadly with the breast cancer treatment field. Standardising with other registries or databases is of secondary importance. If this standardisation conflicts with the ultimate purpose of the audit, or does not create enough benefit for the amount of effort and cost required, it is likely that it will not be implemented.

The audit ensures the standardisation of data it collects in three ways: constraints built into the data entry system which restricts the form of entries (see S5-P25 for more information); the formulation and distribution of a detailed data dictionary (see S5-P12); and the use of clinically standardised terminology or fields. This is to ensure that meaningful comparisons can be made about surgeon performance and is concerned primarily with standardising across surgeon participants rather than between the audit and other registries. That being said, the audit has aligned with various datasets over the years, where appropriate, including published guidelines for Breast Cancer Specific Data Items for Clinical Data Registration.¹ Comparisons between the National Health Data Dictionary (NHDD) specifications for cancer reporting and the NBCA specifications show slight differences; however, the differences are negligible and are in the interests of fulfilling the purpose of the audit. For example, in the NHDD the question on laterality of tumour provides options for left, right or bilateral, whereas the NBCA asks whether the cancer is bilateral synchronous as a separate question because bilateral tumours are recorded as two episodes. Each episode would then specify left or right breast in a second question.

The current dataset was produced in accordance with the Australian Clinical Management Guidelines for the Treatment of Early Breast Cancer² and DCIS management³ and in consultation with surgical and breast cancer experts. The dataset has evolved over the course of its history and will continue to evolve to reflect changes in breast cancer treatment and terminology. When new guidelines or data dictionaries are produced in the cancer or breast cancer field, they are compared with the audit dataset. Dataset changes may occur; however, the NCBA needs to be mindful of scope creep or change for the sake of change and avoiding loss of historical data by changing data items. Contributors will not take to any changes in the dataset unless there appears to be a valid and necessary reason for the change.

It is implied in this section of the draft Operating Principles document that registries should follow NHDD data specifications and use Systematized Nomenclature of Medicine (SNOMED) terminology. While it is a good goal to attain standardisation across the entire health care sector, it is the contention of the NBCA that, currently, registries which operate in a specific field, such as early breast cancer, should concentrate on using terminology consistent with that field rather than using more general 'registry' or 'health' terminology. If data linkage is later to occur, terminology can be mapped. Unless there is to be frequent and extensive data exchanges between registries and/or health care sources (i.e. hospital systems), it would seem

more fruitful to standardise terminology etc. with health care guidelines, providers, data collectors and researchers in the specific field of operation for the registry. However more general terminology would also be considered.

Caution is advised in changing existing terms and formats, unless the change is necessary or the benefits of the change outweigh the cost. Any new terms or formats will need to be adequately explained to collectors, which could necessitate further training. Collectors may also be resistant to change if the registry dataset is long established.

S5-P12: DATA DICTIONARIES USED (currently met)

Relevance = 10; Feasibility = 9; Ease = 9; Impact = 8; Overall value = 36/40

The NBCA data dictionary is seen as an essential tool in the training of data collectors and the assurance of data quality. A clearly expressed data dictionary will standardise data collection across Australia and New Zealand, ensuring that each data collector understands what is required and how to answer each question in the right format. It will also aid in analysing coded data for NBCA data managers as it shows the meaning behind the codes for each question, as well as the allowed values.

The NBCA data dictionary can be downloaded from the NBCA page of the College website. All data collectors are urged to use this as a tool for mastering data entry, especially for those new to the audit. To complement the data dictionary, the new data entry website also has rollover help definitions for each question that needs to be answered.

The data dictionary was originally based on the NHDD and NBOCC CMG. It has been in place since the inception of the audit. As the dataset has undergone major updates, the data dictionary has also been updated and overhauled. This generally occurs every 1 to 2 years. The most recent update included a user-oriented section, with more information on how to answer NBCA questions.

The NBCA supports Principle 12 in requiring the use of a registry data dictionary. A current and valid data dictionary aids in maintaining quality data entry and acts as a help manual for data collectors. Without this document, data collectors would either swamp the help-desk with simple queries or make unwanted assumptions about what they think a question means.

S5-P13: USE EXISTING DATA SOURCES WHERE POSSIBLE (currently met)

Relevance = 8; Feasibility = 7; Ease = 5; Impact = 7; Overall value = 27

After moving to an online data entry system, the use of existing data sources became an important issue. Surgeons often input data which is similar to the audit into their own hospital

database and some do not want to do double data entry. Ignoring the problem would mean a significant limitation in coverage.

Institutional data uploading was common in the NBCA's previous system based in Microsoft Access, but was not continued using the online system as an attempt to preserve the cleanliness of data. Pressure over missing this vital data saw the process revisited in 2007, although due to the need for cooperation from the institution, individually designed software and extensive error checking, this process has been lengthy, expensive and complicated. In 2009 the NBCA piloted a new, more cost-effective way to include this data. In some cases it has been found that simply printing off and manually entering some institutional data is more timely and cost-effective.

In 2009, over 2000 cases will be put into the system from institutional uploading (1420 of these using the new system), compared to 1694 in 2008. This process is still in its infancy. In the future, institutional uploading should boost coverage to an even greater extent.

The draft Operating Principles document also mentions the use of administrative data. This concept does not appear currently relevant to the audit, which is without sufficient technical groundwork in place to allow this data to be easily collected and incorporated into audit procedures.

The NBCA supports Principle 13 and agrees that data should not be used if it is vastly incompatible to the registry's format or the quality is questionable. However, it must be pointed out that there is a judgment call involved in determining whether the quality of data is satisfactory and sometimes compromises are made in order to use existing databases. Registries should not be so restrictive that they reject existing data based on minor differences.

S5-P14: USE RECORD LINKAGE WHERE POSSIBLE (currently met)

Relevance = 7; Feasibility = 7; Ease = 6; Impact = 5; Overall value = 25

As the NBCA records little patient outcome data, record linkage is seen as a good way to obtain this information for research purposes. However, this is an added extra for the audit and is not used to fulfil the audit's main purpose. For this reason, although the principle is relevant to the audit, it is not a high priority. Further linkage will rely on obtaining adequate funding for the initiative in the future.

In 2008, the NBCA completed a trial linkage with the NDI. The project was completed with a fair degree of success, despite issues with less than fully identified data (see S6-P14). We are seeking governance approval to move to fully identified data and if successful a change in our qualified privilege will be required.

The NBCA recommends repeating the linkage process every 2 to 3 years to provide adequate patient outcome data for research purposes. This data can also be used to confirm the link between the NBCA's process of care measures and patient outcome. The audit's ultimate purpose is, after all, to improve the quality of care of the patient.

The NBCA does not have a problem with Principle 14 stating that a registry should have the *capacity* to link with other registers, as long as the principle does not state that registries should link to other registers. Linkage may not be relevant or prioritised in all registries.

5.3 Data elements

S5-P15: COLLECT INDIVIDUALLY IDENTIFIABLE PATIENT OR SUBJECT INFORMATION

(can be met in short/medium term)

Relevance = 6; Feasibility = 8; Ease = 6; Impact = Yet to be completed; Overall value = 20/40

Collecting fully identified data will provide more confidence in identifying patients for: linkage with the NDI; amalgamating patient data across surgeons; data correction; opting out of the database; and patient access to their own records. However, collecting a fully identified dataset has not been seen as a necessity for the NBCA as it has been proven that audit data can be successfully linked in its current semi-identifiable state and the audit dataset includes a clinic code to aid in identifying patients for data correction; however, identified data is being made a high priority for future upgrades. Being able to amalgamate data for patients who were treated by more than one surgeon would be useful for research purposes but would not affect the audit's performance measures.

The majority of registries do collect identified data and it is feasible for the NBCA to move in this direction. The issue will first be considered by the Steering Committee. It will also need to go through ethics approval and will involve a review of security arrangements and Qualified Privilege status.

The NBCA suggests that this principle states that registries should collect individually identifiable patient information if needed for the registry's purpose. Identifying data should not be collected unless necessary, in accordance with the Privacy Act. Necessary reasons include patient contact, follow-up from different sources, data linkage or data correction. The audit has operated successfully without identified data for 10 years. This ties in with Principle 2, which states that a registry's core data collection should contain items required to serve their main purposes. If identified data is needed to serve the registries purpose, then it should be collected as part of the core items. If it is not needed, then it should not be collected. Perhaps then Principle 15 is not needed and identified data could be mentioned under Principle 2.

S5-P16: COLLECT PROCESS OF CARE INFORMATION (currently met)

Relevance = 10; Feasibility = 10; Ease = 8; Impact = 10; Overall value = 38

The NBCA was initiated as a means of assessing surgeon performance and the main activity of the audit is to collect surgical process of care measures and benchmark surgeons' performance against key quality indicators (minimum standards). Principle 16, then, lies at the heart of the NBCA's audit activity and we support this as an operating principle.

Process of care measures have been at the core of the audit dataset since the audit first began as a pilot project in 1998. Throughout the history of the project these measures have been assessed and updated as necessary to ensure that the audit is measuring important aspects of quality surgical care. The dataset is based on the NBOCC CMG^{2,3}, with input from surgeons and other experts in the field. The audit measures the quality of care in early breast cancer treatment by assessing surgeons on how well they follow key areas of these guidelines in their practice (evidence-based, linked to patient outcome with epidemiologically sound method of measurement). By basing the audit dataset on the guidelines it improves the understanding of key guidelines, and measures and increases the implementation of the guidelines, thereby improving quality of care in breast cancer management. The audit would not be able to fulfil its purpose without collecting this data.

The NBCA recommends that the draft Operating Principles document mentions that process of care measures can sometimes be used as proxy measures of patient outcome if patient outcome is unavailable or unable to be measured for whatever reason. For example, the purpose of the audit is to measure the quality of care provided by surgeons according to their adherence to key quality thresholds. The outcome we are measuring is whether surgeons are adhering to these thresholds.

UUS5-P17: COLLECT OBJECTIVE OUTCOME INFORMATION (currently met)

Relevance = 7; Feasibility = 7; Ease = 6; Impact = 8; Overall value = 28/40

The NBCA does not consider the collection of patient outcome data relevant to the purpose of the audit, which is to assess surgeon performance. Relying on patient outcome for this assessment is problematic, as ultimate patient outcome would be dependent on many factors outside the surgeon's control. Often the care is transferred away from the surgeon following the initial treatment process for long-term management, so it is harder for the surgeon to gain follow-up information. Currently, the audit assesses each surgeon against key quality indicators. This is seen as a proxy measure of outcome. That is, the outcome we are measuring is adherence to the key quality indicators rather than individual patient outcomes. All key quality

indicators have been produced according to evidence-based guidelines for care of early breast cancer and DCIS patients.

As stated above, the NBCA considers surgical performance outcome as adherence to key quality guidelines which are based on the NBOCC CMG^{2,3}. It was necessary for the audit to translate these guidelines into objective measures of care in order to assess and improve surgical care through self-assessment and benchmarking. These measures (quality thresholds) were set through consultation and consensus with stakeholders and experts in the field of breast cancer treatment.

The NBCA argues that Principle 17 is covered under Principle 4 which states that all data collected should be confined to items that are epidemiologically sound. This would include outcome data. If Principle 17 continues as a principle in its own right, it is the recommendation of the NBCA that it be re-worded to take into account the fact that some registries concentrate on collecting process of care measures rather than specific outcome data. This can be more reflective of quality of care when there are a lot of other factors which affect patient outcome^{6,7}. Process of care measures also foster a more educative (rather than punitive) atmosphere and target all participants. What this means for the audit is that all participating surgeons are improving care by following the guidelines, and the improvement is not limited to targeted outliers.

5.4 Risk adjustment

S5-P18: COLLECT OBJECTIVE, RELIABLE CO-VARIATES FOR RISK ADJUSTMENT

(requires external changes)

Relevance = 7; Feasibility = 6; Ease = 4; Impact = NA; Overall value = 17/40

Risk adjustment may be a valuable initiative and the next step in developing the thresholds assessment process; however, it is yet to be fully considered by the Evidence and Performance Subcommittee and the Steering Committee. Subjective risk adjustment is built into the standards assessment process as described below.

Informal risk adjustment is built into the standards assessment process (outliers process) with risk factors taken into account through ad hoc examination of the data by clinical specialists. The dataset contains age and region details but does not include comorbidity or general health of the patient. The current process, however, allows surgeons to include extra information in the comments section of data entry, so if these factors had an effect on treatment they could be taken into account in the assessment process.

In terms of comparison between surgeons, no risk adjustment is performed. Providing statistical risk adjustment, both for research and surgeon self-auditing purposes, is considered an

important area for further investigation. The development and validation of a model for risk adjusting threshold values will be investigated more thoroughly in the future once sufficient funding can be found. In the meantime, informal risk assessments will be continued for the outliers process only.

It remains unclear in the Operating Principles draft document exactly what must be achieved for a registry to have implemented this principle. For example, how many co-variables does a registry need to collect before it counts as having implemented this principle? Is age enough? Age and region? Age and region and severity of comorbidity? And is it enough to collect them or does the registry have to perform statistical adjustment? Would subjective assessment on a case-by-case basis of outliers (as achieved by the audit) count as having implemented this principle?

As already stated, NBCA governance has yet to formally discuss the use of statistical risk adjustment for the audit environment; however, the audit does take these into account informally during the setting of threshold values and the outliers assessment process. With this in mind, it is suggested that Principle 18 could be revised to say that a registry should take outside risk factors into account when identifying outliers. This may be in the form of formal statistical risk adjustment or through a more informal assessment of individual cases.

5.5 Data security

S5-P19: SECURE ACCESS CONTROLS AND SECURING MESSAGING (currently met)

Relevance = 8; Feasibility = 9; Ease = 7; Impact = 9; Overall value = 33/40

When collecting sensitive, personal information, keeping this information secure is important. Data security is a vital issue for registries who collect fully identified data. Registries who collect semi-identified data, such as the NBCA, must still keep security issues in mind. Each registry must be aware of what security level is required to keep the data safe from unauthorised access.

In 2004 the NBCA moved to a web-based data entry system. At this time there were no commercially available products, so a programmer was employed to develop a customised secure program. At that time, there was a high degree of difficulty in implementing a secure system. An Audit Technical Advisory Committee was also convened to provide advice and resolve problems associated with the technical challenges of the online data entry system, such as internet security, backup protocols, disaster and recovery strategies and data encryption. This committee comprised a surgeon, an epidemiologist, two computing experts, a statistician, and a consumer representative from Breast Cancer Network Australia (BCNA).

By 2006 the process of implementing a secure system had become more standardised and NBCA's original web data entry system was replaced with a new industry-standard on-line

database with bank-level security. The current version of the database still uses this platform. The majority of data entry is via a secure website, restricted with password authorisation. The site is accessible through Secure Socket Layer (SSL) protocol and all data stored on the server is encrypted. The NBCA server is located off-site, in a data centre, with restricted physical access and maintains a secure firewall to prevent unauthorised electronic access. NBCA paper forms are stored in a locked file cabinet with restricted access.

Secure access controls maintain the confidentiality and integrity of data by ensuring that only those authorised for access can see and modify any stored data. This protects the patient's and surgeon's right to privacy, as well as the quality of audit data.

Principle 19 states that registries must utilise secure access, transfer and messaging. The technical standards refer to messaging as part of web services. This report assumes that if a registry does not utilise web services, this principle can be fulfilled by having secure transfer. This is not made clear in the draft document.

S5-P20: DATA COLLECTION, STORAGE & TRANSMISSION COMPLY WITH RELEVANT LEGISLATION & GUIDELINES (currently met)

Relevance = 8; Feasibility = 9; Ease = 7; Impact = 8; Overall value = 32/40

As stated above, when collecting sensitive, personal information, keeping this information secure is important. All registries must comply with relevant legislation and guidelines for adequate functioning. This includes keeping data safe from loss or disclosure, as well as unauthorised access and modification.

In addition to the data security measures discussed above, the audit has a back-up and recovery process for the database to protect against loss of data. This process has been documented in an official written procedure as part of the audit's current focus on creating and updating all relevant documentation for the audit. Documentation has been a priority area of the College for 2009.

The NBCA could not function as a quality assurance tool without following the legislation and guidelines of Principle 20. Registries must protect participants' right to confidentiality or they would not participate. If the audit did not protect its data from modification or loss, the data collected would not be useful for benchmarking or research as data could be incorrect or missing.

The NBCA questions whether Principles 19 and 20 need to be two separate principles as similar data security issues are covered under both. Principle 33, which is concerned with abiding by Privacy legislation, also covers data security issues, as privacy legislation requires that information collected be protected from misuse, loss and unauthorised access.

S5-P21: POLICIES COMPLY WITH TECHNICAL STANDARDS (can be met in the short/medium term)

Relevance = 6; Feasibility = 5; Ease = 7; Impact = Yet to be completed; Overall value = 18/40

The NBCA feels that it is more relevant to ensure that data security policies comply with the legislation and guidelines specified under Principle 20. That said, the NBCA has taken into account those standards mentioned in the identity management section of the technical standards map in the production of the audit data security policy. The other technical standards were not deemed relevant to Principle 21. For more information on the relevance of technical standards see section 7.

A policy has been drafted on the data security issues of the audit. It must be ratified by both the NBCA Steering Committee and the College Council. The ratification of this policy may take some time; however, in the meantime the audit will continue to meet its security standards without the documentation. The use of the ISO 27002 standard for data security was also hampered by the fact that this standard needed to be purchased to view. However, these principles have been incorporated into the data security policy where possible.

The NBCA supports a principle that recommends registries having a data security policy; however, the draft principles and standards document is not clear on what is needed to implement Principle 21. For example, page 38 states: 'Where registries collect data from multiple institutions, there must be a policy and agreement established within each institution covering storage of data.' It is unclear whether this means a policy for storing data at the audit or at each data collection point.

It is also unclear which technical standards need to be met for this principle as the principle itself only states that policy principles set out in the standards section should be met. The technical standards section of the draft Operating Principles/Standards document lists a large number of standards, not all of which relate to data security. If the principle refers to only 'data security' related technical standards, the draft document should state which of the standards in the standards section apply.

5.6 Data quality

S5-P22: REPORTS PERCENTAGE OF ELIGIBLE PATIENTS RECRUITED

(can be met in short/medium term)

Relevance = 6; Feasibility = 7; Ease = 6; Impact = Yet to be completed; Overall value = 19/40

The NBCA feels that the most important aspect for registries in relation to this principle is to know the percentage of eligible patients recruited (registry coverage) and to work towards

getting this percentage as high as possible. Reporting the percentage in a public report has not been a priority for the audit.

The audit cannot gain an accurate denominator of all eligible patients for the audit as there are no available statistics on the number of early breast cancer cases. The audit has had to work around this problem by reporting on the percentage of all breast cancer cases that are included in the audit, with a caveat that audit coverage will never exceed 95% as the NBCA does not collect cases involving distant metastases which are estimated at between 4% and 6% of breast cancer cases. Obtaining the data for all breast cancer cases was difficult as the AIHW does not include data for DCIS. The audit aimed to present coverage by region which also could not be provided by the AIHW. The alternative was going to each cancer registry in Australia and the New Zealand cancer registry for data. This has been achieved for all regions and the audit now has a denominator for breast cancer cases from 2000 to 2006. Gaining this data was a lengthy process. It took between 2 weeks and 3 months to obtain from the majority of registries. One small registry took 6 months to provide data.

Estimated coverage for each region was reported to audit governance throughout the process, as information became available. Reporting on this coverage will provide audit governance with information on how far it needs to go to meet its quality threshold. Coverage reporting to committees has not had a large impact on the audit's functions, as the governance and management structures already knew that this area was a weakness for the audit, and rough estimations of coverage had been performed previously.

Coverage estimates will also be reported in an annual report to be distributed to stakeholders and made available to the public online. These estimates will provide an indication of the quality of audit data for reporting on early breast cancer care. Previous annual reports contained figures for the total number of cases in the database for that year but did not report this as a percentage of total cases in Australia and New Zealand. The audit has yet to publicly publish these estimated percentages and so is unaware of the impact it will have.

S5-P23: DATA QUALITY CONTROL PLAN USED (can be met in short/medium term)

Relevance = 8; Feasibility = 8; Ease = 5; Impact = Yet to be completed; Overall value = 21/40

The NBCA considers a data quality assurance plan an essential element in ensuring the database provides accurate and reliable output, both for surgeons and for public health reporting. However, creating and implementing a quality control plan involves compromising between what would be the best control and what it is feasible for the audit to implement. For example, site audits are the preferred method of checking data against the source; however, this is costly and time consuming to conduct (see S5-P24 below for more details).

