



Review of the BreastScreen Aotearoa Program

Future Directions for the National Screening Unit

Working in Partnership with Lead Providers for a Sustainable Quality Program

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Executive Summary

The BreastScreen Aotearoa Program is a successful population screening program that has the potential to achieve the stated vision in the Strategic Plan 2008-2013 “*to prevent breast cancer mortality by providing a consistent, high quality, effective and efficient breast screening programme with equitable access and outcomes for those most at risk of dying of breast cancer*”. The Program goal is to reduce breast cancer deaths by 30%.

Progress of the BreastScreen Aotearoa Program

The progress of the Program as measured by the key performance indicators of participation, cancer detection and small cancer detection compare favourably with standards achieved by other national breast cancer screening programs.

The participation rate for women aged 50-69 years has increased from 66.3% in the period January 2008 to December 2009 to 68.7% in the period July 2008 to June 2010. The participation rate reported for Maori women has increased significantly from 53.3% to 57.2% over these same periods as has the participation rate for Pacific women, increasing from 57.2% to 61.5%. These rates exceed the participation rates achieved by BreastScreen Australia for both the target age group and compared with the participation rate for Aboriginal and Torres Strait Islander women.

The cancer detection rate and small cancer detection rate are exceeding the targets set for the Program and compare well with the rates reported for BreastScreen Australia. The preoperative diagnosis of invasive cancer and the open biopsy benign lesion rate are also exceeding the targets set for the Program.

It is critically important to maintain and improve these performance outcomes into the future in order to achieve the longer term aim of significantly reducing the number of New Zealand women who die from breast cancer.

There are several performance measures of concern related to quality and efficiency that may affect performance outcomes for the Program in the future. These are the technical recall rate on the mobiles and the timeliness performance measures for recall to assessment, results provision following biopsy and the time to open biopsy and to treatment.

Structures, systems and resourcing

A national approach to this important cancer screening program is critical as is the recognition that the Program is a key part of the cancer control continuum. A better alignment with the National Cancer Programme in the Ministry of Health would be consistent with the government's strategic directions and priorities for cancer control.

The findings of this review suggest that the National Screening Unit (NSU) with its current structure and staff capability may have insufficient resources to undertake the role and functions, for which it was established in 2001, as a national coordination unit for the cancer screening programs. This national coordination role is critical to the ongoing success of the BreastScreen Aotearoa Program in terms of national leadership, coordination, strategic planning and quality monitoring. However the professional capability of the NSU staff resources for the Program has been somewhat depleted through numerous external and internal restructures, loss of positions and key skills in public health and population screening. Although significant efforts have been made in recent years to redress these impacts the NSU requires further support from the MOH executive to ensure that the current staff resources are retained and an appropriate organisational structure is in place to implement the strategies needed to maintain and enhance the quality of the Program. In addition the current staff and expertise in the NSU requires Program leadership within an integrated team to maximise the use of their skills and ensure cross learning among the team. This will assist in building the capability of the Program leadership in the NSU and its relationships with the Lead Providers.

A reinvigorated NSU could be achieved through the realignment of quality monitoring as core functions in dedicated Program teams for BreastScreen Aotearoa and the National Cervical Screening Program. These teams would be lead by Program Directors and incorporate the staff and functions currently in the Quality and Equity team. This change will be critical in promoting national leadership and strategic planning for these Programs and supporting a strong focus on quality assurance and performance monitoring. The inclusion of the National Bowel Cancer Screening Pilot project in the NSU could assist in rebuilding the knowledge and skill base in population screening and maximise the efficient use of resources across the cancer screening programs. In addition the system platform in place for the National Cervical Screening Program register could be used as the platform for establishment of the BreastScreen Aotearoa national register and for the National Bowel Cancer Screening Pilot Project register. This unique opportunity would make the most effective and efficient use of resources through the ability to share functionality, system management costs and linkage with population and health professionals reference tables. A national register is the cornerstone of population screening that is essential in monitoring quality, performance standards and the outcomes of cancer screening programs.

The transition to digital technology is inevitable for the BreastScreen Aotearoa Program and was identified as a priority in the Strategic Plan 2008-2013. The current fleet of analogue equipment is increasingly unsupported and obsolete, particularly film processing. In order to achieve this priority a comprehensive project of work is required to facilitate the purchase of digital mammography equipment, the conversion or building of digital mobiles, establishment of a central PACS integrated with the national register and networked clinical information system. This strategic project would deliver the ability to capture, store, distribute, view and interpret images and associated information electronically for the BreastScreen Aotearoa Program, the network of eight Services and potentially across the continuum of care.

An investment in this comprehensive approach would deliver major benefits to the Program in increased productivity and capacity, optimise service delivery cost efficiency and address current and potential future workforce issues, particularly for medical radiation technologists and radiologists.

The transition to digital technology needs to be accompanied by capacity planning to ensure the best use of capital resources, taking into account population growth in the eligible age groups and by geographical area. A mapping exercise of current and future physical infrastructure is needed for the Program in conjunction with workforce requirements to ensure the best use of resources to meet current and future needs.

A specific examination of the utilisation of the mobile services may be warranted given a comparison of the throughputs on mobile services for BreastScreen Queensland compared with BreastScreen Aotearoa mobile services. In 2010 BreastScreen Queensland screened 221,696 women of whom 17% (38,505) were screened on mobile services using six digital mobile units across a geographically large State. For BreastScreen Aotearoa of the women screened per year (about 211,921) across July 2008-2010 19% (42,284) were screened on 12 mobiles of which only two were digital.

Given the changes in productivity that should flow from digital technology, demographic changes and potential efficiencies gained through higher screening activity it would be timely and appropriate to review the funding model to ensure the best value for money cost of the Program. It may also be useful to benchmark the cost per woman screened with the published cost per woman screened for the BreastScreen Australia Program.

Clinical Governance and Leadership

Clinical governance and leadership are critically important for the safe delivery of quality population based cancer screening programs. Organised population screening programs, such as BreastScreen Aotearoa, have a higher level of “duty of care” than other medical interventions because although screening may be perceived as simply the application of a test to individuals, when applied to defined populations of asymptomatic eligible women there is a need to ensure that this public health program maximises the benefits and minimises the harms.

The loss of the BreastScreen Aotearoa Clinical Leader position in the NSU left a perceived void and uncertainty about the national clinical governance and leadership of the Program. Breast cancer screening is primarily a radiological procedure therefore it is appropriate that the Clinical Leader for the national program is a radiologist. This leadership role is critical to independent monitoring of the radiological quality of individuals and services based on performance data and audit processes, in leading and supporting quality improvement activities and training new radiologists working in the Program. The position also has a vital role in advising on evidence based clinical pathways, changes in clinical best practice, the application and efficacy of new technologies and revision as appropriate of quality standards and measures. This position could be appointed to the NSU but employed in a Service allowing the individual to maintain their professional entitlements and retain the currency of their clinical practice to maintain peer group respect and authority.

Whilst it is important for the Clinical Leader to provide this national level clinical accountability it is equally important to provide a quality framework and clinical governance structure to support this role. Given the relatively recent establishment of the Clinical Governance Group it would be opportune to consider strengthening its role to be the single point of review for the performance of the Lead Providers. The terms of reference would be to review all the relevant performance measurement data, including the Independent Monitoring Report (IMR), audit reports and recommendations and to make decisions on the level of compliance or otherwise of the Lead Providers to the National Policy and Quality Standards.

The current relationship of the BreastScreen Aotearoa Advisory Group with the NSU appears to be somewhat compromised due to the impact of the loss of positions and staff and structural changes in the NSU over the last two years. In order to make best use of the valuable expertise on the Advisory Group their role and responsibilities need to focus clearly on ensuring the quality of the Program in particular, the oversight of the National Policy and Quality Standards, their implementation and review as needed. The continued meetings of the specialist disciplines for the Program through the uni-disciplinary groups is important to ensuring specialist advice is used to inform best clinical practice.

Quality Framework and Performance Monitoring

The BreastScreen Aotearoa quality management framework and National Policy and Quality Standards are sound. However the implementation of the quality processes by the NSU are under considerable pressure and constraint because of the current fragmented NSU structure in relation to quality processes and the significant loss of key positions, staff resources and expertise. In addition there is not a clear separation of quality monitoring and contract management. Without change it will become increasingly difficult and possibly unsustainable to continue to meet the requirements of

the critical quality monitoring and auditing of the Lead Providers or the national Program.

A Quality Management System for the Program is critical that describes a clear quality structure that maps the relationships and processes that underpin the overall quality management of the Program and the levels of accountability. This system relies on the establishment of a national register that supports information driven quality management processes to monitor performance measures across the screening pathway. An accreditation model similar to BreastScreen Australia could be considered to operate under the auspices of a strengthened Clinical Governance Group.

BreastScreen Aotearoa Sector Relationships with Lead Providers and Clinical Directors

To achieve a sustainable quality BreastScreen Aotearoa Program will require strong clinical leadership and collaborative relationships between the National Screening Unit and the Lead Providers. The continuation of the joint Clinical Directors and Lead Provider Managers meetings, with at least two face to face meetings a year, could assist in overcoming some of the relationship issues currently being experienced. It will be important for the NSU and the Lead Providers to work together to strategically plan for and implement the infrastructure, including workforce, and systems to meet the future capacity needs of the Program. In addition it will be essential to collaboratively develop a Quality Management System that is focused on a quality improvement approach to ensure the Program continues to provide high quality, equitable and accessible breast cancer screening services for the women of New Zealand.

Recommendations

Structures, systems and resourcing

1. It is recommended that the National Screening Unit (NSU) and the BreastScreen Aotearoa (BSA) strengthen its collaborative links and alignment with the Cancer Control team given that cancer screening programs are a key part of the cancer control continuum including the following considerations:
 - i. That the strategic directions and priorities of the cancer screening programs be better identified in the National Cancer Program Workplan, as part of the Government's priorities for cancer and the New Zealand Cancer Control Strategy and that relevant Program and Clinical Leaders have membership on the Steering Group.
 - ii. That the cancer screening programs strengthen their collaborative alignment and the linkage with the regional cancer networks and the development of clinical pathways for breast, bowel and cervical cancers.
 - iii. That the NSU be renamed National Coordination Unit (NCU) for Cancer Screening to assist in communicating the change in focus to Lead Providers, stakeholders and the community.
 - iv. That consideration be given to moving the Antenatal and Newborn screening programs out of the NSU to be aligned with the relevant Maternal and Child Health area in the Ministry of Health to increase the focus and alignment of the cancer screening programs in the NSU.

2. It is recommended that the NSU realign quality and equity functions into the program teams to ensure the most efficient use of resources and to promote national program leadership and strategic direction for BSA including the following:
 - i. Establish a position of Program Director (Manager), that would report directly to the Group Manager (NSU) and remove the current Manager Cancer Screening position. The key role and responsibility of this position would be to provide leadership and strategic direction for the BSA Program and to lead a program team that undertakes national coordination functions and strategic management for BSA.
 - ii. Rebuild the BSA program team by integrating relevant positions from the Quality and Equity team with the current program positions to undertake the key functions of national coordination, strategic and capacity planning, BSA service development and support, community engagement and communication, policy and standards, quality assurance and monitoring including coordination of BSA Service Audits and reporting.

- iii. Ensure the retention of existing staff in the NSU that have significant BSA program knowledge and experience and recruit, to current vacant positions, personnel with the appropriate skills in public health, epidemiology or biostatistics, quality assurance, community engagement and communication.
 - iv. Maintain cross program knowledge, skills and resource sharing, particularly in the disciplines of epidemiology/biostatistics and community engagement and communication, through a matrix structural alignment and formalised processes.
 - v. Ensure that communication and collaboration with the Maori and Pacific Advisory Groups is coordinated as appropriate across the BSA and National Cervical Screening Programs to maintain and continue joint strategies through the Independent Service Providers (ISPs) and Lead Providers to improve participation for these priority groups
3. It is recommended that consideration be given to incorporating the National Bowel Cancer Screening Pilot Project into the NSU to maximise the efficient use of resources in population screening knowledge and skills across the cancer screening programs, in particular the following:
- i. The establishment of the national register for bowel cancer screening on the same system platform as the National Cervical Screening Program (NCSP) and BSA to share functionality, system management costs and population register linkage and reference tables.
 - ii. The quality assurance and monitoring processes could be incorporated into the quality management system and structure recommended for the BSA Program and the NSU quality management framework.
 - iii. Specialist staff resources, in particular biostatisticians/epidemiologists that are critical for monitoring cancer screening programs could potentially work across the programs and provide professional support for other key staff involved in monitoring quality and performance.
 - iv. Relationships with Lead Providers can be coordinated across the three cancer screening programs in negotiating agreements and monitoring outcomes.
 - v. The existing Advisory Groups for Maori and Pacific communities could be broadened to encompass bowel cancer screening or if not culturally appropriate used as a model for engagement with these priority groups.
 - vi. That the recommended systems development for the cancer screening programs be aligned across the cancer continuum to ensure data consistency including electronic use of structured reporting and electronic linkage with national cancer and regional systems.

4. It is recommended that the BSA Program transition to full digital technology including the implementation of a centralised Picture Archiving Communications System (PACS) to ensure the ongoing safety and quality of the breast cancer screening services including consideration of the following:

- i. The NSU in consultation with the Lead Providers coordinate a bulk tender arrangement to gain cost efficiencies and ensure implementation of digital mammography equipment in all BSA Services within a two year period. The tender panel to include representatives of the BSA Clinical Directors, radiographers, physicists and Lead Provider Managers.
- ii. That the NSU urgently undertake a capacity planning project, taking account of a digital environment, in consultation with the Lead Providers to assess the physical capacity, including the mix of fixed screening and assessment centres, sub-contractors and mobile services required for the Program nationally and at catchment level for the projected population of eligible women up to 2016.
- iii. That the NSU in collaboration with the Lead Providers undertake or commission a national workforce capacity project for the BSA Program in particular focusing on radiology and radiography workforce but including other key specialist disciplines such as pathology and breast surgery.
- iv. That the NSU in consultation with the Lead Providers assess the requirements for the replacement of or fit out of the remaining analogue mobile services with digital mammography equipment informed by the BSA capacity plan.
- v. That the PACS be integrated with the national register and clinical information network to facilitate the central storage, distribution and viewing of images at any BSA Service to overcome temporary or permanent workforce shortages of radiologists and enable prior images to be efficiently shared across the Program if women attend different BSA Services.
- vi. That the PACS and clinical information system be designed to store separately breast imaging undertaken for women outside the BSA Program by Lead Providers in a way that information and images can be shared across the different clinical pathways as needed for ongoing care or future reference for screening or diagnostic breast imaging services.

5. It is recommended that as part of the National Information Technology Health Plan a national register, with a networked clinical information system, be established for the BSA Program to provide critical infrastructure to more effectively and safely monitor quality assurance and performance outcomes, reduce the resources required to manage data and provide functional efficiencies for Services including consideration of the following:

- i. That the current clinical systems upgrade be the first phase toward building the BSA national register and taking advantage of the existing National Cervical Screening register system platform in order to share common reference tables, functionality and maintenance costs.
- ii. Investigate existing state based breast cancer screening program register systems in the BreastScreen Australia Program to assess their suitability, feasibility and cost for the BSA Program.
- iii. Establish linkage of the BSA national register with the national population identification data to identify eligible women, unscreened or under screened women to enable invitation or re invitation of these women to improve screening participation.
- iv. Develop systemised quality assurance reporting functions that support national, BSA Lead Provider catchment level monitoring of quality and performance, including quality assurance reporting for readers and radiographers.
- v. Investigate central functions that could be built into the BSA register that could generate cost efficiencies for the Program and reduce the administrative burden for BSA Services such as the use of centralised mail house services and call centre functions.

6. It is recommended that the BSA Program funding model be reviewed to take account of expected efficiency gains through digital technology and projected population growth or decreases in BSA Lead Provider catchments including the following considerations:

- i. That the review of the funding model focus on “value for money” considerations taking account of the cost efficient use of resources including capital and workforce, in particular maximising the use of mammography equipment and radiographers to achieve screening activity targets.
- ii. That a benchmarking exercise be undertaken on a cost per woman screened basis with large States’ cost per woman screened data from the BreastScreen Australia Program that includes costs associated with coordination and all aspects of the breast cancer screening services pathway.

- iii. That the review of the funding model considers the demographic profiles of the Lead Providers in conjunction with the eligible population.
- iv. The review of the funding model should ensure that funding for priority groups, such as Maori and Pacific women, is maintained and recruitment and retention activities are funded based on need to improve participation levels in disadvantaged population groups.
- v. That immediate steps are taken to change from funding activity to funding per woman screened to provide a positive incentive to reduce repeat mammograms of women outside the clinically accepted screening pathway.

Clinical Governance and Leadership

7. It is recommended that the NSU appoint a part time radiologist Clinical Leader for the BSA Program to work with the BSA Program Director (Manager) employed by a Lead Provider to ensure maintenance of their clinical entitlements and practice. Specifically this position would have responsibility for the following:
- i. Providing clinical leadership for the BSA Clinical Directors and advice to the NSU and the Ministry of Health in relation to the clinical aspects of the BSA Program.
 - ii. Development and provision of orientation training, authorisation and ongoing professional development for all radiologists in the BSA Program.
 - iii. Participating in the Radiologist Uni-disciplinary Group meetings, reviewing clinical standards and promoting and undertaking research that informs clinical policy and practice in the BSA Program.
 - iv. Participating as a member of the BSA Advisory Group, the Clinical Governance Group and the Ministry of Health Clinical Advisors Forum as appropriate.
8. It is recommended that the newly formed Clinical Governance Group (CGG) for the NSU have its role and responsibilities strengthened to provide independent review and recommendations on the BSA Services Audit reports and performance monitoring reports, and potentially to oversight the quality performance of the screening programs in the NSU. The key features of this Group would be as follows:
- i. The chair of the Clinical Governance group would be independent from the NSU and the BSA Services but understand the critical quality aspects of population screening. Members to be appointed by the Director General.
 - ii. The membership would include relevant clinical experts in the specialist fields relevant to the screening Programs including a radiologist with

- significant knowledge of the BSA Program, an independent cancer epidemiologist and two consumers. Ex-officio members from NSU would include the biostatistician/epidemiologist, the BSA Program Director and national quality coordinator.
- iii. The operating principles of the CGG would clearly document the decision making processes and any decision tools used by the CGG, ensure the confidentiality of the Audit reports and detail the feedback process to BSA Services in relation to recommendations and include an appeals process.
 - iv. Final decisions from the CGG would be posted on the NSU website along with summary information from the Audit report.
9. It is recommended that the BSA Advisory Group and the Uni-disciplinary groups (UDGs) be maintained and strengthened with specific consideration given to the following:
- i. Consider changing the name of the BSA Advisory Group to BSA Quality Management Committee to emphasise their key role in maintaining the quality of the BSA Services and oversight of the National Policy and Quality Standards (NPQS).
 - ii. Review of the Terms of Reference of the UDGs to ensure their key roles and responsibilities are focused on quality management and standards and to clarify the lines of communication with the NSU and the BSA Advisory Group.
 - iii. Development of an annual workplan for the UDGs that is endorsed by the BSA Advisory Group and reported on to the BSA Advisory Group at each of the meetings.
 - iv. Ensuring the operating principles are consistent for all groups, have a clear process for representation from each of the BSA Services, election of the chair and communication of the minutes and actions from the meetings.
 - v. That at least two face to face meetings of the BSA Advisory Group are held each year and the UDGs biannual meetings continue with at least one face to face meeting.
 - vi. That the NSU continue to organise and provide the secretariat for the UDGs with timely distribution of agendas, minutes and report on actions arising including assisting in the preparation of submissions to the BSA Advisory Group.

