

**NATIONAL SCREENING UNIT,
MINISTRY OF HEALTH**

**INDEPENDENT EVALUATION OF THE
IMPLEMENTATION OF DIGITAL MAMMOGRAPHY AT
BREAST SCREEN WAITEMATA AND NORTHLAND**

Health Outcomes International
4 Rose Rd, Ponsonby, Auckland
(PO Box 41-505 St Lukes, Auckland)
Ph 09 376 6733 Fax 09 378 6149
email: julian@hoi.co.nz
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GLOSSARY

ACPSEM	Australasian College of Physical Scientists and Engineers in Medicine
BSA	Breast Screen Aotearoa
BSAN	Breast Screen Auckland and Northland (the predecessor Lead Provider to BSWN)
BSWN	Breast Screen Waitemata and Northland
CAD	Computer-aided detection and diagnosis
CCS	Cancer Control Strategy (Ministry of Health, 2003)
CMDHB	Counties Manukau District Health Board
CR	Computed Radiography
DICOM	Digital Imaging Communication of Medicine standard
DM	Digital Mammography
DMIST	Digital Mammographic Screening Trial (ongoing clinical trial of DM coordinated by the American College of Radiology)
DWG	Digital Working Group (established to oversee the scoping and selection of DM and PACS equipment as part of the BSWN implementation project)
DR	Digital Radiography
FDA	Food and Drug Administration (United States)
FFDM	Full-Field Digital Mammography
FSM	Film-Screen Mammography
HIS-NZ	Health Information Strategy for New Zealand
ICT	Information and Communications Technology
ISP	Independent Service Provider (Māori and Pacific organisations contracted to the NSU to provide health promotion and recruitment activities to support BSA)
MDT	Multi-disciplinary team
MRT	Medical Radiation Technologist (or Radiographer)

NDHB	Northland District Health Board
NP&QS	National Policy and Quality Standards for BSA (NSU, 2004)
NSAC	National Screening Advisory Committee
NSU	National Screening Unit
PACS	Picture Archiving and Communications System (See Appendix C)
PROBE	Provincial Broadband Extension Project (a multi-agency initiative to make broadband services more widespread throughout New Zealand)
QUDI	Quality Use of Diagnostic Imaging programme (a RANZCR programme focusing on implementing evidence into practice in radiology)
RANZCR	Royal Australian and New Zealand College of Radiologists
RIS	Radiology Information System (See Appendix C)
SBS	Soprano Breast Screening System
WDHB	Waitemata District Health Board



EXECUTIVE SUMMARY

The National Screening Unit (NSU) engaged Health Outcomes International Pty Ltd (HOI) to conduct an independent evaluation of the implementation of digital mammography (DM) at Breast Screen Waitemata and Northland (BSWN). The overarching purpose of the evaluation was to assist the NSU to consider options for the managed introduction of DM into the BreastScreen Aotearoa (BSA) screening programme, and any implications for national policy and quality standards that this introduction may have.

DM is the next step in the evolution of mammography technique and will gradually replace film-screen mammography (FSM). The BSA Age Extension Project showed the need for a significant increase in the BSA screening capacity and exposed the problem of a shortage of the radiologist and medical radiation technologist (MRT) workforce needed to support the increase. Both of these health professional groups are experiencing a global workforce shortage. The NSU is looking to DM as one potential avenue to increase screening capacity and mitigate workforce shortages.

BSWN was the first BSA Lead Provider to use Full Field DM (FFDM). The NSU needs to consider options for the managed introduction of DM into the BSA programme. Accordingly, an evaluation was undertaken covering the process that led to BSWN's decision to implement DM, and the initial impact and cost implications of DM on any changes to service delivery.

The evaluation methods included the collection and analysis of documentation and data from BSWN and the NSU, interviews with key people who were involved in the establishment of DM at BSWN, observation of facilities and processes at BSWN, and a consumer satisfaction survey.

E.1 FINDINGS

E.1.1 DECISION MAKING AND IMPLEMENTATION PROCESSES

BSWN took a structured and staged approach to decision making and implementation of DM, which occurred as part of the overall implementation of BSWN as a new Lead Provider. Decision making and project management processes for DM at BSWN were reported to be robust and have resulted in the implementation of an effective and efficient breast screening service.

The decision to go digital was made in a number of stages, including in-principle agreement within the two DHBs (WDHB & NDHB) that the new breast screening sites should be established with DM, DHB approval of a revised business case based on digital technology, National Capital Committee approval of proposed financing for digital equipment, and the final BSWN decision to order DM equipment.

Because there was a deadline for making the decision, risk management was a key consideration, and stringent risk management processes were put in place. Right up until the point that the contract was signed for the Picture Archiving and Communications System (PACS), BSWN kept open the option of not proceeding with DM but rather reverting to a FSM decision.

To inform decision making processes and DM implementation, a Digital Working Group (DWG), a team of clinical and other experts, was established to evaluate overseas literature, presentations

from vendors, and overseas site visits. This group made recommendations to management during all steps and stages of the decision making process. This group made a significant investment of time to research, plan and implement the digital workflow. This time investment, together with the mix of individuals on the DWG, were seen as critical success factors for implementation.

Key considerations in deciding whether to go digital at BSWN included the planned service configuration (two assessment centres working together as one team), the challenge of recruiting and retaining key staff, the capital and operating costs of the various options, the capacity of each option to maximise resources (equipment and human), and the geography of the region (large rural areas with some women having to travel long distances to be screened).

In summary, BSWN believed that the implementation of DM at BSWN was justified because:

- Digital radiology was being systematically introduced into mammography worldwide (including breast screening programmes), and was considered to be the way screening mammography was heading. Both international and local contributors to the planning process recommended that any service setting up in a green fields manner at that time would be sensible to start off with DM equipment;
- DM was in line with the existing Waitemata District Health Board (WDHB) radiology environment, which was by this stage fully digital both in terms of staff expertise and IT infrastructure, and the strategic direction of the radiology service at Northland DHB (NDHB);
- BSWN had an experienced and skilled implementation team and support team of clinicians, MRTs, IT technicians and Project Managers to manage risks at all stages of implementation;
- DM offered a number of benefits over FSM for the BSWN service in terms of its configuration, geography and requirement to attract new staff to a new service; and
- It was considered potentially financially unsound to invest in new FSM equipment (including mammography machines and all related processing equipment) and facilities to support FSM when this technology was likely to become redundant well before the end of its expected life.

It was also recognised that by going digital, there would be a range of subsequent benefits to the BSA programme overall and to individual Lead Providers when they eventually make the decision to convert to DM.

DM machines and PACS were procured through an open tender process which invited vendors to bid for the supply of either the full suite of technology required or individual components. Short-listed vendors were invited to make formal presentations to the DWG, provide additional follow-up information as required, and to nominate international screening sites where DWG members could observe the equipment in operation and interview local screening staff. Selection of equipment was assisted through the use of specific evaluation criteria which are detailed within this report (section 4.5 and Appendix D). A key issue in the tendering process was the requirement for the various components of the DM screening environment to be fully compatible and work seamlessly.

UNIQUE CIRCUMSTANCES OF BSWN

BSWN experienced a range of challenges during the planning and implementation of DM. Many of these issues were directly related to being the first Lead Provider to adopt new technology and having a very short timeframe in which to make decisions, plan, purchase, implement and train staff in the new DM environment. Other Lead Providers will benefit from the progress that has been made in these issues in the two years since. For example:

- At the time of implementing DM at BSWN, quality standards had not yet been developed for DM in Australia or New Zealand. The NSU required BSWN to implement the digital

standards mandated by the Food and Drug Administration (FDA) in the United States. BSWN initially had to develop its own protocols from these standards. The NSU has now issued *Interim Digital Mammography Standards for FFDM and CR Systems (2007)* as an addendum to the National Policy and Quality Standards. Now that these standards are in place, they will serve to provide more direction to other Lead Providers and simplify the transition to DM.