The audit has drafted a data quality assurance plan which proposes the ideal data quality assurance activities. This plan will be reviewed by the Steering Committee. It should be feasible to implement some form of the data quality assurance plan in the near future, with compromises for activities that may not be achievable at the current time.

In discussing data quality, the draft Operating Principles document uses the terms 'data quality control plan' and 'data quality assurance plan' interchangeably. These two terms do not refer to the same thing. Quality assurance relates to activities performed prior to data collection to ensure that all processes and procedures are geared toward quality data, for example methodology used and documented data entry procedures. Quality control refers to the evaluation of data to find and correct errors, for example completeness checks and site audits.⁸

S5-P24: DATA CHECKS/AUDITS ROUTINELY PERFORMED (requires external changes)

Relevance = 7; Feasibility = 4; Ease = NA; Impact = NA; Overall value = 11/40

Site audits of random data collectors would provide the ideal solution for quality control checks on NBCA data. However, the execution of this initiative would not be feasible without a significant increase in current funding. The audit will discuss an alternative quality check, such as cross checks with external sources or extensive range and consistency checks, when discussing data quality assurance in future Steering Committee meetings.

Principle 24 states that data should be checked in a sample of cases and that this usually involves audit against source records. The term usually implies that there are alternatives to using site audits; however, there are no details on acceptable substitutes. If a registry uses logic checks or cross-checks data with other external sources is it meeting this principle? If a registry asks data collectors to go back and check a selection of data is this meeting the principle or do source data checks need to be performed by an independent registry staff member? The principle requires greater clarification on these points. The NBCA also argues that data checks would be covered in a data quality control plan; as such, data checks would come under Principle 23 and may not need to appear in a separate principle..

S5-P25: DATA MANAGEMENT PROCESSES USED (currently met)

Relevance = 9; Feasibility = 9; Ease = 7; Impact = 8; Overall value = 33/40

Data management processes, or validation rules, are necessary for registries to ensure the accuracy of benchmarks and reporting. If these automated processes are built-in to the data entry system they will identify errors at the data entry stage. If a data collector or transcriber cannot save a file which has blank data fields for example, this will encourage them to fill in the missing data so that the record can be processed. Without automated checks in place, a registry will need to check data after entry. This will either lead to an excessive burden of extra

work for the registry or will only be done occasionally meaning data collectors will receive enquiries about missing or suspected incorrect data long after data entry. The difficulty in retrieving this information so long after data entry may discourage data collectors from correction.

The majority of the validation rules on the current online data entry system were put in place during the 2006 version 2 website upgrade. These rules were implemented as a result of errors found during a data cleansing project prior to the launch of the version 2 website. The exact nature of the validation rules was determined from lessons learned in that project, in consultation with the IT company who designed the new system and with clinical input.

A version 3 data entry website was launched in 2009. New validation rules were incorporated with this upgrade. These were informed by the implementation of the MDS on the online system and were agreed upon by the Steering Committee. The new validation rules include mandatory fields and incompleteness alerts for MDS items. These new rules have produced increases in the completeness of data entry fields, most noticeably in diagnosis date which is up from 90% complete to 100% complete as it is now a mandatory field.

S5-P26: REPORTS PRODUCED TO A SPECIFIC TIMETABLE (can be met in the short/medium term)

Relevance = 5; Feasibility = 6; Ease = 4; Impact = N/A; Overall value = 15/40

Having reports produced along a specific timetable would be of benefit to a registry; however, it is not currently possible for the NBCA. What is more important, for the audit, is increasing and maintaining good coverage, ensuring data quality and providing an instant reporting service for surgeons. Providing more detailed formal reports to surgeons is important and the NBCA is working on a schedule for these.

An attempt was made to produce a rough reporting schedule for the audit during this project; however, the uncertainty of continued funding made it too difficult to be certain what reports could be produced, when and how often. The audit is now in a period of transition, in the process of becoming a Society of Breast SurgANZ audit (see S5-P29 and P42 for more information). This issue will be revisited once the new audit structure and expectations are clearer. The NBCA, and likely other registries, tend to encounter short-term funding contracts which often specify the funder's key deliverables. Reporting timetables are often based on these deliverables and would change regularly as the registry's funding source changed.

The NBCA considers Principle 26 to be somewhat proscriptive and restrictive in not considering other work involved with the registry. The audit would support a principle that requires a minimal amount of reporting to stick to a strict timeline (an annual report for example) in order to be reliable for consumers and users; however, not all reporting should be held to such a strict timeline.

5.7 Organisation and governance

S5-P27: FORMAL GOVERNANCE STRUCTURES (currently met)

Relevance = 9; Feasibility = 10; Ease = 7; Impact = 7; Overall value = 33/40

Formal governance structures which include representatives from all relevant stakeholder groups are essential for the effective running of the NBCA and any other quality registry. Regular consultation with stakeholders ensures that the audit caters to the needs of each group. An important component of this consultation is the involvement of consumer groups as they represent the ultimate beneficiaries of the audit's work on improving quality of care.

The audit has had a strong history of involvement from all relevant stakeholder groups. The NBCA Steering Committee consists of breast surgeons, breast cancer research (NBCF) and policy representatives (NBOCC), consumer representatives (BCNA), a breast care nurse and a medical oncologist. It fulfils all of the roles described in the draft document as important for a steering committee. The NBCA also has clinical direction meetings with the full data management team and two senior clinicians. These meetings occur once a fortnight and cover all of the duties described in the draft principles and standards as the duties of a management committee.

S5-P28: QUALITY OF CARE POLICIES DEVELOPED (currently met)

Relevance = 9; Feasibility = 7; Ease = 5; Impact = 6; Overall value = 27/40

A well thought out and appropriate outliers process is a key function of the audit. As the audit is a voluntary activity, it is important that this area is treated delicately. Results must be watertight as they have the potential to affect a surgeon's reputation. If the outliers process is not seen as robust, surgeons will not participate.

Although the audit has a formal plan for managing outliers, the implementation of this plan has met with several difficulties (See S6-P28). The audit began the Pilot of the Outlier Process in 2008 and it is still refining the process. The plan will undoubtedly be updated as the audit moves into its role as a Society of Breast SurgANZ audit. The impact on the audit has so far been minimal as the process has not been seen through to completion; however, the impact will be larger once the audit has the authority (as a Society audit) to examine and refer outliers to the Breast SurgANZ for monitoring and re-education.

Principle 28 states that policies should be in place to manage a range of contingencies but does not list what policies this could refer to other than one to deal with outliers. If a registry has an outliers management policy, is this principle met? If further policies are needed, these should be explained and listed in the Operating Principles document. This principle could also refer to the

documented specifications of what constitutes good quality of care in the context of the registry. If this is not the intended meaning of the principle, the NBCA recommends that the need for specifications of this kind becomes part of the next version of the draft document.

5.8 Data custodianship

S5-P29: CUSTODIANSHIP EXPLICITLY DECLARED (currently met)

Relevance = 9; Feasibility = 9; Ease = 8; Impact = 6; Overall value = 32/40

Custodianship allows the organisation to determine how the information will be managed and accessed. Data does not belong to the funders nor to the registry; rather the registry has been appointed to manage the data for the contributors. In the case of the NBCA this is the surgeons themselves, who use the data as an auditing tool. Funding contracts should be explicit in defining the access and products granted to funding bodies and explicitly state who is responsible for the data. The NBCA supports this as a principle.

The audit is not currently under contract to an official sponsor. These issues will need to be considered, however, when contracts are drawn up with the Society of Breast SurgANZ and their sponsors. The contract would state that the College is a custodian of the data for the surgeons, as represented by the Society.

S5-P30: DATA ACCESS AND REPORTING POLICIES AVAILABLE (currently met)

Relevance = 8; Feasibility = 9; Ease = 7; Impact = 5; Overall value = 29/40

The NBCA supports the inclusion of Principle 30 in the Operating Principles. The ultimate goal of the NBCA is to improve the quality of surgical care for early breast cancer treatment in Australia and New Zealand. The primary way of doing this is through a full clinical audit cycle; however, providing data for research into early breast cancer issues is also an important aspect of the audit's function. The audit team currently prepares one or more papers on these issues annually. It is also possible to provide data for research carried out externally. The benefits of this research, however, must be weighed against privacy issues. This is where data access and reporting policies are important. Having a solid data access policy in place ensures that all parties follow the requirements for ethical access to sensitive data. These policies need to be readily available to external parties to ensure that each researcher is aware of their rights and responsibilities and the procedure to follow to apply for access.

The NBCA's original data access policy was drafted in 2006 and has been approved by the Steering Committee. Researchers are given this policy after initial enquiries about data access. The data request procedure has been followed through during data extraction for participating surgeons. A new data access procedure has been produced in 2009, taking into account authorship guidelines and request requirements. The policy and procedure will be updated for approval by the Steering Committee in the coming months.

S5-P31: THIRD PARTY ACCESS ONLY VIA STEERING COMMITTEE AND IEC APPROVAL

(currently met)

Relevance = 8; Feasibility = 9; Ease = 7; Impact = 5; Overall value = 29/40

Steering Committee approval ensures that the requirements for access, as set out in the data access policy, are fulfilled. The Steering Committee, following a review from the Data Request Subcommittee, will consider the request for access to ascertain if it would breach privacy legislation and guidelines and that the research proposed is worthwhile. This is an important barrier to the misuse of audit data and the NBCA supports this for inclusion in the final list of Operating Principles.

The audit has a procedure in place for data access and has followed this procedure during data extraction for participating surgeons. The approval process for data requests is dependent on the type of request made. If the enquiry involves assisting a surgeon to extract their own information from the audit, the request can be processed by the audit staff. If the request is from a person or group external to the audit, or involves aggregate data from a group of surgeons, it is referred to a Data Request Subcommittee, comprising the Chair of the Breast Section, the Chair of the Steering Committee and a surgeon representative from New Zealand. Decisions made by this subcommittee then need to be ratified by the audit Steering Committee. External requests on individual surgeon level data (to anyone other than that surgeon) cannot be approved as it would breach the terms of Qualified Privilege. As data is not given at the individual surgeon level and information in the audit does not identify patients, the NBCA has not deemed Ethics Committee ratification necessary.

5.9 Ethics and privacy

S5-P32: IEC APPROVAL GAINED (currently met)

Relevance = 8; Feasibility = 9; Ease = 7; Impact = 9; Overall value = 33/40

Institutional Ethics Committee (IEC) approval must be gained for the establishment of all new registries to comply with privacy legislation and guidelines. The IEC will ensure that the registry does not create an unfair burden on patients and that the ultimate purpose of the registry is worthwhile. The NBCA considers this principle a valuable inclusion in the final Operating Principles document.

The NBCA gained ethics approval from the College on the initial commencement of the audit in 1998. Since this time, ethics approval has been sought on a needs basis for major changes to the audit functioning. In 2009, for example, the audit sought and gained ethics approval for the switch to opt-out consent.

The audit does not gain ethics approval from each institution where data is collected as the collection is done at an individual surgeon level with the audit awarded a Qualified Privilege status under federal legislation. The audit believes that with the consent of patients and surgeons, and the audit's Qualified Privilege status, it fulfils all requirements for quality assurance activities that can proceed without ethical review, as listed in the National Health and Medical Research Council (NHMRC) guide.⁹

S5-P33: PERSONNEL FAMILIAR WITH AND ABIDE BY RELEVANT PRIVACY LEGISLATION AND GUIDELINES (currently met)

Relevance = 9; Feasibility = 9; Ease = 7; Impact = 9; Overall value = 34/40

As the audit collects sensitive, personal information, it is important to comply with all relevant legislation and guidelines for human research and privacy. Although the audit does not contain patient names, it does contain other potentially sensitive health information. Staff must have full knowledge of ethics and privacy requirements to ensure inadvertent mistakes are not made.

NBCA practice abides by privacy legislation and ethics guidelines. An induction document for new employees to the audit provides a summary of all relevant legislation and guidelines, as well as audit practice in relation to these requirements. This document ensures that all new employees are aware of their obligations.

The induction document also contains details of the audit's Qualified Privilege status. In 2005 the audit was declared a quality assurance activity under Qualified Privilege legislation in Australia. The legislation prevents the audit from disclosing identified information unless consent is given or required by law. This covers audit staff to access health information and review medical records for data quality assurance purposes and provides confidence for the surgeon participants that their data is safe and confidential. Without this cover, identified data and data quality site audits may not be possible as surgeons may be breaching the privacy of individuals in releasing patient information to anyone who would not normally have access.

S5-P34: PARTICIPANTS MADE AWARE OF COLLECTION OF REGISTER DATA AND GIVEN OPTION TO NOT PARTICIPATE (currently met)

Relevance = 8; Feasibility = 8; Ease = 6; Impact = 6; Overall value = 28/40

Registries and audits often collect sensitive personal health information. The NBCA agrees that participants must be made aware of this collection and be given the opportunity to refuse to have their own data included. Although this may impact on coverage for the audit, it is important to remember that patients are the ultimate owners of their own health information and should be given a choice in how this information is used. Registries need to be very clear in explaining exactly what will be done with personal information and why. If the registry has a clear and

worthwhile purpose, opt-out is usually very low.^{10,11} One study highlighted that consumers dislike having personal information collected without their knowledge.¹²

During this project the NBCA altered the audit's consent from an opt-in consent system to an opt-out consent system. The audit gained ethics approval from the College for this change and the surgeons were informed via mail out in early June. The change in consent system also involved an update of the NCBA information sheet, which now provides more detail about the audit, its benefits and the process of data collection, in an easy-to-understand format. The wording was reviewed by the BCNA representatives, who have extensive experience in providing breast cancer information to consumers. This collaboration highlighted two points which the BCNA considered essential in drafting the information sheet. The first was that it must be clear to consumers that including their information in the database was their choice. The second was that opting out remained a simple process for the consumer.

The switch to opt-out consent provides benefits for the audit and surgeon participants while ensuring that patients are still given the option to refuse participation if they so wish. The new system should increase the coverage of the audit by losing less data to lack of consent and by maintaining surgeon satisfaction in participation. The switch has lessened the burden on surgeons by alleviating the need for them to actively seek and store consent from patients.

S5-P35: IEC APPROVAL SOUGHT FOR PROJECTS USING REGISTER DATA (not applicable)

Relevance = 3; Feasibility = NA; Ease = NA; Impact = NA; Overall value = 3/40

The NBCA is negligible risk research, that is, there is no foreseeable risk of harm or discomfort to patients or surgeons who participate. The National Statement on Ethical Conduct in Human Research states that research involving negligible risk and collections of non-identifiable data is exempt from ethical review.⁴

The audit has been approved by the College ethics committee, but does not seek approval for individual projects as the audit does not collect fully identified patient data and would not release or use any surgeon identifying information for projects without prior approval from each surgeon. The audit is prevented from doing so by its Qualified Privilege status. All internal projects are part of the quality assurance activity as defined in the audit's Qualified Privilege application.

The NBCA agrees that projects using registry data should be reviewed; however, in cases with de-identified data this may not need Ethics Committee approval but may be reviewed via a Registry Review group. It would then be the review group's decision as to whether full Ethics Committee review needs to occur.

5.10 Information output

S5-P36: QUALITY OF CARE ASSESSED (currently met)

Relevance = 10; Feasibility = 10; Ease = 7; Impact = 8; Overall value = 35/40

Feedback is an essential component of clinical audit. Calculating surgeon performance against key quality indicators and providing practice values on the data entry website aids in improving quality of care by alerting the surgeon to how they are performing against official guidelines. Surgeons with lower than expected levels have in some cases enquired about the possible causes of this lower level and sought to verify their data. Publishing audit data is another means of reinforcing the concept of quality measures for the treatment of early breast cancer and identifying any disparity in treatment between patients across various demographics.

In 2003 the emphasis of the audit began to shift away from a self-audit system and towards a full clinical audit cycle. During 2004 a sub-committee was formed for the purpose of identifying key clinical quality indicators and establishing minimum working standards or thresholds for the treatment of early breast cancer. The priority was to make sure any indicators were measurable, evidence-based and were largely within the domain of control of an individual surgeon. A modified Delphi approach was devised to rank a variety of factors and agree by consensus which ones would form a group of 5 key indicators or benchmarks. Ultimately it was decided that the expert panel would instead devise key issues which would represent areas to measure quality of breast cancer surgery. From these key issues, key indicators would be devised to make the issue measurable. The indicators and threshold values, as well as the procedure for managing outliers (produced by another committee, see S5-P28) were put together into one document 'Process for managing under-performers in breast cancer surgery', which was reviewed by the RACS Surgical Audit Task Force and approved by the Professional Development and Standards Board. This allowed reporting on surgeon performance against thresholds to begin; however, work on the indicators and thresholds themselves is ongoing. They need to be regularly checked against current treatment guidelines and amended where necessary according to new evidence.

The key indicators used are based on the NBOCC Clinical Management Guidelines.^{2,3} Surgeons who input their data online have access to instant calculations of their performance against these key indicators. For the first time in 2008, in The Pilot Outliers Project, the NBCA produced a thresholds report which reports on the performance of each surgeon in the audit against the quality thresholds for their data of the year 2006. The ultimate aim of this report is to identify outliers to be examined by audit governance. The reporting process is still being refined however, and has not reached the stage of outlier management. The thresholds reporting process will be repeated in the coming months, with improvements incorporated from lessons learned in the last reporting process. The intention of the NBCA is to repeat the process every 2 years with review of surgeons identified as candidate outliers occurring in the interim.

The NBCA supports Principle 36 and acknowledges that an outliers process may be used to identify both positive and negative outliers. The audit's current outliers procedure is concerned with negative outliers only, as positive outliers would be difficult to ascertain. This is due to the use of performance indicators as surrogate measures of outcomes, and the lack of statistical risk adjustment. The audit identifies surgeons who fall below the set threshold for each Key Performance Indicator (KPI) and considers these surgeons negative outliers. Any surgeon with a value over the threshold is seen as meeting the threshold. If a surgeon's practice value for a given KPI is well over the set threshold, this may be due to his or her case load mix rather than a better performance than other surgeons. If the audit decides to go ahead with statistical risk adjustment, the identification of positive outliers may be a possibility.

S5-P37: NO DELAY IN REPORTING RISK-ADJUSTED OUTCOME MEASURES

(requires external changes)

Relevance = 8; Feasibility = 8; Ease = 6; Impact = NA; Overall value = 22/40

There are three components to this principle. The first is that there are no delays in reporting. The NBCA feels that the closer reports are in time to the actual behaviour the more impact they will have on further behaviour. The second component of this principle is risk adjustment. Risk adjustment is seen as important as it ensures that comparisons between surgeons are fair. The third component is outcome measures. The main thrust of the audit is reporting on surgeon performance which it does through the comparison of process measures against key quality indicators based on official clinical guidelines. These calculations are regarded as proxy measures of outcome. Outright patient outcome is not reported on as a quality measure; however, patient outcomes are sometimes reported in research papers.

The NBCA's online data entry website provides calculations of surgeon performance against the key quality thresholds (see S5-P17 for more information on the thresholds use as proxy outcome), as well as providing some graphical comparisons between the surgeon and the aggregate on various subjects of interest. Surgeons can access online reporting structure at any time; however, this data is not risk-adjusted. Presently, the NBCA does not perform any formal risk-adjustment, only informal subjective examination of outliers during the outliers management process. More formal statistical risk-adjustment may be investigated when the audit has a more stable funding arrangement (see S5-P18), but has yet to be considered by the audit's governance. In the meantime, the audit will continue to provide instant reporting to surgeons via the online data entry website.

The NBCA does not support Principle 37 as currently worded. As mentioned above, the principle contains three parts. Does a registry need to implement all three parts to confidently state that Principle 37 has been implemented, or is this principle most concerned with the

timeliness of reporting? This principle again refers to outcome measures. Does this include surrogate measures of outcome, as used in the NBCA? The NBCA feels that the principle needs to be clearer on what is required.

S5-P38: FORMAL PEER REVIEW PROCESS PRIOR TO PUBLICATION (currently met)

Relevance = 8; Feasibility = 9; Ease = 6; Impact = 7; Overall value = 30/40

Formal peer review is an important aspect of any publication process. It ensures that the research is of a high quality and does not contain bias. If a registry is to be respected as a quality source of data and research, and a tool for quality improvement, it must be able to hold up to scrutiny.

The thresholds report (benchmarking and identifying outliers) is reviewed on a de-identified basis by the Steering Committee before distribution to participating surgeons. This includes review by an expert in the field of statistics and surgeon peers. If and when outliers are identified, a surgeon representative from the Breast SurgANZ executive will be appointed to review the raw data for that participant to identify any mitigating circumstances and, if necessary, contact the surgeon for more information or re-education.