Quality Framework and Performance Monitoring

10. It is recommended that the NSU review the Quality Framework and develop a sustainable, effective BSA Quality Management System, in consultation with the BSA Clinical Directors and Lead Provider Managers, to ensure a strong focus on quality improvement in achieving the aims and objectives of the BSA Program. In particular consideration of the following:

- i. Review the current audit approach to clearly separate quality assurance and improvement processes, that are focused on population screening and linked to the desired outcomes of the BSA Program and provision of “high quality, equitable and accessible national breast cancer screening”, from BSA service contract compliance.
- ii. Consideration could be given to establishing an accreditation process for the BSA Services, adapted from the Quality Improvement Program and accreditation model used by BreastScreen Australia, under the auspices of the strengthened Clinical Governance Group.
- iii. Review the contractual arrangements with International Accreditation New Zealand (IANZ) to assess the cost efficiency and effectiveness of this arrangement and the number and use of specialist auditors.
- iv. Realign performance monitoring from compliance to a collaborative quality improvement approach with Clinical Directors and Lead Provider Managers. This would incorporate standardised six monthly comparative performance monitoring reports for each BSA Lead Provider, BSA Lead Provider feedback and assessment, specific quality assurance reader reports for radiologists and participation of priority groups based on data from the national register.
- v. Review the audit cycle to ensure that a full audit or accreditation site visit is conducted of each BSA Lead Provider every two years unless the performance of the BSA Lead Provider is exemplary in which case a recommendation may suggest a three or four year reassessment for accreditation.
- vi. BSA Service visits by relevant staff in the NSU would be undertaken on an as needs basis to review BSA Service performance and assist in addressing quality issues.
- vii. Review the current arrangements for the BSA Independent Monitoring Report and the BSA Independent Maori Monitoring Report with the view to combining the two reports and undertaking the work within the NSU with external reviewers or entering into a collaborative arrangement with a local university group with the relevant expertise.

- viii. Establishment of a collaborative partnership with a local university to promote joint research projects for post graduate students or research groups using the BSA data to develop local knowledge and skills in cancer screening programs in particular in the disciplines of behavioural science, epidemiology and biostatistics.
- ix. Assess the use of national level technical quality assurance processes for breast imaging equipment in terms of potential efficiency, consistency and cost savings in the digital environment.

BSA Sector Relationships with Lead Providers and Clinical Directors

11. It is recommended that the Clinical Directors and Lead Provider Managers meet jointly three times a year, with at least two face to face meetings, to work collaboratively with the NSU to deliver a safe, effective and equitable BSA Program and high quality breast cancer screening services including the following roles and responsibilities:
- i. To function as a clinical and management network for the BSA Services to provide business advice on policy, practice and operational management issues including issues of mutual interest or concern and input as appropriate to the annual workplan for the NSU.
 - ii. To establish time limited working groups for specific priority projects such as the Quality and Risk Management Group or for example in the areas of capacity and workforce planning for the BSA Program, the transition to digital technology and central PACS.
 - iii. To provide a conduit for communication of broader MOH developments and wider government activities affecting the BSA Program including the Lead Provider environments.
 - iv. To provide advice to the NSU on operational matters that impact on the safety, effectiveness, quality and equity of breast cancer screening services and refer specific issues to the relevant UDG or the BSA Advisory Group.
 - v. The NSU will identify a BSA Service support staff member of the BSA Program team who will have the role of liaison with Lead Providers and /or Clinical Directors to address enquiries on the NP&QS or operational policy and referral to the relevant staff in the BSA Team as needed. This would not include contract enquiries that would be directed to the Business Performance Manager.

Transition Plan

12. It is recommended that an independent advisory team assist in the development of a three year implementation plan in consultation with the NSU and the BSA Lead Providers to implement MOH endorsed recommendations. It is further suggested that:

- i. This advisory team be comprised of individuals independent of the NSU that have expertise in the following: population screening, organisational change, human resource management, clinical governance and leadership, strategic planning, clinical information systems and public health program development and implementation.
- ii. The advisory team would assist the NSU to transition and provide oversight of the implementation plan, in particular the consultation and communication with the BSA Lead Providers.
- iii. Mentoring support be provided to the NSU leadership, in particular the BSA Program Director through the transition process.
- iv. The advisory team provide regular reports to the MOH executive and Minister as required.

Introduction

A review of the BreastScreen Aotearoa (BSA) Program was commissioned to examine the following broad terms of reference: an overview of progress made for the BSA Program since 2009; BSA structure, resources and systems; the level of clinical support required at the senior management level in the National Screening Unit (NSU); the processes and procedures in place to ensure the clinical safety and quality of the BSA Program, including the project to implement a centralised Picture Archiving Communication System(PACS); BSA Quality Framework and performance monitoring processes and BSA sector relationships, particularly the relationships and processes in place for engagement between the NSU and the BSA Lead Provider Managers and Clinical Directors. The scope of the review was to focus primarily on the BSA and Quality and Equity teams and not include a detailed review of the other screening programs. Subsequent direction was given to take into account the broader working relationships across the NSU screening programs and to consider opportunities to build on existing resources, such as the National Cervical Screening Register, and to maximise the existing staff resources in the NSU. The original terms of reference are attached at Appendix 1.

BreastScreen Aotearoa, commenced in Wellington in 1998, and is the free national breast cancer screening program that provides biennial screening using mammography and any necessary follow up assessment tests up to the point of diagnosis of breast cancer for eligible women aged 45 to 69 years.

The program is delivered through a national network of eight BSA Lead Providers, each within a defined geographical area, including their sub-contractors and mobiles that deliver services to rural and some urban communities. These services work collaboratively with 13 Independent Service Providers (ISPs) to provide health promotion and support services to Maori and Pacific women. The program is supported nationally by the NSU that was established in July 2001 within the Ministry of Health (MOH) with the responsibility for the national operational function and strategic management of the BSA and the National Cervical Screening Program (NCSP).

The BreastScreen Aotearoa Program aims to screen 70% of the eligible population every two years and detect sufficient small breast cancers to achieve a reduction of 30% in breast cancer mortality. Participation in the program by Maori and Pacific women is a key priority of the Program.

The following quote relating to population screening provides a useful focus and context for the review.

“For the programme to be successful, every aspect of the programme from identification and invitation to recall for rescreening must be performed to the highest standard. The best way to ensure that a screening programme is beneficial and minimises the risks from screening is to ensure that the programme is properly organised and appropriately monitored”

(Richardson A.2001.The Gisbourne Inquiry–what can we learn? NZ Med.J; 114:236-8) a quote from the Executive Summary for Improving Quality: A Framework for Screening programmes in New Zealand published by the National Screening Unit October 2005.

Methodology

The review was undertaken using the following methodology;

- 50 interview sessions were undertaken with individuals or groups in Wellington, Auckland and Christchurch over the period 16th May to 27th May 2011. The list of groups of individuals included in the interviews is outlined in Appendix 2.
- The review of relevant documents provided both on the website and in hard copy as appropriate by the NSU. The list of documents provided for the review is at Appendix 3.
- Comparison and consideration of other population cancer screening programs, in particular BreastScreen Australia.
- Drawing on the expertise and knowledge of the reviewers in population cancer screening and leadership, human resource management and organisational change.

This review report contains sections that are grouped around key themes identified in the course of the review process and aims to systematically answer the key questions included in the Terms of Reference for the review and the consultancy proposal accepted by the Ministry of Health.

BSA Program Progress since 2009

The BSA Program is a mature breast cancer screening program that provides two yearly screening for women aged 45-69 years through a national network of Eight Lead Providers that have a geographically defined catchment of eligible women. The original target age group of women 50-64 years was extended in July 2004 to include women aged 45-49 years and 65-69 years.

The most recent Independent Monitoring Report (IMR May 2011 unpublished) presents cross sectional data for the period January–June 2010 and the two year period July 2008 to June 2010. For the purposes of providing a summary of progress of the BSA Program, information for the two year period will be used. BSA and Lead Provider performance is documented separately in the report for women screened aged 45-49 years as there are no established targets for the key performance indicators for this age group. Trend analysis is presented for both the 50-64 year old and 50-69 year age groups, the later age group will be used as this is able to be compared with key performance indicators for the BreastScreen Australia Program.

There are a number of internationally established performance indicators that are used to measure the quality and outcomes of breast cancer screening programs. The key performance indicators that demonstrate whether the Program is likely to achieve the aims of the Program in reducing morbidity and mortality from breast cancer are the participation rate which measures effectiveness and equity, invasive cancer and small cancer detection rate. Other performance indicators such as the rescreen rate, recall to assessment, preoperative diagnosis and open biopsy rates and the rate of conservation surgery also contribute to quality and outcomes. Performance indicators such as technical recall and timeliness indicators are measures of both service quality and efficiency. The following tables summarise the key performance indicators for the BSA Program with a comparison with the most recent nationally published data from the BreastScreen Australia Program (Report on Government Services 2011) ¹.

Participation Rates for women 50-69 years

BreastScreen Aotearoa ¹ (July 2008- June 2010)	68.7%	Range Lead Providers	55.4%-82.9%
Maori Women	57.2%	Range Lead Providers	47.1%-83.5%
Pacific Women	61.5%	Range Lead Providers	54.4%-83.6%
BreastScreen Australia ² (Jan 2008-Dec2009)	55.2%	Range States	53.0% -58.4%
Indigenous women	36.5%	Range States	27.4%-48.5%

Note: ¹Eligible population based on 2001 census population projections. ² Eligible populations based on 2006 population projections. Target 70% of eligible women screened.

Invasive Cancer Detection Rates for women 50-69 years

BreastScreen Aotearoa ¹ (July 2008- June 2010)			
Initial Round	7.3	Range Lead Providers	5.0-9.5
Subsequent Round	4.2	Range Lead Providers	3.7-4.9
BreastScreen Australia ² (Jan 2008-Dec2009)			
Initial round	74.1	Range States	65.5-93.2
Subsequent round	43.9	Range States	42.0-47.1

Note: ¹ Target initial round ≥ 6.1 per 1,000 women screened, subsequent round ≥ 3.45 per 1,000 women screened. ² These data are five year averages and age standardised. Rates are expressed per 10,000 women screened.

Invasive cancer < 15mm for women 50-69 years

BreastScreen Aotearoa ¹ (July 2008- June 2010)			
Initial Round	33.2	Range Lead Providers	5.9-59.5
Subsequent Round	23.6	Range Lead Providers	16.7-26.4
BreastScreen Australia ² (2009)			
All rounds	30.6	Range States	27.4 - 35.7
Note: ¹ Target initial round \geq 30.5 per 10,000 women screened, subsequent round \geq 17.3 per 10,000 women screened. ² Data includes small invasive cancer up to and including 15mm and age standardised. Rates are expressed as per 10,000 women screened. Target \geq 25 per 10,000 women screened			

Comparison of the current and previous IMR data trends in invasive and small cancer detection rates for both initial and subsequent rounds shows they are similar across the current and previous two year period with invasive cancer detection rates of 7.8 and 4.4 per 1,000 women screened respectively in the period January 2008 to December 2009. Small cancer detection rates for this same period for the initial and subsequent rounds were 32.4 and 25.1 per 10,000 women screened respectively. Although there were variations for these measures across Lead Providers all achieved or exceeded the targets.

In relation to other performance indicators, six of the Lead Providers met the target (>85%) for the percentage of women eligible for rescreen who were rescreened with 27 months with the BSA average rate of 86.1%. For the two Lead Providers that did not meet the target this was statistically significant. The recall to assessment rate is a measure that impacts on individual women and the capacity of the service. Overall the BSA average rate (<10% initial and <5% subsequent screen) for recall to assessment was met but three Lead Providers did not meet the target for women aged 50-69 years for their initial screen. The introduction of digital mammography is likely to increase this measure in the short term particularly for initial screens due to enhanced imaging capability.

The desired target of >90% for preoperative diagnosis of invasive cancer was met or more than met by BSA at 95.4% and by all Lead Providers, as was the benign open biopsy rate (less than or equal to 3.5 initial round and 1.6 subsequent round per 1,000 women screened) that measures the number of women referred for open biopsy that have a benign lesion. In relation to the provision of conservation surgery, for women with screen detected Ductal Carcinoma In Situ (DCIS) the proportion was 83.9% and 76.3% for women with a screen detected invasive cancer less than or equal to 20mm, both measures more than meeting the target of >50%.

The technical recall rate measures the percentage of women that are recalled to a fixed or mobile service to have their images repeated due to technical inadequacy. The BSA average rate met the target of less than 0.5% of women for the fixed services as did all but one Lead Provider where the difference was statistically significant. However in relation to the mobile services the BSA average did not meet the target for mobile services with six Lead Providers significantly exceeding the target of less than 3% with three Lead Providers having rates of between 4-5.5% of women returning for their images to be repeated.

In terms of timeliness BSA and all Lead Providers met or more than met the target of 90% of women being notified of their screening results within 10 days. A critical timeliness measure is the percentage of women offered an assessment appointment within 15 working days of their screen that is set at 90%. The BSA average rate did not meet this measure with three Lead Providers being significantly below the target (difference of greater than or equal to 5-10%). The target for the time from final diagnostic results is for 90% of women to receive these results within 5 working days. The BSA average is just below this target at 87.1% with two Lead Providers significantly below the target.

In relation to women who are referred from BSA for an open biopsy or primary treatment there are two key timeliness measures. The target for women who require an open biopsy is that 90% of women have this procedure within 20 working days. The BSA average is significantly below this measure at 64.6% with five Lead Providers being significantly below this target (difference of greater than or equal to 5-10%). The target for the time between women receiving their diagnostic results and their first surgical treatment is that 90% would receive this within 20 working days. This target is also not being met by BSA overall at 60.8% or by any of the Lead Providers with the range from 25.2%-68.2% and it is noted in the report that the achievement of these targets has declined for three of the Lead Providers. These timeliness measures may be to some extent outside the control of the BSA. However these are important measures in terms of the impact on the woman who in the case of an open biopsy referral does not have a final diagnosis and for the woman who has a diagnosis of breast cancer waiting to commence her treatment. Both groups of women are likely to experience high levels of anxiety while waiting.

Discussion

Overall the BreastScreen Aotearoa Program compares favourably with the targets set for the Program and with BreastScreen Australia on the key performance indicators for breast cancer screening programs.

In relation to the participation rates for women aged 50-69 years there has been an increase in participation from 66.3% in the period January 2008 to December 2009 to 68.7% in the period July 2008 to June 2010 noting that these periods overlap. Participation rates reported for Maori women have increased significantly from 53.3% to 57.2% over these same periods as have the participation rates for Pacific women, increasing from 57.2% to 61.5%. The rescreen rate for BSA and most Lead Providers is also of a good standard. This level of coverage is critical to achieving the aims of the Program and demonstrates the effectiveness of the range of recruitment strategies being used by the BSA Program, in particular for Maori and Pacific women and suggests that the BSA Program is progressing well towards achieving equity of participation among the priority groups of Maori and Pacific women.

The cancer detection rates and small cancer detection rates are exceeding the targets and compare well with the rates reported for the BreastScreen Australia Program. The preoperative diagnosis of invasive cancer and the open biopsy benign lesion rate are also exceeding the targets set for the Program. These outcomes provide evidence that the BSA Program overall is delivering quality breast cancer screening services for the women of New Zealand.

These performance outcomes support the view that the national BSA Program is on track to achieving the vision of “high quality, equitable and assessable national screening programmes” stated in the National Screening Unit (NSU) Strategic Plan 2010 to 2015.

However the current IMR also suggests that there are several challenges facing the BSA Program at present related to Program quality and efficiency that may affect BSA performance outcomes in the future. The performance measures of concern are the technical recall rate on the mobiles and the timeliness performance measures for recall to assessment, results provision following biopsy and the time to open biopsy and treatment.

A higher than expected technical recall rate is usually an indicator of poor quality imaging, which may be due to either the radiographer not meeting imaging standards or poor quality equipment either at image capture or processing. The remote processing of images for mobile services contributes to the higher technical recall rates as the radiographer does not have the ability to immediately check the image quality. However given that BSA screens about 13% of the women on the mobile services this technical recall rate affects a small but significant number of women and may have a greater impact for areas of need or areas with a high proportion of priority women who may be reluctant to return for their repeat images either because of inconvenience or anxiety. This experience may also impact on the woman's future participation. It is noted that of the 12 BSA mobiles only two are digital and it is widely acknowledged that it is becoming increasingly difficult to maintain the quality of analogue images due to the obsolescence of most mammography film processors. This exacerbates the situation of remote processing for mobile services.

The time from screening to assessment is critical because it is expected that women who are recalled for assessment will be very anxious about the possibility of being diagnosed with breast cancer. A critical element for a population screening program is the importance of maximising the benefits and minimising the harms. For this reason having women waiting for longer than 15 working days for an assessment appointment is not desirable. The delay between screening and assessment can be a result of a delay in reading or the processing of reading results. Although BSA is meeting the provision of results target of 10 days there may be delays in processing results for women recalled to assessment or insufficient assessment service capacity available. The latter can occur if there are constraints on the availability of specialists for the multi-disciplinary assessment sessions, in particular the radiologists. This suggests that as screening throughputs have increased there may be insufficient assessment capacity for the increased number of women recalled for assessment. For one Lead Provider with the highest recall to assessment rate, which could be the result of an inexperienced reader, they have the worst performance in terms of timeliness. A national BSA workforce capacity project could identify if there are current or possible future workforce shortages or a maldistribution of specialist staff for the Program, in particular radiologists.

The time delay of more than five days in giving women their results from biopsy is also undesirable for the same reasons outlined above in terms of anxiety for the woman, her family and friends. This may be a local issue in terms of access to specialist pathology services or a constraint in clinical service staff providing the results to the woman. Current access and pathology service capacity nationally should be included in a BSA workforce capacity project.

Although the timeliness issues regarding women referred for open biopsy and primary treatment are likely to be outside the control of the BSA Program the ongoing investigation of this issue could inform the development of improved referral pathways or the collaborative development of strategies within the National Cancer Programme Work Plan.

Summary

In summary the performance outcomes of the BSA Program demonstrate the Program's success to date in terms of effectiveness, equity and to a lesser degree efficiency. It is critically important to maintain and improve these performance outcomes into the future in order to achieve the longer term aim of significantly reducing the number of New Zealand women who die from breast cancer. However there are a few early indicators of the future challenges for the Program that could have the potential to impact on these performance outcomes. In particular the technical recall rate that is likely to be associated with the continuing use of analogue equipment on the mobiles and the time between screening and assessment that could be an early indicator of workforce constraints, especially radiologists.

Responding to these challenges will require strong BSA Program and clinical leadership and collaborative relationships between the NSU and the Lead Providers to work together to plan for the future in terms of physical and workforce capacity. These current and future challenges are identified in the NSU Strategic Plan 2010 to 2015. In addition it will be essential to develop a sustainable Quality Management system that is focused on a quality improvement approach to ensure the BSA Program continues to provide high quality, equitable and accessible breast cancer screening services for the women of New Zealand.

Structures, Resources and Systems

Background

“The National Screening Unit (NSU) was established in 2001 to deliver safe, effective and equitable screening programmes nationwide” (NSU Business Plan 2010-2011)². The work of the NSU is to focus on the achievement of the following five strategic objectives;

- Increase awareness and access
- Deliver equitable screening services
- Demonstrate sector leadership and enhance relationships
- Improve delivery standards and quality
- Build information and knowledge

The stated role of the NSU is “to oversee the continuous quality improvement and delivery of New Zealand’s organised screening programmes to deliver maximum benefit for eligible populations” (ibid). The stimulus for this review is essentially about whether, given the changes that have occurred in the Ministry of Health (MOH) and the NSU since 2008, the NSU has the capacity and the right resources to deliver on these objectives or its stated role.

The NSU was initially established as a standalone unit within the MOH informed by the organisational structure for population screening programs in the United Kingdom. These organisational structures were based on the understanding that population screening is a unique form of public health intervention where whole eligible populations of well individuals were invited to undergo a screening test to detect a small but significant percentage of individuals that have the disease, in this case breast cancer. For this reason there is a heightened level of duty of care to all participants in the population screening program to ensure that the benefits outweigh the harms. It is also critical that the benefits are achieved for both the individual, who has their cancer detected early, and at a population level. It is accepted internationally that the critical requirements for population screening programs are to have strong coordination, clear and consistent policies, evidence based standards, continuous quality improvement, quality assurance for all parts of the screening pathway, monitoring and access to appropriate treatment. These criteria are outlined in the World Health Organisation, Principles and Practices of Screening for Disease (1968) and more recently incorporated into both Improving Quality: A Framework for Screening Programmes in New Zealand (2005)³ and the Australian Population Based Screening Framework (2009)⁴.

The Gisborne Inquiry in 2001⁵ clearly led to a series of responses from the MOH that aimed to improve and ensure the quality and safety of the two cancer screening programs established at that time, being the BSA and the National Cervical Screening Program (NCSP). In the period 2001 to 2005, based on the numerous documents developed for these programs relating to quality, there was a clear focus in the MOH on the risks and benefits of these programs in preventing cancer in the case of the NCSP and detecting it early in the BSA program. The NSU at this time, based on these documents and feedback from individuals who had clinical leadership roles in the NSU in this period, had a strong focus on quality and the resources to undertake the national coordination and leadership for these programs.