- As the implementation of DM at BSWN pre-dated the development of national DM policy, it was necessary for BSWN to negotiate what the training requirements would be and lead the development of training packages.
- As the NSU had not yet made a decision to implement DM nationally, DM was implemented at BSWN without formal support or funding from the NSU (the NSU did fund the development of an interface between the PACS and Soprano Breast Screening (SBS) database). WDHB management were cognisant of the risks of proceeding without the support of the NSU and factored this into decision making.
- As BSWN was the first Lead Provider to go digital, none of the potential vendors had established, robust support in New Zealand prior to implementation. BSWN initially encountered issues related to planning and installation processes, and issues of limited access to technical support. Other Lead Providers stand to benefit from the improvements that have taken place.

As a green field development, the implementation of DM at BSWN differed in important ways from the processes that other Lead Providers may follow as they transition to DM. In particular:

- Decision making at BSWN focused on considering the relative costs and benefits of DM and FSM rather than a transition from FSM to DM. A decision needed to be made whether to develop all facilities and processes to accommodate FSM or to design everything from the outset for DM. Mammography equipment has a life of approximately eight years, and hence had the decision been made to install FSM equipment, it was unlikely that a business case could have been made for changing to DM for another eight years.
- The implementation of DM was just one of a number of inter-related sub-projects within the overall BSWN implementation project. In addition to decision making and implementation of DM, parallel processes were under way with regard to facilities, staff recruitment and training, development of operational systems and processes, and other aspects of service development. In one sense this was advantageous as it provided the opportunity to develop a comprehensive DM-based service model from the outset. However, it also increased the complexity of the decision making and implementation processes.

E.1.2 IMPACTS OF DIGITAL MAMMOGRAPHY

DM screening processes differ from FSM processes in a number of ways. Key differences at BSWN include:

- There is greater automation of the screening work flow through the PACS worklist system, including tracking of each woman through the screening process from arrival at reception through to the final screening/assessment outcome, the linking of images and data for electronic storage and retrieval, and the assigning of studies to workstations/users. The processes implemented at BSWN take work flow automation further than the systems observed overseas by BSWN representatives, through the linking of the SBS Radiology Information System (RIS) and PACS. Without this link, the full potential benefits of DM are not realised.
- Prior film images collected from previous screening rounds and/or film-based screening sites are digitised for women attending DM screening and for women recalled to assessment.

- The registration form recording demographic, interview and screening details is scanned into the PACS and stored electronically with the woman's images and electronic data.
- The use of a sub-waiting room, where the woman changes before entering the x-ray room, provides the opportunity to increase work flow per machine by making more efficient use of the x-ray room. Data entry can be completed at a quality assurance (QA) workstation in a separate room, allowing the next examination to commence (with a different MRT) immediately. This work flow enables the Takapuna site to operate three screening schedules across two x-ray rooms.
- The MRT remains in the room with the woman throughout the examination. MRTs are able to QA each image as it is taken, and take any repeat views if needed due to movement or image artefacts. The woman is able to leave immediately upon completion, with less likelihood of a technical recall for repeat views.¹
- There is no film processing involved, no darkroom/processing room required, and no chemical handling or storage.
- After leaving the x-ray room, the MRT completes QA at the QA workstation. 'Hanging' of digital images is performed automatically by the PACS using programmed hanging protocols and is checked/corrected by the MRT during QA. The images are then immediately available for retrieval at any reading workstation with no manual hanging of films required.
- Images are accessed electronically by reading and assessment radiologists and can be prioritised and read in any order. Reading can be shared between radiologists working at different sites. Radiologists are able to 'double read' remotely.
- Electronic images can be sent to treatment providers. Hard copy images are laser printed if needed for other radiology or treatment providers.
- Multi-disciplinary team (MDT) meetings are more sophisticated, using digital technology including videoconferencing with remote sites.
- DM screening technologies and processes are continually evolving, and BSWN is investigating and implementing refinements to its screening processes on an ongoing basis.

As BSWN is not fully digital (FSM is still used by sub-contracted providers and for the mobile unit which collectively perform 30% of BSWN's mammograms), the full benefits of DM are yet to be realised.

WORKFORCE IMPACTS

With regard to workforce utilisation, BSWN has advised the workforce costs associated with providing a DM service have not, to date, differed significantly from those associated with a FSM service. In summary:

- MRTs: BSWN has found that the MRT staffing complement for DM is equivalent to that of a FSM environment. The DM workflow enables MRTs to work three screening schedules across two x-ray rooms, which increases screening volumes per machine but not per MRT.² Future IT enhancements improving the integration of the RIS with the acquisition workstation are expected to improve throughput per MRT.

¹ BSWN data for women screened between 1 February 2006 and 1 February 2008 shows a technical recall (TR) rate of 0.07% for digital, 0.10% for fixed film and 2.15% for mobile film.

² Comparison of MRT throughput in digital and analogue screening sites at BSWN during one week in February 2008 found that an average 3.35 screens per MRT-hour were completed at the Takapuna digital site (across two machines), compared to 3.0 screens per MRT-hour at the Waitakere digital site (one machine) and 2.95 screens per MRT-hour for analogue sites (one machine each site).

- Radiologists: Overall, BSWN has found that radiologist FTE requirements for DM are equivalent to those in a FSM environment. BSWN does not foresee any significant reduction in radiologist FTE. Reading times for DM are slower, especially at the start.³ However, this has not affected costs as radiologists are either paid per read or in some cases salaried.
- Imaging assistants: There is a transitional period of two years following conversion to digital, during which prior analogue films need to be retrieved from storage and digitised. BSWN has found that the FTE complement of imaging assistants during this period is roughly equivalent to that of FSM. A slight reduction in imaging assistant FTE is anticipated beyond the two-year mark.
- IT support: Additional IT support is needed in a DM environment, reflecting the increased use of IT in the screening work flow. This includes the new role of a PACS Administrator. Excellent IT support has contributed significantly to the success of DM at BSWN by developing and implementing solutions to problems such as network speed issues.
- Physicist: More intensive medical physicist support is needed both during implementation and in the first few years of DM operation. This is due to maintenance issues, physicist involvement in MRT training for QA programmes, and to the dynamic environment of DM, in which systems and processes are continually being adjusted and refined.

As anticipated, the implementation of DM has made BSWN an attractive employer for both MRTs and radiologists. In particular, it has been cited as a key reason for New Zealand and overseas applicants to MRT positions. Moreover, it is easier to recruit graduate MRTs to a digital screening service as few new graduates have film experience.

For MRTs there are OSH benefits of DM including improved ergonomics and elimination of film, cassette and chemical handling. However, physical stressors associated with positioning women remain the main cause of musculoskeletal problems for MRTs and require adherence to safe technique and regular breaks. DM may introduce new risks if it drives expectations of increased throughput per MRT.

SITE INTEGRATION

DM has proved successful in enabling the integration of screening processes between the Whangarei and Takapuna screening and assessment sites. Under the previous breast screening provider, this integration required frequent visits of the Clinical Director to Whangarei, each of which consumed an entire day. The ability to transmit images and associated data electronically has effectively widened the pool of clinical expertise available to each site, both for reading and to obtain a second opinion during assessment clinics. Use of videoconferencing facilities has also enabled BSWN to conduct high quality and accessible MDT meetings with images viewed by staff at both sites simultaneously.

MAINTENANCE

BSWN has experienced significant maintenance issues associated with equipment failures – in particular, multiple failures of x-ray tubes and detectors as well as a range of other problems. Equipment failure and the associated down-time reduces the overall capacity of the service and causes inconvenience for women whose appointments have to be re-scheduled. BSWN experienced unscheduled machine down-time almost every week for the first 18 months of the service, and this had a significant impact on capacity during this time.⁴

³ BSWN data for the 2007 calendar year shows an average reading time of 64 seconds for digital reads and 47 seconds for film reads.

⁴ For the year ending 30 June 2007, total machine down-time associated with equipment failures was 199 hours. At an assumed rate of 5 postponements per hour, this equates to 995 women affected (3.5% of targeted volumes). Although of great inconvenience to these women, it is likely that most re-scheduled.

These problems have stemmed from two fundamental issues: DM is a new and evolving technology and can therefore be expected to break down more often than FSM equipment; and as BSWN was the first Lead Provider to adopt the technology, the local pool of expertise in servicing the equipment was developing from a small base. Access to good technical support is critical to making DM work and, as discussed above, BSWN has invested time in managing relationships with the vendors to improve their service and support capabilities in New Zealand.