Other audit publications, both formally published papers and informally published annual reports and other NBCA documents, are also sighted by members of the Steering Committee prior to publication. Each stakeholder group has an interest in the nature and output of the audit, and in the continuation and improvement of its activities. It is for this reason that committees have the final say in what will and will not be sent for publication. Each member of the audit's committees is an expert in the field of breast cancer treatment, research and/or advocacy.

Principle 38 needs to be more clear on what needs to be peer reviewed. If a research paper goes through a peer-reviewed journal it will be peer reviewed as a matter of course. So does this refer to other publications such as annual reports? Or does this refer only to the reports where quality is assessed? The thresholds report is not a public report and is only available to participating surgeons.

S5-P39: LOCAL DATABASE MANAGERS CAN PERFORM AD HOC ANALYSES (currently met)

Relevance = 7; Feasibility = 9; Ease = 7; Impact = 8; Overall value = 31/40

Without this ability the audit would not be able to perform basic quality assurance procedures such as incompleteness checks or estimates of timeliness of data entry. If every query had to go through the IT database manager, queries would be performed less often as the process would not be cost effective.

The NBCA's senior research officer can perform data analyses on backup data. Backups are created daily. This data is then exported into Access where the senior research officer can perform necessary analyses. This provides an alternative to using live data, which is constantly being updated throughout the day.

Surgeon contributors can also perform analyses on their own data by using the 'Export My Data to Excel' function on the data entry website. A more interactive reporting suite for surgeons is on the list of priorities for a further website upgrade to be completed as and when funding allows.

It has been assumed that this principle refers to audit staff as local database managers, rather than surgeon contributors who do not have access to the full database and cannot therefore be database managers. If Principle 39 does refer to contributors, it should be rewritten to make this more clear.

S5-P40: ANNUAL REPORT PUBLICLY AVAILABLE (currently met)

Relevance = 6; Feasibility = 8; Ease = 7; Impact = 7; Overall value = 28/40

The ultimate aim of the audit is to improve the quality of care received by early breast cancer patients from their surgeon. As these consumers are the ultimate beneficiaries of the audit process, they should have access to information on the results. However, as the main thrust of the audit has always been to provide feedback to participating surgeons in order to encourage improvements in the quality of service, reporting to consumers has been minimal. The NBCA does support Principle 40 as a principle and will consider the issue in the future.

In the past, the NBCA has provided an annual report in two parts. The statistical analyses of yearly data is provided in an annual public health report. The reporting of organisational changes and improvements are reported in the annual ASERNIP-S report. The 2008 ASERNIP-S report has been uploaded to the NBCA website and distributed in hard copy to stakeholders and interest groups. The public health report on 2007 data is also available on the web.

As the NBOCC funding contract expired in June 2009, and in preparation for becoming a Society of Breast SurgANZ audit, the NBCA would like to produce a more personalised, extensive public annual report for future years. This report could be distributed to stakeholders and made available on the College website. The format and content of this report would be determined by the audit team, clinical directors and committees and should include both clinical findings and corporate summaries. Coverage estimations, data submission timeliness and MDS use are all areas suggested for inclusion. The annual report may also include a short statement on the ability to request access to the audit data and how to go about it. None of these areas have been previously reported on in an annual report.

In 2009 the audit has also produced consumer summaries of past research which are now available on the BCNA consumer website.

S5-P41: DOCUMENTED PROCEDURES FOR REPORTING ON QUALITY OF CARE (currently met)

Relevance = 7; Feasibility = 8; Ease = 7; Impact = 7; Overall value = 29/40

Identifying and managing outliers, based on key performance indicators, is considered a core aspect of the audit as a quality assurance program. A documented policy and procedure for this process is necessary to ensure the continued accuracy of this process.

A procedure for running the thresholds (outliers) process and reporting threshold values has been drafted by the audit's senior researcher. This process has been completed in 2008 as a pilot exercise and will be run again in 2010, taking into account the issues encountered in the pilot test (see S6-P41).

5.11 Resources and funds

S5-P42: APPROPRIATE AND SUSTAINABLE FUNDING (can be met in short/medium term)

Relevance = 10; Feasibility = 6; Ease = 4; Impact = NA; Overall value = 20/40

Sustainable funding is essential for the ongoing functioning of any registry. Without ongoing funding, a great deal of effort must be put into searching for the next source of funds. This distracts from the actual work of the audit. Unfortunately it is difficult to gain both ongoing funding and sufficient funding to resource all areas of the audit adequately. Funding is a problem dealt with by all registries and is often the issue at the heart of possible expansion and improvements to the registry. Registries struggling to gain appropriate and sustainable funds can easily spend a significant amount of their limited resources on the search for more funding, reducing time for other activities.

The audit is moving toward becoming a Society of Breast SurgANZ audit. The Society will provide core funding through sponsors and subscriptions (however this is still dependent on the Society gaining enough corporate sponsorship on a regular basis). This will release some of the pressure on the audit to raise funds on a continual basis, although some research funds may still come from other sources.

5.12 Final discussion

The NBCA currently meets twenty-seven of the forty-two draft principles (1, 2, 4-6, 8, 12-14, 16, 17, 19, 20, 25, 27, 29-34, 36, 38-41). A further five are considered feasible for the audit and are the process of being considered and worked on (15, 21-23, 42). Principles regarding identified data and documentation need to be ratified by the Steering Committee. Delays in

implementing the other two principles are due to the current transition period of the audit as it moves towards becoming a Society of Breast SurgANZ audit.

Four Operating Principles are judged feasible by the audit team, but are yet to be considered by audit governance(18, 24, 26, 37); three of these may require significant funding (18, 24, 37). Setting up the audit to statistically risk adjust the quality threshold measures may be worthwhile; however, this will require a thorough investigation of the issue, including a peer-reviewed validation of proposed risk indicators. It is estimated that this could cost \$50,000 to cover staff time and consultants' fees. Currently the audit does not have the funds or human resources to devote to this project, which will first need to be thoroughly discussed by the audit's Committees before approaching this area of work. Depending on the model of verifying source data employed, sending audit staff to sites would also necessitate a significant cost to the audit's annual budget. This is estimated at \$5000.

Three more principles could not be fully met, but have been met to the best of the audit's abilities (3, 10, 11). This has more to do with the structure of the audit than cost of implementation. The audit does not have the authority to alter data sources but may change audit data items if there are sufficient issues with compatibility and ease of data collection (P10). Similarly the audit does not have the authority to enforce the format of institutional data collection which will limit the implementation of Principle 3. This data is important to consider, however, if the audit wishes to increase its coverage of breast cancer cases in Australia and New Zealand. Lastly, the audit does not consider the move to SNOMED feasible or worthwhile at the current time (see the section on Technical Standards for more information). Many data items are not covered by the SNOMED nomenclature; implementing these could lead to confusion and dissatisfaction amongst surgeons currently contributing data. All three of these areas will continue to be monitored to ensure that the quality of the audit is not compromised.

Of the three remaining principles (7, 9, 35), complete coverage is something the audit strives toward, but may be unfeasible to achieve. Timely data collection requires better definition, as this will vary according to the type of data required for different registries. Furthermore, the data submission process may be skewed by institutional data uploading. Lastly, obtaining ethics approval for each project using the audit data is largely considered irrelevant as data used is de-identified and external use is approved by the audit's Data Release Group. The need for additional ethics approval for projects is at the discretion of the Data Release Group and the Steering Committee.

A summary of how each principle has progressed in the implementation process is given in Table 2 of Appendix 1. Further detail is provided under the relevant headings of section 5.

Overall, the NBCA considers the draft principles relevant for clinical quality registries and feasible to implement; however, implementation may not be easy in all cases and it questions whether following all the principles would be appropriate for each registry. The NBCA has rated

each principle according to its relevance and feasibility to the audit environment, how easy it was to implement and how much of an impact it has had on audit functioning (see Table 2 and Figure 1 in Appendix 1). According to the NBCA rating scale (considering relevance, feasibility, ease and impact), the most important principles in order of rating score are:

- Principle 1: Registries should have a clear and precisely-defined purpose.
- Principle 16: Registries should collect processes of care measures with an established link to patient outcome.
- Principle 12: A detailed and up-to-date data dictionary must be used to ensure a systematic approach to data collection.
- Principle 36: Registry data should be used to evaluate quality of care by benchmarking performance.
- Principle 33: Registries should abide by Privacy legislation.
- Principle 8: Data collection must not impact on provision of care or place a burden/cost on consumers.
- Principle 4: Data collection methods should be identical across institutions/collectors.
- Principle 2: Core data collection should focus on essential elements required to fulfil the main purpose of the registry.
- Principle 32: IEC approval must be obtained to establish a registry, and for any significant changes in functioning.
- Principle 27: Registries must have a formal governance structure, with input from all relevant stakeholders.
- Principle 25: Incorporate in-built data management processes into the data entry system for improved data quality.
- Principle 19: Protect register data with secure access controls and transfer systems.
- Principle 29: Custodianship of register data needs to be made explicit in contracts with research partners or funding bodies.
- Principle 20: Data security must be in line with relevant legislation (could this be merged with Principle 33 above?)
- Principle 39: Local database managers should be able to perform ad hoc analyses of data.
- Principle 6: Consider the burden and cost of data collection.

The principles rated least important for the NBCA audit environment were:

- Principle 35: IEC approval must be sought for each project undertaken using register data.
- Principle 7: Complete registry data must be collected from the eligible population.
- Principle 11: Standard definitions, terminology and specifications are to be used to enable meaningful comparisons and linkage with other registers.

Further detail is provided under the relevant headings of section 5.

5.13 Improving the audit

The ultimate aim of the audit is to improve and maintain the quality of surgical care received by early breast cancer patients in Australia and New Zealand. It does this through collecting data on surgeon performance measures, which are based on NBOCC CMG.^{2,3} These guidelines recommend specific treatment protocols which are linked to better patient outcomes. The NBCA's commitment to benchmarking performance against the guidelines and managing performance outliers will improve the quality of care provided by surgeon participants.

The Clinical Quality Registries project has provided the NBCA with an opportunity to grow and develop, bringing it up to a higher standard of performance that can be sustained into the future. Many of the areas of improvement had been labelled as priority areas for 2009 prior to the commencement of the Registries project. The implementation of the MDS, updating the website with new validation rules and estimating and improving coverage are examples of these priority areas. The draft Operating Principles document has also suggested further areas for improvement that may not have been discussed or implemented if not drawn to our attention by the Registries project.

The move to opt-out consent was a major implementation in 2009 resulting entirely from the Registries project. Opt-out consent will decrease the burden on surgeon participants which will increase satisfaction and encourage participation from non-participants. This will have a positive impact on coverage. Opt-out consent is proven to lower the proportion of cases which are excluded due to consent issues.¹⁰ Again, this will have a positive impact on coverage.

The NBCA will consider producing a more personalised, extensive public annual report in 2009, following recommendations in the draft Operating Principles document. The format and content of this report will be determined by the audit team and NBCA governance and will include both clinical findings as well as general audit information. This report will be distributed to stakeholders and made available on the audit's College website.

Data quality and data security have both been areas of concern throughout the history of the audit. As a result of the Registries project, the audit will make it a priority to ensure that these areas are planned and documented thoroughly. The concept of site audits has also been re-introduced on the audit agenda due to recommendations of the Registries project.

Formal, statistical risk adjustment of surgeon performance on thresholds has been discussed for the first time in 2009 as a result of the Registries project. This adjustment will be discussed by the NBCA governance before it is considered for incorporation into the outliers process

development. However, the audit will need sufficient funds to ensure that risk indicators can be convincingly validated before this can be fully implemented.

The Steering Committee is yet to decide on the issue of identified data but discussions on the issue have been re-introduced after the idea was rejected at the initial development of the audit. After 10 years, data security has greatly improved and audit management are confident that identified data is now a possibility. Identified data will aid in data linkage, correction and patient access. However, data security and qualified privilege will need to be reviewed if the use of identified data goes ahead.

The NBCA is confident that these changes have enhanced the audit as a tool for improving and maintaining the quality of care received by early breast cancer patients. Improvements in coverage and participant satisfaction will ensure that the proportion of surgeons following these guidelines and benchmarking their performance is high. Improvements in the completeness and quality of core data entry due to MDS implementation and new website data entry validation rules will improve the accuracy and effectiveness of thresholds figures in the next thresholds report. An automated risk adjustment model (if this can be achieved in the short term) will improve the identification of outliers in the thresholds reporting process and increase surgeon confidence in the accuracy of this process. Identified data would aid in data linkage with the NDI, which is important to periodically check that performance indicators are still linked to patient outcome. A more personalised, extensive annual report will improve the image of the audit with surgeons, consumers and other stakeholders (general practitioner referrers, for example).

6. Issues, barriers and problems encountered

6.1 Attributes

S6-P1: CLEAR PURPOSE

ISSUE: SCOPE CREEP

The difficulty for the audit does not lie in defining a purpose; rather it lies in not straying outside of this purpose, what the draft document refers to as 'scope creep'. The audit contains data that would be valuable for research and there has been some success with utilising the data in this way. However, the NBCA must be cautious in expanding audit activities, and not lose sight of the ultimate aim and core mission of the audit. For example, expanding the collection of patient outcome data may be useful for research purposes but is outside the scope of the audit, and any significant increase in core data collection will impact on coverage and user satisfaction. A decrease in coverage will harm the overall aim of the audit to improve quality of care for all early breast cancer cases in Australia and New Zealand.

S6-P2: CORE DATA COLLECTION

ISSUE: STAKEHOLDER PRIORITIES; OUTDATED TECHNOLOGY

The draft document states that core data collection should include only essential elements for fulfilling the purpose of the registry. The purpose of the NBCA is to monitor and improve the quality of surgical care received by early breast cancer patients in Australia and New Zealand and this is achieved through a full clinical audit cycle. To fulfil this purpose the MDS (minimum dataset) should include only elements needed for fairly assessing surgeon performance against set quality thresholds. This means collecting data that is necessary for threshold calculations and risk adjustment. However the MDS was produced by a sub-committee consisting of experts in the field of surgery and in consultation with the NBOCC. As a result the MDS includes data items the surgeons felt were clinically significant but not needed for threshold values (e.g. menopausal status, tumour type) and items that are deemed mandatory by the College (e.g. hospital). Much discussion went into ensuring that only items with a significant reason for inclusion were part of the MDS, and the dataset was trimmed down to one printed page.

The MDS was implemented as a short paper form in late 2008 and in an online version in late March 2009. The upgrade of the online system was a lengthy process and limitations to the extent of the improvement meant delays in getting the MDS form online. Small changes were made difficult by an old style platform. In discussion with our database and website manager, it was decided that any further major overhauls would be put on hold until there was time and funding to upgrade to a new platform. The 2009 upgrade focused on getting the MDS form on the website. This was important to improve timeliness of submission and increase participation. Some surgeons had been waiting for the MDS online form to upload their data.

Over half of the data submitted after the implementation of the MDS online, submitted MDS questions only. Several surgeons have written to the audit, expressing satisfaction with the new format of data entry and the shortness of the dataset.

S6-P3: SYSTEMATIC DATA COLLECTION

ISSUE: INSTITUTIONAL DATA

The audit does not have control over the format of collection for institutional data. Some institutions collect data in ranges rather than in specific measurements as required by the NBCA, and some institutions do not collect all data points required by the NBCA. Comparisons cannot be made between audit collected data and institutional data if this information is not collected in the same way and cannot be mapped. If this is the case, the audit will contain missing data where the necessary data could not be extracted.

The NBCA datasets are in accordance with those recommended by the NBOCC as per the published guidelines for Breast Cancer Specific Data Items for Clinical Data Registration.¹ The NBCA will encourage institutions to evaluate their datasets so that linkage with the NBCA can be achieved simply and accurately. In the meantime, the NBCA will continue to strive for

uniformity in data collection across web and paper forms. If institutional data arrives in a different format and cannot be simply incorporated into the database then questions must either be left blank, estimated or placed into the database as extra 'noted data' rather than as an answer to that question. The audit team have created and documented rules to reduce the amount of missing data due to institutional data formats. For example, an institution which sends data regularly uses a range for tumour size so it has been documented that the middle of the range will be a proxy value.

S6-P4: EPIDEMIOLOGICALLY SOUND DATA

ISSUE: UNCLEAR AND SUBJECTIVE TERMS

The NBCA have encountered difficulties in the collection of sound data on clear margins. Although experts on breast cancer treatment agree that there should be a clear margin around the excised tumour, there is debate over what constitutes a clear margin. The NBCA have opted to record margin size in mm which is epidemiologically sound. When there is a consensus on what constitutes a clear margin, the NBCA will have data available to analyse. However, the need for a specific value has also created a problem for surgeons who receive pathology reports stating margins are 'more than 10mm' or 'clear' (see S6-P10 for more information).

It is important for registries to adjust these terms into a measurable format; however, the source data is often only available to data collectors in a subjective format. Nevertheless, it is currently possible to retrieve a single data result for resection margins which is in accordance with the recently published guidelines for Breast Cancer Specific Data Items for Clinical Data Registration.¹

S6-P5: OUTCOMES PROPERLY ASCERTAINED

ISSUE: ASSUMES PATIENT OUTCOME IS RELEVANT AND AVAILABLE TO ALL REGISTRIES.

Surgeons remain hesitant to collect outcome or side effects data as it is seen to be outside the scope of the audit. Furthermore, the time burden for this outcome measure is too great for surgeons to volunteer further data entry. Currently the audit is set up to measure surgeon performance against key quality indicators based on NBOCC CMG.^{2,3} Side effects were also seen as outside the scope as they are not included in key indicators and are generally minor and common.

Due to patient outcome being outside the scope of the audit, the NBCA has considered this principle in terms of ascertaining the outcome of surgeon performance against the quality indicators. That is, the measurement of whether surgeons are adhering to the key quality of care guidelines. As such, surrogate measures of performance are used to determine the quality of care. These are much easier to measure and form the basis of the minimum thresholds for the key performance indicators of the NBCA.

It should also be pointed out that follow-up of patients may be difficult (or impossible in some circumstances) due to population migration (to different treatment providers, centres, states or countries). Nevertheless, there is an optional follow-up data collection form for surgeons who wish to use it.

S6-P6: BURDEN OF COLLECTING CONSIDERED

ISSUE: STRUCTURE OF AUDIT

The draft principles strongly promote the idea of collecting patient outcome data and state that outcome data needs to be collected to be defined as a clinical quality registry. However the burden and cost for surgeons of collecting this data was considered and determined to be too high, considering the ultimate purpose of the audit (see S6-P5). Surgeons had already expressed displeasure in the amount of data collected by the audit (leading to the construction of the MDS) and as a voluntary audit, the NBCA cannot afford to alienate contributors by attempting to collect data which they consider unnecessary. As the performance indicators are used as proxy measures of outcome, the NBCA has based the responses to this principle on the burden of collecting in general.

Unfortunately, unless a system of payment is developed for provision of data linked to Medicare Benefits Scheme items, there will always be a cost to the health professionals contributing, either in time or staffing. The NBCA does not provide a service to collect data from notes for surgeons, but endeavours to support surgeons and their staff in collecting and submitting data as much as possible. Surgeons can contact staff via telephone or email the helpdesk with any queries and a user guide and data dictionary have been supplied to all data collectors. The inclusion of data from other sources (institutional databases for example) is also important for decreasing the burden of data collection as it frees surgeons from double data entry (see S5-P13 for information on the audit's work in this area). Although the institutional data uploading process decreases the burden on individual surgeons, it does require time and effort from the data manager at the institution and adds considerable cost to the audit.

S6-P7: COMPLETE COLLECTION

ISSUE: VOLUNTARY NATURE OF AUDIT

As a voluntary audit, the NBCA is aware that total coverage may be unachievable and have concentrated on ensuring the representative nature of the data collected. This is done through inviting all surgeons performing breast surgery to participate, from Breast Section members who specialise in the area to general surgeons in rural areas who may only see a couple of breast cancer patients a year. The audit also takes a bi-national approach, aiming to cover all regions, rather than be focused on one area.

Increasing coverage is still a priority for the audit, however, and a Coverage Working Party has been formed to concentrate on this issue. Various strategies for increasing coverage have been

discussed and implemented. The latest includes increasing the profile of the project with surgeons, referrers and consumers and providing more feedback to surgeons to increase the buy-in of surgeons and incentives to participate. Once the audit is officially under the Society banner, participating surgeons will be required to enter all of their eligible cases into the audit, and the NBCA will have the authority to check that this is done. Even with this help, it is anticipated that coverage will remain a top priority going into 2010.