Organisational and structural issues

Since 2006/2007 the NSU and the wider MOH have undergone significant and numerous structural changes. Since 2007 the NSU has been located in three different areas of the MOH; the Public Health Directorate; the Health and Disability National Services Directorate (HDNS) and most recently the National Services Purchasing Group (NSPG) within the National Health Board (NHB). In July of 2007 the NSU completed an internal Organisational Review process. The report of this review states that the review was needed to respond to significant changes in the role of the NSU and to external organisational requirements. Prior to this review the NSU organisational and staff establishment had been largely unchanged since 2003/04, despite an increase in workload. At this time there was an organisational expectation that the NSU continue to provide leadership in the delivery of high quality national cancer screening programs but to incorporate antenatal and newborn screening programs.

This review of 2007, referred to as Strengthening Foundations⁶, fundamentally changed the roles and responsibilities of the cancer screening programs in the NSU by structurally integrating the BSA and NCSP under a Cancer Screening Team and creating a Manager Cancer Screening role. This structural change meant that neither of the leadership positions of both Programs were part of the Senior Management Team. The restructure in the NSU was partly along functional lines with an attempt to create generic positions that would work across both cancer screening programs, although the Antenatal and Newborn Screening Programs were retained in an integrated program team. The BSA Program Manager had eight aligned positions and the NCSP Program Manager had three positions remaining in their teams. In this review Performance Manager positions were established as stated to ensure “better alignment with DHB decision making and improved performance management focus for the sector” (National Screening Unit Organisational Review 24th July 2007)⁷. A Quality Assurance team was also established and a Manager Quality Assurance position created to “have a team

dedicated to quality assurance activities for all programmes, including the evaluation of programme outcomes and inequities” and “increase the Unit’s focus on monitoring and quality improvement” (ibid). Standard setting and quality management was to remain with the Program teams. In this structure the Clinical Leader positions for the BSA and NCSP were removed from the Senior Management Team and grouped into a Clinical and Public Health Leadership Team and Strategic Leadership Team along with the Maori and Pacific Strategic Advisors and the position of Public Health Leader.

In July 2009 a further NSU Structural Review was undertaken under the direction of the then Deputy Director General, Health and Disability National Services Directorate. The decision rationale and design principles of the review were to “be consistent with the overall direction of the Ministry and group like functions together: centralising core speciality advice and services” (Structural Changes–Decision Document 21 July 2009)⁸.

The document states that at the time of the restructure the Ministry had not determined NSU’s “future role in the national coordination, leadership and provision of advice to government regarding screening strategy” (ibid).

As part of the consultation process of this organisational review specific feedback is documented about the need for the cancer screening programs to be individually visible at a senior management level in the NSU (with Program Managers represented on the Senior Management Team). Similarly feedback included the comments that Clinical Leaders had a role in strategy and services development not just quality. However the NSU structure that was endorsed aligned positions along functional lines with the BSA and NCSP programs grouped under the Manager Cancer Screening and the designation of three Senior Performance Management Analyst positions, one Senior Service Development Analyst and a Senior Advisor Cancer Screening. In this configuration there was a Programme Leader for BSA and NCSP with four and five aligned positions respectively for these Programs although it was intended that the positions work across the cancer screening programs. In this restructure the Antenatal and Newborn Screening program team structure was retained to develop policy, quality standards and guidelines with the view to quality, monitoring performance and reporting being later established in the expanded Quality and Equity Team.

The expanded Quality and Equity team had 10 positions including an executive assistant shared with the Information Services Team and two Senior Advisors for Maori and Pacific women respectively, with the stated key accountabilities across the screening programs covering; the provision of national leadership for screening among Maori and Pacific peoples, creating specific inequalities strategies and plans, establishment of quality standards and guidelines, leading the audit programme, designing and producing data for quality monitoring, developing and managing programme evaluation. The key accountabilities of the cancer screening team Programme Leaders included; providing expert programme advice and advice on evidence and emerging issues and interventions; describing health outcomes including

desired coverage for the programme; and identifying required services at the programme level. In addition these positions had line management responsibility to manage their teams of two Senior Performance Management Analysts for BSA and four for NCSP to manage contracts and monitor provider performance and two Service Development Analysts to develop service strategies, operational policy and participate in sector engagement activity. The document states that “overall accountability for the two organised national cancer screening programs sits with the Manager Cancer Screening”.

In this structure the Clinical Leaders for BSA and NCSP reported to the Manager Cancer Screening and their stated role was to provide expert best practice clinical advice. There was also a Senior Advisor Cancer Screening position established to support the Manager Cancer Screening in the development of high level policy, development of health reports and participate in or manage cancer screening projects.

Staff Resource Issues

In addition to the restructures from 2007/08 to the present there have also been concurrent reductions to funding of Full Time Equivalent (FTEs) positions in the NSU. In 2007/08 the NSU budget and FTEs was set at 56.4. In 2008/09 after the Strengthening Foundation review 31 FTE positions were included for the NCSP Register to equal 87.4 FTE. During that financial year the budget was subjected to a non-recurring reduction by Corporate Finance team to 76.66 FTE to reflect vacant positions. In 2009/10 the budget was set at 88.90 FTE which was reduced to 86.0 FTE following the 2009 NSU restructure. In 2010/11 the NCSP Register team (31 FTE) was outsourced to Datam leaving 55 FTE in the NSU which was further reduced to a budgeted FTE of 49.0 because of the exclusion of long term vacant positions including the BSA Clinical Leader position. However the NSU successfully requested an increase against the proposed budget and the FTE was increased to 50.4 FTE including .8 FTE for the BSA Clinical Leader position. In the lead up to 2011/12 a further four positions that were vacant have been removed from the NSU although two of these vacancies were filled by long term IT contractors working on the key project to move to one version of the clinical information system for BSA that is not yet complete. Therefore the currently proposed FTE for the NSU in 2011/12 is 46.8 representing a reduction of almost 10 FTE from 2007/08.

During this period, from 2007 to the present, of continuous change there appears to have been a significant loss of key knowledge and skills related to the cancer screening programs. It was the most recent loss of nine staff, most of whom had specialist knowledge and long term experience in the cancer screening programs, that prompted the letter to the Minister from the BSA Clinical Directors Group expressing their concern

about this loss of key staff, particularly the BSA Clinical Leader position and the clinical risk to the BSA Program. This in turn prompted this review.

Information synthesised from interviews with individuals and groups including the BSA Advisory Group, the BSA Clinical Directors and Lead Provider Managers Groups and members of staff in the NSU suggested several key themes relating to the changes to the NSU: its position in the MOH, the structure in the NSU, the loss of personnel and positions. Although for the BSA Clinical Directors and Lead Provider Managers it is not clear whether they knew the detail of the structural changes in the NSU they very clearly stated that they believed that there had been a significant shift in the focus of the NSU and their relationship with the NSU had deteriorated particularly over the last two years. Most BSA Clinical Directors and Lead Provider Managers have been involved in the BSA Program for a long period of time, some from the commencement of the Program who would have been in a unique position to observe changes over time. Their reflections were based on their prior understanding of the role and responsibility of the NSU to provide national coordination and operational functions, strategic management and leadership of the two cancer screening programs as outlined in *Improving Quality: A Framework for Screening Programmes in New Zealand (2005)*.

The lack of leadership and strategic direction for the BSA Program was a key theme identified almost universally by individuals and groups. In addition there were concerns consistently raised that there was a limited understanding in the NSU of the BSA Program, in particular the clinical aspects of service delivery. While it was suggested that one or two of the longer term staff in the BSA understood the Program it was stated by several of the groups and individuals interviewed that it was evident that these individuals had limited positional power. It was often stated in interviews that the current NSU senior management did not seem to understand breast cancer screening or the principles of population screening and the high risk nature of the Program which underlined the need for close monitoring of the quality of every aspect of the screening pathway. It was further stated that there was limited support for the Manager Cancer Screening position both from individuals and groups external or internal to the NSU. It seemed that there were two aspects to this response, one that there was no understanding of the role and responsibility of the position and the second was that it was clearly seen as a downgrading of the national leadership of the BSA Program, as an important cancer screening program, not to have a BSA Program Manager at a senior management level in the NSU.

Some comments suggested that this situation meant that there was insufficient advocacy for the BSA Program within the MOH and a loss of community profile, both of which were impacting on the level of support the Program was able to receive for such major issues as the capital investment required to transition to digital technology. This was cited as a clear example of leadership failure for the NSU. Although New Zealand was an early adopter of digital technology, with one Lead Provider implementing digital

technology as early as 2005/06 and a national policy agreed in 2007, the advocacy from the previous BSA Clinical Leader to invest in a national and comprehensive transition to digital technology did not lead to a successful business case being presented to the MOH. Digital technology is internationally the most important and critical change to breast cancer screening programs since the inception of this population screening program for breast cancer in the early 1990s. It is understood that a business case for a central Picture Archiving and Communications System (PACS) developed by the NSU was not supported by the MOH in 2009 but secured Ministerial support and funding in 2010.

There was also a theme identified repeatedly that the NSU had shifted its focus to compliance and contract management away from coordination and collaboration with the Lead Providers to deliver a quality Program. This criticism was highlighted with the strong objections expressed by the Clinical Directors and Lead Provider Managers toward the Performance Management Analysts (PMAs). In particular there was a common view that the PMAs had limited knowledge of the BSA Program and were focused on compliance with low level processes, for example whether a client satisfaction questionnaire had been completed and not those issues of quality that are critical in a breast cancer screening program such as timeliness of recall to assessment or the clinical outcomes. In contrast the Clinical Directors and Lead Provider Managers reflected on a time when visits from the NSU were part of a continuing quality improvement process where they worked together with the Clinical Leader and relevant staff from the NSU to address issues that may have been identified in the IMR or audit process. They also expressed the view that they were previously able to seek advice from staff in the NSU who had the knowledge and skills to respond on such issues as the interpretation of a policy or standard from the National Policy and Quality Standards document or an audit report comment.

In addition there were specific issues raised by the Clinical Directors and Lead Provider Managers, the BSA Advisory Group and several individuals about the whole quality management approach. There was concern expressed about the fact that the scheduled three yearly audits of BSA Lead Providers were delayed in 2008/09 due to lack of funding. The Audit review process was also questioned, in terms of the membership of the audit team, the currency of the information and how the IMR performance report was used in the audit process, the lack of transparency in the decisions regarding the audit, and the delay in receiving the final audit outcome and recommendations report. In addition there were comments received that questioned the allocation of risk ranking to the standards where the BSA Lead Provider was found to be partially compliant or non compliant and a Corrective Action Request (CARs) was generated. The ranking could be from negligible to critical, the latter requiring immediate corrective action to ensure consumer safety. The general expressed concern was that some of the CARs categorised as critical were not about clinical risk to safety and quality requiring immediate action. This concern was exacerbated with the loss of the

Clinical Leader from the NSU and the work was being undertaken by PMAs to visit BSA Lead Providers to discuss the critical CARs. The view expressed was that these visits were unhelpful as the individuals were not able to provide any advice or support to address the CARs as their knowledge of service delivery and breast cancer screening was poor and that the focus of the visits seemed to be more about use of funding and compliance with contracts.

Some of the concerns outlined above and related issues of concern were also identified by a significant number of staff in the NSU who expressed the view that they thought the NSU focus was on contracts and that there was not enough understanding of the BSA Program and the quality assurance and monitoring needs of high risk performance indicators. It was stated that the emphasis in terms of monitoring the BSA Program was on coverage in general and for priority groups. Whilst these measures are important in terms of the success of the program in achieving its aims these measures do not address the broader quality of the breast cancer screening services being provided. NSU staff also stated that the professional advice from staff who did understand the critical quality issues for population screening was not taken into account or was actively blocked.

An example of BSA quality management issue in the NSU is that it is only recently that an interval cancer study was commissioned, five years after the last study for BSA undertaken in 2006. The monitoring of interval cancers is a key performance outcome for breast cancer screening programs as it measures the sensitivity of the program to detect invasive cancer in women attending for screening. This measure relies on routine matching with Cancer Registry data and is usually monitored on an annual basis internationally, as in the BreastScreen Australia Program. Although this measure cannot be assessed in isolation from other key performance measures it provides valuable feedback to the BSA Clinical Directors and the radiologist readers. It was apparent that some interval cancer monitoring may be occurring locally by Lead Providers through linkage with other services. However this does not accurately measure the interval cancer rate at a population level that can be compared with international standards in terms of program sensitivity nor does it allow for independent routine review of this measure for each BSA Lead Provider.

It was suggested by some people interviewed that as a result of the issues identified above the recently announced Bowel Cancer Screening Pilot Project has been located in the Cancer Control team with the NSU providing some advice in the area of service delivery costings, contracting for the pilot sites, linkage with Australian screening programs and information management. The opportunity to draw on specialist skills in the NSU has clearly been difficult because of the internal structural issues identified and the loss of knowledge and clinical leadership in the NSU. This may be a lost opportunity for resource sharing in particular in setting up systems, infrastructure and frameworks for quality assurance and monitoring.

Delivering on the BSA Strategic Plan

The BSA Strategic Plan 2008-2013⁹ (the Plan) set out a vision for the BSA Program to achieve “improvements in equity, effectiveness and efficiency for BSA”. This Plan acknowledges that significant investment would be required to realise the goals of the Plan by 2013. A key strategy in the Plan that required capital investment related to new technologies, in particular, comprehensive digital conversion and integrated PACS “to convert the BSA radiologists workforce into a single national pool using telemammography, reduce variation in quality between large central and small rural centres, ensure service sustainability and quality despite impending obsolescence of film screen mammography”. Another key strategy that would require capital investment relates to the national development of the clinical information system to improve the provision of performance data for Medical Radiation Technologists (MRTs), radiologists and other specialists involved in the multi disciplinary team at assessment. The Plan also identified the need to improve equitable participation among Maori and Pacific women.

There was interest raised by the various groups and individuals interviewed about whether the Plan is likely to be implemented by the MOH through the NSU. Although several strategies in the Plan have been acted on, in particular in relation to strategies to improve the coverage for Maori and Pacific women and work has begun on the clinical information system and PACs projects, the feedback from the BSA Clinical Directors and Lead Provider Managers was that they had not been appropriately involved or sufficiently engaged in these critical strategies for the BSA Program.

The general consensus from individuals and groups interviewed was that a recent Workforce Development Forum held by the NSU was a missed opportunity. This Forum failed to effectively involve and engage the BSA Lead Providers, in particular the health promotion staff and the ISPs, in the planned regional planning and development process to improve BSA participation for priority group women. There was a strong perception expressed by the Lead Providers that this Forum was a chance for the staff across the BSA Program to network and share ideas about what worked and what didn't work. It was also suggested that it could have been an occasion to celebrate the success of the Program in already achieving an increase in the participation rates for priority women. Instead the perception was that the Forum was all about the business specifications and the contracts. The concern was expressed that the NSU did not seem to recognise the work and successful collaborations that were already occurring at the local level. The view expressed was that the NSU instead focused on presenting an “interventional logic methodology” that was highly theoretical and of minimal relevance to the community development strategies needed to influence priority groups

of women. The other major concern expressed was that the Forum was not well organised, there was no clarity about the agenda, objectives or the purpose of the Forum and Lead Providers were not invited to present at the Forum. There also seemed to be confusion arising from this being a joint activity with the NCSP.

Similarly the feedback on the major strategies in the Plan relating to the PACS and clinical information systems (CIS) was not supportive of a true collaborative approach. While there was overall strong support for these initiatives from the Lead Providers, there were generalised concerns about the level of involvement of the Clinical Directors in particular and the Lead Providers in the development and implementation planning for these projects. There was some appreciation of the representation on the BSA Upgrade Project Team, made up of NSU staff, Lead Provider Managers and Data Managers but there was some concern that the Clinical Directors were not represented on the project team. Although there had been some consultation with Lead Providers and Clinical Directors about the central PACS project the communication about the project seemed to be poor.

Among the individuals and groups interviewed there was limited visibility of the project governance of these major BSA initiatives, the benefits to be realised or the solutions to be delivered. There had been some stakeholder consultation on the Business Requirements Specifications (BRS), but having a large dense document sent out for final consultation in November with a deadline for response before December 30th was not well regarded. Various individuals also questioned the advantages of continuing with the current CIS vendor given the recent issues relating to significant errors in data migration and upgrading of the various versions of the application being used by the Lead Providers. It was suggested that the Data Managers had raised issues about the data migration plan, exclusion codes and the inherent issues in the reporting structure of the application. These issues had contributed to the major failure of BSA to recall 10,000 women for their routine rescreen that occurred in 2009. It was also apparent that the vendor was moving the product to a different platform and was imposing the version of the application designed for the NSW BreastScreen Program to reduce their maintenance support in the region. In general the key informants and stakeholders for the CIS and PACS could not be regarded as well engaged in these strategic projects.

Another key strategy identified in the Plan was a mortality and cost effectiveness study that was planned to commence in 2009. Although somewhat delayed this study has now been commissioned to a highly regarded research collaborative group and is currently being scoped and the proposed methodology peer reviewed.

BSA Systems

A key priority for the BSA Program is the transition to digital technology, specifically the “implementation of an interconnected digital mammography service” as identified in the Strategic Plan as outlined above. In order to achieve this priority a comprehensive project of work is required that includes the implementation of digital image capture, and the establishment of a central PACS that is integrated with a national register incorporating a networked clinical information system that captures information at the point of care. Elements of this change including upgrading the current CIS to one version, as is planned in the current BSA CIS Upgrade Project, the purchase of digital mammography equipment and the planned establishment of a central PACS will deliver the basis for this priority to be achieved in the longer term. However the full delivery of this strategic priority will require strong support from the MOH’s Information Directorate and a more comprehensive project to deliver the ability to capture, store, distribute, view and interpret images and associated information electronically within the BSA Services and potentially across the continuum of care.

It would seem from the difficulty experienced by the NSU to gain support for these critical infrastructure changes for the BSA Program, despite significant effort by the NSU over the period 2005 to 2010, that the New Zealand health system’s operating principles may impede rather than support such important national strategic directions and their implementation. An investment in a comprehensive approach would deliver major benefits to the BSA Program in terms of increased productivity and capacity, optimise service delivery cost efficiency and address current and potential future workforce issues, particularly for Medical Radiation Technologists (MRT) and radiologists. In addition digital technology in conjunction with a national register and networked CIS could enhance quality and streamline quality assurance and performance monitoring for the BSA Program.

These changes would have a positive impact at the service level for Lead Providers and for the NSU in terms of staff resources and cost by systemising information capture, processing and reporting at a national level. This functionality would allow all BSA Services to input data at point of care, at a fixed or mobile site, and have nationally standardised system reports at a service catchment and national level. The integration of the CIS with a national PACS would lead to consistent storage of images and the ability to distribute these images anywhere at any time across the BSA Program for viewing, interpretation and recording of the results. This capability would address timeliness issues for reading and recall to assessment, particularly for smaller regional and rural BSA services. The project would be expected to deliver benefits to eligible women, key clinicians, the BSA Program, the MOH and importantly the community in

general through the efficient use of resources and enhancement of quality and timeliness of service delivery. Efficiency gains would be in staff resources, due to the reduction in transactional tasks such as data extraction, cleaning and manual data matching and reporting. This would be achieved by establishing a national information system that ensured data integrity through inbuilt data validation, systemised matching software and standardised report production. There would also be efficiencies in the cost of consumables as a move to electronic records and digital mammography will reduce the use of paper, charts and X-ray film to extremely low levels and reduce the cost and need for storage of charts and films.

Role and Responsibilities of NSU

When asked, the groups and individuals interviewed identified what they wanted from a NSU BSA Program team. In broad terms they wanted the NSU to refocus on national coordination, and strategic leadership for the BSA including but not limited to the following:

- A strong identity for the Program in NSU, the MOH and the community
- Support and advocacy for the strategic vision for the Program
- Strategic and capacity planning and support for capital infrastructure
- Strong quality assurance to ensure quality and safety and reduce risk
- A quality improvement approach for performance monitoring and the audit process
- Clear lines of communication and accountability and good clinical governance
- Engagement and collaboration in strategic projects including PACS and CIS
- Increased focus on clinical engagement in quality assurance and operational policy
- A supportive environment to facilitate peer support and information sharing

Summary

It is clear from the information gathered that the NSU with its current alignment and structure and staff capability is somewhat constrained in undertaking the role and functions, for which it was established, as a national coordination unit for the cancer screening programs. This national coordination role is critical to the ongoing success of the BSA in providing high quality, equitable and accessible breast cancer screening for the women of New Zealand. The BSA Program needs to be recognised as a key part of the cancer control continuum and be better aligned with the National Cancer Programme to enhance the opportunity to address the quality and structural challenges facing the Program, such as the transition to digital technology and workforce issues. It is also clear that the current organisational structure for the NSU does not support the BSA in terms of national leadership, coordination, strategic planning and quality monitoring and that it is critically important that changes are implemented as a priority to the organisational structure. It is equally clear that the professional capability of the staff resources for the BSA team have been heavily depleted through restructures and loss of positions. The findings of this review strongly suggest that there has been a significant impact on the NSU and in particular the BSA Program of the numerous external and internal restructures.