IMPACTS FOR WOMEN

Survey responses from 39 women who attended screening at Takapuna during one week in October 2007 and had previously attended FSM screening, found that the change to DM was positive for some women and neutral for others. Benefits include elimination of waiting times while films are processed. As a result, some women may perceive the process as faster and/or experience reduced anxiety. Women are also able to view their images. None of the women surveyed identified any disadvantages of DM screening compared to FSM.

ADVANTAGES AND DISADVANTAGES OF DM OVER FSM

For BSWN, key advantages of DM are:

- Increased volumes per machine including the ability to work three screening schedules across two machines;
- Greater automation of the screening work flow, through integration of the SBS and PACS;
- Easier transmission of the images for all purposes including reading, assessment, MDT meetings, cover for remote sites, teaching, and treatment providers, with associated reduction in clinical staff time, particularly travel between Takapuna and Whangarei;
- Faster image acquisition, eliminating waiting times for women while films are processed, and enabling the MRT to view images almost immediately. As a result, some women may perceive the process as faster and/or experience reduced anxiety;
- There are no film processing tasks and the MRT can remain in the x-ray room with the woman;
- Image QA and 'hanging' is automated and can be completed quickly;
- DM is beneficial in attracting radiologists and MRTs to the service and thus eases recruitment challenges somewhat; and
- Improved ergonomics including motor-assisted machine movements and no heavy cassettes to move or lift.

For BSA, key advantages of DM include benefits for individual sites as summarised above, plus the increased potential for addressing maldistribution of the radiologist workforce through a national PACS network. DM technology combined with carefully designed work flows can increase the capacity of equipment. BSWN's experience of the workforce impacts of DM to date suggests that DM is beneficial for staff recruitment and may assist in retention, but may not mitigate MRT workforce shortages by increasing the capacity of a given workforce, at least initially.

Facilitating quality improvement is another potential advantage for BSA of DM equipment. There is considerable variation in performance between assessment sites within Lead Provider regions. Combined regional MDTs, utilising DM and videoconferencing, allows region-wide establishment of best practise assessment protocols.

Key disadvantages of DM include:

- A steeper learning curve with the adoption of a new technology and the need to keep abreast of rapid advances in technology;

- DM is new technology, and therefore less reliable. There is also less expertise in fixing it. The output of BSWN has been affected by frequent maintenance issues in the first 18 months. Machines have been unreliable but vendors are working with BSWN to address this;
- Network speed issues can cause delays in image retrieval, impacting on work flow efficiency;
- Re-training is required for staff to convert to DM;
- Reading times are slower (especially initially) due to learning curve and more viewing options;
- For the early adopters of DM, there is a lack of available relief/locum MRTs and readers;
- Additional IT support (including PACS Administrator) is needed due to increased use of IT in the screening work flow;
- Greater input is needed from the Medical Physicist, at least initially and in response to equipment failures; and
- Physical stressors for MRTs associated with positioning women remain, and could be exacerbated if throughput per MRT were increased.

E.1.3 FINANCIAL IMPLICATIONS OF DIGITAL MAMMOGRAPHY

Analysis was undertaken to enable the NSU to understand the financial implications (costs and savings) of introducing DM into the BSA programme, and to inform the development of a framework to aid Lead Providers when considering the use of DM. The analysis draws on stakeholder feedback and BSWN financial data, with a focus on identifying findings that are generalisable to other Lead Providers and to BSA as a whole. Specific costs of DM will vary between Lead Providers.⁵ BSWN experience can assist in identifying the main types of costs involved, explaining how the costs of DM differ from those of FSM, and exploring how costs may vary between Lead Providers.

⁵ For example, implementation costs for each Lead Provider will vary depending upon projected service volumes, current and planned service configuration, number of sites, suitability of existing facilities for DM workflow, specific DM equipment selected, and other factors. As a new technology, DM equipment costs are likely to come down in the future. Therefore, BSWN's specific implementation costs are not necessarily a useful predictor of costs for other Lead Providers. Moreover, BSWN's implementation costs were for a green field development. Although some costs can be directly attributed to DM (e.g. the purchase of DM machines), other costs are jointly attributable to both the implementation of DM and the implementation of a new Lead Provider, and cannot be separated in a robust way.

IMPLEMENTATION COSTS

Capital costs include facilities (e.g. fitout and modifications to air conditioning and power supply) and DM equipment (e.g. modalities, RIS and PACS, workstations, and supporting software and peripherals).⁶ Key differences between DM and FSM include:

- FFDM modalities cost more than FSM.⁷ The higher cost per machine may be offset by greater throughput capacity per machine which brings down the cost per mammogram.
- DM requires additional IT infrastructure including PACS and data storage. BSWN was able to make use of existing data storage solutions. Other Lead Providers would need to investigate their data storage requirements and options.
- Hard copy storage requirements should reduce over time with DM (there is an initial two-year lag while prior films are digitised). At BSWN, all archiving is on site. Other Lead Providers may be able to reduce costs of offsite archiving.
- Darkroom, processor space and film processing equipment are not required once the service is fully digital, but may need to be retained on site during the transition to DM. Analogue films from the mobile unit are either processed at a private practice in Whangarei, or at BSCM.

Any Lead Provider preparing a business case to move to DM would need to ascertain current costs for the specific capital items required. Facilities costs will vary with the individual characteristics of each site and whether the transition to DM is made all at once or in stages. Equipment costs depend on factors such as the equipment required, the number of units purchased, and the terms of the contract (e.g. maintenance provisions).

WDHB's Capex report for BSWN shows capital expenditure of \$1.7 million associated with DM equipment at Takapuna, covering: \$1.49 million for two FFDM modalities, stereotactic device, QA equipment, QA and reading workstations;⁸ and \$209,000 for PACS and PACS workstations, laser printer, digitiser and videoconferencing equipment. Note that the \$1.49 million is for the capital investment at only one of BSWN's three digital sites, but nevertheless serves to indicate the level of capital investment required for the items listed. Additionally, \$187,000 of NSU funding was spent on enhancements to the SBS system.

Operational costs of implementing DM include:

- Time spent by the DWG and others in planning and purchasing of DM equipment (to an estimated total of 1,597 hours at BSWN);
- Travel and related expenses for site visits to evaluate digital systems; and
- Training delivered to Radiologists, MRTs and other staff, including approximately two days per MRT and two days plus 200 dummy reads per radiologist (detailed in section 6.6.2).

ONGOING COSTS OF SERVICE PROVISION

The net costs of DM include savings from changes to the screening work flow (e.g. potentially higher screening volumes per machine than FSM) and the elimination of some costs associated with FSM (e.g. films, chemicals). Net costs/savings will vary between Lead Providers and over time.

⁶ Section 4.2 details the digital equipment purchased by BSWN. Appendix C details the information and communications infrastructure required to support a DM environment.

⁷ NSU analysis found that total annualised equipment costs for a DM system would be 1.9 to 2.3 times higher than FSM equipment (NSU, 2007b).

⁸ Costs of individual items cannot be disaggregated due to confidentiality agreements with vendors.

The following overarching principles apply to the net cost of DM relative to FSM:

- The higher capital costs of DM compared to FSM mean that the *fixed costs* of service provision (costs that are incurred regardless of the number of mammograms performed) are higher for DM.
- The *variable costs* of DM (costs that vary with the number of mammograms performed) may be lower than FSM due to lower consumable costs. However, some other costs (e.g. maintenance) may increase in a DM environment.
- For both DM and FSM, the *average cost per screen* (the sum of all fixed and variable costs divided by the number of mammograms) reduces as screening volumes increase, because the fixed costs are spread across a greater number of mammograms.
- The higher capital costs of DM compared to FSM mean that the average costs per mammogram of DM are higher at low screening volumes. As screening volumes increase, a breakeven point may be reached where the average costs of DM are equal to those of FSM. High screening volumes per machine are required to reach this point.

The **ongoing cost of capital** is a fixed cost. The average capital cost per mammogram reduces as the total service volumes increase. BSWN has stressed that it is important to ensure business cases include realistic assumptions about the screening volumes that will be provided (i.e. Lead Providers should not expect to screen maximum screening volumes).