6.2 Data collection

S6-P8: NO IMPACT ON CARE OR BURDEN TO CONSUMER

ISSUE: INTERACTION WITH OTHER PRINCIPLES

This principle can interact with two others in the draft list of operating principles. Firstly, this principle can interact with collection of outcome data. The draft document mentions surveys of patients conducted at a reasonable time from care to ascertain their health and outcome of surgery. It is the contention of the audit that this would place an unnecessary burden on the consumer as this information is outside the scope of the audit. The burden of data collection has always fallen upon the surgeon or the surgeon's appointed data manager. At no point in the audit's history has the patient been asked to provide any data and this will likely remain the case in the near future.

To meet Principle 8, a registry needs to be sensitive in its implementation of an outliers process. If this process is seen as overly punitive or dismissive of mitigating risk factors, the process may lead to either selective acceptance of surgical cases which may affect surgical care or selective case submission to the registry, which will limit the impact the registry can have on improving care. This is one of the reasons why the audit has reinforced the idea that the standards assessment process is an educative initiative, not punitive and that investigating bodies will examine suspicious data for any and all mitigating risk factors before action is taken (see principle 28 and 18 for more information on the outliers process and risk adjustment).

S6-P9: COLLECTION CLOSE TO TIME OF CARE

ISSUES: VOLUNTARY NATURE OF THE AUDIT; DIFFICULTY IN MEASURING COLLECTION TIME; DELAYS IN INSTITUTIONAL UPLOADS AND USE OF HISTORICAL DATA IN THESE UPLOADS

The NBCA has no measure of the time of data collection, only the time of data submission. For electronic data entry, this may be simultaneous, or there may be a delay between collection and submission if surgeons first collect using paper forms and then transfer into the electronic system at a later date. Paper forms themselves do not have a date of collection so surgeons who send in paper forms do not have a record of data collection either. If surgeons wait until there are enough submissions to send then there may be some delay between collection and data entry at the NBCA office.

As the NBCA cannot provide a measure of time between care and data collection, timeliness measures are based on time between care and data submission. The audit cannot restrict time of submission without heavily impacting on coverage and data completeness. However, an extended time period between time of care and data collection may also lead to lower coverage and data entry errors. Surgeons may forget to input cases if they are not collected soon after care, and errors may creep into collection if data entry is very far from time of care.

Delayed data submission may also lead to delayed reporting for the audit or the exclusion of data from reporting. Delayed reporting may result in data that is no longer applicable to the current climate of breast cancer treatment. Exclusion of data could mean that the results are not reflective of true care of early breast cancer at that time.

The compromise for the audit is to set an annual data submission deadline and to remind surgeons about this several times prior to the deadline. This deadline is in place to ensure that submissions occur before scheduled reporting for that period and to encourage surgeons to collect data in a timely manner. Currently over 80% of data is in by this time. The median time between surgery and data entry is approximately 4.5 months. The average time is much longer due to outliers with large time lags, such as institutional data. Ignoring this old data would decrease the coverage of the audit and this would not be recommended.

It is important to realise that breast cancer treatments may take place over a 12-month period. Decisions about breast cancer management may alter during this time. Although the diagnostic and surgical aspects of patient management are realised early during the treatment period, time is required for the reporting surgeon to ascertain the nature of adjuvant treatments (that is, chemotherapy, radiotherapy, hormone therapy) before data submission. It is likely that definitions for timeliness of data submission will vary according to the type of registry.

S6-P10: EASILY ACCESSIBLE

ISSUE: LIMITATIONS OF PATHOLOGY REPORTS

Surgeons obtain some of the audit data from pathology reports. New pathology reporting guidelines for breast cancer were released by the NBOCC in 2008, including a new synoptic report, which suggests providing a measurement for a single closest margin. This may become a barrier for the full implementation of principle 10 if there is widespread uptake of the synoptic report format by pathologists. This is because the NBCA dataset requires measurements for both circumferential and vertical margins. Also, it is practice for some pathologists, if a margin is sufficiently wide, to provide no measurement at all, merely a statement of 'clear'. If surgeons cannot easily access what is required for the audit dataset they may either leave the information out altogether or estimate values. This will lead to inaccuracies within the database. Despite this, it is possible to retrieve data relating to resection margins in accordance with the guidelines for Breast Cancer Specific Data Items for Clinical Data Registration.¹

S6-P11: STANDARD TERMS/FORMATS

ISSUE: DATASET TAILORED TO PURPOSE OF AUDIT

The most important function of the NBCA dataset is to fulfil the purpose of the audit. It has been tailored for this purpose over many years and audit management does not consider a change in terms in the best interests of the audit. The dataset is already consistent with the NHDD where this will not interfere with audit function and purpose; however, management does not see the value at present in including SNOMED terms, considering the limited data linkage currently entered into by the audit.

NBCA IT providers/programmers have assured the team that if linkage needs to occur in the future, the dataset can be mapped to SNOMED or similar terminologies. Currently SNOMED is not widely used enough for this to be necessary. The audit may review its stance on SNOMED application at a later date, when the uptake of this system is higher.

The draft document doesn't specify the optimal level of SNOMED CT classification; if registries adopted different levels of SNOMED CT then interoperability could still be impeded. The emphasis on SNOMED is also biased towards new registries, there could be significant costs and data loss in remodelling the entire dataset of an established registry, especially as this has only recently been recommended as the national terminology, and there is little evidence it has been widely taken up. It would be reasonable to expect a transition period for uptake of this new system.

S6-P12: DATA DICTIONARIES USED

ISSUE: OUTDATING OF DICTIONARIES VS. USEFULNESS OF FREQUENT UPDATES

Production of a detailed data dictionary is one of the challenges involved in ensuring standardised data entry. Meanings of each term used must be well-established and sufficiently detailed and it must be clear to data collectors and transcribers how to respond to each data item. However as the dataset is updated, for whatever reason, these detailed documents become out of date. It is important to keep them updated or they will not be useful. Continual and frequent updates with minor changes however, will be counterproductive as users will not keep up with the changing versions. The audit has a policy of reviewing the data dictionary every 1 to 2 years and then updating as needed. This is usually done to coincide with website upgrades as these upgrades often entail significant changes to the dataset. In this way, the new data dictionary will be promoted as a tool for use with the newly upgraded website.

S6-P13: USE EXISTING DATA SOURCES

ISSUES: NOT COST EFFECTIVE; DIFFICULTY IN CORRECTING RECORDS; INCOMPATIBLE FORMATS; DATA NOT FULLY IDENTIFIED.

The audit has identified four issues associated with using existing data sources:

1. Uploading data from institutional databases means an increase in coverage and no double entry for surgeons; however, the mapping process is complicated, lengthy and expensive.
2. Once institutional data is uploaded to the NBCA database, surgeons can view their data but cannot update it. This means a lengthy delay for corrections as they will need to correct original institutional database and then re-upload data.
3. Data received may not directly correspond to audit specifications (e.g. measurements given in a range rather than specific number) or may not include all data fields. This limits the completeness of records if fields need to be left blank.
4. As the audit does not collect identified data or universal identifiers such as Medicare number or Medical Record Number (MRN) and is not linked to hospital or health area network, there is no possibility of auto filling sections using other data sources.

The audit is addressing the first two of these concerns by designing and piloting a new way of uploading data from institutions. The majority of the work will be done by audit staff rather than external database programmers. This will make institutional data easier and less expensive to upload into the database and will be more flexible than the old process. The necessary software for this process is currently in development. This method transfers more of the work involved away from consultants and towards audit staff. It is felt that transferring more responsibility onto the institutions at this stage will be too much of a deterrent to participation and prevent inclusion of that data.

Audit staff have also devised and recorded rules on how to deal with variant specifications during the institutional data uploading process which addresses issue 3. The consideration of a move to identified data may have an effect on issue 4.

S6-P14: USE RECORD LINKAGE

ISSUE: LITTLE IDENTIFYING DATA COLLECTED

The NBCA collects limited identifying data on patients. There was some concern that this would impact on the audit's ability to link with other databases, such as the National Death Index (NDI). To assess the likely accuracy of any linkage using this limited information, a pilot linkage was carried out in 2008 with selective South Australian cases. The accuracy and completeness of results were deemed favourable in comparison to a similar linkage with identified SA Cancer registry and NDI data. The NBCA/NDI linkage was then extended to national data, where accuracy was measured through comparisons to expected survival patterns, according to similar international survival figures and prognostic indicators in the NBCA dataset itself. Again the results were deemed credible, with concordance with expected patterns very high. The final report for the NDI linkage project concluded that although the accuracy of linking would be higher with identified data, the level of accuracy currently obtained was sufficient for epidemiological purposes.

Although this linkage has provided much useful information, the NDI has advised that future linkages would be aided by the inclusion of at least the full name of the patient. This would result in a higher level of linkage and be a lot faster as the previous linkage involved a customised linkage structure. The NBCA governance will take this into consideration when deciding on the issue of identified data.

6.3 Data elements

S6-P15: IDENTIFYING INFORMATION

ISSUE: CONCERNS OVER NEED FOR CHANGE

Without fully identified data the audit will have less certainty in any future linkage, either externally or internally across surgeons. It will also provide difficulties in ascertaining the correct record for patient access or opt-out, as well as for data checks/correction.

The Evidence and Performance subcommittee was concerned over the repercussions of a switch, especially on the audit's status as a Quality Assurance Activity under Qualified Privilege legislation. In response to this concern, the audit team has produced a briefing paper on the issue which includes information on the benefits and repercussions of this change in the dataset.

S6-P16: COLLECT PROCESS OF CARE DATA

No issues encountered.

S6-P17: OBJECTIVE OUTCOME

ISSUE: CLINICAL GUIDELINES OFTEN NEED TO BE TRANSLATED INTO MEASURABLE QUALITIES

Extending the core dataset with patient outcome data will not be possible in the immediate future unless there is a major change in the scope of the audit. Consultation with surgeons around collection of additional adverse event data showed there was little support for extending the remit of the audit in this way. If survival outcome data is required for research purposes, this can be ascertained through linkage with the NDI.

The current focus of the audit is on whether surgeons are following the NBOCC CMG^{2,3}. The audit measures adherence to the early breast cancer treatment guidelines, and not the outcome of surgery (other than re-operation – if with same surgeon; survival through the NDI linkage and optionally follow-up). To measure surgeon adherence to guidelines, the NBCA first need to translate these guidelines into objectively measurable criteria, for example, what constitutes a clear margin or a high-risk case. This was originally the role of the Minimum Standards subcommittee. The task is now undertaken by the Evidence and Performance subcommittee (EPS) which is an amalgamation of two former committees: the Minimum Standards

subcommittee and the Outliers subcommittee. The EPS also recommends a best practice level, or threshold, for each quality criteria (e.g. 90% of invasive cases undergoing axillary surgery). The criteria and level then needs to be approved by the Steering Committee. An issue arising from this process is that while quality criteria are evidence based, the required level of adherence to these criteria (that is, the threshold) is necessarily based on expert consensus to take into account any mitigating circumstances that may preclude a surgeon from achieving 100% on any given criteria.

The audit currently measures surgeons against four key quality indicators. One new quality indicator (post-mastectomy radiotherapy in high-risk cases) has now been endorsed by the Steering Committee, and a further quality indicator (referral for chemotherapy in moderate/high-risk cases) is nearing completion. The current four quality indicators are straight forward, measurable items and were implemented quickly. Where the guidelines contain more ambiguous recommendations, the associated quality indicators have proven more difficult to implement. Examples of this are the clear margins and high-risk cases mentioned above. The audit team is optimistic on implementing two more quality indicators based on high-risk cases in the short term.

6.4 Risk adjustment

S6-P18: RISK ADJUSTMENT

ISSUE: PROPOSAL YET TO BE SUBMITTED TO EPS; FUNDING UNCERTAINTY

The audit does include limited co-variables that can be used for risk adjustment and allows surgeons to leave extra risk adjustment information as a note in records. The audit does not use this information for statistical adjustments, either during the outlier process, or in reporting to surgeons. This adjustment could be a valuable addition to the audit; however, there is currently no funding for adequate investigation and implementation of a formal statistical risk adjustment model and the issue is yet to be discussed at a governance level. Informal and ad hoc risk adjustment of cases highlighted by the Evidence and Performance Subcommittee has been planned as part of the Outliers assessment and will be carried out by the Breast SurgANZ Review Group when necessary.

Implementing a formal statistical risk adjustment model on threshold calculations would improve the accuracy of benchmarking for NBCA participants. Currently evaluators determine risks through a manual examination of data; however, the thresholds report shows raw threshold calculations only, with no mitigating factors. Surgeons will therefore be benchmarking themselves against their colleagues with raw figures and will remain unaware of extenuating circumstances for their colleagues.

Risk factors are informally taken into account during the SAP through subjective analysis of outlier data. Further detailed analysis may be possible if case notes can be sought. Statistical risk adjustment for reporting purposes will be investigated once approved by the Evidence and

Performance Subcommittee and Steering Committee; however, only if adequate funding can be obtained. In the meantime, it must be emphasised to surgeons that risk factors can be taken into account during the SAP process if these factors are noted on the case record.

6.5 Data security

S6-P19: SECURE ACCESS CONTROLS

ISSUE: PASSWORD SYSTEM NOT UNIQUE FOR EACH USER

Currently, surgeon data collectors have one password to log-in to their account. This means that anyone else doing data entry for the surgeon will also require access to this password (secretaries, data administrators or NBCA staff). If there is only one password per account, the system will not track who is making changes to the data as it cannot discriminate between surgeons, data entry staff or NBCA staff. This creates problems for event logging. The password system is due to be overhauled with the next website upgrade which will move the audit onto a newer, more flexible platform. Unfortunately, with the current funding uncertainty, this upgrade is not yet possible and may not be completed in the short term.

S6-P20: COLLECTION, STORAGE AND TRANSMISSION COMPLY WITH LEGISLATION

ISSUE: SECURITY LIMITATIONS IN POSTAL SYSTEM; RELUCTANCE TO MIGRATE TO ONLINE SYSTEM

A number of data security limitations were associated with the old Access database and paper form approach to data collection, principally, the privacy issues involved in posting paper or electronic data, the risk of losing data when computers were updated, stolen or broken, and the lag time involved in having up-to-date aggregate information for the use of individual surgeons. To overcome issues associated with this approach, the online data entry system was developed in 2004. This system is described in S5-P19. As already described in section 5, there was no model on which to base the online system which meant that work had to start from scratch. There was also some initial reluctance on the part of surgeons to migrate to the new system, although this has improved dramatically over time as surgeons become more aware of technology and user friendliness of the system increases (only 8% of cases are still being submitted on paper).

Any changes to identified data will necessitate a change to registered mail for paper form users which could act as a deterrent. However, with continued improvement of the electronic data submission systems this deterrent may be welcome to encourage surgeons to take up the other options and lessen the burden of data entry by audit staff.

S6-P21: POLICIES COMPLY WITH TECHNICAL STANDARDS

ISSUE: DELAY DUE TO UNCERTAINTY ON SPECIFICS OF PRINCIPLE

This principle is still in the process of implementation. A draft Data Security Policy has been prepared following the data security principles laid out in the technical standards. This will need to be ratified by the Steering Committee and the College.

6.6 Data quality

S6-P22: REPORT COVERAGE

ISSUE: LENGTHY PROCESS OF GAINING DENOMINATOR

In the past, annual reports for the audit have published the total number of cases in the database for that year. If the audit is to be counted as an important bi-national registry of breast cancer treatment, this figure needs to be put into the context of total cases around Australia and New Zealand. That is, we need to show the proportion of breast cancer cases that we are capturing.

Publicly reporting on coverage has been delayed due to slow responses from individual state cancer registries on the total number of invasive breast cancer and DCIS cases in the periods 2000-2006. The initial plan was to gain a denominator with a tailored query from the AIHW. The AIHW, however, does not collect data on DCIS cases or stage of tumour for invasive cases. State data is also only collected in 5-yearly intervals. To gain a more detailed view of breast cancer in Australia the NBCA decided to approach the cancer registry of each region. This has provided a complete picture of breast cancer incidence in Australia and New Zealand. The original enquiries were made in early March, with the final registry data becoming available in September. Once coverage calculations are completed, coverage can be reported to audit governance. Interim reporting to governance committees on coverage estimates for each region have been occurring throughout the process.

The audit has a focus on 'early' breast cancer. This means that the audit does not include data on cases involving distant metastasised tumours. Ideally the denominators for coverage estimations would exclude metastasised tumours. The reality, however, is that the majority of cancer registries do not record spread of disease accurately enough to make this possible. What is known is that the proportion of cases with distant metastases is approximately 5-6% in any given year.^{13,14} It can then be assumed that NBCA coverage will never exceed 95% of the total cancer cases in each region. It is proposed that the NBCA report coverage according to the total breast cancer numbers with a caveat that coverage will not exceed 95%.

The main problem now faced by the NBCA in accurately reporting coverage is that registry data has a 3-4 year lag, so for any recent data on coverage the NBCA has to revert to estimations as it has in the past. However, these estimations are now based on more precise data.

S6-P23: DATA QUALITY CONTROL PLAN

ISSUE: NOT YET PROVIDED TO STEERING COMMITTEE

A data quality assurance plan has been drafted and will be discussed by audit governance. Important data quality assurance procedures such as site audits cannot commence without the authority of the Steering Committee and further funding.

Some form of the data quality assurance plan will be implemented in the near future. The audit is already informally performing some of the proposed activities, running data checks for example, both amongst internal data transcribers and through automated online data entry systems. Coverage estimates are being produced as described in the previous section, and checks on data completeness, timeliness etc. will be run annually (if approved by the Steering Committee). The audit will need to ascertain an appropriate method of checking data against source material. Site audits are the best option but may not prove cost-effective in the current climate (this issue is discussed below). The audit is also producing procedure documents to ensure quality data entry, quality assessments and reporting.

S6-P24: DATA CHECKS/AUDITS

ISSUE: YET TO BE APPROVED BY STEERING COMMITTEE

NBCA data received on paper forms and entered by NBCA staff is checked between in-house transcribers and there are automated error messages on suspect data during online data submission. There are currently no checks against source data. Site audits of source data have been included in the first draft of the data quality assurance plan; however, they are unlikely to be implemented in the near future due to insufficient funding. Without site audits the audit will remain unaware of the true quality of the data, the common data entry errors made by data collectors and whether surgeons are entering all of their cases. An alternative to these costly site audits may need to be found when the data quality assurance plan is discussed by the Steering Committee.

S6-P25: DATA MANAGEMENT PROCESSES USED

ISSUE: INHERENT GLITCHES IN NEW SYSTEMS

Data management processes (i.e. validation rules) have been built into the online data entry system. As with all new systems there were glitches that needed to be fixed after the initial implementation. All new website designs and upgrades are heavily piloted before going online; however, even after implementation some unforeseen problems needed to be dealt with by the data management team and contracted IT and programming consultants. For example, with the latest website upgrade, one unforeseen problem with the implemented data management rules was that the rule behind mandatory core data items made it impossible to input follow ups to old cases. Postcode is now a mandatory item, but is a fairly new addition to the dataset. Cases which were submitted prior to the implementation of postcode in the dataset did not include this information, but data collectors could not proceed into the case record with this field empty as it is now mandatory. Further work with the database management company ensured that these problems were ironed out in a timely manner.

It has also been brought to the attention of the data management team that the platform of the current system is problematic as it is based on outdated customised database programming. This makes it brittle and difficult to make even minor alterations. To combat this problem, the audit intends to upgrade to a new platform once sufficient funding can be raised for the endeavour.

S6-P26: REPORTING TIMETABLE

ISSUE: PERIOD OF TRANSITION FOR AUDIT

Reporting specifics are currently uncertain as the audit is going through a period of transition. The funding contract with the NBOCC expired in June and over the next few months the audit will be moving away from being a College audit and toward becoming a Society of Breast SurgANZ audit, although it will still be affiliated with the College. It may take some time before key requirements and timing for reporting are established. This uncertainty will make it difficult to market the audit to potential contributors as we cannot give them a concrete list of relevant reporting beyond the audit's basic website reporting structure.

The NBCA will have a better idea of how its new reporting structure will work once it is officially a Society audit, with all contracts in place. Historically, reporting has been heavily dependent on the requirements of funders, which change every few years. Hopefully, the arrangement of oversight by the Society will see more stability in the deliverables of the audit, even though the ultimate source of the funding (Society sponsors) may change over time.