To regain a national approach to this important cancer screening program a reinvigorated NSU and BSA team, along with the NCSP and the BCSP, need to be: appropriately aligned in the MOH consistent with the government's strategic directions and priorities in cancer control, have an organisational structure that will support national leadership and strategic planning, a strong focus on quality assurance and performance monitoring, the systems in place to make the most effective and efficient use of resources and enhance quality and achieve the outcomes of the cancer screening programs at a value for money cost.

Discussion

At present the NSU and the cancer screening programs are not visible at a strategic or leadership level in the MOH with the NSU being somewhat isolated from the current work being done to develop the National Cancer Programme Work Plan. This isolation and limited collaboration does not recognise the important contribution cancer screening makes to the cancer control continuum. It is critically important that the BSA be part of the Government's priorities in cancer control because BSA is a successful Program that is currently achieving its aims of delivering quality, equitable and accessible breast cancer screening in particular in reaching priority groups of women, being Maori and Pacific women. However as outlined above there are currently a number of challenges

and risks facing the NSU and BSA Program that the government and the MOH need to give urgent priority to addressing to ensure the sustainability and quality of the BSA Program into the future. There is an opportunity to acknowledge the achievements of the BSA Program to date and to identify strategies that will address these challenges and risks in the National Cancer Programme Work Plan currently being developed.

It is internationally accepted that cancer has a high impact on populations and the health system and is a key challenge for governments, health agencies and the community. For New Zealand, as in most other developed countries, cancer is the leading cause of death and a major cause of hospitalisation. As long ago as 2002 the Director of the International Agency for Research on Cancer (IARC) World Health Organisation (WHO) stated in the World Cancer Report 2003¹⁰ that with the knowledge we have now it is possible to prevent a third of all cancer, to detect and treat early a further third, and provide quality palliative care to the remaining third. The WHO promoted the development of national cancer control programs that can reduce cancer incidence and mortality and improve the quality of life of cancer patients through the systematic and equitable implementation of evidence based strategies for prevention, early detection, diagnosis, treatment and palliation making the best use of available resources. For these outcomes to be achieved health agencies and organisations are developing systematic and coordinated approaches to work collaboratively across the continuum of cancer control to achieve the best outcomes for individuals and at a population level. Cancer screening programs contribute to the cancer control continuum by preventing bowel and cervical cancer through the detection of pre-invasive disease and the early detection of breast cancer that when treated appropriately prevents deaths from breast cancer. All three cancer screening programs therefore contribute to reducing deaths from cancer and significantly reduce hospitalisation either through prevention or detecting cancer early leading to less intensive and costly management and treatment.

Bringing together the cancer screening programs and providing a stronger linkage with the cancer control continuum would mean that it may be more appropriate for the Antenatal and Newborn screening programs to be realigned with other maternal and child health services within the MOH. The nature of these programs, although they are also population screening programs is different from cancer screening. The Antenatal and Newborn screening programs requires passive compliance, with the active assistance and intervention of their primary and midwifery care providers to undertake these screening tests for mothers and their babies. In contrast the cancer screening programs require active recruitment and encouragement of eligible populations of well individuals to undergo a screening test to prevent or detect disease. Although clearly the issues of quality assurance and performance monitoring are the same in principle, the information systems and processes required are different and there are different

clinical disciplines involved. In addition the community stakeholder groups and organisations are also different. For the cancer screening programs the clinical disciplines have some overlap, for example in pathology and surgery, the systems require the same reference tables for their eligible populations and the community stakeholders and organisations are shared as they relate to cancer.

Recommendation

1. It is recommended that the National Screening Unit (NSU) and the BreastScreen Aotearoa (BSA) strengthen its collaborative links and alignment with the Cancer Control team given that cancer screening programs are a key part of the cancer control continuum including the following considerations:
 - i. That the strategic directions and priorities of the cancer screening programs, particularly BSA be better identified in the National Cancer Program Work Plan, as part of the Government's priorities for cancer and the New Zealand Cancer Control Strategy, and that relevant cancer screening Program and Clinical Leaders have membership on the Cancer Control Steering Group.
 - ii. That the cancer screening programs strengthen their collaborative alignment and the linkage with the regional cancer networks and the development of clinical pathways for breast, bowel and cervical cancers.
 - iii. That the NSU be renamed National Coordination Unit (NCU) for Cancer Screening to assist in communicating the change in focus to Lead Providers, stakeholders and the community.
 - iv. That consideration be given to moving the Antenatal and Newborn screening programs out of the NSU to be aligned with the relevant Maternal and Child Health area in the Ministry of Health to increase the focus and alignment of the cancer screening programs in the NSU.

Discussion

The history of the NSU and the BSA Program at a national level since 2007/08 to the present has been one of almost constant change related to external and internal restructures due to MOH policy changes and directions, and more recently changes in the line management of the NSU from the Health and Disabilities National Services Directorate to the National Services Purchasing Group in the National Health Board. During this same period the NSU has experienced significant loss of positions, totalling 10 FTEs and a concurrent loss of key staff with public health and population screening capability. Therefore without change the NSU will have insufficient capacity nor the right staff resources to deliver on the stated objectives or undertake the roles and responsibilities outlined in the NSU Business Plan 2010/11².

There has been a particularly negative impact on the BSA Program, not only because of the loss of the Clinical Leader position, currently only appointed temporarily, but this important national Program in the period from 2007 to the present has had a significant loss of public health professional staff with knowledge, skills and experience in population screening. This has effectively left the small team of five dedicated staff with insufficient capacity and capability to provide the national coordination and strategic leadership needed for this Program and expected from the Lead Providers. The BSA team has been reduced to a Programme Leader, part time Clinical Leader and four dedicated positions. This has not only been as a result of a loss of FTE positions but the impact of the two internal restructures the first in 2007 that merged the two cancer screening programs. There was an additional impact from the downgrading of the Program leadership position, creating a Manager Cancer Screening to line manage the Program Manager positions for both BSA and NCSP and shifting quality assurance responsibility into a different team. The quality assurance and performance monitoring for the BSA Program was further fragmented in the 2009 structural review that focused on functional alignment. This left the BSA Program team as primarily content advisors and contract managers although they retained a relationship with the BSA Services through the provision of secretariat support to the uni disciplinary groups and Advisory Group. The national leadership for some elements of the BSA Program were placed in the enhanced Quality and Equity Team. This structural divide is not consistent with the principles that underpin breast cancer screening as an organised population screening program. Clearly established quality management systems are essential and part of the core function for breast cancer screening programs to balance the achievable benefits of screening with the potential harm. Internationally organised breast cancer screening is usually delivered through a structured national Program with a central unit that undertakes planning, coordination, quality assurance, performance monitoring and evaluation of all activities along the screening pathway. These principles are reflected in *Improving Quality: A Framework for Screening Programmes in New Zealand (2005)*³ and are similar to the principles outlined in the *Australian Population Based Screening Framework (2008)*⁴ for program management of population screening. These functions are usually undertaken by a multidisciplinary team of staff with skills in public health, epidemiology, community engagement and communication, often with a clinical background and with access to clinical advice in radiology and radiography.

The current NSU organisational divide of the national functions of the BSA Program has fundamentally changed the focus of the work for BSA nationally and its relationship with the Lead Providers. The interviews with individuals and groups identified a range of issues including, but not limited to, the following;

- fragmentation and limited communication and consultation,
- loss of the relevant expertise in the NSU to monitor the quality of the breast cancer screening services,
- lack of clinical leadership for the Program,
- significant delay in the implementation of digital technology posing quality and safety risks to the Program,
- system failures due to multiple versions of the clinical information system,
- lack of strategic leadership, planning and advocacy for the BSA Program, and
- limited to no engagement of key stakeholders in major projects, in particular the PACS and CIS upgrade.

It was identified in the interviews with individuals and groups that at least three of the Quality and Equity (Q&E) Team (NSU organisational chart 16/05/2011) work primarily on BSA functions and tasks, in addition two vacancies exist in the Q&E team one for a epidemiologist/biostatistician and one for Senior Analyst Monitoring and Evaluation. It is suggested that these five positions could be transitioned back to the BSA Program team be added to the existing five positions. This team of ten staff would be lead by a BSA Program Director (Manager) reporting directly to the Group Manager. The current Manager Cancer Screening position would be removed. This change would also require the establishment of a similar level position of Program Director (Manager) for the NCSP, returning both positions to their original status in the NSU.

In addition the .4 FTE radiologist Clinical Leader position would work with the BSA Program Director to provide the program and clinical leadership for the BSA Program. This staffing compliment and structure is consistent with the organisational arrangements for the BreastScreen Queensland (BSQ) Program, Cancer Screening Services Branch that provides state coordination functions for Queensland for breast, bowel and cervical cancer screening programs. The BSQ team of ten staff and a Program Director undertakes the range of functions to coordinate and provide State level leadership to the BSQ including capacity and strategic planning, service development and support for the network of eleven geographically defined BSQ Screening and Assessment Services, community engagement, health promotion and communication, development and review of policy and standards, organising and supporting the uni-disciplinary Quality Groups, quality assurance and monitoring including the coordination of the BreastScreen Australia Accreditation process and national and state level reporting.

This comparison of staffing levels is considered valid as the number of women screened is similar, as the number of women screened in Queensland in 2010 was 221,698 and in New Zealand 211,921. Also the network of Screening and Assessment Services for the BSQ and the BSA is similar in number with eleven and eight respectively, as is the mix of regional, rural and remote services. Although these service networks are clearly geographically different in size, they experience similar issues and challenges in maintaining a high quality service network, workforce issues and communication with multiple clinical disciplines across the Program.

State Coordination organisational structures in the BreastScreen Australian Program differ with the smaller states and territories essentially having one service provider and the coordination functions incorporated into a joint structure. This includes South Australia, Tasmania, Western Australia, the Australian Capital Territory and Northern Territory. The NSW BreastScreen Program state coordination unit functions sit within the NSW Cancer Institute along with other state level functions for cancer programs, services and strategies. In Victoria the Program is outsourced to BreastScreen Victoria a non government entity, including the State Coordination Unit, that is managed by a community board. They contract the breast cancer screening and assessment services to mostly private but some public providers. The Victorian Departmental Unit, Screening and Cancer Prevention that manages this arrangement is aligned with the Cancer Control team but has policy responsibility for antenatal and newborn screening. The current organisational structure for BreastScreen Queensland is closest to the NSU in terms of the population size for Queensland and New Zealand, the geographical catchments that in some areas cover more than one Health Service District because of the density of the population in regional and rural areas and Cancer Screening Services Branch incorporates the three cancer screening programs that work together and share expertise and resources.

The suggested changes to realign positions within NSU could be achieved within the NSU FTE of 53.8 positions as at May 2011, with two of the remaining four positions (Senior Analyst Monitoring and Evaluation and Principal Scientific Advisor) from the Q&E team being transitioned to a NCSP dedicated team to support the quality and monitoring needs of this Program and two positions transitioned to the Information Services team as their tasks are primarily data management. These changes are not expected to impact on the programs in Antenatal and Newborn Screening, that has 10 FTE based in Auckland, as it was stated in the 2009 review document that as the programs were still under development the functions of developing and implementing quality standards and guidelines, monitoring and evaluation were to remain included in the program team with the possibility of these functions being transitioned as the programs became more established.

Recommendation

2. It is recommended that the National Screening Unit (NSU) realign quality and equity functions into the program teams to ensure the most efficient use of resources and to promote national program leadership and strategic direction for BreastScreen Aotearoa (BSA) including the following;
 - i. Establish a position of BSA Program Director (Manager) that would report directly to the Group Manager (NSU) and remove the current Manager Cancer Screening position. The key role and responsibility of this position would be to provide national leadership and strategic direction for the BSA Program and to lead a program team that undertakes national coordination functions and strategic management for BSA.
 - ii. Rebuild the BSA program team by integrating relevant positions from the Quality and Equity team with the current BSA program positions to undertake the key functions of national coordination, strategic and capacity planning, BSA service development and support, community engagement and communication, policy and standards, quality assurance and monitoring including coordination of BSA Service Audits and reporting.
 - iii. Ensure the retention of existing staff in the NSU that have significant BSA program knowledge and experience and recruit, to current vacant positions, personnel with the appropriate skills in public health, epidemiology or biostatistics, quality assurance, community engagement and communication.
 - iv. Maintain cross program knowledge, skills and resource sharing, particularly in the disciplines of epidemiology/biostatistics and community engagement and communication, through a matrix structural alignment and formalised processes.
 - v. Ensure that communication and collaboration with the Maori and Pacific Advisory Groups is coordinated as appropriate across the BSA and National Cervical Screening Programs to maintain and continue joint strategies through the Independent Service Providers (ISPs) and Lead Providers to improve participation for these priority groups.

Discussion

The inclusion of the Bowel Cancer Screening Pilot Project (BCSPP) in the NSU would provide an opportunity to strengthen the focus on cancer screening as part of the cancer control continuum. At the formative stages of this important cancer screening program it would be useful to make the most effective and efficient use of scarce staff resources that have knowledge, skills and experience in cancer screening and public health. Sharing these resources and building on the existing systems and structures for quality assurance and monitoring for the BSA and NCSP could have a mutual benefit in helping to reinvigorate the NSU and share knowledge with the BCSPP. The bringing of all the cancer screening programs together would also allow for a single point of contact and accountability within the MOH for cancer screening advice and given the many shared stakeholders it could simplify communication and consultation in particular with Lead Providers. Although there are different clinical disciplines involved in each of the cancer screening programs the priority groups and community and organisational stakeholders overlap so having all three programs in the NSU could help rationalise the communication, linkages and community engagement strategies.

In addition the establishment of the NCSP Register platform, the work underway for the BSA upgrade and the work of developing the system functionality for the BCSPP creates a synergistic opportunity to develop registers and systems to streamline and better coordinate functions such as quality assurance, performance monitoring and reporting for all three cancer screening programs. In addition it may be opportune to investigate centralising administrative and systems functions that are common to the cancer screening programs, this could include the use of mailhouse services, on line booking, linkages with the national population identifier data and the Cancer Registry, use of common population and reference tables, reporting and information sharing with primary care and treatment services. There is a timely and unique opportunity to develop the cancer screening national registers, in conjunction with the PACS for breast cancer screening, as a key part of the information flow across the continuum of care for cancer control. New Zealand is uniquely placed to undertake this work because of the advanced use of the National Health Identifiers and the potential for a national population register.

Recommendation

3. It is recommended that consideration be given to incorporating the national Bowel Cancer Screening Pilot Project into the NSU to maximise the efficient

use of resources in population screening knowledge and skills across the cancer screening programs in particular the following;

- i. The establishment of the national register for bowel cancer screening on the same system platform as the National Cervical Screening Program and BSA to share functionality, system management costs and linkage with population and reference tables.
- ii. The quality assurance and monitoring processes could be aligned with the quality management system and structure recommended for the BSA Program and the NSU quality management framework.
- iii. Specialist staff resources, in particular biostatisticians/epidemiologists that are critical for monitoring cancer screening programs could potentially work across the programs and provide professional support for other key staff involved in monitoring quality and performance.
- iv. Relationships with Lead Providers can be coordinated across the three cancer screening programs in negotiating agreements and monitoring outcomes.
- v. The existing Advisory Groups for Maori and Pacific communities could be broadened to encompass bowel cancer screening or used as a model for engagement with these priority groups.
- vi. That the recommended systems development for the cancer screening programs be aligned across the cancer continuum to ensure data consistency including electronic use of structured reporting and electronic linkage with national cancer and regional systems.

Discussion

The transition to digital technology is inevitable for the BSA Program and was identified as a priority in the BSA Strategic Plan 2008-2013. The current fleet of analogue equipment is increasingly unsupported and obsolete, particularly film processing. Early indications of the impact of the delay in implementing digital technology for BSA are the unmet performance measures in technical recall, particularly on the mobile services, and timeliness issues for recall to assessment for some of the BSA Lead Providers. The delay in implementation could be attributed to several factors including: the lack of leadership and support for a business case for a comprehensive project for BSA to transition to digital technology, the loss of the Clinical Leader who supported and advocated for the project, the limited understanding of the risks and the benefits of digital technology in the NSU and the relatively high cost of the capital investment that is expected to be borne by the Lead Providers in a very competitive environment for capital funding.

Of the eight BSA Lead Providers one is fully digital, three are mixed analogue and digital and four are solely analogue. Of the total of 59 mammography units used in the BSA Program 16, less than a third (27%) are digital. Of the 12 mobiles only two are digital. It is noted that of the women screened (423,843) from July 2008-2010 (IMR) 19% (84,569) were screened on a mobile service.

The use of digital mammography on mobile services has the most immediate and direct positive impact as it reduces technical repeats to almost zero because the images can be checked immediately by the MRT instead of being returned for processing. This in turn increases screening capacity as appointments for technical repeats are freed up for other women to be screened. This is a major benefit for women screened on mobile services in terms of not being required to return for repeat images and it also has an indirect impact on the time to receiving results as the images are immediately available for reading, particularly if they are transmitted electronically to a PACS rather than on DVD.

The use of digital mammography equipment increases the capacity to screen as the number of women screened per mammography unit increases as there is no down time for processing the images. Most studies of the increase in capacity of digital mammography suggest a reduction in time per woman screened by a third to a half of the time taken with analogue equipment. Therefore the transition to digital technology needs to be accompanied by capacity planning to ensure the best use of capital resources taking into account population growth in the eligible age groups and by geographical area. A mapping exercise of current and future physical infrastructure needed for the BSA Program in conjunction with the workforce requirements would allow the appropriate transition to digital technology for the BSA Program. Simply replacing existing equipment or mobile services may not be the best use of resources to meet current and future needs.

A specific examination of the utilisation of the mobile services may also be warranted given a comparison of the throughputs on mobile services for the BreastScreen Queensland (BSQ) Program and the utilisation of the BSA mobile services. In 2010 BSQ screened 221,696 women of whom 17% (38,505) were screened on mobile services using six digital mobile units across a geographically large State. For BSA of the women screened per year (about 211,921) across July 2008-2010 19% (42,284) were screened on 12 mobiles of which only two were digital. Part of the difference in the throughputs could be explained by the difference in efficiency in digital compared to analogue but it may also reflect an under utilisation of these resources due to catchment or Lead Provider boundary issues. The BSQ Program has adopted state coordination of the mobiles to maximise the utilisation of these costly resources across the relatively low density of population widely dispersed across some rural and remote catchments

across the State. For five of the BSQ Services that are totally regional, rural and remote, 30-40% of women are screened on the mobile. A specifically designed four wheel drive digital mobile is included in the fleet and has been successful in increasing access and acceptability for remote Aboriginal and Torres Strait Islander women.

Similar to the BreastScreen Australia Program (BreastScreen Australia Final Evaluation Report 2009)¹¹ as the eligible population increases and the workforce of specialists ages there are increasing pressures and workforce constraints for MRTs and radiologists and in regional and rural areas an acute maldistribution of these key professionals. The use of PACS and digital technology can address these constraints to a large degree.

In order to overcome the risks associated with the delay in implementing digital technology for the BSA Program facilitating a bulk tender process for the remaining mammography units would be likely to reduce the unit price of the equipment through enhanced purchasing leverage. It would also have the benefit of reducing duplication in developing the specifications, standardising the purchase of equipment that is of a consistent quality and type which in turn will reduce compatibility issues with the PACS and CIS and reduce the technical support costs of configuration and ongoing maintenance.

A similar approach could be undertaken for the replacement or rebuild of the mobiles once the capacity planning process had been completed. Again cost efficiency could be achieved through reducing the duplication of effort in the design and tendering of the mobiles to be replaced or rebuilt and some economies of scale could be achieved if the supplier was commissioned to produce more than one mobile unit at a time.