The ongoing cost of capital for DM depends upon the total capital investment at implementation, the method of financing, and the method of depreciation used. As the capital costs of DM are higher than FSM, the ongoing cost of capital is generally higher in a DM environment.

WDHB purchased DM equipment using borrowed funds. The Board approved this borrowing on the basis of a business case showing that the capital costs could be recovered through net operating cashflow.⁹ BSWN's DM machines are depreciated over seven years. IT equipment (including the PACS and workstations) are depreciated over a three year period. Thus, the ongoing cost of capital is highest in the first three years. If the serviceable lives of DM machines and/or ICT equipment exceed their depreciation periods, the cost of capital may reduce over time. Moreover, the costs of upgrading existing equipment should reduce as the technology becomes more widely adopted and prices come down.

Ongoing operating costs include workforce and other costs. Although DM units are more expensive than FSM to purchase initially, there are operational cost savings that may tip the balance in favour of DM, especially where service volumes are high. Key areas of difference in operating costs between DM and FSM include:

- Consumable costs are lower for DM than FSM as no chemicals or films are needed for DM. A few (less than 1%) mammograms are printed, which incurs ink and film costs.
- Archiving/storage costs should reduce as a service transitions to DM and an increasing proportion of images and records are stored electronically.
- Courier costs are significantly reduced due to electronic sharing of digital images between sites. Telecommunications costs increase with DM.
- DM requires additional specialised staff including a PACS Administrator and an increased level of medical physicist input.
- Maintenance costs can be high for DM, especially initially. The first three years of servicing and unscheduled maintenance costs are covered within the price of the modalities, and the cost of replacement parts are initially covered under warranty. However, unscheduled downtime can affect productivity.

⁹ The original business case sought capital funding to establish BSWN as a Lead Provider, based on FSM assumptions. The decision to go digital, supported by further analysis, was made subsequently.

As discussed above, BSWN has advised that the workforce costs associated with providing a DM service have not, to date, differed significantly from those associated with a FSM service. Therefore, the core workforce costs for DM at BSWN have been comparable to those of FSM. This is significant because the combined costs of salaries and outsourced clinical services at BSWN comprise 73% of total costs (based on 2006/07 records).

Other general screening programme costs, such as health promotion, appointment scheduling, and service management, are equivalent for DM and FSM.

Ongoing costs of service provision are not constant over time. For example:

- BSWN did not go fully digital from the first day of operation. The proportion of mammograms that were digital was 52% initially and increased to approximately 70%.¹⁰
- The transition to DM involves a learning curve for all staff.
- DM systems and processes are continually being adjusted and refined in response to technological improvements and ongoing learning about the DM work flow.
- There are lags associated with some efficiencies (e.g. imaging assistant input may take two years or longer to reduce due to the digitising of priors).
- Equipment reliability issues affected screening volumes and costs at BSWN in the first 18 months of the service.

AVERAGE COST PER WOMAN SCREENED

In its first year of operation, BSWN provided 25,916 screens at an average cost of \$210 per screen. At the completion of its first full financial year (five months later), the number of screens had increased to 28,062 and the average cost had reduced to \$169 per screen.

In comparison, available BSA data shows that in the previous (2005/06) financial year, the cost per woman screened for the eight BSA Lead Providers ranged from \$147 to \$199 and averaged \$176 for BSA as a whole. Estimated volumes and funding for 2007/08 suggest the average cost per screen for BSA this year will be \$188.

This analysis suggests that BSWN costs, although high initially due to various factors that impacted on screening volumes, are now at a level commensurate with BSA as a whole. This accords with the WDHB revised business case and supporting financial analysis for the establishment of a DM service, which established that the capital costs of DM could be recovered through net operating cashflow at existing BSA funding levels (WDHB, 2005b).

The following caveats must be noted:

- It would not be valid to directly extrapolate BSWN average costs per woman screened against current national volumes to assess the implications of DM for the BSA programme overall, due to differences between Lead Providers, as these would affect local costs of DM.
- In particular, the BSWN Lead Provider region has high numbers of eligible women, and can keep its DM machines busy full time. Other Lead Providers serving lower populations may not be able to operate a DM machine at close to its maximum capacity, or may have screening volumes that exceed the capacity of one DM machine but cannot justify the purchase of two machines.

¹⁰ BSWN does not account separately for its DM and FSM costs and these cannot be disaggregated in a robust way. Nevertheless, the aggregate costs are relevant in that they represent a service in transition to DM.

- Apparent cost per screen varies between Lead Providers due to accounting differences as well as actual differences in service profile and cost.
- As already noted, costs of service provision are not constant over time and there are sound reasons for anticipating a reduction in the average cost per screen at BSWN over the next few years.

E.2 RECOMMENDATIONS

BSWN's experience in the implementation of DM, its impacts post-implementation and the financial implications of transitioning to DM, highlights a number of pertinent lessons for other Lead Providers and BSA as a whole during the managed introduction of DM into the BSA screening practice. It is recommended that the NSU draw on the following lessons identified in this report to assist other Lead Providers in identifying factors to consider in their Business Cases and Implementation Plans for DM.

IMPLEMENTATION

Key issues and lessons from BSWN suggest that other Lead Providers considering the transition to DM should:

- Adopt a staged transition approach rather than changing all fixed, mobile and subcontracted sites to DM in one 'big bang' approach. A staged approach has a number of benefits including opportunities for learning and refining processes and minimising any temporary adverse workforce impacts such as slower reading times. Implement site-by-site. Mixed digital and analogue at a single site would make it difficult to maintain QA adequately.
- Plan for significant project management, clinical, technical and other multi-disciplinary input and a time investment from those involved including time dedicated away from day to day work. A critical success factor is establishing the right multi-disciplinary team from the outset.
- Pay close attention to ensuring the compatibility of DM components including PACS, RIS, storage servers and modalities. Ensure contractual agreements for DM implementation place responsibility on vendors for seamless integration.
- Note that BSWN's RFP evaluation criteria and submission forms provide a potential model or starting point for the development of tender evaluation tools for future tendering processes.
- Plan for contingencies, recognising that throughput on DM (both in taking and reading mammograms) will be slower initially. To minimise disruption to work flow, clinics and clients, a conservative approach should be taken to booking appointment slots until all aspects of installation have been improved and completed.
- Learn directly from other programmes, both in New Zealand and overseas, that have already done planning and implementation for DM. This should include site visits to comparable sites with well-established screening processes, observing work flow patterns, and conducting consultations with screening staff in order to learn of possible pitfalls.
- Seek IT guidance from an established DM screening site with a similar PACS configuration.
- Note that BSWN has gone further in terms of connectivity between RIS, PACS and DM machines than the overseas sites observed by the DWG, and is therefore a key reference site for other Lead Providers preparing to convert to DM, both to maximise effectiveness for Lead Providers individually and to minimise risks associated with incompatibility between Lead Providers.
- Involve a medical physicist from the outset in equipment selection in order to assess key performance and QA parameters of each machine.

- As part of the due diligence process, ensure that vendors provide full details against all requirements and criteria including sufficient evidence/plans for the provision of prompt and readily available service support.
- Pay particular attention to negotiating an effective service contract, including availability of technical expertise and storage of spare parts to ensure timely access; escalation and penalty clauses; minimum response times for service; and whether evening/weekend cover is necessary and available.
- Manage vendor service risks by ensuring good relationships with vendors, undertaking sufficient input and planning with engineers and trainer prior to installation, and allowing sufficient time to thoroughly test equipment before the go-live date and before final payment is made to the vendor.
- Maintain a risk register at all times during the project so mitigation strategies can be found for all new risks as they become known.
- Investigate collective bulk buying opportunities with other Lead Providers, as DM vendors may be prepared to make substantial discounts if multiple machines are purchased.
- Allow time for staff training and plan additional staff for service continuity.
- Allow time for MRTs to be trained in QA for each new modality. Establishing new QA programmes for DM equipment is an extensive process which is made more complicated by inconsistent terminologies used by different vendors. Each machine has specific QA processes and requirements.