6.7 Organisation and governance

S6-P27: FORMAL GOVERNANCE STRUCTURES

ISSUE: LARGE GOVERNANCE STRUCTURE

The NBCA has striven to include all relevant stakeholders from the beginning of audit activities. Although this has meant significant and important contributions, the large governance structure of the audit and the lengthy time lag between meetings can mean that decisions are often delayed. The current audit Steering Committee comprises 13 members. There are also three active subcommittees or working parties and two other groups that can be called on when necessary. The size of the audit governance structure may need to be reviewed once the audit becomes a Society of Breast SurgANZ audit. The intention would be to have a more streamlined audit structure to avoid this problem, while still allowing a voice to all relevant stakeholders.

S6-P28: QUALITY OF CARE POLICIES DEVELOPED

ISSUE: RELUCTANCE ON PART OF COLLEGE, SURGEONS AND FUNDERS TO MOVE IN THIS DIRECTION; LACK OF SUFFICIENT FUNDING

The audit was originally set up as a self-auditing tool. In the last 5 years, the audit has been working towards becoming a full clinical audit (including an outliers process); however, this has proved difficult without significant funding for the process. The main issue has been the reluctance on the part of both the College and the funding body at that time to be seen as policing the surgeons. The Society will be able to move forward on this once established.

There has also been some wariness on the part of surgeons as to what the outliers process entails. This has been overcome through fully informing the surgeons of the process and its implications, portraying it as an educative rather than punitive tool. Surgeons have also been assured of complete confidentiality during the process of identifying and dealing with outliers. The audit's status as a Quality Assurance Activity under Qualified Privilege legislation aids in this assurance.

Due to the issues described, the audit did not carry out the Pilot Outliers Project until 2008, when funding was provided by BCNA to test the process as the Steering Committee was concerned the audit was not performing its primary purpose. The system requires further refinement, according to results of the pilot process. A journal article on the process of assessing thresholds is proposed and the plan for managing outliers will undoubtedly be updated as the audit moves into its role as a Society of Breast SurgANZ audit. This will be a major direction for the NBCA as a Society audit.

6.8 Data custodianship

S6-P29: CUSTODIANSHIP EXPLICITLY DECLARED

ISSUE: TRANSITION PERIOD

When the audit officially becomes a Society of Breast SurgANZ audit, the agreement between the Society and the College will need to be explicit about custodianship of the data. At present, the Royal Australasian College of Surgeons is the custodian. The audit will also need to address the issue of surgeons who submit data to the audit (or have in the past) but do not become members of the Society. These surgeons will receive the same treatment as Society surgeons and their data will be held to the same security standards. The NBCA may not have the same authority over these surgeons, however, in terms of data site audits and mandating submission of all cases.

S6-P30: DATA ACCESS AND REPORTING POLICIES AVAILABLE

ISSUE: NOT WIDELY AVAILABLE

The data access policy is currently being updated to include authorship issues. This will need to be ratified by the Steering Committee and the College before replacing the old policy. In the meantime, the current data access policy is available on the NBCA College website. Previously this policy was available on request from audit staff; however, during the implementation of the draft principles in the Australian Clinical Quality Registries document, the audit data

management team decided that making this policy more widely available would be a positive move for the audit.

S6-P31: THIRD PARTY ACCESS VIA STEERING COMMITTEE

No issue with this Principle.

6.9 Ethics and privacy

S6-P32: IEC APPROVAL GAINED

ISSUE: ETHICS APPROVAL AT EACH PARTICIPATING SITE IS NOT RELEVANT FOR THE AUDIT

Gaining institutional ethics approval from the College for the audit was not a problem. However, the draft document implies approval may be required from each site the registry collects data from. The audit does not gain ethics approval from each institution where data is collected as the collection is done at an individual surgeon level with the audit awarded a Qualified Privilege status under federal legislation (see S5-P32 for more details).

For very large registries where data may be obtained from a large number of sites, the additional workload of applying for and reporting on ethics for each site may be prohibitive to the functioning of the registry.

S6-P33: PERSONNEL FAMILIAR WITH & ABIDE BY PRIVACY LEGISLATION

ISSUE: LENGTH AND LANGUAGE OF DOCUMENTS; LIMITATIONS OF QUALIFIED PRIVILEGE STATUS

Principle 33 references privacy legislation, the National Statement on Ethical Conduct in Human Research⁴ and the Australian Code for the Responsible Conduct of Research¹⁵. Not all of the requirements in these documents are relevant to the audit and as the documents are quite long and formally written, it was decided that it was counter-productive for personnel to have to read the entire documents. A summary of all requirements and how the audit abides by these requirements has been produced and read by all current staff. This document will become part of new staff inductions in the future. This will ensure that personnel are familiar with expectations of their job specifically and also the more general workings of the audit as a whole.

It has been brought to the attention of the NBCA that its status as a Quality Assurance Activity under Qualified Privilege legislation may impede any future plans for two-way data linkage or automated data collection from external administrative sources. This issue warrants further investigation before any detailed work can be done in these areas.

Currently, the benefits of Qualified Privilege are considered to outweigh the disadvantages as data linkage is not a priority for the audit. The NBCA does acknowledge, however, that the case

may be different for new registries that have a higher interest in linkages and establish infrastructure to support this linkage from the outset.

S6-P34: PARTICIPANTS GIVEN OPTION TO NOT PARTICIPATE

ISSUE: BURDEN ON SURGEONS; IMPACTS COVERAGE

The audit has historically been an opt-in consent system. The NBCA felt that this system was placing an unfair burden on surgeons to gain and store consent. The system may have also contributed to the audit's low coverage figures as patients would need to actively desire to participate for data to be collected.

This issue has been alleviated by the implementation of an opt-out consent system in 2009, as recommended in the draft Operating Principles document. This consent system ensures that each patient is still fully informed of what the audit does, what information will be collected and how their information will be used; the system also allows for patients to exclude their data from the database if they truly do not want to participate. Both of these points are important to comply with privacy legislation. The new system will also decrease the burden on surgeons and may improve coverage.

The only issue still to be resolved in terms of consent is the recording of opt-out cases. A procedure for handling opt-outs has been drafted but is yet to be employed as no opt-outs have been encountered.

S6-P35: IEC APPROVAL – PROJECTS

ISSUE: GENERALLY UNNECESSARY

The NBCA is negligible risk research, that is, there is no foreseeable risk of harm or discomfort to patients or surgeons who participate. Indeed, its purpose is to improve breast cancer outcomes for women with early breast cancer. It collects only semi-identified patient data and is bound by Qualified Privilege, which restricts the release or reporting of identified information. The National Statement on Ethical Conduct in Human Research states that research involving negligible risk and collections of non-identifiable data is exempt from ethical review.⁴ This will mean that less time is wasted on ethics approval applications, as the audit only requests ethics approval for major changes to audit activities but does not request ethics approval from the College for side projects using NBCA data or data release projects.

Internal projects are reviewed by the Steering Committee. Data release projects are reviewed by the data request group and de-identified before release. Depending on the nature of the project, each group could refer the matter to the College Ethics Committee if it was deemed necessary.

6.10 Information output

S6-P36: QUALITY OF CARE ASSESSED

ISSUE: LACK OF HIGH-LEVEL EVIDENCE FOR SOME BENCHMARKS

To maintain surgeon confidence in the audit, the NBCA data management team felt it important to base benchmarks on evidence based recommendation; however, not all of these are high-level evidence. Some indicators were more strongly supported by evidence than others, some of the recommendations in the guidelines can only have low level evidence due to difficulty of conducting randomised controlled trials for intuitively common sense recommendations, e.g. clear margins. However including issues with a low level of evidence creates a problem for setting up a punitive outliers process, as surgeons could argue the authority of the audit. The committee took this into consideration by setting the parameters wide for those indicators that had less evidence. They are regarded as a recommendation rather than a prescription. This will still catch those outliers who are significantly outside of the parameters.

The outliers process is designed to be educative not punitive. It is the intention of the audit that once aberrant behaviour is brought to the attention of the surgeon outlier they will take steps to alter this behaviour before any punitive action needs to be taken.

S6-P37: NO DELAY IN REPORTING RISK ADJUSTED OUTCOMES

ISSUE: NO RISK ADJUSTMENT PERFORMED

Surgeons can access online reporting structure at any time; however, this data is not risk-adjusted. The NBCA does not perform any formal risk-adjustment, only informal subjective examination of outliers. As already stated under Principle 18, without adequate risk adjustment, benchmarking efforts will remain imprecise. More formal risk-adjustment may be implemented if approved by the Steering Committee and then only when the audit has more funding. Currently, if surgeons question their figures, NBCA staff can go over the calculation of threshold values for them but these figures are raw figures only.

S6-P38: FORMAL PEER REVIEW PROCESS

No issues.

S6-P39: CAN PERFORM ANALYSES LOCALLY

ISSUE: LIMITED IN-BUILT ANALYSES

NBCA staff use backups of the data to perform local analyses. To restore a backup, local IT personnel need to set up a link between a PC and the backup server. This often means that one audit staff member is entrusted with periodically restoring backups to ensure an updated data source for analyses. Audit staff can only access the restored backup once their log-on has been authorised by IT support. This keeps the audit database secure from unauthorised access.

The reporting suite for individual surgeons who wish to analyse their own data is limited under the current website platform. This is one of the major changes anticipated for the next website upgrade.

S6-P40: ANNUAL REPORT PUBLICLY AVAILABLE

ISSUE: FORMAT AND CONTENT CONSTRAINED BY REQUIREMENTS OF FUNDING

Previously the annual reporting of the audit has been split into two sections. The general reporting of audit activity, governance and so on, has been reported in the ASERNIPS annual report. Annual statistics based on data collected has been reported in a public health report. The public health report was co-written with the funding body (NBOCC) and concentrates on areas of interest to this body. As the NBOCC funding contract expired in June 2009, and in preparation for becoming a Society of Breast SurgANZ audit, the audit team wishes the Steering Committee to consider making a public annual report part of the reporting timetable for the future.

S6-P41: DOCUMENTED PROCEDURES FOR REPORTING ON QUALITY OF CARE

ISSUE: MAY NEED FURTHER DEVELOPMENT

The NBCA's procedure for threshold reporting is new and still evolving as the standards assessment process has only been piloted recently. This procedure may need to be further reviewed after the next round of reporting.

6.11 Resources and funds

S6-P42: APPROPRIATE AND SUSTAINABLE FUNDING

ISSUE: PERIOD OF TRANSITION

The audit will officially be under the newly formed Society of Breast SurgANZ later in 2009. The audit will then be funded through Society sponsors and subscriptions. The audit may still receive funding directly for research initiatives; however, the Society funds will alleviate the need for a constant search for core funding. The new arrangement is likely to result in tighter budgets initially; however, it does provide the audit a more stable environment and should give surgeons a greater sense of ownership.

The transition to a Society audit has been delayed as the Society is currently in a fledgling status and not in a position to take responsibility for the NBCA. The delay in moving to a Society audit means that future funding for the NBCA is still uncertain and funding issues are still being dealt with by audit staff. The NBCA is currently offering the Society any help it needs to become established, as well as investigating further avenues for funding sources.

Principle 42 may well be an issue for all registries as the aims of registries - data collection, monitoring, epidemiology and quality assurance - are not often attractive to research grants. There is a perception that registries and audits provide a regulatory role and therefore should be the responsibility of the Government; however, Government funding is rarely forthcoming. Registries and audits do not fit the mould for the usual funding opportunities afforded to research ventures, and long-term sustained funding is often a distant horizon. Such states of desperation often result in short-term constrictive contracts simply to prevent the project from collapsing. A system where registries could sustain their own funding, e.g. through research collaboration and paid data releases, would require much groundwork and set up, which often doesn't get done as resources are instead focused on finding the next source of funding and contract deliverables.

It is known that funding bodies place a greater emphasis on translational research rather than clinical research to determine where funding is to be used. Clinical researchers find this disappointing. Significant improvements in health care provision and outcomes can be achieved through clinical research and audit.

6.12 General issues

The NBCA advises that for each principle, a registry must have a clear understanding of how and why the implementation of that principle will benefit that registry, otherwise acceptance will prove difficult. Audit committee members wanted clear information on why these changes needed to be made and how they would positively or negatively affect the audit. A recommendation from the draft documents was not considered a sufficient reason for changes. A suggestion for the revised version of the draft document may be to add a justification section to each principle. This would aid registries in justifying changes.

The inclusion of patient outcome data, for example, is of large importance in the Operating Principles draft document. Audit governance, however, felt that the addition of patient outcome data, in the form of an adverse events database, was an added burden for data collectors and outside the original scope and intention of the audit. The inclusion of fully identifying data is still under consideration with information provided outlining the pros and cons, the justification for the switch and any negative impacts on the audit. Opt-out consent on the other hand was approved by the Steering Committee after each member was provided with a document outlining the benefits and effects of opt-out consent on the audit, and assuring them that privacy legislation was still being followed.

7. Assessment of technical standards document

Section seven of this report assesses the relevance of each standard in the Standards Map to the audit environment. As the technical standards document was complex from a lay perspective, these standards have first been translated into lay terms and then assessed for relevance. It must be emphasised that the following assessment provides the viewpoint of registry staff. An added appendix, as provided by Alcidion Corporation (IT company), includes more information on the relevance of the technical standards document from a technical perspective (see Appendix 4).

The majority of standards listed in the Standards Map have not been deemed relevant for implementation in the NBCA at the current time. The relevance of various standards will need to be reviewed during and after planned changes to the audit in the coming year. These changes include: a potential switch to include identified patient data (currently under consideration by the Evidence and Performance Committee); upgrading the data entry website platform (what Alcidion refer to as Version 2 in Appendix 4); and changes to the operation and oversight of the audit as it moves towards becoming a Society of Breast SurgANZ audit.

7.1 Interoperability framework (architecture)

Interoperability is defined as a continual state of readiness to exchange meaningful data/information and participate in collaborative delivery of services. The NEHTA Interoperability Framework (see 7.1.1 below) emphasises the need to look at organisational issues as well as connectivity. The main task for this section is to generate documentation on the enterprise architecture of the organisation. This architecture should be guided by NEHTA's interoperability principles (see 7.1.1 below) and generated using TOGAF, OPD-RM and UML.

7.1.1 INTEROPERABILITY FRAMEWORK V2.0 (OPTIONAL)

(Data exchange not current priority of audit)

The Interoperability Framework (IF) provides guidance to business and IT experts in delivering interoperable systems. The IF is designed as an overarching framework to be used in conjunction with various enterprise architecture approaches (as listed below). Being interoperable with other registries and healthcare systems is not a current priority for the audit. At present, the audit is focused on core activities which does not include upgrading systems or entering into data exchanges. Any existing data uploading that is necessary for audit will continue to use the current form of upload system.

7.1.2 UNIFIED MODELLING LANGUAGE V2.0 (NOT REQUIRED)

(Not relevant unless 1.4 used)

UML is a modelling notation for describing architecture of software systems. It describes how concepts should be represented in the reference model (see 7.1.4 below). The reference model was defined in a notation neutral manner to increase flexibility of use. This will not be relevant unless the reference model is used.

7.1.3 TOGAF “ENTERPRISE EDITION” V8.1 (OPTIONAL)

(Relevant – not currently feasible)

TOGAF is a process. The documentation describes how to generate enterprise architecture (EA). EA refers to documents or diagrams which describe the structure of a business. This architecture is a picture of the current state of the enterprise, a blue print or vision for the future and a roadmap on how to get there. The concept would be useful for the audit but under current conditions is not feasible to implement. Audits and registries do not often have long-term business plans as funding agreements are usually short-term (3 years at most) with no guarantees of continuing audit activity beyond this. Without the security of long-term existence, goals are often confined to what can be accomplished within the current funding period.

7.1.4 INFORMATION TECHNOLOGY – OPEN DISTRIBUTED PROCESSING (OPTIONAL)

(Not relevant unless 1.3 carried out)

This section refers to the Open Distributed Processing Reference Model (ODP-RM) family of standards. The reference model (RM) provides a framework for structuring specifications of open distributed processing (ODP) systems including definitions of essential concepts and the relationships between these concepts. The documentation specifies the required characteristics that qualify distributed processing as open. This will not be required unless EA is documented (see 7.1.3).

7.2 Clinical communications

This section is concerned with the exchange of information between systems. The aim is to organise the registry to have the same data specifications, terminology and datatypes as other health information systems in order to gain information directly from health systems (in a standardised exchange format).

7.2.1 TERMINOLOGY (REQUIRED)

(Not currently relevant, may be reviewed)

Terminology refers to terms used to populate data specifications - in value domain. NEHTA recommends the use of SNOMED CT for clinical data stored in a registry. They also recommend this as the national terminology for health information systems in general. A standard terminology will aid in exchange of data between systems. The NBCA does not see the value at present in including SNOMED terms considering the limited data linkage currently entered into by the audit. IT consultants for NBCA, Alcidion, have assured the team that if linkage needs to occur in the future, the dataset can be mapped to SNOMED or any other terminology/format in use. Currently SNOMED is not widely used enough for this to be an issue. The audit may review its stance on SNOMED application at a later date, when the uptake of this system is higher and significant updates to the database and web system are viable.

7.2.2 DATA SPECIFICATIONS (REQUIRED)

(Not currently worthwhile, may review)

Data specifications specify the format for collecting data. This is what is shown in a registry's data dictionary. NEHTA has produced several data specifications for various health care topics, for example, Medication data specification, Pathology data specification and Adverse reaction data specification. The specifications suggest a format for collecting data under these topics. If every registry follows the specifications, systems will become more interoperable as the data is stored in the same format. This may be relevant to the audit once these formats are taken up by the majority of large hospital systems. The NBCA has not demanded conformity of databases held by institutions in order to maintain buy-in and encourage participation. The NBCA feels it is not in a position to risk alienating potential data providers; this has resulted in the extensive mapping and checking currently required before institutional data can be included with NBCA data. This process can be costly and time-consuming. In 2009 the audit team designed a new way to complete this process which will be a more flexible and cost-effective option for small institutions; however, mapping and checking is still a requirement.

Undoubtedly if the NBCA and hospital systems were in the same format the institutional data uploading process would be much simpler; however, the current format of the NBCA dataset has been tailored to fulfil the purpose of the audit and is consistent with the NHDD and NBOCC guidelines and recommended dataset where appropriate. The NBCA management considers fulfilling the purpose of the audit and being consistent with specific breast cancer datasets to be of more value than trying to conform to institutional formats, especially when currently each institution is different. The NBCA may engage an expert to look into this matter further when more relevant (i.e. when more institutions are following these national data specifications).

7.2.3 HL7 MESSAGES (NOT REQUIRED)

HL7 is an exchange model for transferring messages between data capture systems and storage systems. It specifies the structure and semantics of a document for the purposes of exchange. For more information on messages see section 5 Secure Messaging. Level 2 registries (such as the NBCA) are not required to use HL7.

7.2.4 DATATYPES (REQUIRED)

(Implemented)

In a database each field must have a specified datatype. A datatype is an attribute of data that tells the computer what kind of data it is handling. The NBCA uses numeric, date/time, text and integer datatypes. These are similar to those mentioned in NEHTA's data specifications; however, what we call numeric they call coded text.

7.3 Unique healthcare identification

This section refers to the unique health care identifiers which are currently under development by NEHTA. This will provide a way to uniquely identify both the provider and the client.

7.3.1 HEALTH CARE PROVIDER IDENTIFICATION (REQUIRED)

(Relevant, not currently available)

Health care provider identifiers are being developed for both individual health care providers and institutions. This initiative also involves a strong authorisation system which will require a provider to authenticate their identity. NEHTA recommends this standard be used when recording identification and demographic details of a healthcare provider. If this standard was implemented once available, it would provide a more authoritative source for institutional identification. Currently the NBCA utilises a custom-made list of institutions, and these are added when requested by individual surgeon participants.

Including the Health Care Provider Identifier is relevant and feasible for the audit; however, due to the difficulty of implementing additions to the current website, implementation will be delayed until the identification system is totally functional and then will be included with the next website upgrade. See Appendix 4 for more details on the technical aspects of implementation.

7.3.2 HEALTH CARE CLIENT IDENTIFICATION (OPTIONAL)

(Relevant, not currently available)

A client identifier record will include both a unique identification number and a record of information to enable matching of an individual to their identifier (name and date of birth for example). Activation of these identifiers will only occur subsequent to gaining an individual client's consent. This means that not all clients will have an identifier. NEHTA recommends this standard be used when recording identification and demographic details of a healthcare client. In future, if this identifier were added to the NBCA dataset it would provide more confidence in record linkage, following across providers and error checking.

The implementation of this standard will be delayed until the next website upgrade and once the system is adequately in place.

7.4 Identity management

Identity management involves ensuring that entities gain access only to information for which they are entitled.