In undertaking the capacity planning for the BSA Program consideration should be given to models of care that co-locate diagnostic and surveillance breast imaging services with the BSA Screening and Assessment facilities. These co-location models of breast care centres are well established in the UK, and were recommended for investigation in the BreastScreen Australia Final Evaluation Report as a means of maximising the specialist resources now available and recognised in breast imaging, management and treatment. There is also a growing need for such specialised services as the knowledge of breast cancer and risk has grown rapidly over the last five years to the extent that there are recognised groups of high risk women such as those with a genetically proven high risk family history or women with significant breast density. These women require a different surveillance pathway including for some women access to breast MRI. There appears to be a gradual shift toward such models of care in New Zealand to take advantage of the infrastructure and specialists involved in the BSA Program including use of the information system and the quality assurance processes. This model of care was exemplified by the facility and services offered at BreastScreen Counties Manukau and it is understood different models of full or partial co-location of breast care services exist elsewhere in the BSA Program. For this reason

and for reasons of technical efficiency it would be an opportunity to incorporate the capture of these images and information on the BSA PACS and CIS during the development of these systems. The data for each stream of clients can be separated by service type in the BSA PACS and CIS but the information and images could be accessed as the woman moves from a diagnostic service to screening when she becomes eligible or from a screening type service to treatment, surveillance and possibly back to screening. This approach would enable New Zealand to have a unique almost complete national database of breast care services that would lend itself to linkage with the national population identifier data, cancer networks and the Cancer Register for quality monitoring along multiple clinical pathways and enhance the opportunities for valuable evaluation and research studies to be conducted.

Recommendation

4. It is recommended the BSA Program transition to full digital technology including the implementation of a centralised Picture Archiving Communications System (PACS) to ensure the ongoing safety and quality of the breast cancer screening services including consideration of the following;
 - i. The NSU in consultation with the Lead Providers coordinate a bulk tender arrangement to gain cost efficiencies and ensure implementation of digital mammography equipment in all BSA Services within a two year period. The tender panel to include representatives of the BSA Clinical Directors, radiographers, physicists and Lead Provider Managers.
 - ii. That the NSU urgently undertake a capacity planning project, taking account of a digital environment, in consultation with the Lead Providers to assess the physical capacity, including the mix of fixed screening and assessment centres, sub-contractors and mobile services required for the Program nationally and at catchment level for the projected population of eligible women up to 2016.
 - iii. That the NSU in collaboration with the Lead Providers undertake or commission a national workforce capacity project for the BSA Program in particular focusing on radiology and radiography workforce but including other key specialist disciplines such as pathology and breast surgery.
 - iv. That the NSU in consultation with the Lead Providers assess the requirements for the replacement of or fit out of the remaining analogue mobile services with digital mammography equipment informed by the BSA capacity plan.
 - v. That the PACS be integrated with the national register and clinical information network to facilitate the central storage, distribution and viewing of images at any BSA Service to overcome temporary or permanent workforce shortages of radiologists and enable prior images to be efficiently shared across the Program if women attend different BSA Services.

- vi. That the PACS and clinical information system be designed to store separately breast imaging undertaken for women outside the BSA Program by Lead Providers in a way that information and images can be shared across the different clinical pathways as needed for ongoing care or future reference for screening or diagnostic breast imaging services.

Discussion

A central register of information is a key component of population screening programs to enable participants to be uniquely identified for invitation and re-invitation of the eligible population as appropriate. A central register also supports quality assurance processes, performance monitoring of quality along the screening pathway and clinical outcomes. An important tenet of a State or national register is that women can move between services for their screening episodes of care but their entire screening history and information is available on the register for all services to access. It is the same concept of quality and safety required for the NCSP Register and ensures that a woman's prior episode of care, and for breast cancer screening importantly their images, are available for reference for each subsequent screening round. A national register also ensures that women do not fall through the system, providing a safety net, if they move between services so that they are rescreened at the appropriate interval.

A BSA register would also allow for matching at a national level against the mortality and cancer registry data to ensure that women are not inappropriately invited for screening. When matched against the New Zealand national population identifier data the BSA register of screened women will identify those eligible women who have not been screened so that specifically targeted strategies can be developed for these women and their characteristics and any barriers to screening can be assessed.

A national BSA register can also provide a range of administrative efficiencies through centralised functions such as a mail house function for the large number of letters sent by the BSA Program, this removes the administrative burden from BSA service level staff. Other central functions could include online or centralised bookings, which it is understood some BSA Lead Providers have but not all. A key efficiency of a national register for the BSA Program would be in the consistency and accuracy of data capture which would negate the significant effort currently in place for data management and data cleaning that currently happens at the BSA services and at the NSU. In addition in the absence of a register a BSA fail safe reporting system has been developed to ensure that duplicate clients are not in the system or that women are not missed for their re screen invitations. This is resource intensive and not reliable, as evidenced by the recent systems failure to re invite 10,000 women, due to systems errors and lack of consistency in exclusion codes and clinical outcome reporting. A register would overcome this resource dependency and risk and should be able to deliver timely data for standardised reporting at a service catchment and national level and have ad hoc reporting capability.

The design of the national register and networked clinical information system could be such that a single CIS would provide the point of care data capture for the BSA register. Authorised access to the register and information would be at BSA service and national levels with differing levels of operational, quality and performance monitoring reports available. Business rules in the system would determine access and govern data integrity through internal validation checks and audit processes.

The current BSA CIS Upgrade Project initiated by the NSU could provide phase one of the development of a national register as it will for the first time mean that all BSA Lead Providers will be using a single version of the CIS. However there were some reservations expressed by various users about the current vendor product and concern that the proposed Upgrade may not meet all their business requirements. An example given was that the current application does not enable critical information, such as the identification of a high risk woman following assessment, to be used to trigger clinically appropriate screening intervals, this has to be entered into the system manually. In addition where BSA Services operate in a co-location setting, with diagnostic or surveillance breast imaging services, the system does not allow for clinically relevant information to be imported into the BSA CIS. It was also observed in one of the BSA Services that the categorisation of reading outcomes are not mandated in the system nor can the system trigger events such as the generation of well woman letters for the 90-92% of women who have a normal outcome. This functionality in conjunction with system based rules could streamline what appears to be a very manual and risky process of results provision. The CIS is not integrated with the PACS that, at present where they exist, are stand alone systems this means that while there is messaging between the PACS and the CIS there is some potential that clients are not as accurately linked as in integrated system approach where the CIS drives the PACS. Given that several Australian States have ownership of state based registers that are fully integrated with PACS, with the same PACS vendor, it may be opportune to investigate these existing solutions to build on the current work being undertaken to move to one version of the software application for BSA. This approach may be cost efficient and if the license was purchased outright would give BSA ownership of the solution. The approach could provide a timely solution that would enable BSA to move to a national register with some adaption and customisation for a best fit to the future BSA Business Requirements to incorporate the benefits and to take full advantage of the digital technology.

The recently established NCSP register would provide an appropriate system platform for the development of a BSA register and would take advantage of the shared functionality that each register requires in data matching software applications, reference tables such as population, mortality and cancer registry data and mail house functions. In the longer term the registers could be linked with other cancer systems for ease of electronic transfer of information along the continuum of care. This would seem

to be consistent with current planning in the NSU and National Information Technology Health Plan.

It is envisaged that a national BSA register would make better use of staff resources at both the BSA service and NSU level and whilst requiring a significant up front capital investment should deliver efficiencies and reduce transaction costs over time as the benefits of the system are realised.

Recommendation

5. It is recommended that as part of the National Information Technology Health Plan a national register, with a networked clinical information system, be established for the BSA Program to provide critical infrastructure to more effectively and safely monitor quality assurance and performance outcomes, reduce the resources required to manage data and provide functional efficiencies for Services including consideration of the following:
 - i. That the current clinical systems upgrade be the first phase toward building the BSA national register and taking advantage of the existing National Cervical Screening register system platform in order to share common reference tables, functionality and maintenance costs.
 - ii. Investigate existing state based breast cancer screening program register systems in the BreastScreen Australia Program to assess their suitability, feasibility and cost for the BSA Program.
 - iii. Establish linkage of the BSA national register with the national population identification data to identify eligible women, unscreened or under screened women to enable invitation or re invitation of these women to improve screening participation.
 - iv. Develop systemised quality assurance reporting functions that support national, BSA Lead Provider catchment level monitoring of quality and performance, including quality assurance reporting for readers and radiographers.
 - v. Investigate central functions that could be built into the BSA register that could generate cost efficiencies for the Program and reduce the administrative burden for BSA Services such as the use of centralised mail house services and call centre functions.

Discussion

An Analysis of BSA Lead Providers Financial Performance July 2005 to June 2008¹² was finalised in July 2009. Since that period the screening throughput for BSA Lead Providers has increased significantly. Higher throughputs should lead to some cost efficiency over time due to the linear relationship between fixed costs and activity with the fixed costs spread over increased activity leading to a lower unit cost per woman screened. The current funding model funds activity separately to a fixed funding component. Whilst this may provide an incentive to screen additional women it may underestimate the total cost per woman efficiencies that occur with increasing activity. The current funding model also funds on the basis of the eligible population without loadings to account for the different demographic mix of population in each Lead Provider catchment, including the proportion of Maori and Pacific women and women from lower socio economic backgrounds. It is understood that the District Health Boards (DHB) are funded under a demographically determined formula.

There is also an anomaly inherent in the current funding model that funds activity on the number of screens undertaken, not the number of women screened. It was reported that in the last financial year the difference was about 21,000 screens more than there were women screened. This was equivalent of about 9% of women having more than one screening episode in this period. This would be well outside clinically accepted best practice for this number of women to have an early rescreen without a definitive clinical outcome, possibility because of an indeterminate assessment outcome. Most women recalled to assessment should have sufficient clinical work up undertaken at the time or be referred for open biopsy to ensure they receive a definitive outcome instead of being rescreened within the twelve month period. This leaves women in a state of high anxiety not knowing if they have breast cancer or not. Funding on the basis of screens rather than women screened provides a perverse incentive for this undesirable clinical practice.

In addition since that analysis period several BSA Lead Providers have or are planning the implementation of digital technology which incurs capital upfront costs but should deliver some cost efficiency over time due to a higher throughput per mammography unit and the savings in consumables such as paper and x-ray film and physical storage of client charts. Most of these efficiencies may not be delivered as true savings but offsets to increasing labour costs to increase service capacity.

As identified previously if capacity planning is undertaken this also may lead to a reduction in capital assets, such as mobiles, leading to a reduction in the capital maintenance costs and depreciation. In addition there are potential reductions in the maintenance costs of the clinical information system and PACS if a centralised approach is achieved with a national register, clinical information network and integrated

national PACS. Although the overall costs may be less the centralised approach would also need these costs to be pooled centrally to meet the ongoing maintenance and infrastructure costs.

It is therefore timely and appropriate to review the BSA funding model to ensure the most cost effective and efficient cost to the Program and the MOH. It may also be useful to take the opportunity to benchmark the cost per woman screened with the published cost per woman screened for the BreastScreen Australia Program this information includes the cost for the state coordination functions. These data are published by State and Territory in the Report of Government Services produced by the Australian Productivity Commission annually.

Recommendation

6. It is recommended that the BSA Program funding model be reviewed to take account of expected efficiency gains through digital technology and projected population growth or decreases in BSA Lead Provider catchments including the following considerations:
 - i. That the review of the funding model focus on “value for money” considerations taking account of the cost efficient use of resources including capital and workforce, in particular maximising the use of mammography equipment and radiographers to achieve screening activity targets.
 - ii. That a benchmarking exercise be undertaken on a cost per woman screened basis with large States’ cost per woman screened data from the BreastScreen Australia Program that includes costs associated with coordination and all aspects of the breast cancer screening services pathway.
 - iii. That the review of the funding model considers the demographic profiles of the Lead Providers in conjunction with the eligible population.
 - iv. The review of the funding model should ensure that funding for priority groups, such as Maori and Pacific women, is maintained and recruitment and retention activities are funded based on need to improve participation levels in disadvantaged population groups.
 - v. That immediate steps be taken to change activity funding to funding per woman screened not number of screens, to provide a positive incentive to reduce repeat mammograms of women outside the clinically accepted screening pathway.

Clinical Governance and Leadership

Clinical governance and leadership are critically important for the safe delivery of quality population based cancer screening programs. Organised population screening programs, such as BSA, have a higher level of “duty of care” than other medical interventions because although screening may be perceived as simply the application of a test to individuals, when applied to defined populations of asymptomatic eligible women there is a need to ensure that this public health program maximises the benefits and minimises the harms. Therefore every aspect of the population screening program needs to be of the highest quality with quality assurance and monitoring of every step of the screening pathway, from recruitment to the detection of a histologically confirmed breast cancer and referral to treatment or re-invitation to rescreen at the appropriate intervals.

New Zealand, like other developed nations, has appropriately implemented the BSA Program as a national organised population based screening program through significant public investment. Therefore the responsibility for both the duty of care to the individuals participating in the Program and the need to ensure that every aspect of the program is evidence based, effective, and efficient ultimately rests with the MOH and the Minister. There is also an ethical dimension to this responsibility as the national BSA Program invites and encourages women, in this instance, to participate in the Program with the knowledge that of the women screened only a small but significant proportion will have an early breast cancer detected. For the remainder it is critically important to ensure that any harm of participating in screening is minimised through managing the proportion of false positives and false negatives. Therefore there is an ethical duty to maximise the benefits for both the individual and at a population level and to ensure the overall quality of the national program through a quality management framework and systems. It needs to be recognised that for these reasons population screening has an inherent level of complexity and risk that requires strong clinical governance and leadership that includes clear national clinical accountability. This is also important to provide the high levels of trust needed in the quality of population screening programs so that a sufficient proportion of the population is screened to ensure that the population health benefits are gained and the return on investment of this public health program is achieved.

The importance of this clinical governance and leadership was recognised at the outset of establishing the BSA Program in New Zealand with the inclusion of a Clinical Leadership position in the NSU and the establishment of the Uni-disciplinary Groups (UDGs) for each of the professional disciplines involved in the BSA Program. In addition the BSA Advisory Group structure was put in place in 2002 after a review that established separate Advisory groups for the NCSP and the BSA Programs. At this time the National Screening Advisory Group was established that reported to the MOH with

terms of reference to provide oversight of and advice on screening activities throughout the health sector, including population screening programs. The level of program oversight of this group was not clear, nor was its role and responsibility to oversight individual or service level clinical performance of the screening programs. It was reported that this group had not maintained its meetings in recent times and had perhaps lost its status through the many changes to the MOH.

A Clinical Director for the BSA Program, a Public Health Physician, was in place from the commencement of the Program in 1998 until 2001, and the BSA Clinical Leader, a radiologist was in place from the establishment of the NSU in 2001 until October 2009. A temporary replacement, a radiologist who was a Lead Provider Clinical Director, was employed two days a week from November 2009 to March 2010. In April 2010 until December 2010, a public health physician undertook the role of Chief Advisor Screening on a part time basis. In the financial year 2010/11 the position of BSA Clinical Leader, which was vacant at the time, was not funded. Following a successful submission to have this position re-funded the BSA Clinical Leader position was filled on a short term temporary basis, at the request of the clinician, for 2 days a week by a breast physician in April 2011 to the present.

It was apparent from the comments and observations in the individual and group interviews that there had been a very high reliance by the NSU on the significant knowledge, experience and skill of the long term radiologist Clinical Leader to provide all clinical input for the BSA Program. It was also evident that there was a strong relationship and respect for the BSA Clinical Leader and to some degree reliance on this position in the NSU by the Clinical Directors over a long period of time. Her leaving the role and the inability of the NSU to find a permanent replacement that was a radiologist was a key trigger for this current review.

The BSA has a well developed audit process underpinned by internationally accepted and evidence based National Policy and Quality Standards for the Program¹³. The BSA Audit Workbook (2007)¹⁴ outlines the decision making process for finalisation of the Audit Report. Following the audit that is undertaken by IANZ, under contract to the NSU, the report and recommendations are sent to the Lead Provider for response. These responses are then assessed and incorporated by IANZ as appropriate. This draft final report is submitted to the NSU for review and acceptance and finalisation before sending it to the Lead Provider with the recommendations and actions to be taken, each of which has a risk rating. It is then the responsibility of the NSU to follow up the recommendations and actions and any non compliance issues with the Lead Provider.

Based on the information gathered, through interviews with individuals and groups, it would seem that the review and acceptance of the independent audit report by the NSU has in the past relied on the assessment of the Clinical Leader. However, with the absence of this role in the NSU, the perception gained from the BSA Lead Providers was that the current staff were not qualified to comment on or sign off on the final audit

report and in particular allocate the level of risk to any unmet clinical performance standards. These comments were contrasted with their view of the situation and experience they had had in the past where the Clinical Leader would follow up with the Lead Provider being audited with a visit and offer support and assistance in addressing unmet standards, in particular those that related to radiological practice or skill. There were strong and consistent negative comments about the current lack of specialist clinical knowledge or experience in the NSU to assist with addressing clinical quality issues such as reader performance or assessment procedures. It was a clearly expressed view that the BSA Clinical Leader should be an experienced senior radiologist with specialist skills in breast imaging.

In addition there was a very strong view expressed in the interviews that without a permanent Clinical Leader in place there was no clinical leadership for the BSA Program that could take on the role of providing advice to the NSU and the MOH in relation to the quality, clinical pathways, new technologies and evidence based best practice. The Lead Providers, especially the Clinical Directors, also looked to this position to provide orientation training and authorisation for new readers, ongoing professional support in continuous quality improvement and to facilitate professional development and in particular, peer review of reader quality.

One of the reasons given for not being able to recruit to this position despite several attempts, including the use of an external human resources agency, was the difficulty of being able to match the professional entitlements available through the District Health Boards compared to the remuneration package available in the MOH. The other reasons cited that discouraged applications to the position included the constant restructuring and downsizing of the MOH and the impact on the NSU that lead to the loss of so many knowledgeable and experienced staff in a relatively short period of time.

The Advisory Group structure for the BSA Program, including the UDGs is well established although the group meetings have been somewhat curtailed in recent years due to the Minister's directives to reduce the number of committees providing advice to the MOH. This does not recognise the importance of these groups as part of the quality management structure of the BSA Program. These groups have an important role in the clinical governance and leadership to the BSA Program for each of the professional discipline groups represented. A review of the terms of reference for each group shows that they appear to vary slightly and be a little ill defined. They do however contain elements of professional oversight, peer review, professional development, and identification of training needs and review of quality standards. Most of the clinical UDGs do not have clear operating principles or processes for escalating issues of concern about clinical practice or quality standards. They are advisory to the NSU through the BSA Advisory Group.

The BSA Advisory Group membership is comprised of one representative from each of the UDGs, an epidemiologist/public health physician, representatives from the

Consumer, Maori and Pacific Advisory Groups respectively and the Royal New Zealand College of General Practice (RNZCGP). The NSU is represented ex officio on the group by the BSA Programme Leader and Clinical Leader with the secretariat provided by BSA team members. The terms of reference for this group focus on provision of advice on workplans for BSA, policy and strategic directions, multidisciplinary issues, monitoring, research and development opportunities. A key focus has continued to be the review and acceptance of the six monthly BSA IMR that is produced by the independent contractors. However the terms of reference for this group seem to be ambivalent in their intent and do not articulate clear processes for the provision of advice or recommendations about strategic directions for BSA and there are no operating principles for the group apart from the chairing role. The terms of reference state that the group reports to the BSA Manager and BSA Clinical Leader.

Interviews with members of the BSA Advisory Group clearly outlined a range of frustrations and general dissatisfaction with the relationship between the BSA Advisory Group and the NSU. It was the consensus of the group interviewed that they were concerned that the NSU had not consulted the BSA Advisory Group on major strategic projects such as the PACS and the CIS upgrade or the current workplan for the NSU. There was clearly a loss of trust and respect for the staff in the NSU due to what was referred to as the “dismantling of the BSA team” and the significant loss of knowledgeable and experienced key staff including the BSA Clinical Leader. There were strong concerns for the safety and quality of the BSA Program and the expressed view of “feeling unsafe”. This was illustrated by the group that referred to the issue of the missing data to re-invite women for their routine screen due to a systems failure related to a CIS system upgrade. In general the view expressed by the members of the BSA Advisory Group was that of genuine concern that their expertise and knowledge was not used or valued by the NSU. They were also concerned that the BSA Program lacked leadership in general but more importantly they were concerned about the lack of Clinical leadership for the BSA Program and the risks associated with this lack of oversight of clinical quality.

NSU has recently established an independent Clinical Governance Group that has met on several occasions but has not as yet finalised its terms of reference nor its roles and responsibilities. The CGG has an independent external secretariat and chair who is a public health physician with knowledge and experience in the cancer screening programs. The membership of the CGG is multidisciplinary and representative of the various clinical areas covered by the current screening programs. Information based on interviews with some members of the CGG suggests that this group has a good understanding of the complexity of cancer screening programs and has strong and appropriate linkages with the broader cancer control direction for the MOH including the developing regional cancer networks and information systems and has links to the National Health Board.