IMPACTS

In considering the impacts of DM on screening work flow, Lead Providers should note that:

- DM offers a number of advantages over FSM, but converting to DM involves risks and may not be all 'plain sailing'. In particular, Lead Providers should allow for down time and should not expect to screen maximum screening volumes.
- DM screening technologies and processes are continually evolving. Implementing DM requires acceptance of this, and commitment to keeping abreast of technological developments and refining screening processes on an ongoing basis.
- Experience of BSWN to date has been that individual MRT volumes are similar to FSM, reflecting clinical practice considerations, cultural issues, OSH considerations, and QA processes. However, it is anticipated that throughput would increase if the MRT form were available in its entirety as data entry fields on the RIS.
- DM requires greater interpersonal skills for MRTs because they stay in the x-ray room with the women and because women want to see their images.
- Overall, radiologist FTE requirements for DM at BSWN are similar to those in a FSM environment.
- Reading capacity is constrained by the number of workstations. Sites need to provide sufficient workstations for flexibility, especially where radiologists alternate between screening work and other clinical roles.
- There is a transitional period following conversion to DM where analogue priors are retrieved from storage and digitised. As a result, workforce efficiencies in relation to imaging assistants are subject to a two-year lag phase.
- Excellent IT support is critical to the success of DM. This support is specialised because of the complexity of the DM environment, the need for seamless integration of components, and the substantial data transmission and network speed requirements.
- Excellent medical physics support is critical to the success of DM. Physicist services may be required urgently and unexpectedly if there are equipment failures.

- Ensure vendors keep spare parts on hand (including x-ray tubes and detectors) to minimise down time in case of equipment failure.

FINANCIAL IMPLICATIONS

BSWN experience is potentially useful in identifying the main types of costs involved in implementing DM and providing screening services in a DM environment, and how these differ from FSM. However, individual Lead Providers need to conduct a thorough analysis of the financial implications of DM taking into account local service configuration (current and planned), volumes (current and projected) and other relevant factors.

Average cost per woman screened at BSWN is commensurate with costs for BSA as a whole. It is important to note that the BSWN Lead Provider region has high numbers of eligible women and can keep its DM machines busy full time.



INTRODUCTION

The National Screening Unit (NSU) of the Ministry of Health engaged Health Outcomes International Pty Ltd (HOI) to conduct an independent evaluation of the implementation of digital mammography (DM) at Breast Screen Waitemata and Northland (BSWN). The overarching purpose of the evaluation was to assist the NSU to consider options for the managed introduction of DM into the BreastScreen Aotearoa (BSA) screening programme, and any implications for national policy and quality standards that this introduction may have.

DM is the next step in the evolution of mammography technique and will gradually replace film-screen mammography (FSM). DM is similar to FSM in that x-rays are used to produce detailed images of the breast. From the woman's perspective, DM uses a similar procedure to acquire the image. However, with DM, the image is captured electronically using a digital receptor instead of a film cassette, and is stored directly in a computer. DM offers a number of advantages over FSM in regard to radiation dose, image acquisition, display, transmission and storage, and has the potential to lead to more efficient use of a constrained workforce.

The BSA Age Extension Project showed the need for a significant increase in the BSA screening capacity and exposed the problem of a shortage of the radiologist and medical radiation technologist (MRT) workforce needed to support the increase. Both of these health professional groups are experiencing a global workforce shortage. The NSU is looking to DM as one potential avenue to increase screening capacity and mitigate workforce shortages.

BSWN was the first BSA Lead Provider to use Full Field Digital Mammography (FFDM). The NSU needs to consider options for the managed introduction of DM into the BSA programme. The overarching purpose of the evaluation was to assist the NSU in this regard and to advise on how the introduction of DM may impact on national policy and quality standards. Accordingly, the NSU contracted HOI to evaluate:

- The **process** undertaken by BSWN that led to their decision to implement DM; and
- The initial **impact** of DM on any changes to service delivery.

The evaluation focused on:

- The process undertaken to introduce the FFDM technology at BSWN (including decision making processes and criteria, development of the business case, workforce issues, and lessons learned);
- Impacts of FFDM on the process of service delivery across the screening pathway;
- The advantages and disadvantages of using FFDM in a Lead Provider system, and for the BSA programme overall;
- The financial implications including capital, workforce and operational costs of the introduction of FFDM for an individual Lead Provider and BSA as a whole; and
- The cost-effectiveness of the introduction of FFDM for a Lead Provider and the BSA programme overall.

The findings from this evaluation will inform the NSU regarding the strengths, weaknesses and financial implications of introducing DM to the BSA programme. In turn, these findings will help to ensure that implementation of DM in other Lead Provider regions is focused on the optimum outcome for the programme. The evaluation will also inform the development of a framework to aid Lead Providers when they are considering the use of DM (including the DM Implementation Plan and guidelines to inform best practice for implementation), and will assist the NSU to give informed and consistent advice on the use and implementation of DM.

METHODOLOGY

The evaluation involved the collection and analysis of documentation and data from BSWN and the NSU, feedback from key people who were involved in the establishment of DM at BSWN, observation of facilities and processes at BSWN, and a consumer satisfaction survey.

Interviews were conducted with:

- BSWN Manager;
- BSWN Clinical Director, Lead MRT, and other Radiologists and MRTs at Takapuna and Whangarei;
- The physicist serving BSWN's Takapuna and Whangarei sites;
- The ICT Project Manager involved in the implementation of DM at BSWN;
- The BSWN Implementation Project Sponsor;
- The Waitemata DHB (WDHB) Business Manager responsible for BSWN financial accounting; and
- NSU representatives.

In addition, the BSWN Manager and key radiologist and MRT representatives provided written responses to the interview questions, and all BSWN radiologists and MRTs were invited to provide feedback on draft process maps (discussed below). The interview questions are attached at Appendix A.

The Project Manager for the implementation of DM at BSWN provided input into the evaluation by reviewing and providing feedback on a preliminary draft of the evaluation report with regard to its accuracy and completeness and by guiding the evaluators to additional documentation to inform the evaluation.

Evaluation questions covered DM processes, impacts and financial implications. Specific evaluation questions, methods and data sources used in the evaluation are summarised in the following paragraphs.

2.1 PROCESSES

The first group of evaluation questions focused on the process undertaken to introduce DM technology at BSWN, and the rationale for the decisions that were taken. The evaluation questions were:

- What process did BSWN use to help make the decision to go digital?
 - How were decisions made?
 - Who made the decisions?
 - What criteria/bases were used to aid in the decision making process?

- What evidence did BSWN gather to help make the decision to go digital? How useful was the evidence from overseas in terms of its application to the New Zealand context?
- What were the strengths/weaknesses of the decision making process? (e.g. what worked well? What would you do differently?)
- What are the most important features of a successful decision making process that other Lead Providers should consider?
- How was the business case developed?
- Why did BSWN decide to go digital?
- What processes were involved in establishing the DM service, once the decision to go digital was made?
 - What processes were used in planning and budgeting for the implementation?
 - What processes and criteria were involved in selecting the type (make and model) of DM equipment?
 - What processes were used in implementing the service (e.g. key phases, tasks and timeframes, approach to project management, key personnel involved)?
 - What were the strengths/weaknesses of these processes? (e.g. what worked well? What would you do differently?)
 - What are the most important features of a successful implementation process that other Lead Providers should consider?

These evaluation questions were addressed through semi-structured interviews, as detailed above and through a review of source data and documentation provided by BSWN including:

- May 2005 Capital Expenditure Proposal to the WDHB Board (this pre-dated the decision to go digital and was based on FSM);
- May 2005 High Level Project Plan for Establishment of BSWN;
- August 2005 Proposal to the NSU for BSWN to pilot the implementation of FFDM;
- Reports from visits to established DM sites overseas;
- Notes from DM planning group meetings;
- Records of the procurement process for the DM equipment;
- Records of the procurement process for ICT infrastructure;
- Estimates of time spent on digital planning and purchasing at BSWN;
- Details of training provided to BSWN radiologists, MRTs and other staff; and
- January 2007 Post Audit Evaluation Report to the Audit and Finance Committee.