The standards in this section describe policies and processes involved in identity management. An initial risk assessment should lead to an assessment of authentication requirements and implementation of authentication solutions. There should then be a follow through with continual

risk monitoring and management. NEHTA also recommends the use of standardised formats and languages for access control to ensure their vision of a central portal of registries becomes a reality.

Identity management systems will also need to be aligned with the principles described in the NEHTA Interoperability Framework (IF) and Enterprise Architecture (EA) documents (see 7.1 Interoperability Framework).

7.4.1 AUTHENTICATION ASSESSMENT METHODOLOGY (OPTIONAL)

(Relevant, but delayed for decision on identified data)

This methodology describes a business process to be followed when assessing and establishing authentication requirements for online transactions. It is a risk-based approach which follows the Australian Government e-Authentication Framework (AGAF) structure (see 7.4.4 below). This process may be useful to implement if the audit moves to identified data. The use of this standard will be looked into after Steering Committee has discussed the feasibility and relevance of moving to identified data.

7.4.2 FRAMEWORK FOR ANALYSING, PLANNING AND IMPLEMENTING IDENTITY MANAGEMENT (OPTIONAL)

(Partly relevant, utilised for Data Security Policy)

This document provides a framework to assist in analysis, planning and implementation of Identity Management within healthcare systems. It identifies the issues a registry needs to address in order to implement and maintain secure e-health systems. This framework has been utilised in preparing the draft data security policy for the NBCA. However, both the identity management framework and the identity management resource set are focused on how to become part of NEHTA's national E-health community. The NBCA seeks advice on the relevance of this for the audit.

7.4.3 IDENTITY MANAGEMENT RESOURCE SET (OPTIONAL)

(Not relevant)

These documents should be used when registry systems are being analysed, designed, and implemented to help guide decisions on Identity Management. It describes a system of policies, processes and technologies on data to be collected/reported, authentication issues, auditing, digital signatures etc. Again, this appears to be geared towards those organisations that desire to become part of NEHTA's E-health community.

7.4.4 AGAF (OPTIONAL)

(Relevant, but delayed for decision on identified data)

This framework (now called NeAF) relates to ensuring the identity of an individual. It guides an agency in determining both the level of authentication required and a solution to authentication requirements. This standard will be used along with the authentication assessment methodology in the process of implementing identified data in the audit (see 7.4.2 above for more details).

7.4.5 ACSI 33 (OPTIONAL)

(Relevant, utilised in Data Security Policy)

This document provides guidance for government agencies on how to protect their ICT systems. NEHTA recommends registry architecture should follow these recommendations. Issues covered include: documentation (policies, SOPs, plans etc), accreditation, roles and responsibilities, regular reviews, event logging, vulnerability analysis, change management and access. The guidelines suggested here have been incorporated into the draft data security policy of the audit. The draft data security plan is based on principles found in ACSI 33 documentation, as well as the standards from 4.6 below. There was also some input from the NEHTA identity management framework (7.4.2 above).

7.4.6 SECURITY TECHNIQUES (OPTIONAL)

(Relevant, utilised principles in Data Security Policy but ISMS not implemented)

The standards listed here (ISO 2700 family) establish guidelines and principles for initiating, implementing, maintaining and improving information security management. They are aimed at organisations creating and maintaining an information security management system (ISMS). An ISMS is a cyclical management process where risks are continuously managed by applying appropriate safeguards to either reduce the likelihood of these risks occurring or mitigate the consequences. (Note these standards need to be purchased to view.) The guidelines suggested here have been incorporated into the draft data security policy of the audit. A full ISMS will not be implemented at the current time as the NBCA, as part of the Royal Australasian College of Surgeons (RACS), is currently focused on ISO certification in Quality Management (ISO 9001). Following this process, the audit may review the implementation of 2700 standards.

7.4.7 OASIS EXTENSIBLE ACCESS CONTROL MARKUP LANGUAGE (XACML) TC (OPTIONAL)

XACML is an access control policy language describing how to interpret the access control policy for computer systems. Use of this language would standardise user and system access to registry functions, which will aid in NEHTA's overall aim of providing one central portal for all registries as users could access several affiliated web sites with a single logon. Further consultation is necessary to assess the potential benefits of the central portal for the NBCA prior to implementation of associated standards.

7.4.8 OASIS SECURITY SERVICES (SAML) (OPTIONAL)

This is a framework for communicating user authentication, entitlement and attribute information. Use of this framework will minimise the number of times users will need to authenticate while interacting with many different registries. Each separate registry should be designed to accept and trust previously established authentication.

7.5 Secure messaging

7.5.1 WEB SERVICES (NOT REQUIRED)

(Not currently relevant, but will be implemented in next upgrade)

Web services, as described in the secure messaging section, are in limited use for the audit. Data entry that occurs via the data entry website feeds directly into the database. It does not pass through web services technology as detailed in the technical architecture overview. Neither does the audit receive data directly from hospital systems. Institutional data goes through a manual mapping process by audit and database management staff. The limited use of web services technology is due to the outdated framework of the current website. When the audit has the funds for a full redevelopment of the website, the use of web services technology will be expanded. The extent of this expansion is yet to be determined.

7.5.2 XML (RECOMMENDED)

This section relates to XML digital signatures attached to messages transmitted from and to the registry. The benefits of digital signatures are authentication (confidence in the sender identity) and integrity (confidence that the message has not been changed - if encrypted, along the way hackers cannot read but they can still change). However messages are the basic unit of data sent from one web services agent to another. The NBCA does not utilise web services technology at present (see 7.5.1 above).

7.6 Supply chain

7.6.1 SUPPLY CHAIN (REQUIRED)

(Not relevant)

This section promotes the use of the National Product Catalogue to ensure a standardised identification of any products recorded. The NBCA does not focus on products used, only surgeon performance. This standard appears then irrelevant to the NBCA environment.

7.7 Engagement and adoption

NEHTA recommends assessing governance structures and processes according to guiding principles (see 7.2) to identify the best way to implement the standards described in previous pages.

7.7.1 UNDERSTANDING STANDARDS (OPTIONAL)

(Not relevant)

This provides very general guidance in how to read standards, for example that the term 'shall' mandates a required element, or that the preface contains a history of the standard. It does not provide useful information for implementing or understanding standards and must be purchased to view.

7.7.2 CORPORATE GOVERNANCE OF INFORMATION AND COMMUNICATION TECHNOLOGY (OPTIONAL)

(Implemented)

The NBCA is already following the principles outlined in AS8015-2005 - Australian Standard for Corporate Governance of Information and Communication Technology (ICT) as specified in the engagement and adoption area of the technical standards map. In 2003, as a part of the move from a distributed Access database to online data entry, an Audit Technical Advisory Committee (ATAC) was formed. The ATAC comprised epidemiologists, software development experts, statisticians and other stakeholders. Its duties were to evaluate the software and hardware employed by the audit, and oversee the development of the new online data entry system. ICT governance provided by this committee followed the six principles associated with the AS standard. In following the principles, the ATAC ensured: the smooth running of NBCA ICT initiatives; successful modifications for improved performance when required; and expert planning for future requirements. Once the new data entry system was effectively in place, all technical governance was assigned to the Steering Committee, where the AS governance principles continue to be followed.

8. General recommendations for draft document

Section 5 contains recommendations for alteration in wording of specific principles. Section 8 is related to more general recommendations for the document as a whole.

8.1 Purpose and benefits of document made clear

The registries involved in this project appeared to view this document as an aid in achieving funding. It is unclear whether there is an accreditation associated with the document. They hoped to achieve the label of clinical quality registry by fulfilling the criteria set out in the operating guidelines and believed this will give them an edge in funding talks. The Commission's intent, however, appeared that the document would be used as a tool for registries, to help them get set up and running effectively and encourage all registries to operate similarly to allow for collaborations between them. It is not the intention of the government to provide a tick or label that a registry is or is not a clinical quality registry.

The document needs to make clear what a registry will achieve by meeting the principles: whether they can then label themselves as fulfilling the criteria; whether it is merely a guiding

tool, giving suggestions; or whether following these principles provide some other benefit (becoming part of the national portal for clinical quality registries for example).

If there is a hierarchy to the principles, this is not entirely clear from reading the document. If they are meant to be read as a series of principles that either SHOULD be met, or MUST be met, then a short statement defining these distinctions might be of benefit to readers.

It was also noted that the document appears to be biased toward new registries. Early in the draft document the Operating Principles and Technical Standards are described as recommendations for new and existing registries; however, on the same page (p. 14) in summarising the principles they are described as: 'a sound basis to underpin the establishment of future registries'. Undoubtedly the principles and technical standards would be useful for those attempting to establish a new registry; however, many of the recommendations would prove difficult to implement for established registries and may not be considered by registry governance structures as a valuable use of staff time and effort when funding is low and current methods have shown no sign of failure. It is the belief of the NBCA that it will prove challenging to convince long-established registries to follow the principles without some added benefit, especially if changes involved will be difficult and costly to implement.

8.2 Concise structure

The NBCA recommends a more concise version of the principles document (with standards listed in a separate document). This would make for a clearer understanding of what a registry needs to do to follow a principle as well as excising extraneous detail to be more concise.

If the document is to be used as a tool for gaining funding by assessing the quality of a registry (as many of the registries are keen to do), it needs to be more specific in exactly what a registry needs to do for a principle to be considered implemented. It also needs to explicitly state exceptions where a principle may not be relevant for specific registries. The NBCA acknowledges that blanket exemption rules may not be suitable for all principles, as what constitutes a valid exemption will be different in different domains. However, it is felt that the document needs to be clearer about who determines whether a registry should follow a principle or not, whether that be the steering committee, some government body or the funding body.

Listing potential benefits and impacts of implementation would be useful for registries in gaining approval from governance bodies (see 6.12 for why this information is important). Barriers to implementation and advice in overcoming them would also be beneficial.

Lastly, the NBCA believes that providing an appendix of templates for creating policy and documentation will aid in the standardisation of registry processes. For example, data release policies, Standard Operating Procedures and data quality assurance plans are important documents, and the draft principles acknowledge this but do not provide guidance on structure

or content. A few mock documents in an appendix would be a valuable resource, not to prescribe as a required format, but as a suggestion of how they could be done.

The general format of the newly created Operating Principles document could be as follows:

- The main document should be separated into 42 sections, with a section for each of the principles. Each section will contain:
 - a) a statement of the principle
 - e.g. a registry should collect fully identified data
 - b) a description of what a registry needs to do to meet this principle
 - e.g. full name, postcode and healthcare identifier should be collected for each patient to accurately identify them
 - c) reasons a registry should implement this principle
 - e.g. identified data will aid in contacting patients, data linkage, analysing patient data across health providers, data correction and data access or opt out for patients
 - d) impacts of implementing principle
 - both positive and negative e.g. will aid in data linkage, may also effect qualified privilege or increase opt outs as patients do not want their information recorded
 - e) barriers to implementing principle and how to overcome or acceptable compromises
 - e.g. ethics approval needed, may need to alter qualified privilege applications, reluctance from data collectors/participants
 - f) exceptions to implementation
 - e.g. if small registries are not going to contact patients or link data and have another way to check quality they may not need to collect fully identified data. Fully identified data should not be collected unless necessary.
- Added appendices should include:
 - a) example templates of necessary documentation
 - b) any other relevant information not directly related to implementing the forty two principles.

8.3 Recommend more adequate output to consumers

The introduction of the draft principles document states that 'data collected by registries should be made available to consumers in a manner that allows them to participate fully in decisions about their care' (p12). However, the only principle that registries are asked to follow in regard to this is to have a publicly accessible annual report (principle 40). It is questionable whether this is sufficient to disseminate findings to the general public as there is a difference in writing and presentation of reports that are aimed at health professionals compared to reports for

reading by consumers. Some consumers may not have heard of the registry, let alone consider downloading an annual report from the registry website. In 2009 the NBCA has begun to produce consumer summaries of past research (distilling research data into shorter, easy-to-understand, consumer language) and working with the peak consumer group to increase awareness of the audit. Without being too prescriptive, perhaps the principles could recommend that registries also provide consumer specific information.

9. References

- ¹ National Breast and Ovarian Cancer Centre (2009) Breast cancer specific data items for clinical cancer registration. <http://www.nbocc.org.au/view-document-details/bcd-breast-cancer-specific-data-items-for-clinical-cancer-registration>
- ² National Breast and Ovarian Cancer Centre (2001) Clinical Practice Guidelines For The Management Of Early Breast Cancer. <http://www.nbocc.org.au/bestpractice/early/>
- ³ National Breast and Ovarian Cancer Centre (2003) The clinical management of ductal carcinoma in situ, lobular carcinoma in situ and atypical hyperplasia of the breast. <http://www.nbocc.org.au/bestpractice/dcis/>
- ⁴ National Health and Medical Research Council, Australian Research Council, Australian Vice-Chancellors' Committee. (2007) *National Statement on Ethical Conduct in Human Research*. Canberra: Australian Government.
- ⁵ National Breast and Ovarian Cancer Centre. (2008) The pathology reporting of breast cancer. A guide for pathologists, surgeons, radiologists and oncologists 2008. <http://www.nbocc.org.au/resources/resource.php?code=PAT>
- ⁶ Mant, J. (2001) Process versus outcome indicators in the assessment of quality of health care. *International Journal for Quality in Health Care* vol. 13, no. 6: pp. 475-480.
- ⁷ Lilford, R.J., Brown, C.A. & Nicholl, J. (2007) Use of process measures to monitor the quality of clinical practice. *BMJ* vol. 335; pp. 648-650.
- ⁸ Arts, D.G.T., de Keizer, N.F. & Scheffer, G. (2002) Defining and Improving Data Quality in Medical Registries: A Literature Review, Case Study, and Generic Framework. *J Am Med Inform Assoc*. Vol 9, no.6: pp. 600–611.
- ⁹ National Health and Medical Research Council. (2003) When does quality assurance in health care require independent ethical review? Canberra: Australian Government.
- ¹⁰ Williamson, O.D., Cameron, P.A. & McNeil, J. J. (2004) Medical registry governance and patient privacy. *MJA* vol. 181, no. 3: pp. 125-126.
- ¹¹ Busby, A., Ritvanen, A., Dolk, H., Armstrong, N., De Walle, H., Riano-Galan, I., Gatt, M., McDonnell, R., Nelen, V. and Stone, D. (2005) Survey of informed consent for registration of congenital anomalies in Europe. *British Medical Journal*, vol. 331: pp. 140-41.
- ¹² Westin, A.F. (2007) How the public views privacy and health research: Results of a National Survey commissioned by the Institute of Medicine Committee on “Health Research and the Privacy of Health Information: The HIPAA Privacy Rule”. Washington: The National Academy of Sciences. <http://www.iom.edu/Object.File/Master/48/528/%20Westin%20IOM%20Srvy%20Rept%2011-1107.pdf> [Accessed August 2009].
- ¹³ Cancer Institute NSW. The NSW Central Cancer Registry, 2000-2006. Sydney, NSW. Craft PS, Zhang Y, Brogan J, Tait N, Buckingham JM. (2000) Implementing clinical practice guidelines: a community-based audit of breast cancer treatment. *MJA* vol. 172, no. 3: pp. 213-216.
- ¹⁴ National Breast and Ovarian Cancer Centre (2001) The Clinical Practice Guidelines for the Management of Advanced Breast Cancer. <http://www.nbocc.org.au/bestpractice/advanced/>
- ¹⁵ National Health and Medical Research Council, Australian Research Council, Universities Australia. (2007) *Australian Code for Responsible Conduct of Research*. Canberra: Australian Government.

Appendix 1: Assessment of principles

Table 1: Implementation status of individual principles

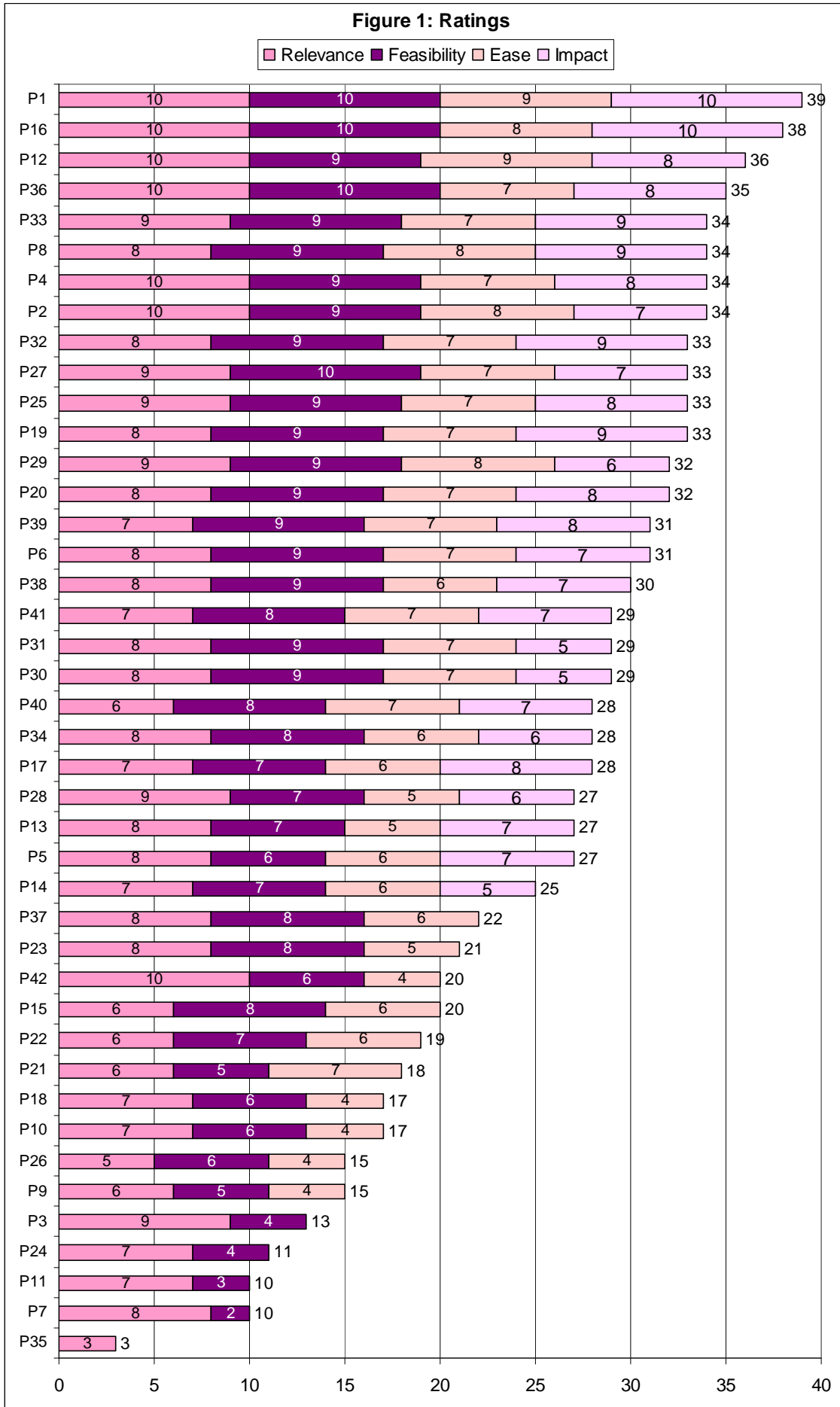
Attributes		
1	Clear and precisely defined purpose	currently met
2	Core data collection of essential elements	currently met
3	Systematic data collection at all contributing sites	cannot be implemented fully
4	Epidemiologically sound data	currently met
5	Outcomes properly ascertained	currently met
6	Burden and cost of collection considered	currently met
7	Complete collection from entire eligible population	cannot be implemented
Data collection		
8	No impact on care/no burden or cost to consumers	currently met
9	Data collection as close as possible to point of care	cannot be implemented
10	Uniformly and easily accessible from data source	cannot be implemented fully
11	Standard definitions, terminologies and specifications used	cannot be implemented fully
12	Data dictionaries used	currently met
13	Use existing data sources where possible	currently met
14	Use record linkage where possible	currently met
Data elements		
15	Collect individually identifiable patient / subject information	can be met in short/medium term
16	Collect process of care information	currently met
17	Collect objective outcome information	currently met
Risk adjustment		
18	Collect objective, reliable co-variates for risk adjustment	requires external changes
Data security		
19	Secure access controls and securing messaging	currently met
20	Data collection, storage and transmission complies with all relevant legislation and guidelines	currently met
21	Policies comply with Technical standards – Standards Map	can be met in short/medium term
Data quality		
22	Reports percentage of eligible patients recruited	can be met in short/medium term
23	Data quality control plan used	can be met in short/medium term
24	Data checks/audits routinely performed	requires external changes
25	Data management processes used	currently met
26	Reports produced to specific timetable	can be met in short/medium term
Governance		
27	Formal governance structures	currently met
28	Quality of care policies developed	currently met
Custodianship		
29	Custodianship explicitly declared	currently met
30	Data access and reporting policies available	currently met
31	Third party access via Steering Committee & IEC approval	currently met
Ethics and privacy		
32	IEC approval gained	currently met
33	Personnel familiar with and abide by relevant privacy legislation, etc.	currently met
34	Participants or their next of kin made aware of the collection of register data and given the option to not participate.	currently met
35	IEC approval sought for projects using register data	not applicable
Outputs		
36	Quality of care assessed	currently met
37	No delay in reporting risk-adjusted outcome measures	requires external changes
38	Formal peer review process prior to publication	currently met
39	Local database managers can perform ad hoc analyses	currently met
40	Annual report publicly available	currently met
41	Documented procedures for reporting on quality of care	currently met
Resources		
42	Appropriate and sustainable funding for collection, quality control and reporting	can be met in short/medium term