Summary

Based on information gained through interviews with groups and individuals and the relevant documents it would appear that there are two levels of clinical governance and leadership of the BSA Program, being at the Lead Provider level and at a national level. The Clinical Directors for each BSA Lead Provider, who is expected to be a radiologist, have a mandatory and clearly defined role and responsibility set out in the BSA National Policy and Quality Standards manual for clinical governance and leadership of their service and single point accountability. The national level clinical governance and leadership is less clearly defined and appears to be largely managed internally by the NSU through the BSA Advisory Group structure, including the UDGs and the Clinical Leader position. The loss of the BSA Clinical Leader position has contributed to the gradual fracturing of the relationships of the NSU with the BSA Advisory Group and the UDGs and is perceived to have left a void and uncertainty about the clinical governance and leadership of the BSA Program.

The CGG was established to strengthen the clinical leadership for the NSU. An accepted definition of clinical governance is that it is *a framework by which health organisations are accountable for continuously improving the quality of their services and safeguarding high standards of care by creating an environment in which excellence in clinical care will flourish*. It was not clear that this environment was present for the BSA Program.

Discussion

Breast cancer screening using mammography is primarily a radiological procedure, and therefore it is appropriate that the national clinical leadership of this Program is a radiologist. In New Zealand as in other countries that have implemented national breast cancer screening programs, such as Australia and the UK, there is a lead clinician/designated radiologist in each of the Screening and Assessment Services. These clinical leadership roles are similar across these national programs and have responsibility for the quality of the mammographic images, screening reading and reporting, assessment and the technical quality of the equipment at the service level.

In addition in these national programs there is generally a radiological clinical leadership role in place at either the State level as in the Australian program or nationally in the UK. This role is similar to the Clinical Leader that was established initially for the BSA.

In Queensland and New South Wales the position is known as the State Radiologist and is based in the State Coordination Unit (SCU) in a role independent from the BreastScreen Screening and Assessment Services. This position has the clinical

leadership role and responsibility to oversight all the radiological/clinical aspects of quality for the Program. This State level clinical leadership role is critical to independent monitoring of the radiological quality of individuals and services based on performance data and audit processes. In the context of a quality improvement approach they also have a key role in leading and supporting quality improvement activities and training new radiologists working in the Program. These positions also have a vital role in advising on evidence based clinical pathways, changes in clinical best practice, the application and efficacy of new technologies and revision as appropriate of quality standards and measures. These positions function within a quality framework and the support of a clinical governance structure for the Program at a State and national level.

In both the situations outlined above the State Radiologist is employed at a service level and maintains their clinical practice in the Program but is appointed to the State radiologist position in the SCU on a part time basis. They are employed at the Service level with funds recouped by the Service for their SCU part time position. This allows the individuals to maintain their professional entitlements, such as sabbatical leave and professional development payments. It is also important that they retain the currency of their clinical practice to maintain peer group respect and authority.

Based on the strong desire from the BSA Lead Providers to have the Clinical Leader position filled part time by a radiologist and the experience of this role in other BreastScreen Programs it would seem appropriate to endeavour to recruit a suitable radiologist to the position.

Recommendation

7. It is recommended that the NSU appoint a part time radiologist Clinical Leader for the BSA Program to work with the BSA Program Director (Manager) employed by a Lead Provider to ensure maintenance of their clinical entitlements and practice. Specifically this position would have responsibility for the following:
 - i. Providing clinical leadership for the BSA Clinical Directors and advice to the NSU and the Ministry of Health in relation to the clinical aspects of the BSA Program.
 - ii. Development and provision of orientation training, authorisation and ongoing professional development for all radiologists in the BSA Program.
 - iii. Participating in the Radiologist Uni-disciplinary Group meetings, reviewing clinical standards and promoting and undertaking research that informs clinical policy and practice in the BSA Program.
 - iv. Participating as a member of the BSA Advisory Group, the Clinical Governance Group and the Ministry of Health Clinical Advisors Forum as appropriate.

Discussion

The clinical governance structure for the BSA Program at a national level has largely relied upon the Clinical Leader position that has in the past had a strong and respected oversight of the clinical, particularly the radiological aspects of the program. The loss of this experienced and knowledgeable individual and the difficulty recruiting to the position has highlighted the fragility and dependency on this role to fulfil the clinical governance and leadership of the BSA program. Whilst it is important for the Clinical Leader to provide this national level clinical accountability it is equally important to provide a quality framework and clinical governance structure to support this role. The BreastScreen Australia National Accreditation Standards Quality Improvement Program¹⁵ requires the establishment at the State level of a State Accreditation Committee (SAC) or similarly named group, as part of the national quality framework that provides clinical governance for the Program. In Queensland, as is the case in other States, the SAC has been established as a subcommittee to the BreastScreen Queensland Quality Management Committee.

The BSQ SAC, similar to other States, has an independent chair with experience and knowledge in quality assurance and accreditation. Membership of the SAC includes expert representatives from each of the relevant BreastScreen specialist disciplines, the Royal Australian College of General Practitioners, the State radiologist and State radiographer, two consumer representatives, and an external clinical epidemiologist. The SAC is supported by the BSQ advanced epidemiologist, the BSQ Team Leader for Quality and the Program Director. The role and responsibility of the SAC is to assess the performance data for each of the BSQ Screening and Assessment Services (SAS) related to six or twelve monthly performance reports against the BreastScreen Australia National Accreditation Standards (NAS) and/or related to their application for accreditation for the BreastScreen Australian Program that is required every two or four years depending on the performance of the BSQ Service.

This SAC reviews all the information required for the BreastScreen Australia national accreditation process including the application, performance data, responses from the BSQ Service related to their performance data, the accreditation site visitor's report and recommendations, the data audit and any other relevant information provided by the SCU about the performance of the BSQ Service. The outcome of the assessment of this information is a recommendation for the level of accreditation that the SAC believes is appropriate for that BSQ Service. This is formally submitted to the National Quality Management Committee (NQMC) by the chair of the SAC. The SAC operates under strict confidentiality provisions as it is reviewing BSQ Service specific performance data

and is covered by Queensland Government Quality Assurance Committee legislation that protects individual members of the SAC from being legally compelled to provide evidence about performance data related to any BSQ Service.

The NSU processes for the review of BSA performance data and the audit process and follow up appear to be fragmented with no single point of accountability. In the past the synthesising of the various components of quality monitoring was possibly managed in the main by the Clinical Leader with assistance from knowledgeable staff in the BSA team. However at present, with the current structure and the loss of the Clinical Leader all the relevant information to assess the performance of the Lead Providers and the BSA Program is not brought together in one place for review and recommendations. The IMR is reviewed by the BSA Advisory Group, the audit process is managed internally by the BSA team, and the performance data is extracted and managed by the Quality and Equity team. This has resulted on some occasions in data and information from different periods being used to assess the performance and clinical outcomes for the Lead Providers. This has been a source of criticism of the NSU from the Lead Providers who don't have trust or have confidence in the current process of decision making in the NSU nor is the decision making process clear, consistent and transparent.

Given the relatively recent establishment of the Clinical Governance Group (CGG) it would be opportune to review the roles and responsibilities of the CGG to consider strengthening its role to be the single point of review for the performance of the BSA Program. This would mean that the CGG would be tasked with the review of all the relevant performance measurement data, including the IMR, the audit reports and recommendations and for making decisions on the level of compliance or otherwise of the Lead Providers to the National Policy and Quality Standards. The CGG would be expected to commend Lead Providers on their achievements and make recommendations on actions for areas of non compliance and the level of risk, and provide oversight of the NSU to follow up on performance issues through the BSA Program Director and the Clinical Leader. This would be undertaken within a framework of continuous quality improvement with clearly identified performance improvement processes and plans to be undertaken to work toward meeting the standards.

The terms of reference for this CGG would need to be clear and the decision making process transparent, perhaps with developed decision tools for levels of risk and quality achieved. The operating principles and membership of the current CGG may need to be reviewed to ensure the appropriate membership for any change in role and responsibility. However it would be critical to ensure the inclusion in the membership of a senior radiologist with knowledge and experience in breast imaging and the BSA Program, two consumers, MOH representation for the priority groups of Maori and Pacific women, an external clinical epidemiologist and a DHB representative. While

operationally the CGG would report to the NSU with recommendations for decisions and /or actions the members would be appointed by the Director General for a term of office to ensure high level acknowledgement of this important clinical governance role for the BSA Program.

The combination of a radiologist appointed to the Clinical Leader position and well developed CGG roles and responsibilities should provide improved and clearer clinical leadership for the BSA Program.

The structural relationship of the BSA Clinical Leader within the MOH will depend on the alignment of the NSU with other units in the organisation. The alignment and linkages of the CGG within the MOH likewise will depend on the location of the NSU in the organisation.

Recommendation

8. It is recommended that the newly formed Clinical Governance Group (CGG) for the NSU have its role and responsibilities strengthened to provide independent review and recommendations on the BSA Services Audit reports, performance monitoring reports and potentially to oversight the quality performance of the screening programs in the NSU. The key features of this Group would be as follows:

- i. The chair of the Clinical Governance Group would be independent from the NSU and the BSA Services but understand the critical quality aspects of population screening. Members to be appointed by the Director General.
- ii. The membership would include relevant clinical experts in the specialist fields relevant to the screening Programs including a radiologist with significant knowledge of the BSA Program, an independent cancer epidemiologist and two consumers. Ex-officio members from NSU would include the biostatistician/epidemiologist, the BSA Program Director and national quality coordinator.
- iii. The operating principles of the CGG would clearly document the decision making processes and any decision tools used by the CGG, ensure the confidentiality of the Audit reports and detail the feedback process to BSA Services in relation to recommendations and include an appeals process.
- iv. Final decisions from the CGG would be posted on the NSU website along with summary information from the Audit report.

Discussion

The BSA Advisory Group that was established in 2002 to support the NSU to achieve the Program vision at that time, namely “Saving lives, reducing inequalities, and building the Nation’s health by leading the delivery of screening programmes, uncompromising in their quality and trusted by the communities we serve”. It would appear from the strong support expressed by the members of the current BSA Advisory Group that they see their role in these terms and believe that they can make an important contribution to the BSA Program and the NSU. However the relationship with the NSU currently appears to be somewhat compromised due to the impact of the loss of positions and staff and structural changes in the NSU over the last two years. In order to make best use of the valuable expertise on the BSA Advisory Group, consideration should be given to reviewing the role and responsibilities of the Group to focus more clearly on ensuring the quality of the BSA Program while continuing its role to provide strategic advice on planning and policy. Given the representation of all the specialist disciplines involved in BSA it would be appropriate that the BSA Advisory Group have oversight of the National Policy and Quality Standards and their implementation and review as needed. This role is not explicitly spelt out in the current terms of reference nor is it clear how recommendations are progressed to the NSU. The frustrations expressed by the current members could be overcome to some extent by better clarity of the terms of reference and the operating principles. The frequency and scheduling of meetings was also an expressed concern from the current members. With a well planned agenda and meeting papers the BSA Advisory Group should be able to provide sufficient support to the NSU through two one day face to face meetings a year with the option for out of session consideration of issues and documents and teleconferencing.

To highlight the importance of the role of the BSA Advisory Group in ensuring quality and to give the Group a new impetus a name change to the BSA Quality Management Committee would be worth considering.

The current UDGs appear to be working well but have been constrained from being able to meet as frequently as previously was the case. As specified in most of the terms of reference for the UDGs these groups plan to meet face to face once a year with teleconferences in between as necessary. This should be maintained to ensure the continuation of professional peer support, the opportunity to review quality standards, discuss new and emerging evidence in clinical practice and identify issues for monitoring or research that would improve the quality of the BSA Program. It is noted that some of the terms of reference for the UDGs were reviewed in 2010 so it would be appropriate to finalise a review of all UDGs terms of reference and operating principles.

In order to formalise the relationship of the UDGs with the BSA Advisory Group it may be worth considering developing a workplan for each group annually for endorsement.

This could inform the workplan for the BSA Advisory Group and the NSU and identify issues or standards for review that require supporting data analysis or background research.

The ongoing support of the UDGs and the BSA Advisory Group/Quality Management Committee will depend on the realignment of positions and recruitment of sufficient appropriately qualified staff for the integrated BSA Program team as outlined in Recommendation 2.

Given the BSA Program team has sufficient capacity it would be the expectation that the NSU would continue to organise and facilitate the meetings of the UDGs and the BSA Advisory Group/Quality Management Committee.

Recommendation

9. It is recommended that the BSA Advisory Group and the Uni-disciplinary groups (UDGs) be maintained and strengthened with specific consideration given to the following:

- i. Consider changing the name of the BSA Advisory Group to BSA Quality Management Committee to emphasise their key role in maintaining the quality of the BSA services and oversight of the National Policy and Quality Standards (NPQS).
- ii. Review of the Terms of Reference of the UDGs to ensure their key roles and responsibilities are focused on quality management and standards and to clarify the lines of communication with the NSU and the BSA Advisory Group.
- iii. Development of an annual workplan for the UDGs that is endorsed by the BSA Advisory Group and reported on to the BSA Advisory Group at each of the meetings.
- iv. Ensuring the operating principles are consistent for all groups, have a clear process for representation from each of the BSA Services, election of the chair and communication of the minutes and actions from the meetings.
- v. That at least two face to face meetings of the BSA Advisory Group and the UDGs biannual meetings continue with at least one face to face meeting.
- vi. That the NSU continue to organise and provide the secretariat for the UDGs with timely distribution of agendas, minutes and report on actions arising including assisting in the preparation of submissions to the BSA Advisory Group.

Quality Framework and Performance Monitoring

It is internationally recognised that to achieve the best outcomes for breast cancer screening an organised approach is required. A meta analysis undertaken by twenty four experts from eleven countries for the International Agency for Research in Cancer (IARC) WHO Working Group confirmed that breast cancer screening using mammography through an organised program is efficacious in reducing the mortality from breast cancer for women aged 50-69 years by 30% (IARC 2002).

A critical feature that underpins a national organised population screening program are the systems and structures for ensuring strong quality assurance processes for all aspects of the screening pathway. For breast cancer screening due to the radiological nature of the screening test, being mammography, technical quality assurance of the equipment used for screening and assessment is critically important as are all aspects of quality clinical practice for screening and the specialist multidisciplinary assessment process.

The NSU as the national coordination unit for the BSA program developed a quality framework in 2005, the Improving Quality: A Framework for Screening Programmes in New Zealand. The framework is very sound and includes principles that are consistent with other national organised population screening programs and incorporate a quality improvement approach. The framework was also based on the New Zealand Improving Quality (QI): a Systems approach for the New Zealand Health and Disability Sector: Wellington: Ministry of Health, 2003¹⁶. This approach included recognition of the Treaty of Waitangi principles of partnership, protection and participation. The framework identifies eight key quality requirements that underpin quality management in screening programs and an implementation structure based on the principles and the key requirements.

The screening pathway and the relevant quality initiatives are outlined for the NCSP and the BSA. There are some key differences in the screening pathways for these two population screening programs. BSA requires more complex technical quality assurance and involves a broader range of clinicians in the screening pathway compared to the NCSP screening pathway. The quality initiatives that were to occur at all stages of the screening pathway are detailed and include; performance management, data collection, monitoring quality standards through provider audits and contracts, quality improvement, workforce development initiatives, input from uni disciplinary groups, strategic oversight from the BSA Advisory Group, Maori and Pacific Advisory groups, accreditation of providers, multidisciplinary biannual site visits and an overall program evaluation. The list of quality initiatives is consistent with the expected range of activities required for breast cancer screening programs. The technical quality assurance activities and assurance processes are not mentioned explicitly but are assumed to be covered in the provider based quality assurance processes.

The initial National Policy and Quality Standards for BSA were developed by Standards New Zealand in line with internationally recognised processes while working with representatives from the health sector and key stakeholders. Subsequently this was moved into the newly established NSU that had an established dedicated BSA team. The current National Policy and Quality Standards (NP&QS revised 2008) were developed as a collaborative effort of the NSU BSA team, BSA Lead Providers, the Independent Service Providers (ISPs), key stakeholders and consumers. They were also strongly aligned with other national breast cancer screening programs in particular BreastScreen Australia National Accreditation Standards (NAS). The NP&QS forms the basis for the quality management of BSA and monitoring of the Program's performance at the Lead Provider and national level.

While the BSA and the NSU have a very sound underpinning quality framework and a quality management document in the NP&QS the implementation of the quality processes could be strengthened to ensure they meet the requirements for a breast cancer screening program. Critical quality processes such as the Lead Provider audits and performance reporting, have been constrained in recent years. Some of the routine Lead Provider audits were delayed due to funding issues and performance reporting has been compromised by the loss of key positions and staff in the NSU who had unique knowledge of the system used to generate the reports. In addition the process of generating performance reports at the national level is highly resource intensive. It is also potentially subject to error due to the inconsistency of the current data capture systems used by the Lead Providers.

Without a national register of every screening episode of care and a national unique identifier for every woman screened it is possible to have duplicate records in the collated reports, even with intensive data cleaning and matching. The national collation of reports from different versions of the system that can be altered at the Lead Provider level can also lead to different outcome data being reported for women in different time period data extracts. This could happen for example if an error in capturing the woman's histopathology results was identified in a data quality audit in the Lead Provider and therefore corrected in the system but it may not have been changed in the system extract at the national level. Although these variations may not make a significant statistical difference in the overall performance report at a national level it means that there is not one source of truth for the BSA and it may make a difference at the BSA Lead Provider level particularly where the confidence intervals are large due to small statistical denominators for some performance indicators in the smaller throughput services.

The CIS Upgrade Project underway will go part of the way in addressing these issues but will still leave the data partitioned by Lead Providers in the central database that will not reliably be able to report at a national population level on every episode of care for every woman screened without significant cleaning and matching due to the issue of

data changes that can be made at the Lead Provider level or duplicate NHIs which is reported to be a common occurrence. It also leaves a resource intensive process for data extraction and collation and does not facilitate national level comparative analysis of key performance measures on an ad hoc basis if a quality issue was identified that required examination. The other major limitation in terms of quality assurance, of a partitioned database, is that it does not easily facilitate national level reader quality assurance. As a mammographic screening program the quality of the readers is critical, in terms of their sensitivity and specificity of reading. Both need to be closely monitored so that there are very low levels of false negatives, those women with the disease who go undetected and that there is an acceptable level of false positives, those women who do not have breast cancer being subjected to further diagnostic tests.

It was identified in the interviews with the Clinical Directors that reader quality assurance needs to be undertaken at a national level for a number of reasons. A key reason is that at the Lead Provider level, particularly for smaller services, all the readers are known to one another which leads to both professional and personal sensitivities. The other reason is that reader performance can be subject to variability over time and significant amounts of data need to be assessed independently with trend analysis, funnel plots and comparison with large groups of readers to gauge whether there is a true issue of quality and safety of an individual reader. Continuous and timely feedback is also critical to improvement in performance. This can only be enabled easily at a national level with a national BSA register. This would be a key responsibility of the BSA Clinical Leader in conjunction with a small Reader Quality Assurance Group.

A major source of negative comments from the BSA Lead Providers was about the current quality processes, particularly about the Performance Management Analyst follow up visits to discuss unmet NP&QS. Comments such as “NSU staff lacked an understanding of the BSA, they were compliance focused on the contract and the funding”. These comments and information provided through individual and group interviews with NSU staff suggest that there was limited understanding of the critical importance of clinical outcome measures for the BSA and that staff had been directed instead to be contract managers. This was contrasted with the Lead Providers previous experience of follow up visits from the NSU BSA team including the Clinical Leader at the time of being supportive with a strong continuous quality improvement focus.

As outlined in the previous section there was also concern expressed by the Lead Providers about the decision making processes in producing the final audit report, in particular the lack of clinical or knowledgeable assessment in the NSU. In addition the current quality processes do not have an end point that recognises high performing Lead Providers or measured sanctions for poor performing Lead Providers. There are also no clearly stated sanctions for Lead Providers that do not meet critical performance NP&QS other than discontinuation of the contract with the Lead Provider. This latter step would be extremely difficult to implement given the significant public sector

investment in expensive equipment and facilities. This would also be complicated by potential staff industrial relations issues that could ensue with the closure of a service as well as the political and community sensitivities.