2.2 IMPACTS

The evaluation focused on two groups of “impacts”, based on BSWN’s experience to date:

- Impacts of FFDM on the process of service delivery across the screening pathway; and
- The advantages and disadvantages of using FFDM (to a Lead Provider, and to the BSA programme overall).

Questions aimed at addressing these impacts included:

- How does the screening pathway for DM at BSWN differ from the screening pathway for FSM? Including consideration of:
 - Sequence of stages in the process (analysed through process mapping of the screening pathway);
 - Personnel involved at each stage;
 - Throughput ratios such as average elapsed and cumulative time taken per patient (if available) and/or average number of screens per unit of time; and/or
 - Any changes to work flow.
- How do the workforce requirements for an equivalent service volume for DM compare to the workforce requirements for FSM?
- What are the advantages and disadvantages of DM over FSM for BSWN? For BSA?
- What different systems of appointment scheduling were considered? How were they assessed? What system is used, and why?
- What lessons learned may assist the NSU to develop guidelines to aid other lead providers in deciding whether the advantages of DM outweigh the disadvantages?

To address these questions, workshops were initially conducted involving two MRTs, ICT Project Manager, a radiologist and a physicist to identify the key stages and tasks in the screening process and differences between the processes for DM and FSM. These workshops were followed up with guided observation of the facilities and process flow for DM at Takapuna and FSM at Orewa (a site subcontracted to BSWN providing fixed FSM screening services). Based on these workshops and observation, draft process maps were produced and were distributed to BSWN radiologists and MRTs inviting feedback with regard to accuracy, completeness and estimates of average or typical times taken at each stage. Where feasible, BSWN provided data to support the analysis.

A range of work flow and other data was provided by BSWN, summarising:

- Reading times for DM and FSM at BSWN during the 2007 calendar year;
- Current and recent MRT screening schedules;
- Actual MRT screening appointments and hours of work for selected DM and FSM sites during a one week period in February 2008;
- Technical recall data for all BSWN DM and FSM sites from 1 February 2006 to 1 February 2008; and

- Details on equipment failures/maintenance issues, and the impacts of these on screening services.

Consumer feedback was elicited through a short, anonymous, voluntary survey administered to the first 50 women who attended screening at Takapuna during the week of 8-12 October 2007. A total of 46 women responded to the survey (a response rate of 92%). The survey asked women to identify any differences they noticed between the digital screening process and any film-based screening they had in the past (where applicable). The survey form and information sheet are attached at Appendix B.

2.3 FINANCIAL IMPLICATIONS

The evaluation included analysis of the financial implications of DM, covering:

- The direct costs of implementing and operating DM at BSWN, comparison with the costs of FSM, and discussion of implications for other Lead Providers and the BSA programme overall; and
- The average cost per mammogram of DM at BSWN and discussion of implications for the BSA programme overall.

The *net* costs of DM include cost savings from changes to the screening work flow (e.g. potentially higher screening volumes per machine than FSM) and the elimination of some costs associated with FSM (e.g. films, chemicals). The balance of costs and cost savings involves a complex interplay between a number of factors such as screening volumes, facility layout, type of DM modality in use, and so on. Consequently, the *net* costs (or savings) of DM relative to FSM will vary significantly between Lead Providers and over time. As an overarching principle, however, the higher capital costs of DM compared to FSM mean that higher screening volumes per machine are required to reach a breakeven point for DM.

It was beyond the scope of this evaluation to model the net costs/savings of DM relative to FSM under a range of scenarios. Instead, the analysis identifies and discusses each of the main cost components individually, and how each component differs between DM and FSM. The aggregate effect of these differences at BSWN is then assessed by analysing the average cost per mammogram at BSWN.

The financial analysis includes only the direct costs of DM to BSWN, and excludes indirect costs (such as transport costs of women attending screening) and indirect benefits (such as the potential of DM to help mitigate national staff shortages).

Analysis of the costs at BSWN was undertaken by referring to financial data provided by BSWN together with qualitative information from MRTs and the ICT Project Manager, and focused on identifying issues and lessons that will be useful for other Lead Providers. The analysis explored the financial implications of DM under two key headings:

- Implementation costs (costs associated with the initial set-up of DM); and
- Ongoing costs (costs associated with the provision of a DM service).

Within these overarching categories, the analysis also distinguishes:

- Capital (facilities and equipment); and
- Operating costs (including the screening workforce, and other operating costs such as contractors, consumables, etc).

The financial analysis draws on stakeholder feedback and financial data related to the implementation of DM at BSWN, with a focus on identifying findings that are generalisable to other Lead Providers and to BSA as a whole. Capital costs associated with DM equipment were subject to commercial confidentiality clauses and therefore could not be disaggregated for this report. Furthermore, as costs will vary between Lead Providers according to their individual service contexts and business decisions, quantifying the specific costs incurred by BSWN was considered to be of limited value. Therefore, the cost analysis focused on qualitative discussion of the key cost items involved in DM and a high-level comparison of DM and FSM costs.

The average cost per mammogram at BSWN was estimated from financial and output data, and compared against the average cost for other Lead Providers and BSA as a whole.

CONTEXT

This section provides contextual information relevant to the evaluation, based on a review of core documentation and literature. It sets out key features of the service, policy and research contexts underpinning breast screening in New Zealand and the specific application and operation of DM.

It is important to note that some of the information presented in this section pertains to the current situation but was not applicable to BSWN at the time of decision making and implementation of DM. For example, the NSU Digital Mammography Policy was not in place when BSWN made its decision to go digital, but will be relevant to other Lead Providers as they consider the implementation of DM technology.

3.1 SERVICE CONTEXT

Among New Zealand women, breast cancer is the most common cancer and most common cause of cancer death, with 2,310 new cases of breast cancer registered and 615 deaths from breast cancer in 2001 (NZHIS, 2007). The risk of breast cancer increases with age, with three quarters of diagnoses occurring in women aged 50 years and over (BSA, 2007).

Due to effective treatments, the majority of women who develop breast cancer do not die from it. Screening further improves survival rates, reducing the chances of dying from breast cancer by about 20% for women under 50 years of age, 30% for women aged 50-65, and 45% for women aged 65-69 (BSA, 2007).

3.1.1 BREASTSCREEN AOTEAROA

In New Zealand, breast screening mammograms and follow up are available free to all asymptomatic women aged 45-69 through the BreastScreen Aotearoa (BSA) programme. BSA was established in 1998¹¹ and aims to reduce women's morbidity and mortality from breast cancer by identifying cancers at an early stage. Breast screening is delivered via a network of eight Lead Providers, their sub-contracted providers, and mobile units. Independent Service Providers (ISPs) work alongside the Lead Providers in defined geographic areas to provide health promotion and recruitment for Māori and Pacific women (NSU, 2003).

The BSA programme aims to screen at least 70% of the general target population of women every two years in order to achieve a 30% reduction in breast cancer mortality (NSU, 2004; NSU 2006a).

BSA initially targeted asymptomatic women aged between 50 and 64 years old. In 2004 an announcement was made that the age of eligibility of BSA would be extended to women aged between 45-69 years (NSU, 2006). In the first two years following Age Extension (July 2004 to June 2006), 294,421 women were screened, an increase of 43.1% over the previous two year period.

As an organised population-based screening approach, the BSA programme includes:

- Promotion of Screening;

¹¹ In 2000, the Ministry of Health took over the BSA programme from the Health Funding Authority.

- Education about breast cancer, screening and treatment;
- Identification and invitation of women eligible for screening;
- Invitation and recall of women eligible for screening at two yearly intervals;
- Screening mammography for eligible women;
- Multidisciplinary assessment for screened women including clinical examination, ultrasound, fine needle aspiration biopsy, core needle biopsy, stereotactic directed biopsy, open biopsy and pathology services;
- Communication of screening results to women and their primary health care provider;
- Support and counselling for women undergoing assessment procedures;
- Referral to treatment for those women identified with breast cancer;
- An information system to support the screening programme; and
- Quality assurance (QA), audit, monitoring and evaluation (NSU, 2006a, pp. 24-25).