Table 2: Ratings of individual principles

Principle	Relevance	Feasibility	Ease	Impact	Overall
1. Purpose	10	10	9	10	39
2. Core data	10	9	8	7	34
3. Systematic collection	9	4			13
4. Epidemiologically sound	10	9	7	8	34
5. Outcomes ascertained	8	6	6	7	27
6. Burden considered	8	9	7	7	31
7. Complete collection	8	2			10
Attributes (average)	9.00	7.00	5.29	5.57	26.86
8. No impact on care	8	9	8	9	34
9. Close to time of care	6	5	4		15
10. Easily accessible	7	6	4		17
11. Standard terms/formats	7	3			10
12. Data dictionaries	10	9	9	8	36
13. Existing sources	8	7	5	7	27
14. Record linkage	7	7	6	5	25
Data collection (average)	7.57	6.57	5.14	4.14	23.43
15. Identifiable info*	6	8	6	--	20
16. Process of care	10	10	8	10	38
17. Objective outcome	7	7	6	8	28
Data elements (average)	7.67	8.33	6.67	6.00	28.67
18. Risk adjustment	7	6	4		17
Risk adjustment	7.00	6.00	4.00		17.00
19. Secure access/messages	8	9	7	9	33
20. Comply legislation	8	9	7	8	32
21. Comply standards*	6	5	7	--	18
Data security (average)	7.33	7.67	7.00	5.67	27.67
22. Report coverage*	6	7	6	--	19
23. Data quality control*	8	8	5	--	21
24. Data checks/audits	7	4			11
25. Data management	9	9	7	8	33
26. Reports timetable*	5	6	4	--	15
Data quality (average)	7.00	6.80	4.40	1.60	19.80
27. Formal governance	9	10	7	7	33
28. Quality of care policies	9	7	5	6	27
Governance (average)	9.00	8.50	6.00	6.50	30.00
29. Custodianship declared	9	9	8	6	32
30. Data access policies	8	9	7	5	29
31. Third party access ...	8	9	7	5	29
Custodianship (average)	8.33	9.00	7.33	5.33	30.00
32. IEC approval	8	9	7	9	33
33. Relevant legislation	9	9	7	9	34
34. Opt out offered	8	8	6	6	28
35. IEC approval - projects	3				3
Ethics / privacy (average)	7.00	6.50	5.00	6.00	24.50
36. Quality care assessed	10	10	7	8	35
37. No delay in reporting	8	8	6		22
38. Formal peer review	8	9	6	7	30
39. Ad hoc analyses	7	9	7	8	31
40. Annual report public	6	8	7	7	28
41. Reporting procedures	7	8	7	7	29
Outputs (average)	7.67	8.67	6.67	6.17	29.17
42. Sustainable funding*	10	6	4	--	20
Resources	10.00	6.00	4.00		20
TOTAL (average)	7.86	7.40	5.67	4.79	25.71

*These principles are still in the process of implementation.

Figure 1: Ratings



Appendix 2: NBCA case submission statistics

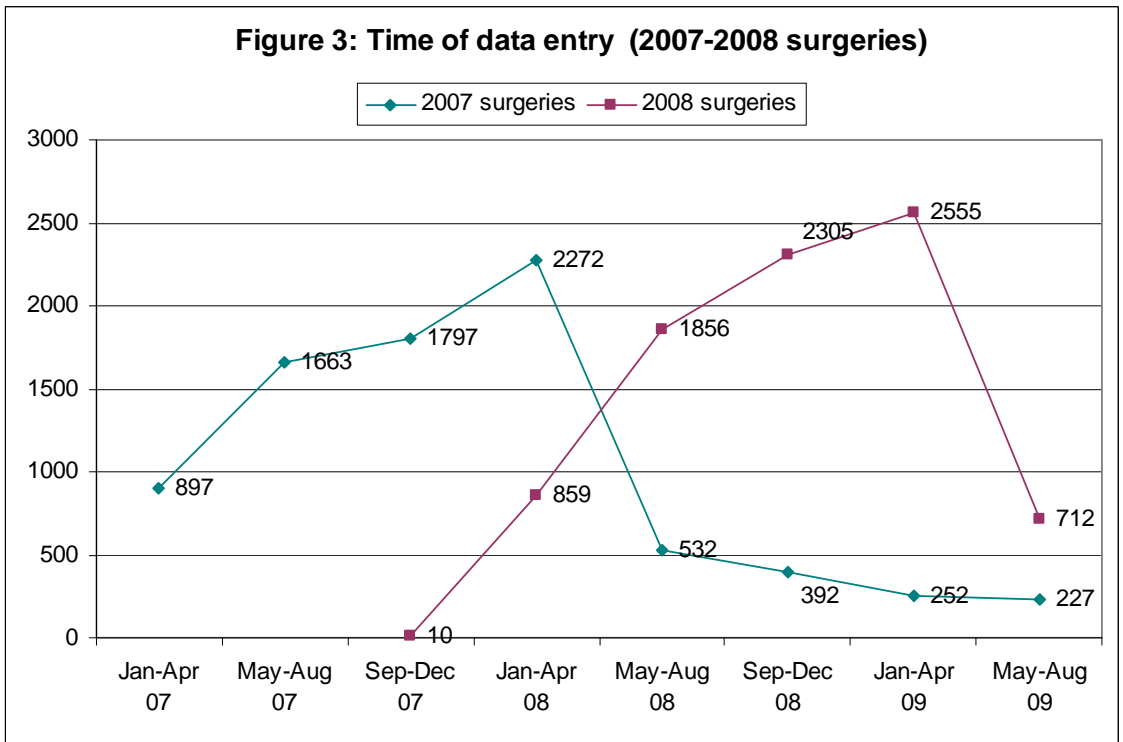
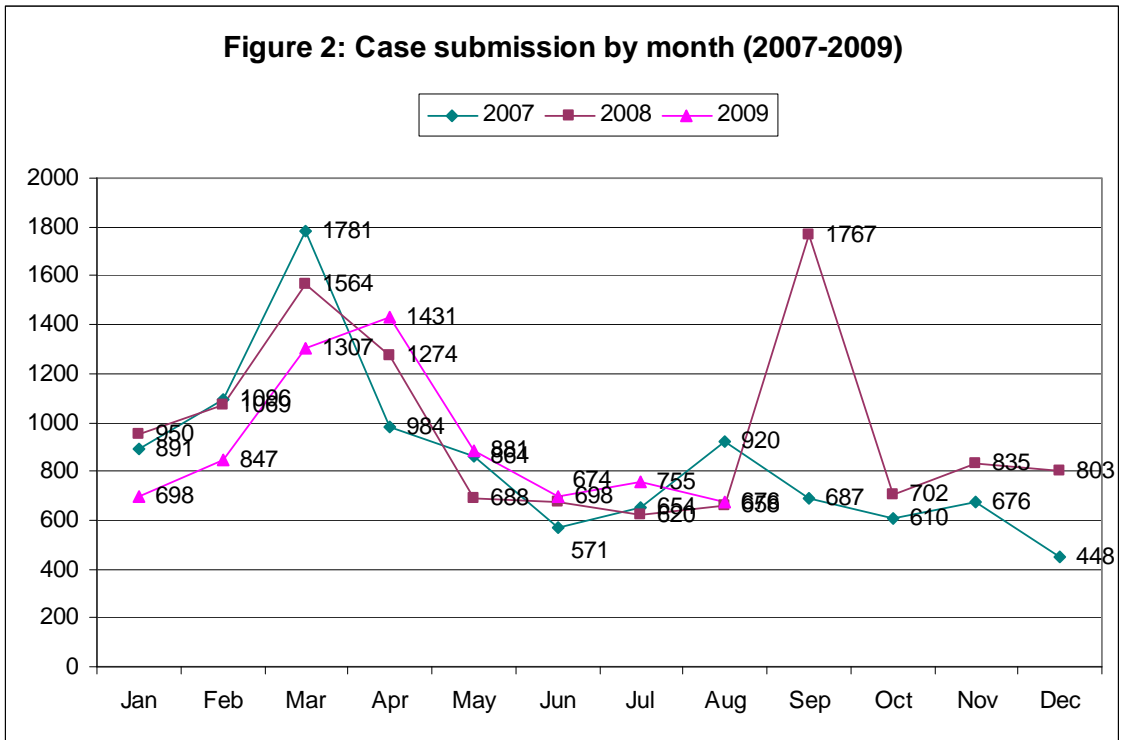


Figure 4: Days between surgery and data submission (average)

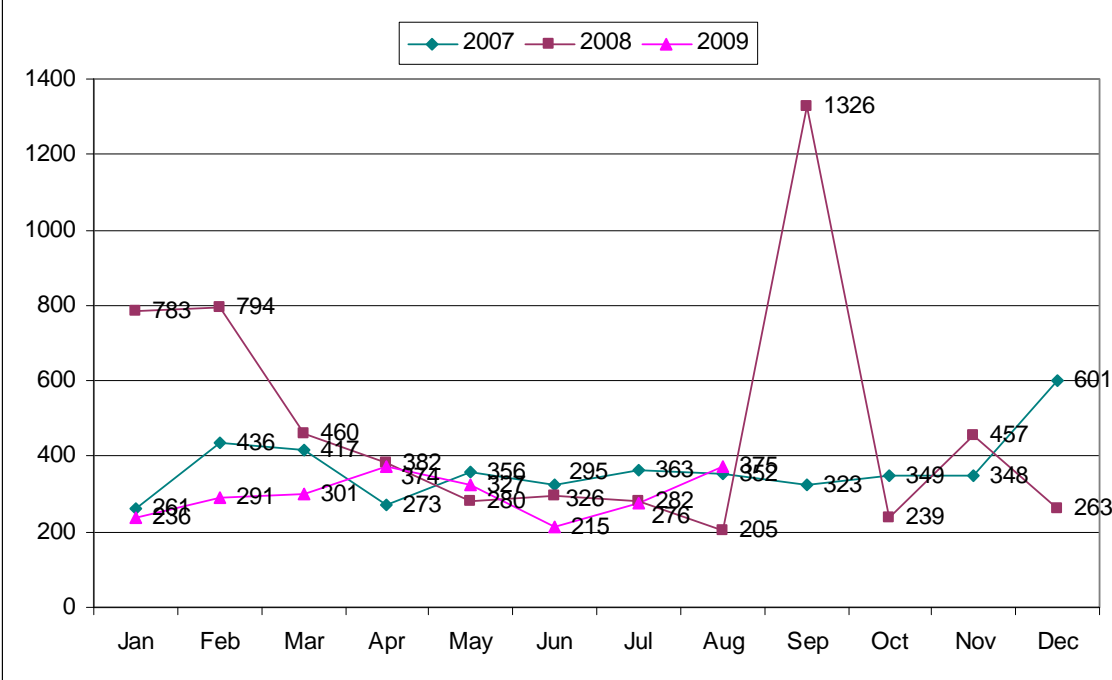
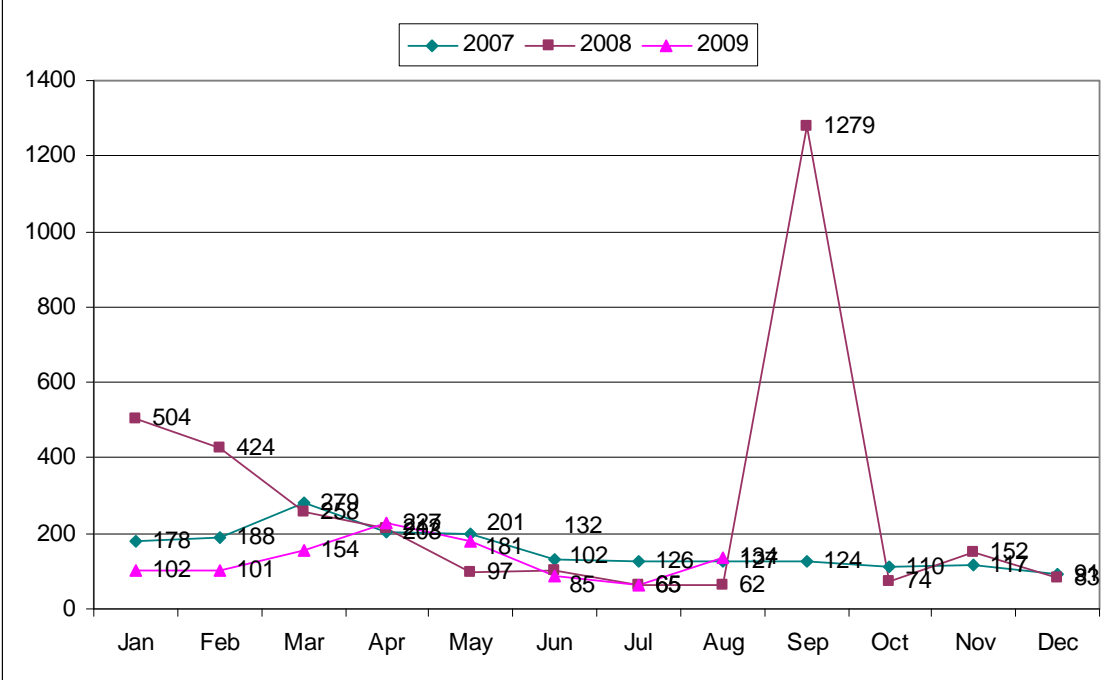


Figure 5: Days between surgery and data submission (median)



Appendix 3: MDS comparison

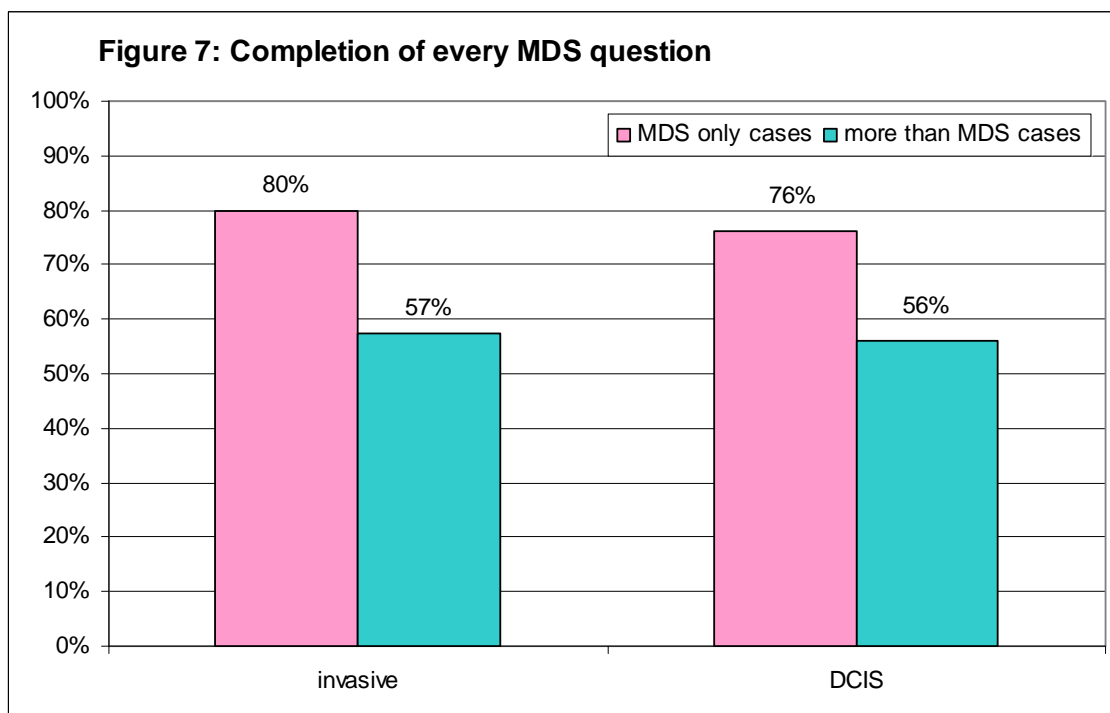
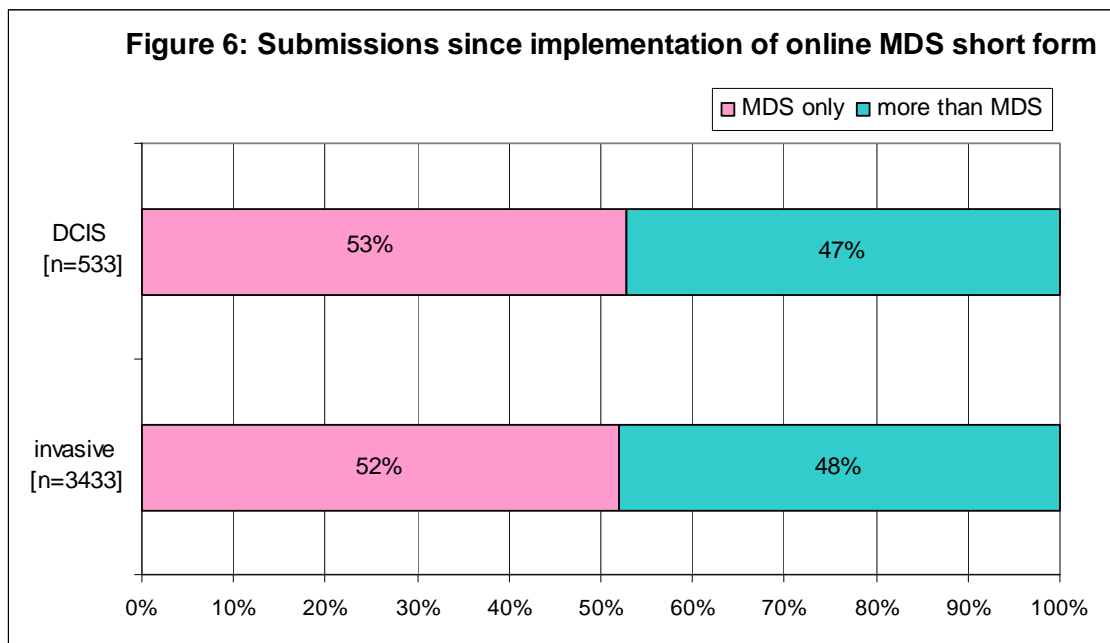


Figure 8: Days between surgery and data submission after implementation of MDS short form (average)