It would appear based on interviews with NSU staff and Lead Providers that there is a somewhat fragmented approach to quality measurement and monitoring for BSA in the NSU. The information needed to periodically assess the performance of the BSA Program and the Lead Providers is collated from data extracts provided by each of the Lead Providers to the Information Directorate of the MOH and then sent as a single file to the NSU. This data is cleaned and collated into performance indicator tables and provided as tabulated data, under an outsourced contract, to the University of NSW who produce the six monthly IMR. The IMR provides descriptive epidemiological data, tests measures for each of the Lead Providers for statistical significance and includes confidence intervals and provides trend analysis for performance indicators and targets. These monitoring reports are used to measure the performance of the national BSA Program and the Lead Providers.

There is a separate process that is outsourced to the University of Otago, undertaken under contract with the NSU, to produce an Independent Maori Monitoring Report (IMMR). This report is developed using tabulated data provided by the NSU to monitor performance measures and targets for Maori and Non-Maori women. The most recent published report (December 2010) is for the two year period January 2006-December 2007 includes data on participation, screening and assessment quality and timeliness for the BSA Program and by Lead Providers. The comparative and trend analysis is essentially the same as for the IMR only for a different time period. Both reports include participation data disaggregated by Maori and non-Maori women. The IMMR provides disaggregated data for all performance measures.

Currently the IMR is used for quality management in combination with the outcome of the audit process, the audit report and recommendations. It is also used for assessment during the audit and for follow up of compliance with quality measures with Lead Providers after an audit. This has caused some issues of concern for the Lead Providers. They stated that there have been occasions when the IMR available to the auditors is for an earlier time period. This can mean that the Lead Provider may have acted on the performance measures that are unmet in the previous IMR but the expected changes in the performance measures are not available to the auditors for assessment at the time of the audit visit. The Lead Providers can generate these performance measures at the service level so could be aware of these changes. This anomaly has caused some disquiet with Lead Providers in particular the Clinical Directors that are endeavouring to continuously improve the quality of their Services.

Currently the external audit process is outsourced by the NSU under contract to IANZ. The audit process is covered in detail in the BSA Audit Workbook that includes the audit framework, principles and expectations, definitions of routine compliance audit, issues

based audit and follow up audit. The Workbook also covers in detail the scope of the audit, the materials to be audited, the audit team, the approach to be taken by the auditors, the reporting process and follow up process. The workbook is expected to be used by Lead Providers for internal audits and is the basis for the periodic external audits.

The Audit Workbook under principles and expectations states that “auditing acts as a catalyst for continuous quality improvement and provides better information for decision making”. It goes on to state that audit “improves efficiency and effectiveness and contributes to better services and funding relationships”. It also explicitly states that it is important to ensure that BSA Providers’ service delivery conforms to the NP&QS and the contract”. This suggests that the audit process is not just focused on achieving high quality breast cancer screening services for the BSA Program but compliance with contractual arrangements with the Lead Providers. Due to the natural tensions that may arise in meeting these dual purposes the audit process could easily shift to focus much more on compliance, as it reportedly has done, and less on quality outcomes and a continuous quality improvement approach.

Based on feedback from the Lead Providers and interviews with NSU staff it would seem that recently there have been some issues in terms of the membership of the audit team, in particular the radiologist. In one instance there were concerns expressed that the radiologist was not a current practising radiologist in breast imaging so had limited knowledge of digital technology. On another occasion the NSU representative expressed concern that an audit team member was commenting on issues of policy. Under the current arrangements the audit team can be ten or more people that are present in a BSA Lead Provider service for varying times of up to one week.

The NP&QS manual includes information about mandatory leadership positions and their roles and responsibilities. One of the key responsibilities of the Lead radiologist is to coordinate the Mammography Quality Assurance program undertaken by the MRT with or without involvement of the site medical physicist. Breast imaging and equipment is increasingly becoming a sub specialist area in medical physics particularly with the increased use of digital technology including PACS. Technical quality assurance of the mammography image at the time of capture and for reading is critical. The highest quality imaging must be assured for the effective early detection of breast cancer in a population screening program. The NP&QS has an addendum Interim Digital Mammography Standards for Full Field Digital Mammography and CR Systems that outlines the service level quality control procedures and annual testing of equipment.

Although it is not the core business of the BSA Program or the NSU there appeared to be limited opportunities for research projects to be developed or undertaken in collaboration with local universities.

Summary

Although the BSA quality management framework and NP&QS are sound the implementation of the quality processes by the NSU are under considerable pressure and constraint. This is in the main because of the current fragmented NSU organisational structure for the BSA Program and the ongoing loss of key positions and staff. Without change it will become increasingly difficult and possibly unsustainable to continue to meet the requirements of the critical quality monitoring and auditing of the BSA Lead Providers or the national Program.

In the current NSU structure the quality management processes are fragmented across the few remaining BSA team members and the Quality and Equity team with neither having complete access to the full range of information required to monitor the quality of the services provided or have oversight and accountability for their performance outcomes. Without the Clinical Leader position as a radiologist and with the gradual loss of positions and the knowledge and skills in breast cancer screening from NSU the situation has become untenable. There is currently very limited capability to appropriately monitor the quality of the BSA Program within the NSU. The quality management processes that are in place are very resource intensive, in particular in relation to the collation of performance data. This is exacerbated by the high dependence on external providers to produce reports which serves to undermine further the recognition of the remaining staff with the appropriate skills and increase the costs.

Discussion

The BSA Program has a well developed quality framework as outlined in the Improving Quality document (2005) and NP&QS (2008) based on international evidence based standards. However, the Quality Framework states that it would be reviewed two years after publication to incorporate feedback based on local experience and new international evidence. The essential components of the quality framework are sound but may require some minor revision to ensure that the quality processes remain appropriate to the breast cancer screening pathway, in particular in the context of changes to digital technology.

In addition it would be useful to have a clear quality structure for the BSA Program so that the quality processes that underpin the Program are well managed and the levels of accountability known. A draft Quality Management System based on the BreastScreen Queensland Program is included at Appendix 4. This schema attempts to map the relationships and processes that underpin and are needed for the overall quality management of the breast cancer screening program. This system relies on the established BSQ State register (BSQR) that supports information driven quality management process to monitor performance measures across the screening pathway and places less weight on audit processes. The audit quality processes used currently

for BSA were initially modelled on the UK Program that does not have a true national register of data.

The current audit process for BSA has a stated dual purpose to monitor quality against the NP&QS and contracts. This has led to the need for extensive and expensive auditing visits and potentially with less focus on quality and more on compliance with contracts. This is certainly the perception of the Lead Providers and to some extent the staff in the NSU. This dual purpose audit process may not be desirable given the high level of quality required to effectively and efficiently provide breast cancer screening services to a the highest standard possible so that the BSA Program achieves its aims and importantly retains the confidence the community. This model of auditing it would appear is tied to the model of health service delivery operating in New Zealand. In some States of Australia BreastScreen services are similarly delivered under contract with either private or public sector providers but it is understood that quality monitoring is undertaken separately to contract compliance management. Although clearly if a contracted Service Provider did not meet the required standards of quality as assessed through routine performance monitoring or the accreditation process the contract could be discontinued. A refocusing on the importance of quality management to achieve high standards of breast cancer screening services would be appropriate.

A key part of the quality management process is the IMR that is used as part of the audit process and follow up. The nature of the IMR as a population based epidemiological report, as stated by the lead author, means that it should not be used for monitoring compliance with contracts. Instead the IMR should be used as an annual BSA report. It would then be the responsibility of the NSU BSA team to produce the six monthly performance measure reports for each Lead Provider against the quantitative performance measures. These reports could become part of a suite of nationally consistent reports to independently monitor the quality of the Lead Providers. An Important report would be reader quality assurance reports with non identified peer group data that are provided back to individual readers and the Clinical Directors who have responsibility for the reading quality in their service. Although service level performance reports can be generated out of the current multiple versions of the CIS the issues of duplication of women's records, the potential differences in the denominator and the constraints in interpreting the data where there may be small numbers at the Lead Provider level may lead to some inaccuracy in analysis of the information. There is also no single point of accountability for independent national oversight of this process undertaken at the Lead Provider level. This means that if there was a quality failure at the Lead Provider level not identified by the relevant Clinical Director or Lead Provider Manager this failure may not become apparent for some time.

A different approach to the current follow up of unmet NP&QS identified through the audit and/or IMR would be to more proactively monitor quality through the establishment of a routine cycle of six monthly performance reports. These reports would be

developed by the NSU BSA team provided to the Lead Providers for comment and presented to the CGG annually or more frequently if required to monitor the performance of a Lead Provider. This proactive approach would be more supportive of a continuous quality improvement approach and possibly reduce the need for visits to Lead Providers to discuss lists of CARs. The use of a CARs risk level for unmet NP&QS is also perhaps more suited to acute health services where a failure in quality or safety could cause immediate harm or death. Population based cancer screening programs are very unlikely to cause immediate harm but, as outlined earlier in this report, need to maximise benefits and minimise harm to prevent longer term harm of missed cancers or unnecessary interventional assessment procedures and unnecessary anxiety. The assumption in considering the implementation of this approach to quality management is that the NSU BSA team has the skill and capability to undertake this role and has access to the performance data from a central database ideally a national register. A subset of performance data such as participation rates for priority groups could be developed as needed to report on the BSA Program against planned strategies to evaluate their efficacy.

If there was a refocusing on quality management separate from contract compliance and an information driven approach there would need to be a review of the current contractual arrangements with IANZ. The number of audit team members may be able to be reduced and the time taken which would lessen the cost and burden on the Lead Providers. If the cost of the audit process was reduced this would provide a cost off set for the development of a national register and networked CIS. The other issues raised by the Lead Providers about audit team members should also be reviewed with the contractors.

In addition a more robust and transparent quality assurance process such as the National Accreditation process developed by BreastScreen Australia could be worth considering. The accreditation of providers is included in the BSA Quality Framework (2005) as a quality initiative. If the CGG was strengthened and new terms of reference agreed as outlined in recommendation eight there is the potential to establish an accreditation process for BSA. This would provide an opportunity for highly performing Lead Providers to be recognised publicly and for standardised processes to be developed for the quality management and continuous quality improvement of Lead Providers that needed to improve their standards. This accreditation process based on the assessment of all the relevant performance information by a group of independent experts could be perceived as being more transparent than the current processes. It could also be perceived as being somewhat more robust than the current audit follow up process that is largely self-regulatory and relies on the Lead Providers to make positive changes without any real leverage except withdrawal of their contract. The publication of summary accreditation /audit results could be a more effective stimulus for positive change although at all times the approach would be of continuous quality improvement and not punitive. This would need to be developed collaboratively with the Lead

Providers and relevant stakeholders and conform to the New Zealand Health Quality and Safety Commission guidelines and policies.

The key to a sound audit /accreditation process is that it is undertaken on a planned cycle at intervals that are regarded as relevant to managing a quality breast cancer screening program and the actual performance of the individual service providers. In the BreastScreen Australia National Accreditation process there are different levels of accreditation awarded to services according to their performance. An exemplary service would receive for example four years accreditation whereas a service that does not meet all the level one standards may be awarded two years with high priority recommendations. The performance measures for these high priority recommendations are then closely monitored with six monthly or annual reports by the State Accreditation Committee. The State Coordination Unit is then responsible for working with the Screening and Assessment Service (SAS) to develop an action plan to address any unmet measures. This can include visits to the SAS and a range of interventions covering technical or clinical audits. The outcome of the national accreditation process, that is the level of accreditation awarded to the individual service, is published on the BreastScreen Australia website.

As stated above the IMR, given the two yearly screening interval for breast cancer screening, may be more useful as a national report produced annually. Using the two year screening rounds of data would provide a more accurate view of the performance of the BSA Program and overcome some of the caveats in the current reports due to overlapping years or six month periods of data that may distort some measures. This also overcomes issues related to the accuracy and currency of population projection denominator data, for example the current report is based on 2002 estimated resident population data (ERPs) that may under or over estimate the eligible population. If the IMR process was changed the current contract with the University of NSW would need to be reviewed. It may be worth considering the review of the IMMR at the same time given the duplication of data in the two reports. This could provide further cost off sets to support the establishment of a different quality management system for the BSA underpinned by a national register.

A further efficiency and recognition of the importance of the technical quality required for breast cancer screening would be to consider centralising at a national level the technical quality assurance processes currently undertaken by the medical physicists engaged by each individual Lead Provider. This could lead to some economies of scale and cost efficiencies, recognise the increasing sub specialisation of breast imaging equipment quality control procedures and ensure consistency. In addition with the implementation of digital equipment and PACS some of the quality control can be undertaken remotely through web enabled software applications.

Although not necessarily the core business of the NSU or BSA collaborative relationships could be developed with local universities to make use of the wealth of

data produced by BSA and facilitate a range of research projects that would be of mutual benefit to the researchers and the Program. A structured mechanism would need to be put in place to ensure that the research was appropriate and to provide ethical access to the BSA data. This could be a multidisciplinary sub-committee to the BSA Advisory Group.

Recommendation

10. It is recommended that the NSU review the Quality Framework and develop a sustainable, effective BSA Quality Management System, in consultation with the BSA Clinical Directors and Lead Provider Managers, to ensure a strong focus on quality improvement in achieving the aims and objectives of the BSA Program. In particular consideration of the following;

- i. Review the current audit approach to clearly separate quality assurance and improvement processes, that are focused on population screening and linked to the desired outcomes of the BSA Program and provision of “high quality, equitable and accessible national breast cancer screening”, from BSA service contract compliance.
- ii. Consideration could be given to establishing an accreditation process for the BSA Services, adapted from the Quality Improvement Program and accreditation model used by BreastScreen Australia, under the auspices of the strengthened Clinical Governance Group (see recommendation 8).
- iii. Review the contractual arrangements with International Accreditation New Zealand (IANZ) to assess the cost efficiency and effectiveness of this arrangement and the number and use of specialist auditors.
- iv. Realign performance monitoring from compliance to a collaborative quality improvement approach with Clinical Directors and Lead Provider Managers incorporating standardised six monthly comparative performance monitoring reports for each BSA Lead Provider, BSA Lead Provider feedback and assessment, specific quality assurance reader reports for radiologists and participation of priority groups based on data from the national register.
- v. Review the audit cycle to ensure that a full audit or accreditation site visit is conducted of each BSA Lead Provider every two years unless the performance of the BSA Lead Provider is exemplary in which case a recommendation may suggest a three or four year reassessment for accreditation.
- vi. BSA Service visits by relevant staff in the NSU would be undertaken on an as needs basis to review BSA Service performance and assist in addressing quality issues.

- vii. Review the current arrangements for the BSA Independent Monitoring Report and the BSA Independent Maori Monitoring Report with the view to combining the two reports and undertaking the work within the NSU with external reviewers or entering into a collaborative arrangement with a local university group with the relevant expertise.
- viii. Assess the possible use of national level technical quality assurance processes for breast imaging equipment in terms of potential efficiency, consistency and cost savings in the digital environment.
- ix. Establishment of a collaborative partnership with a local university to promote joint research projects for post graduate students or research groups using the BSA data to develop local knowledge and skills in cancer screening programs in particular in the disciplines of behavioural science, epidemiology and biostatistics.

BSA sector relationships with Lead Providers and Clinical Directors

Initially Standards New Zealand, on behalf of the MOH, facilitated the development of the NP&QS. The process was moved to the NSU that was established in 2001 along with a dedicated BSA team that was subsequently responsible for developing the NP&QS as a collaborative effort with the BSA Lead Providers, the Independent Service Providers (ISPs), key stakeholders and consumers. The stated intention of the Quality Framework was to “shape the culture of the New Zealand Screening Programmes. The programmes include: the National Screening Unit, Providers of services to the national screening programmes, and the eligible populations the programmes intend to serve” (BSA, NP&QS). The NP&QS also states that “The National Screening Unit, in its leadership role, wishes to share its quality and purpose, vision and language and foster a culture within the screening programmes of:

- Working together as ‘one programme’
- Striving for excellence in a collaborative, learning environment
- Encouraging clarity of accountability for quality
- Managing quality through a ‘systems approach’
- Enhancing coordination of quality improvement activities.”

These important key statements were agreed during the review process of the NP&QS in 2008 and underline the expectations of the collaborative group, identified above, involved in that review process. The roles and responsibilities of the NSU for the BSA Program were also clearly identified as:

- “national management and oversight of BreastScreen Aotearoa
- Funding of BreastScreen Aotearoa Providers
- national coordination of Providers

- national health promotion activities (including development of standardised resources and national promotions)
- national strategy and policy development
- national monitoring, evaluation and audit”

Based on the information gained from interviews with groups and individuals it would appear that these expectations of collaboration and leadership from the NSU for BSA are not currently being met. As outlined earlier in this report the NSU and particularly the BSA team have been subject to major changes since 2007, including both external and internal reorganisations and loss of key positions and staff. These major changes included a shift from a dedicated BSA team in the 2007 internal reorganisation to fragment core roles and responsibilities for the quality monitoring of BSA to a generic Quality and Equity team within the NSU. This splitting of roles and responsibilities away from a dedicated BSA team has no doubt contributed to the current difficulties in the relationship of the NSU with the Lead Providers as there is no single point of accountability for the BSA Program in the NSU. At the time of this change the leadership of the remaining staff in the BSA team and subsequently the position of the BSA Clinical Leader were downgraded in the NSU structure, which in part precipitated her leaving this role in the NSU in 2009. These changes along with a perceived negative organisational culture, that is covered in the complementary report to this document, in time lead to a significant loss of key BSA staff with the knowledge and experience of breast cancer screening.

The major concerns expressed consistently by the Lead Provider Managers and the Clinical Directors included the perceived lack of expertise in the NSU about the BSA Program, frustration with the NSU in decision making processes related to audit reports and review of some of the NP&QS and in particular the communication style of the NSU senior management. All of these concerns suggest a breakdown in the relationship between the NSU and the Lead Providers from what was envisaged as a collaborative ‘working together’ as ‘one programme’ to a culture more akin to ‘them’ and ‘us’. The relationship seems to have drifted from the original intent partly due to the changes outlined previously and partly due to the direction given by the executive management for the Directorate to focus on performance monitoring and contract compliance in line with MOH directives. This shift was perceived by the Lead Providers as undermining the quality of the BSA Program and as a lack of recognition of the importance of the BSA and its contribution to saving New Zealand women from dying from breast cancer. The Clinical Directors particularly held the view that the loss of the BSA Clinical Leader in the NSU potentially damaged the reputation of the BSA Program and lessened the overall clinical leadership within the MOH.

The other major concern was the expressed view from the Lead Provider Managers and the Clinical Directors that their expertise was not being used to advise the NSU. They felt the reduction in meetings and the approach taken at the meetings by NSU senior

management was dismissive of their views and ideas for BSA. It was clear from the meetings with these groups that although they may have been consulted about the CIS Upgrade Project and the centralised PACS they did not seem engaged. The groups in general expressed support for the projects but did not have very much knowledge of the project plans, service impacts or possible business process changes or the potential benefits.

Summary

As outlined previously in this report this review was prompted in the main because of concerns expressed by the Lead Providers, in particular the Clinical Directors about the current administration of the BSA Program by the NSU. The information gained from these groups supported their concerns about the current capability of the NSU to provide leadership for the BSA and to support the Lead Providers in the delivery of quality breast cancer screening in New Zealand. They contrasted the current relationship with the NSU with their prior experience and expectations of a collaborative working relationship.

It is clear that important and immediate change to the current arrangements in the NSU are needed to ensure that a dedicated BSA team is re-established with a Program Director that provides strategic leadership and undertakes the functions required to coordinate this important national breast cancer screening program. It will be critical that there are clear roles and responsibilities for the BSA team in the NSU. More importantly it is essential that the relationship of the NSU with the Lead Providers returns to a collaborative approach that is critical in sustaining an organised national breast cancer screening program for the future.

Discussion

At present the Clinical Directors' uni-disciplinary group combines twice a year with the Lead Provider Managers' group. This combined group effectively brings together the BSA operational expertise and service level leadership. This BSA Service Management Group could be the key to developing an improved working relationship with the NSU to share the management of the BSA in a collaborative way. The focus of the meetings would be a two way exchange of information about issues impacting on the BSA, sharing ideas, for example about the strategies that are working to recruit women and retain them in the BSA Program, workforce development, implementing operational policies and protocols, service planning and quality assurance. The meeting should be chaired by the BSA Program Director in a leadership role with an agenda based on feedback from all the Lead Providers. The re-established dedicated BSA team would organise the meetings and provide the secretariat. The agenda may include emerging issues, actions that the NSU were tasked to undertake such as research and analysis for a policy or standards review or a range of standing items. These discussions should inform the development of the annual workplan for the BSA team in the NSU.