The ongoing provision of breast screening at the service level involves teams of multidisciplinary health professionals including: breast care nurses, health promoters, physicists, MRTs, pathologists, quality care coordinators, radiologists, and surgeons. The success of the BSA programme is largely dependent on the effective collaboration and inter-coordination of these various staff at different points along the screening pathway.

The BSA programme is independently monitored under a three-year contract with Queensland University that began in 2005. The most recent report on progress from July – December 2005 indicates that despite some variation across lead providers, overall BSA targets for key performance indicators are either being exceeded or are almost being achieved (NSU, 2007a).

Originally BSA was provided by six Lead Providers, of which BreastScreen Auckland and Northland (BSAN) was the largest. In 2002, the large size of the BSAN area relative to other Lead Provider areas was noted as well as high screening demands and relatively low coverage rates. In response, and in an attempt to improve screening coverage in Auckland and Northland, the NSU decided in 2004 to split the Auckland and Northland region into three separate Lead Provider areas. As a result of this decision, the NSU contracted Counties Manukau DHB (CMDHB) to provide the new BreastScreen Counties Manukau programme and Waitemata DHB to provide the new BreastScreen Waitemata and Northland programme. These programmes began screening in September 2005 and February 2006 respectively (Blue, 2005; NSU, 2007a). As a result of this reconfiguration, the BSA programme is now provided via eight Lead Providers¹² who deliver services to women through both fixed and mobile sites.

The majority of mammography conducted as part of BSA is currently film-screen based. However, BSWN introduced DM from the first day of its operation, 1 February 2006 and BreastScreen HealthCare (BSHC, the Lead Provider for Otago/Southland) commenced providing DM services in April 2007. Overseas, an increasing number of screening sites in the UK, Europe, the USA and Australia have introduced or are introducing digital mammography and softcopy reading into their screening practices.

3.1.2 DIGITAL MAMMOGRAPHY

DM is the next step in the evolution of mammography technique and will gradually replace film-screen mammography (FSM). DM incorporates the most recent advances in image acquisition, processing, display and storage. Both DM and FSM utilise low-energy x-rays that pass through breast tissue to produce images, and both require breast compression. The difference between

¹² BSA Lead Providers include: Waitemata and Northland (BSWN); BreastScreen Counties Manukau (BSCM); BreastScreen Auckland Limited (BSAL); BreastScreen Midland (BSM); BreastScreen Coast to Coast (BSCC); BreastScreen Central (BSC); BreastScreen South Limited (BSSL); and BreastScreen HealthCare (BSHC).

the two techniques lies in the way the image is captured and reproduced for further interpretation.

In FSM, images are recorded on films using x-ray cassettes which are then chemically processed in a dark room. The resultant film images are stored in a manual filing system with the woman's paper files.

In FFDM the x-ray is picked up by a digital detector and is directly converted into digital signals for displaying on a computer monitor. The displayed image can be manipulated on screen and can also be printed onto film. Digital images are stored directly into a computer system together with details about the woman screened. This evaluation focuses on the implementation and impacts of FFDM, as this is the DM technology used by BSWN.¹³

FFDM offers a number of potential advantages over FSM. Potential advantages cited in the international literature are summarised below (BSWN experience in regard to the advantages and disadvantages of DM is discussed in section 5.10).

Workforce and telemedicine

- The FFDM work flow provides the potential for increased workforce productivity including a more streamlined work flow for MRTs and potential time savings for some administrative tasks.
- Images can be shared electronically between sites, providing opportunities for remote image reading and peer review (Legood & Gray, 2004), with associated potential for more efficient use of radiologist time.

Image acquisition

- The time between exposures is shorter with FFDM than with film as there are no cassettes to change. The overall cycle time is therefore faster.
- The image is available for the MRT to view almost immediately, without having to wait for film processing. As a result, the MRT can tell straight away whether the image is adequate.
- There is the potential for fewer technical recalls, therefore fewer repeat screenings and increased cost savings in equipment use and staff time. There is also the potential for reduction in the need for repeat assessments (Legood & Gray 2004).
- In DM, the electronic signal has a linear relationship with the intensity of the x-ray and has a wider dynamic range (1000:1) than FSM (40:1). This provides greater contrast resolution in digital images compared to film (Dershaw, 2006; Legood & Gray, 2004; NSU, 2006a).

Image processing

- DM obviates the need for film processing and handling tasks associated with FSM. As such, MRTs do not need to work with processing chemicals, which translates into a potentially safer work environment as well as savings in staff time. There are also savings in facility development costs as dark rooms and other processing space are not required.
- Image QA and 'hanging' are automated (BSWN, 2005b).

¹³ Another form of DM, known as Computed Radiography (CR), uses conventional x-ray equipment to capture an image, but stores the image to a cassette-based imaging plate which is subsequently removed from the x-ray machine in the same way as a film cassette. When processed, a digital image is produced.

Image display and storage

- The magnification, orientation, brightness and contrast of the image can be altered after the examination is completed, which allows the radiologist more image viewing options than with FSM. Additionally, under or over-exposure can be corrected without having to repeat mammograms.
- Electronic storage enables more rapid storage and retrieval of images, and reduces the likelihood of images being lost in transfer, misplaced in filing systems due to human error, or damaged/deteriorated (Medical Devices Agency 2001).
- Hardcopy storage of films becomes unnecessary in DM, whereas for FSM, films are stored for 10-15 years from last episode, with the associated costs of office space, transport, off-site archiving and retrieval.

Benefits for women

- Examination time and waiting time (post examination) are shorter due to the direct capture of images and the elimination of film processing.
- The ability to repeat images immediately with the woman still in the x-ray room means less waiting time and less associated anxiety for women (Medical Devices Agency, 2001).
- Depending on the type of system used, DM may provide a lower average radiation dose than FSM (Medical Devices Agency, 2001).
- The time required for a stereotactic biopsy procedure (where required) is shortened. Stereotactic biopsy procedures may also be more effective due to greater resolution of FFDM as compared to biopsy units with small field of view (NSU, 2006b).
- Diagnostic performance may be improved for pre- and peri-menopausal women and women with dense breasts (Pisano et al, 2005).

Overall, DM appears to have greater flexibility in terms of imaging capabilities. However, there are some trade-offs. For example, although DM has greater contrast of images, FSM has greater spatial resolution due to its reliance on the size of the grains of the emulsion on the film screen, whereas in DM, spatial resolution is based on pixel size (Dershaw, 2006; Parikh, 2005).

For BSA, key potential benefits of DM centre on the potential to help mitigate workforce shortages. Currently, turnover rates are high for MRTs as a result of issues such as repetitive strain injuries and the use of chemicals to process films. Furthermore, staff retention may be improved as a result of opportunities for skills advancement and utilisation. For example, MRTs may be able to obtain greater job satisfaction from development and utilisation of advanced skills and knowledge, as well as the opportunity to work with state of the art technology.

Implementation of DM in New Zealand may also help to mitigate problems associated with shortages of radiologists. For example, telemammography could help to overcome the uneven distribution of radiologists around the country, with a relatively high number of radiologists in Auckland and long-term shortages in other parts of the country (NSU 2006a).

Other anticipated benefits of implementing DM in New Zealand include increased screening capacity to meet increasing demand for services, the establishment of a national archive of digital images, and the opportunity to keep pace with global trends in imaging (NSU, 2006b).

3.1.3 DIGITAL MAMMOGRAPHY AT BREAST SCREEN WAITEMATA AND NORTHLAND

BSWN commenced operating in February 2006 and provides breast screening services to the women of Waitemata and Northland.

Waitemata DHB (WDHB) holds a Service agreement with the Ministry of Health for these services, and is responsible for the overall BSWN service including the clinical, quality and operational management of the programme and for achieving participation/coverage targets.

BSWN is managed by a Clinical Director and a Lead Provider Programme Manager responsible for the entire region. Both the Clinical Director and the Lead Provider Programme Manager report to the General Manager, Clinical Support Services.

WDHB contracts with Northland DHB (NDHB) to provide screening and assessment services to women of Northland, and with other private providers to provide screening services. WDHB and NDHB work collaboratively together to ensure the success of the programme. NDHB has a leading role in the programme for Northland.