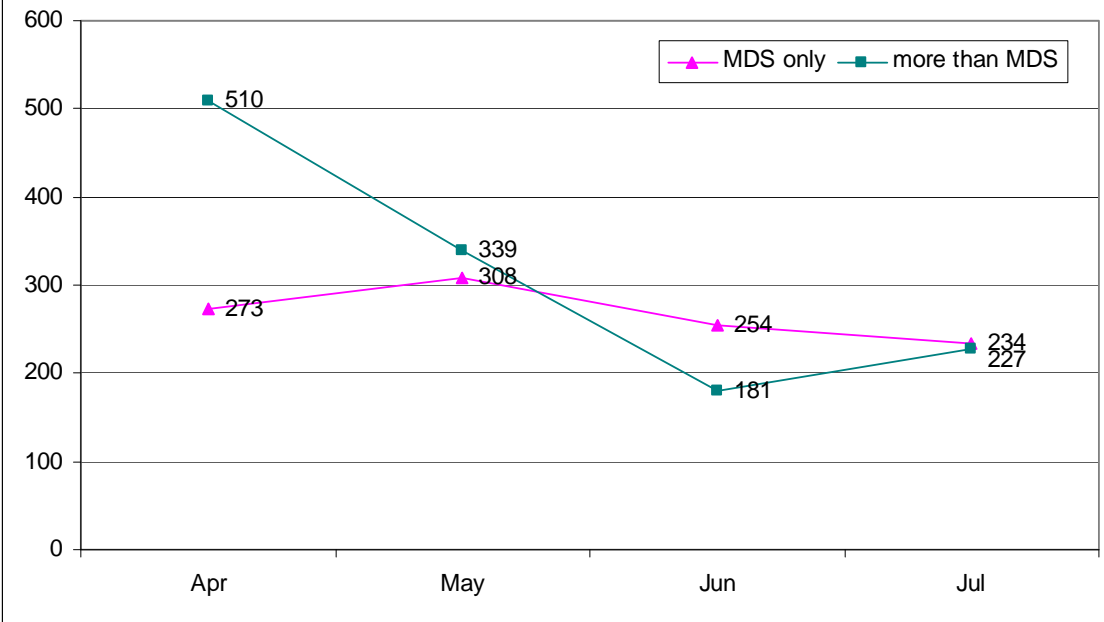
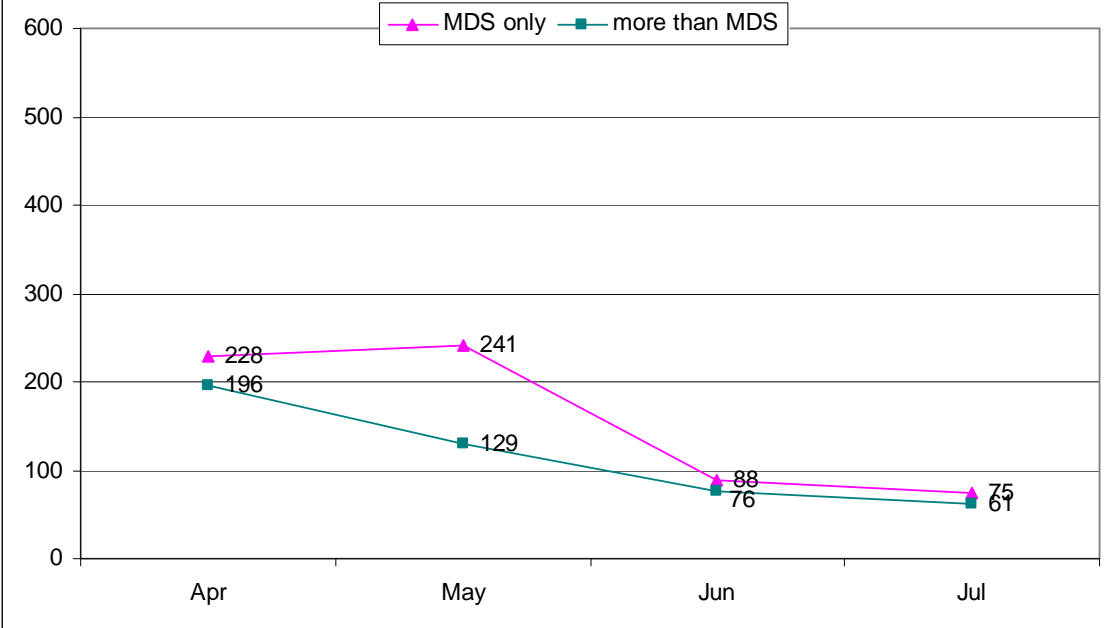


Figure 9: Days between surgery and data submission after implementation of MDS short form (median)





A Review of Emerging Technical Standards for the NBCA

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Comments on Technical Standards

Overview

The Australian Clinical Quality Registries Part B: Technical Standards (the standard) seeks to address issues of interoperability of systems with a view to creating a patient centric Electronic Health Record(EHR) by using an infrastructure defined by The National E-Health Transition Authority (NEHTA). In order to achieve this goal a standard framework has been designed that will enable a better interconnected e-health system in Australia than currently exists.

This document reviews the standards outlined in the “Australian Clinical Quality Registries” document, in the section “Part B: Technical standards — Architecture Overview” and how they might impact upon the National Breast Cancer Audit (NBCA).

Approach

The current implementation of the NBCA captures de-identified patient data; in the future RACS aims to capture patient identification against the registry entries to better track the longitudinal treatment of patients. Some technical standards will not impact the current version of the NBCA but will be important consideration In this document the current de-identified implementation will be called NBCA Version 1. A future version of NBCA with patient identification will be referred to as Version 2.

General Comments on Document

The Technical Standards document is a comprehensive set of references that may be of value to those running registries or audits. However, the document would greatly benefit from the following clarifications:

- Is NEHTA the enterprise stakeholder in the context of the proposed enterprise framework? Therefore, is each registry a component in the framework? If so, should NEHTA define with precision the requirements for each registry to participate in the enterprise framework.
- Is each registry to interpret each standard with respect to their applicability, and then attempt to implement them independently? Consider that there are over 4000 pages of standards referenced in this document.

To gain rapid adoption and maintain high quality registries we recommend that NEHTA works with a reference registry to create an implementation toolkit that can serve as the template for all registries that are to participate in the NEHTA registry strategy.

Review of Technical Standards

Interoperability Framework

The interoperability standards are a set of recommendations for how the technical architecture of registries should be constructed for compliance with the goals of the registries vision. NEHTA's interoperability framework (IF) is a set of principles that should be applied to software systems, and it is recommended that certain standards be used in the creation of the systems.

General Comments

The NEHTA IF presents an excellent set of principles on how systems can be built to be part of an e-health landscape that can deliver improved efficiency and health benefits to the population. However, experience in dealing with the IF has shown that both health care organisations and many IT vendors struggle with applying the principles to individual projects, or even understanding the implications on project design and creation.

While the standards mentioned in the document for architecture development are all useful standards that can play a role in best-practice software development (UML, TOGAF, RM-ODB) the technical standards document does not demonstrate how these standards can apply to the creation of a registry. Therefore, the onus is left to the registry owner to decipher and interpret how these standards can apply to their specific project.

In the case of the registry standards, NEHTA represents the enterprise (i.e. "health system") and the individual registries are individual systems that are to be integrated into an enterprise architecture. Therefore, we would expect more specific guidance from NEHTA as to the specific requirements it needs to achieve this task. The document seems to confuse whose role is the enterprise architect, often applying this to the registry maintainer. The document would benefit greatly from a clear definition of roles, and therefore responsibilities.

Some questions arise on how the application of these standards can be improved within the breadth of organisations involved in registry creation and maintenance:

- Should NEHTA provide a reference set of documentation using the recommended standards of a generic registry?
- Should NEHTA provide consultants to assist with applying IF standards into registries
- Should NEHTA provide a reference implementation of a generic registry that implements all standards?

This would provide specific examples and assets to existing and future registries on how to apply the standards, and significantly reduce the variation and cost of interpreting how to apply the general standards to the specific case of registry creation.

NEHTA Interoperability Framework

This document outlines how e-health systems can share data and services. While the specific scenarios of which data in RACS audits should be shared is not clear, the IF framework will be important in the implementation of the NEHTA identity standards.

The general implication of the IF is that all software in e-health should consider using web services and open standards for data communication. The current NBCA web site has not been implemented in this manner but it can be incrementally migrated to the new architectural recommendations when upgrades are made to the site.

Unified Modelling Language

The UML is used by software developers during the specification stage of a development process. This is not required at this stage. It is worth noting that the use of UML, or any of the standards mentioned, does not guarantee a good architecture will be implemented. The approach and skill of the architects are key to the outcome.

It would be useful for NEHTA to provide a set of use cases for the registry scenarios.

TOGAF

TOGAF is one of many enterprise architecture frameworks that are designed to assist in building a cohesive system based on multiple information system products. Essentially, TOGAF provides an approach that considers information systems as building block that are represented formally using the TOGAF methodology and tools, so that a consistent infrastructure can be created from the otherwise disparate systems.

In the context of registries, NEHTA is the enterprise integrator, and the registries are the individual systems. Therefore, we would expect that NEHTA creates and presents the enterprise architecture using the methodology and works with registries to map their systems into the appropriate framework. Again, if NEHTA worked with a specific registry to create the compliance assets it requires then this could be released as a template and example to all registries.

Reference Model for Open Distributed Processing

The Reference Model for Open Distributed Processing (RM-ODP) is a complementary enterprise architecture. The comments related to TOGAF apply here: NEHTA is the enterprise architect and should provide a reference set of examples and templates on how registries should comply with the target architecture.

Clinical Communications

These recommendations seek to improve the communication of information between systems so that they follow a consistent structure (data specification), consistent terms (SNOMED), consistent data definition (datatypes) and are communicated in understandable formats (HL7, XML).

Note that these standards apply to the communication of messages in and out of the registry. Compliance with these standards does not necessitate a restructure of the existing registry database, but rather a set of

mappings from the internal registry data items to external standards, and a set of transforms that can use the mappings to send and receive data.

Data Specifications

The data specification standards are in various states of development. Again, it would be ideal if NEHTA could provide the specific scenarios that would guide registries in understanding which standards are relevant.

The NBCA may wish to start a mapping project that defines the NBCA data set in NEHTA standard terms and structures that would form the basis of an import definition for the audit. This mapping task does not affect the current use of the NBCA, and should be considered when resources are available

Terminology

It is recommended that RACS works with NEHTA to define the reference set of SNOMED CT terms and concepts that form the basis of the registry data set. SNOMED CT is a large collection of terms, many of which have alternative representations; the creation of a reference set defines the specific terms to use for representing concepts using SNOMED CT.

HL7 CDA

The HL7 Clinical Document Architecture is a definition of how information is to be structured for interchange. This standard can be applied when required. The standard can be applied to outgoing and incoming messages and does not affect the internal database structure of the registry.

Datatypes

The datatype definitions will be created as part of the mapping of internal data to external message structures.

Unique Healthcare Identification

Client Identification

The IHI will allow the NBCA to identify the record against the unique health identifier for patients. This is a minimal technical change to the NBCA, however the workflow for the users will be modified as they will have to enter the 16 digit IHI into the NBCA Audit. However, once entered the NBCA should retrieve the patient information from the Identification Services to automatically populate the rest of the identifying fields, such as name, age etc.

In the future the presence of an IHI will potentially mean the opportunity for other clinical systems to send data to the NBCA Version 2 which can be automatically added to the audit data for the specific patient. For example, if a specialist is using a desktop clinical IT system that implements data fields required by the NBCA an automatic, encrypted message can be sent to the NBCA Version 2 for inclusion in the audit without data re-entry.

Healthcare Provider Information

The HPI-I and HPI-O are relevant to NBCA Version 1. The technical change to support these identifiers (health care provider and organisation) is minor, but again, the clinical users will have to enter their HPI-I when they register in the system. The mapping of organisational ID in the system will happen transparently

when selecting institutions, however RACS will have to create a mapping between the institution names in the NBCA system to the respective HPI-O.

Identity Management

NEHTA has recommended numerous standards and methods for identity management which are considered best practice. The resources to effectively interpret and apply these to each registry will be significant. We observe that the usage scenarios for registries are likely to be quite consistent, while their variation lies in the individual data items collected. Therefore, we recommend that NEHTA could work with the registries to create a specific set of recommendations and practices (including examples and templates) that would ensure that best practice identity management is documented and applied in registry implementations.

Currently, the standards and methods listed are broad and only small sections may be relevant to registry implementations. The narrow use cases for registry interactions would imply that the specific applications of the Framework for Analysing, planning and implementing identity management, AGAF and ACSI can be defined for registries in a consistent manner. In other words, a set of assets that defined the common risks and mitigation strategies for registries could be provided by NEHTA.

Security Techniques

The effective application of security techniques has implications both technically and in the organisation. This process would start with a security risk assessment and include both technical assessments and management reporting and evaluation.

This item has the biggest implication for the audit. We recommend that RACS considers planning this process.

OASIS Control Markup and Security Services

These standards are relevant if allowing users authenticated on one system to move their credentials across to other systems. These standards are still developing with respect to web services and web sites. Currently, the scenario of people moving between registry sites is not considered to be a significant barrier to usability.

Secure Messaging

The NBCA web site is built upon five year old technology and is made up of the following tiers:

- User interface implemented in ASP.NET Version 2.
- Server side application component implemented in NET 2.
- RDBMS - Microsoft SQL Server 2000

Review of the NBCA application architecture has been envisaged but no implementation date has been set. This process will involve a total redesign of the upper and middle tiers operating on the current MS SQL Server database and the utilisation of secure web services (middle tier) for communication between the user interface (upper tier) and database.

The revision of the architecture of the NBCA for a Version 2 would allow more alignment with the short-term and long-term architecture goals of NEHTA.

Web Services & XML

The technical ability to create XML (e.g. SOAP-based) web services is straightforward with the technology used by the NBCA web site. However, the more critical question is what services are to be provided by the registry, and what are the specific interoperability use cases? These questions and subsequent standards could be defined if NEHTA participated in creating a reference registry.

Supply Chain

If the NBCA wishes to identify devices (e.g. implants), then the mapping of these items to the standards on supply chain should be created. The relevance of the e-procurement standards is unclear and perhaps reflects the needs for NEHTA to target the technical section on specific registry scenarios/use cases.

Engagement & Adoption

We believe that engagement and adoption of the principles outlined in the Technical Standards document from NEHTA would be significantly improved if:

- NEHTA provided more scenarios/use cases that highlighted which specific standards should be implemented, and specifically how they should be implemented as part of best practice for registries.
- That NEHTA prepare a much more specific set of recommendations rather than listing many thousands of pages of references for each registry to review and interpret.
- The above points would then allow a resource estimate to be created that would allow registries to understand the investment required to achieve different levels of maturity of compliance against the benefits to the data quality and data access.

We strongly recommend that NEHTA considers working with a reference registry to define a specific set of requirements against a registry maturity model, with examples, templates and even source code that directs which standards are applicable for registries, and that demonstrate how a registry can implement the standards. Without this specific advice we fear that the cost of implementation will be high, the adoption low and potentially a high degree of variability in the quality of implementation.

Understanding standards

This is a general document that would be of interest to management staff.

Corporate governance of Information and Communication Technology

This document is relevant to the audit management team, and is addressed in another document.

Short-Term Architecture Implications

Registries and External Data Integration

The current NBCA registry and the proposed Version 2 are by default Level 2 Registry types according to the Technical Standards document: “Web-based submission of data into the registry.”

Higher levels of technical integration, such as electronic cross checking of data against external data sources, or automatic data collection from local clinical systems will be logistically enabled in NBCA Version 2 with support of the patient IHI. However, to allow this to occur on a technical basis, workflows and data formats must be agreed upon. These agreements are based on multiple vendors agreeing to support data standards and open communications. Healthcare IT vendors do not have a strong track record of cooperation, so the barriers to gaining further integration once the IHI is in place will be around funding to gain vendor support, patient consent, and security to allow data to move between institutions.

National Portal

Providing information to the proposed National Registries Portal is relevant in NBCA Version 2. Once the data requirements for participation in the National Registries Portal is defined, and the mechanism of communication, the participation of the NBCA will not be a significant technical issue.

The recommendations for the National Portal include the ability for an audit to support multiple identities per provider. Alcidion’s recommends rejecting this approach because it will result in a significant amount of rework of the database and login process without significant benefit to the clinical users. Because of the identification of users via the RACS this step is unnecessary.

The short term goal for the National Portal is to allow users to search within the audit system to find patients, and for the registry to support multiple identifiers. Alcidion recommends rejecting this approach for the following reasons:

- The work to support this will require significant changes to the NBCA. Alcidion’s hospital systems already support this functionality so we are aware of the changes required.
- Supporting multiple identifiers will put burden on the clinical users who will have to manage multiple identifiers, with little benefit to them.
- Supporting the single IHI rather than multiple identifiers will provide search capability and provide benefits to the clinical users via longitudinal data gathering and data integration capabilities.

- The security implications of multiple identifiers within the registries is under-specified in the technical standards document.

Alcidion recommends moving to the use of the IHI during the development of the Version 2 audit to avoid significant and redundant work required to support multiple identifiers.

Report Requests

The NBCA Version 1 supports feedback to users and data access. This section is vague on what is best practice. Reporting can be updated in the NBCA as this area is developed.

Authentication

The Technical Standard recommends using the OpenID framework to reduce the number of times clinical users must login to different portals. The OpenID system provides the option for users to use OpenID rather than the NBCA specific login. Because of the specific nature of the NBCA it is unclear how often breast surgeons use different audits and if the issue of separate logins is a burden for them.

This can be supported when required with moderate effort when required.

Secure Messaging

The current architecture of the NBCA Version 1 is based on older methods of linking the web pages with the database. Alcidion recommends the support for secure messaging from other devices and systems via secure web services as be considered for a revised Version 2 system. Alcidion has considerable experience in the development and use of secure web services, but this approach would require a revision of the existing web pages to maximise consistency and use of the new architecture.

Long-Term Architecture Implications

The long-term vision of NEHTA is for registries to directly gain data from clinical data systems, including the ability to recruit patients via publishing eligibility criteria.

While this goal is admirable the amount of integration between multiple vendor systems is considerable, and it assumes a degree of flexibility within clinical systems that generally does not exist in current versions.

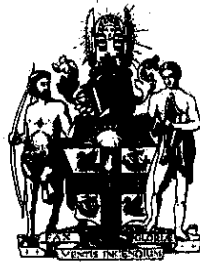
A revised NBCA Version 2 with updated architecture to support NEHTA standards and maintain patient identifiers would be built with the ability to support the long-term architecture as outlined in the Technical Standards document.

Support for the longer term vision requires the ability to support the proposed workflows and data definition standards. The technical support for the scenarios would be best implemented during a Version 2 revision of the NBCA.

Alcidion notes there is significant definition required before the long-term vision can be realized; there may be significant and further work to support the long-term architecture goals after a Version 2 depending on the details of standards required to support the vision when NEHTA specifies these.

Appendix 5: Expenditure

A full final expenditure report is pending and will be provided by the end of 2009.



ROYAL AUSTRALASIAN COLLEGE OF SURGEONS

A.B.N. 29 004 167 766

**OPERATING PRINCIPLES AND TECHNICAL STANDARDS FOR
AUSTRALIAN CLINICAL QUALITY REGISTRIES PROJECT**

FINANCIAL REPORT

FOR THE PERIOD 24 NOV 2008 - 30 SEP 2009

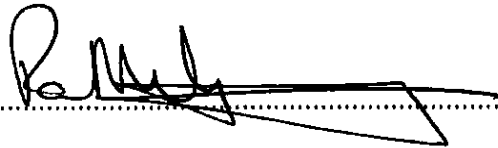
ROYAL AUSTRALASIAN COLLEGE OF SURGEONS
OPERATING PRINCIPLES AND TECHNICAL STANDARDS FOR
AUSTRALIAN CLINICAL QUALITY REGISTRIES PROJECT
CERTIFICATION BY ORGANISATION OFFICE BEARER
FOR THE PERIOD 24 NOV 2008 – 30 SEP 2009

I, Pam Montgomery, hereby certify that the information contained in the financial records and the Statement of Income and Expenditure of the Operating Principles and Technical Standards for Australian Clinical Quality Registries Project give a true and fair view of its performance for the period 24 Nov 2008 – 30 Sep 2009.

I am satisfied that:

- a. Amounts relating to the total grant paid have been expended on the approved project/service according to conditions specified in the Funding and Performance Agreement with the Commonwealth of Australia.
- b. A full and complete set of accounting and financial records has been maintained.

P MONTGOMERY
Acting Chief Executive Officer



Date 16 October 2009

MELBOURNE

ROYAL AUSTRALASIAN COLLEGE OF SURGEONS
OPERATING PRINCIPLES AND TECHNICAL STANDARDS FOR
AUSTRALIAN CLINICAL QUALITY REGISTRIES PROJECT
STATEMENT OF INCOME AND EXPENSES
FOR THE PERIOD 24 NOV 2008 – 30 SEP 2009

	2008-09 24/11/08 to 30/09/09 \$
Project Income & Assoc Fees (ii)	140,227
Staff Payroll, On-Costs and Other Staff Costs	(91,269)
Other Staff Costs	(192)
Consultants Fees	(20,175)
Communications	(491)
Printing, Stationery & Photocopying	(905)
Postage, Courier & Freight	(633)
Computer Related Expenditure	(462)
Travel & Accommodation	(2,021)
Bank Fees	(10)
Depreciation	(1,750)
Overhead Charge	(12,262)
College Contribution	472
Operating surplus/(deficit) for the reporting period (iii)	10,528

- (i) The Statement of Income and Expenses has been prepared on an accruals basis.
- (ii) Please note that the final project income amount of \$35k is still to be billed on 31 October 2009 and has not been included in these figures.
- (iii) Please note the final operating surplus is expected to reduce with payment of consultancy invoices not yet received valued around \$15k, staff costs up to \$20k and software licence fees of around \$2k. These will all be included in the final financial statement updated to 31 October 2009 to be submitted in November as agreed.