The operating principles of the group would enable the establishment of time limited working groups focused on specific issues or projects. The current Quality and Risk Management group could be an example of a time limited working group. In the future this Service Management Group could play a critical role for consultation, feedback and discussion for the transition to digital technology, a central PACS, upgrade to the CIS and potential national register.

This Group would be the mechanism to communicate significant changes in the MOH environment or opportunities for collaboration with other sections of the MOH. The two way communication could include information from the Lead Providers about their local environment and impacts on service delivery. The clear example for the later would be the various short and long term impacts of the earthquakes in Christchurch on the BSA in that area. There may also be BSA operational management or quality and safety issues that need to be escalated in the MOH that the NSU could progress. An example at present is the difficulty being experienced by several Lead Providers in securing the capital investment required to transition to digital technology in the constrained funding environment and competing demands of the District Health Boards. As suggested previously, facilitating a bulk tender arrangement may assist in this process through a collaborative effort coordinated by the NSU with a time limited working group of the relevant discipline representatives from Lead Providers with some co-opted technical expertise from the medical physicists. This process would clearly need to be undertaken within the purchasing framework of the MOH and with the relevant organisational area with this responsibility so would require the NSU to facilitate the process.

Issues of a clinical or non clinical nature may also be identified that need referral to one of the UDGs or to the BSA Advisory Group. There may be a requirement for the BSA team to undertake a data extract or review the literature to support such a referral and action. An example of such an issue was the response to the promotion of non evidence based breast imaging, in particular thermography. The BSA Lead Providers stated that although this issue was managed by the NSU they expressed their concern that they were not involved or informed.

Given the fractured nature of the relationships with the BSA Program between the NSU and the Lead Providers it would be desirable to have a nominated and appropriate member of the dedicated BSA team to provide service support. This staff member would be the conduit to the rest of the BSA team for referral as appropriate any enquires outside their expertise. It would be important that this person provide an informed single point of contact for the Lead Providers and it would be the expectation that they had significant knowledge and experience working in the BSA Program. The primary focus of the role would be to answer enquires about the NP&QS, audit processes or to communicate and seek advice on issues that may impact on the national Program such as workforce constraints for radiographers and radiologists. The

establishment of this role in the NSU along with a strengthened engagement with the Lead Provider Managers and Clinical Directors through the BSA Service Management Group meetings should begin to re create the collaborative approach needed for BSA to effectively achieve its aims.

Recommendation

11. It is recommended that the Clinical Directors and Lead Provider Managers meet jointly at two face to face meetings a year, to work collaboratively with the NSU to deliver a safe, effective and equitable BSA Program and high quality breast cancer screening services including the following roles and responsibilities:
 - i. To function as a clinical and management network for the BSA Services to provide business advice on policy, practice and operational management issues including issues of mutual interest or concern and input as appropriate to the annual workplan for the NSU.
 - ii. To establish time limited working groups for specific priority projects such as the Quality and Risk Management Group or for example in the areas of capacity and workforce planning for the BSA Program, the transition to digital technology and central PACS.
 - iii. To provide a conduit for communication of broader MOH developments and wider government activities affecting the BSA Program including the Lead Provider environments.
 - iv. To provide advice to the NSU on operational matters that impact on the safety, effectiveness, quality and equity of breast cancer screening services and refer specific issues to the relevant UDG or the BSA Advisory Group.
 - v. The NSU will identify a BSA Service support staff member of the BSA Program team who will have the role of liaison with Lead Providers and /or Clinical Directors to address enquiries on the NP&QS or operational policy and referral to the relevant staff in the BSA Team as needed. This would not include contract enquiries that would be directed to the Business Performance Manager.

Transition Plan

This report attempts to set a future direction for the NSU that will build on the sound work undertaken initially, during the formative years of the BSA Program and more recently to initiate major projects such as the BSA Upgrade Project and the centralised PACS. While it is clear from the findings of this review of the BSA Program that there are some current challenges there are also some clear opportunities to work in partnership with the BSA Lead Providers to ensure that the success of the BSA Program to date is sustainable and of a high quality. The recommendations proposed in this report aim to make changes that will support the NSU to effectively and efficiently

function as the national coordination unit for the BSA Program as one of the population cancer screening programs. These changes are consistent with the critical requirements of an organised population screening program for breast cancer that is focused on ensuring high quality standards for every aspect of the program. The best way to ensure that the BSA Program is beneficial and minimises the risks from screening is for the program to be properly organised and monitored. The key to this outcome being achieved and sustained over time is that a dedicated team for BSA to be re-established and the NSU to be reinvigorated and recognised as providing national leadership in cancer screening with sufficient staff resources to undertake these functions.

Any changes resulting from the report recommendations will require careful planning and are likely to extend over at least a three to five year period. There are also likely to be a range of sensitivities in any change process given the immediate past history of almost continuous change and uncertainty for staff in the NSU.

It is suggested that an implementation plan for agreed recommendations be developed as a collaborative effort in consultation with the NSU and the Lead Providers as a first step in developing a partnership approach to the management of the Program.

It is suggested that a multidisciplinary advisory team be established to assist in the development of an implementation plan that includes individuals with an understanding of public health and in particular population screening to bring knowledge and expertise to the team along with individuals that have knowledge of clinical governance, clinical information systems and strategic planning. Given the nature of some of the changes recommended it would be important to have included in such a team, individuals with a background in organisational change management and human resource management.

In re-establishing a dedicated BSA team in the NSU the critical first step will be establishing the position of BSA Program Director. It is unlikely that there will be a strong pool of applicants with a good knowledge and experience in the BSA but there may be applicants with the requisite strategic leadership and management skills to be mentored into the role. A mentoring arrangement with an individual with experience and knowledge in population screening particularly breast cancer screening may be a means of assisting in the development of the role and supporting the individual through a period of change.

It is envisaged that this team would assist in the transition process for the NSU and provide an oversight of the implementation plan once it was agreed. The team may only be required to meet initially and then infrequently for a time limited period and could potentially function as a virtual team with periodic teleconferences or reporting as appropriate to the relevant MOH executive.

Recommendation

12. It is recommended that an independent advisory team assist in the development of a three year implementation plan in consultation with the NSU and the BSA Lead Providers to implement MOH endorsed recommendations. It is further suggested that;
- i. This advisory team be comprised of individuals independent of the NSU that have expertise in the following; population screening, organisational change, human resource management, clinical governance and leadership, strategic planning, clinical information systems and public health program development and implementation.
 - ii. The advisory team would assist the NSU to transition and provide oversight of the implementation plan in particular the consultation and communication with the BSA Lead Providers.
 - iii. Mentoring support be provided to the NSU leadership in particular the BSA Program Director through the transition process.
 - iv. The advisory team provide regular reports to the MOH executive and Minister as required.

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Appendix 1

Investigation into concerns raised by BreastScreen Aotearoa (BSA)

Clinical Directors

Terms of Reference

Purpose of the review

The purpose of the review is to investigate the concerns raised by Dr Sally Urry (on behalf of the BSA Clinical Directors) in her 28 January 2011 letter to the Minister of Health, Tony Ryall (with copies to the Associate Minister, Tariana Turia, and the National Director of the National Health Board Business Unit, Chai Chuah), and subsequent telephone conversation with the Director General of Health, Kevin Woods.

Approach

The review will be led by an appropriately qualified individual external to, and independent of, the National Screening Unit (NSU) who will report to the Acting Director, National Services Purchasing. The individual will be tasked with compiling a report that will address the key questions identified in this terms of reference and make recommendations for action as appropriate.

The review will not include other screening programmes managed by the NSU beyond the BSA programme.

Concerns Raised

The concerns raised by Dr Urry include:

- The number of resignations of staff in key positions since 2009, and the risk to BSA
- The length of time taken to recruit a new BSA Clinical Leader, and that the new appointee will be part time and on a short term contract only.
- Clinical developments within BSA have been on hold while the BSA Clinical Leader role was vacant
- The directive management culture within the NSU and lack of support for clinicians

- The use of the job title 'Performance Management Analyst' and reports from some Lead Provider Managers that they feel micro-managed
- The timeframes and process for the implementation of a centralised Picture Archiving Communication System (PACS) and single version of Concerto Breast Screen (cBS) software

Context

The NSU was established in 2001 to deliver safe, effective and equitable breast and cervical cancer screening programmes. The NSU now manages five national screening programmes, including BSA, and one quality improvement initiative. BSA provides free biennial mammography and any necessary follow-up tests, up to the point of breast cancer diagnosis, to eligible women aged 45 to 69 years. The BSA programme was established nationally in December 1998 and originally covered women aged between 50 and 64 years. Expansion to the current age range occurred in July 2004.

The NSU and wider Ministry have undergone significant change management processes since 2007. In 2009 the NSU underwent an internal restructure which sought to ensure that there was clarity regarding accountabilities, and that the NSU was equipped to deliver on its objectives and wider Ministry requirements. As a result of this restructure the Quality & Equity team was established to focus on monitoring and evaluation, and a Clinical Governance Group was established to focus on clinical governance.

Proposed scope for the review

It is proposed that the scope of the review will include the two-year period to December 2010 and will have six main areas of focus as listed below.

1. The concerns raised by Dr Urry as above;
2. The changes that have occurred in the Ministry of Health and the National Screening Unit (NSU) since 2008, the impact of these changes, the mitigation actions undertaken by the NSU, and whether there are any outstanding issues resulting from these changes;
3. The processes and procedures in place for ensuring the clinical safety and quality of the BSA Programme, including the project to implement a centralised PACS;
4. The relationships and processes in place for engagement between the NSU and the BSA Lead Providers and Clinical Directors.
5. Overview of progress made on the BSA programme since 2009
6. The level of clinical support required at NSU senior management level

Key questions the review will address

BSA resourcing

- What process is used in the development of the BSA workplan?
- Does the BSA team have sufficient resources to deliver on its work programme and its wider leadership and co-ordination functions?
- Is the NSU, as a part of the Ministry, well placed to meet current and future challenges?
- Has the programme been able to meet the workplan deliverables?

Staff retention and HR policies and practices

- Has there been an issue with staff retention and recruitment in the BSA and Quality & Equity teams? If so, why?
- Do the Ministry HR policies and processes impact on staff retention and recruitment?
- What HR impacts have there been in the last two years that were caused by Ministry of Health restructuring, recruitment freezes, and NSU restructuring?
- What process was followed to recruit a new BSA Clinical Leader (including timeframes, people involved in selection, and conditions of employment)?
- What do staff feel supports them in their roles? What other supports would staff welcome?

Implementation of a Centralised PACS and one consistent version of BSA software across all providers

- What processes were followed to facilitate engagement in the project to implement a centralised PACS and a single version of Concerto BreastScreen software?
- What activities have been undertaken to progress a centralised PACS?

BSA Quality Frameworks

- What policies and processes (including monitoring, audit and clinical governance, clinical expertise and input), are in place to manage clinical quality and safety across the BSA programme?
- Are clinical risks appropriately identified, monitored and addressed?
- With the challenges of securing clinical leadership within the NSU, what strategies have been put in place to address this?

BSA sector relationships

- What processes and procedures are in place to manage relationships between the NSU and BSA Lead Provider Managers and Clinical Directors?
- What structural changes have occurred and how have they impacted the NSU's ability to establish wider engagement and increase capacity and capability as part of ensuring the progress of the BSA programme?

Out of Scope

The review is primarily focused on the BSA and Quality & Equity teams and will not include a detailed review of the other screening programmes managed by the NSU beyond the BSA Programme.

Deliverable

The reviewer will produce a report that addresses the key questions listed above. In the report the reviewer will provide an objective view on these questions and will make recommendations for actions to address any concerns.

In completing the report the reviewer will:

- Undertake interviews with the NSU Group Manager, members of the National Services Purchasing Group Leadership Team, the Chair of NSU Clinical Governance Group, members of the NSU Senior Management Team, the former Director National Services Purchasing (Geraldine Woods), the Personal Assistant to the Group Manager NSU (Anne Batten-Thomas), relevant staff in the BSA and Quality & Equity teams, and other staff in the NSU as appropriate
- Undertake interviews with relevant clinical and management staff from BSA Lead Providers, including Clinical Directors and Lead Provider Managers
- Review relevant NSU and BSA documentation including policies and procedures
- Make comparisons with other comparable national screening programmes, specifically BreastScreen Australia

Timeframes

The review will be completed within 7 weeks of agreeing a start date with the selected reviewer as shown in the table below.

Milestone	Timeframe (shown in weeks from start date)
Individual selected to complete review	0
Draft report will be provided to the Acting Director National Services Purchasing	5 weeks
Feedback provided by the Acting Director National Services Purchasing to the reviewer	6 weeks
Final report submitted to the Acting Director National Services Purchasing	7 weeks

Appendix 2

List of groups of individuals interviewed

National Screening Unit Senior Management Team

Lead Provider Managers BreastScreen Aotearoa Program

Clinical Directors BreastScreen Aotearoa Program

BreastScreen Aotearoa Advisory Group members

National Screening Unit Clinical Governance Group

BreastScreen Aotearoa Program team members

National Cervical Screening Program team members

National Screening Unit, Quality and Equity team members

National Screening Unit, Information Services team members,

National Screening Unit, Former staff members (resigned or retired),

Ministry of Health

GSL Network

Former organisational consultant to National Screening Unit

National Health Board Business Unit

ERU Pomare Centre, University of Otago, Wellington

Professor of Public and International Health, University of New South Wales

BreastScreen South Limited team members

BreastScreen Counties Manukau team members

Chair Surgeons Unidisciplinary Group, BreastScreen Aotearoa Program

Acting Chief Medical Officer

Sector Capability and Implementation, Cancer Control Program

BreastScreen Aotearoa Radiologists

Appendix 3

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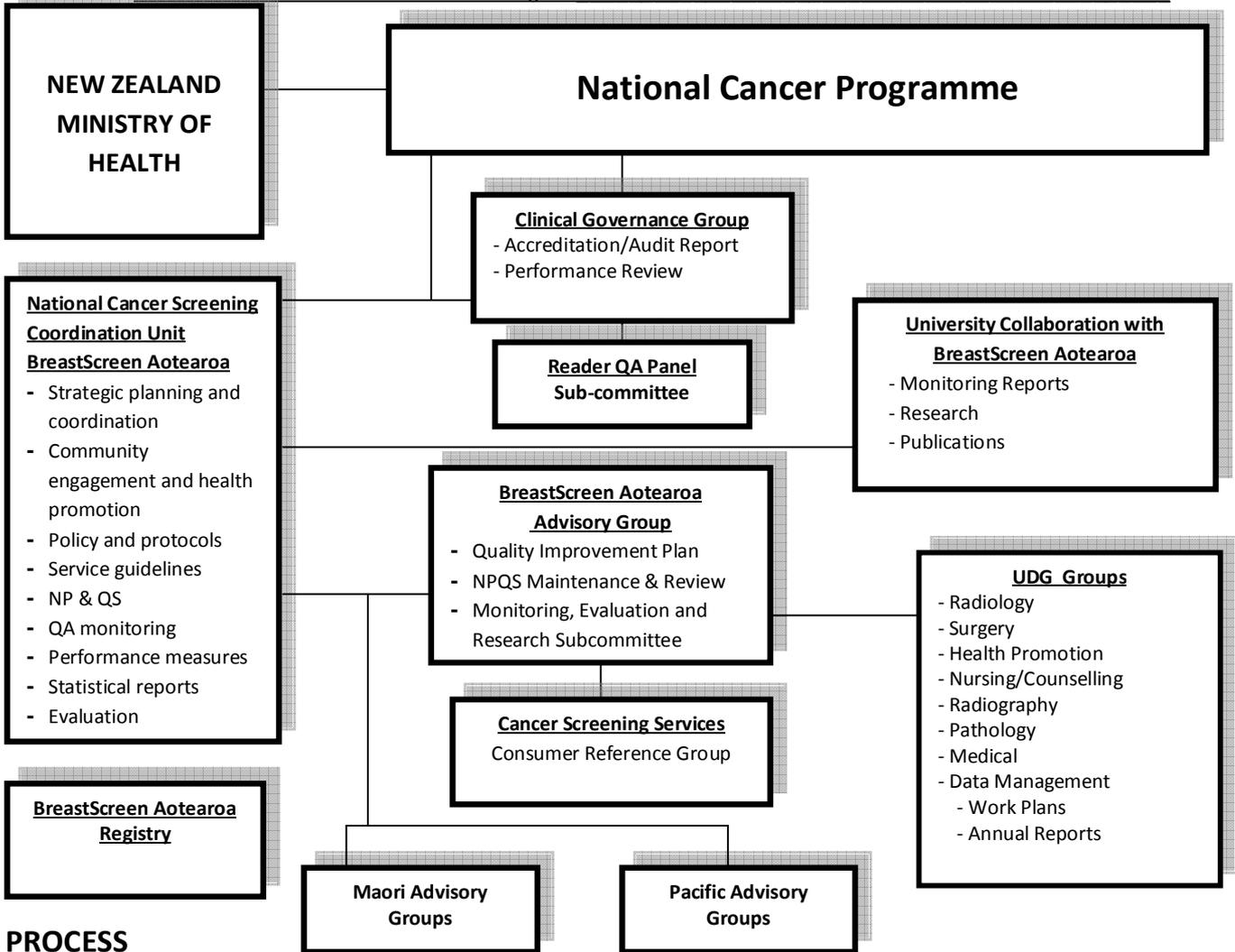
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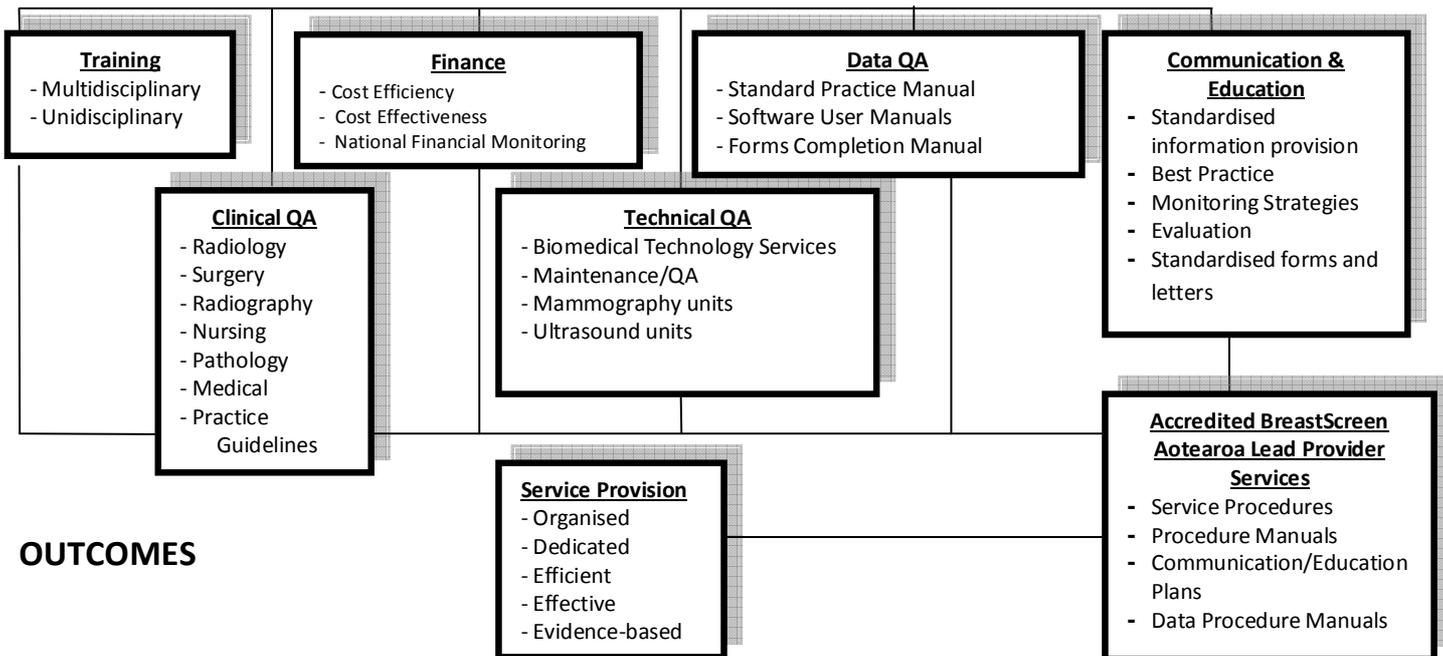
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Review of the BreastScreen Aotearoa Program



PROCESS



OUTCOMES