BSWN was the first BSA Lead Provider to use FFDM. Four FFDM machines are currently operating; two in Takapuna (since February 2006), one in Whangarei¹⁴ (since July 2006), and one at Waitakere (since July 2007). BSWN also operates a mobile FSM unit. Fixed FSM units are operated by subcontractors in Orewa, Warkworth and Kerikeri. The service configuration of BSWN is summarised in the following table.

The two main sites (Takapuna and Whangarei) work collaboratively, with Takapuna radiologists conducting second reads of Whangarei mammograms and vice versa, radiologists at both sites providing mutual backup cover for first reads and second opinions at assessment clinics, and weekly multidisciplinary videoconferences involving both sites.

Table 3.1: Overview of BSWN Service Configuration

Screening	Reading	Assessment	Regional management, health promotion, call, recall
Takapuna (2x DM – BSWN)	Takapuna and Whangarei (as required)	Takapuna	Takapuna: All statutory positions (required in NP&QS) including Clinical Director, Programme Manager, Data Manager, Quality Manager, Lead MRT, Lead Radiologist, Lead Surgeon, Lead Pathologist. Administration centre managing and coordinating all call/recall arrangements for entire BSWN region. Takapuna, Whangarei and ISPs: Health Promotion.
Whangarei (1x DM ¹⁴ – BSWN)	Whangarei (1 st reads); Takapuna (2 nd reads)	Whangarei	
Waitakere (1x DM – BSWN)	Takapuna and Whangarei (as required)	Takapuna	
Mobile unit (1x FSM – BSWN)	Takapuna and Whangarei	Takapuna and Whangarei	
Orewa (FSM – subcontractor)	Takapuna	Takapuna	
Warkworth (FSM – subcontractor)			
Kerikeri (FSM – subcontractor)	Takapuna	Whangarei	

¹⁴ NDHB has two DM machines. One of these was purchased for BSA work. Operationally, both machines are used for screening and assessment on some days of the week, and on other days are used by the diagnostic service.

In 2005 there was estimated to be 90,370 women domiciled in the Waitemata and Northland regions who were eligible to be screened every two years within the programme. The eligible population for BSWN was projected to increase by an average of 30% in the subsequent ten year period to 117,890 women in 2015. The numbers of eligible women in Rodney and Waitakere and the number of eligible Māori and Pacific women will increase at above average rates over this ten year period (WDHB, 2005a).

In its first 12 months of operation (year ending 31 January 2007), BSWN performed 25,916 screens (28.7% of eligible women). This represented a substantial increase from the annual coverage of the previous provider (18.7%). The number of screens conducted in BSWN's first year was lower than the expected coverage of 29.6%. Contributing factors included lower than planned throughput in Whangarei during the initial five months until the NDHB service commenced; and insufficient capacity of private subcontracted providers in West Auckland (addressed through the establishment of the new BSWN owned and operated digital site in Henderson). The budgeted volume for 2007/08 is 31,300 screens.

3.2 POLICY CONTEXT

Numerous New Zealand policy documents are aimed at highlighting the incidence and burden of cancer in New Zealand, inequalities in cancer care faced by different community sectors, and strategies such as screening programmes for reducing the social, psychological and economic impacts of cancer. Key documents include the *Cancer Control Strategy* (Ministry of Health, 2003) and *Cancer Control Action Plan 2005-2010* (Cancer Control Taskforce, 2005).

Policies more specific to breast screening include the *National Screening Unit Strategic Plan 2003-2008*, the *National Policy and Quality Standards* (NSU, 2004) and, released subsequently to the implementation of DM at BSWN, the NSU's Digital Mammography Policy (NSU, 2006).

3.2.1 THE NATIONAL SCREENING UNIT STRATEGIC PLAN 2003-2008

The NSU is a business unit of the Ministry of Health. It is responsible for the safety, effectiveness and quality of health and disability screening programmes. The NSU is guided by its vision: "*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*" (NSU, 2003, p. vii).

The *National Screening Unit Strategic Plan 2003-2008* (NSU, 2003) documents the directions for enacting this vision and identifies six priority action areas for screening in New Zealand: service development; partnership and understanding; overall management; research and development (R&D); quality improvements; and workforce development.

With regard to the R&D priority area, the Plan asserts that screening must be responsive to changing knowledge, technology and consumer expectations. It identifies an ongoing need for identification of research issues, conduct of research projects in service settings, incorporating or building on relevant research from other countries, and evaluation of new and/or changing services.

This ongoing R&D is important for continued quality improvement and promotes understanding of the balance between identified benefits and potential harms associated with screening, as well as its costs. Moreover, R&D can identify important trends in screening, some of which have been

listed in the Plan and include the need for rigorous evaluation of screening programmes and the development of new technologies such as DM.¹⁵

3.2.2 BREAST SCREENING POLICY IN NEW ZEALAND

All services within the screening programme need to be of the highest quality and all providers of BSA services are contractually obliged to meet the extensive and specific National Policy and Quality Standards (NP&QS).

The NP&QS were developed in 2004 and replaced the *BreastScreen Aotearoa Interim National Quality Standards* (1996) and the *BSA National Operations Manual* (1998). The standards align with international standards of breast screening programmes and were developed by Standards New Zealand for the NSU, with input from Lead Providers, representatives of all main professional disciplines working in screening, and ISPs, consumers and other key stakeholders (NSU 2004). Additional quality standards for mammographic screening are provided by the Royal Australian and New Zealand College of Radiologists (RANZCR, 2002).

The NP&QS address policy and quality issues associated with screening, the screening pathway, mandatory leadership positions and professional requirements. The standards form the basis for ongoing monitoring and auditing of service provision, and apply to all providers of the BSA programme, who are contractually obliged to meet the NP&QS. The NP&QS work in tandem with health and welfare legislation (e.g., Health and Disability Services Act 1993) with which providers must also comply.

The NP&QS were developed prior to the implementation of DM screening at BSWN and therefore do not address quality and standards issues specifically related to DM (DM policy is discussed below). However, the NP&QS more generally address the step-by-step protocols that must be followed along the screening pathway and these steps generally apply to processes in both DM and FSM screening.

The NP&QS addresses the possibility of new procedures for breast screening and directs that the technology or treatment should be:

- Used in accordance with RACS Breast Section Policy;
- Evaluated under the appropriate assessment process for New Zealand, for example the Australian Safety and Efficacy Register of New Interventional Procedures (ASERNIPS); or
- Approved either by BSA, a national body established with ethical approval, a local ethical committee, or be part of a research protocol. (p.66)

In addition, new technologies or treatments under BSA must comply with standard 18 of the NP&QS, which indicates that the approval and inclusion of new technologies are managed in accordance with evidence-based principles and the NSU's Framework for New Technology Assessment, relevant policies and procedures, and ethical review where required.

The quality framework of the NP&QS is consistent with the New Zealand Health and Disability System Quality Improvement Strategy, in that it follows a shift in emphasis from quality assurance to quality improvement. As part of this shift, QA becomes part of a wider quality system that aims for continual improvements in knowledge, technology, and changes in expectations.

In recent years, there has been a rapid rise in utilisation of screening services. This has been influenced by the introduction of age extension as well as the maturation of the programme, including better health promotion.

¹⁵ It is important to note that BSWN's decision in 2005 to implement DM was independent of the NSU's strategic priorities. As discussed in section 4, BSWN implemented DM without NSU support as the necessary policy work had not been undertaken at that time.

This increase in the utilisation of screening services has placed pressure on service providers who require increased screening workforce capacity, equipment, and fixed and mobile screening units. The NSU and BSA have recently identified the national implementation of DM as a potential means of addressing supply and demand issues for BSA (NSU, 2006). Specific policy on DM is presented below and detail on DM including its relative advantages/disadvantages in comparison to FSM is presented in section 3.2.3.

3.2.3 DIGITAL MAMMOGRAPHY POLICY

The NSU Digital Mammography Policy was not in place when BSWN made its decision in 2005 to go digital. Subsequently, in 2006, the NSU produced and released its policy specific to the use of DM in New Zealand. Now that this policy is in place, it will serve to provide more direction to other Lead Providers and simplify the transition to DM.

The policy is based on an extensive literature review and cost modelling, and provides national direction for the use of DM in the BSA programme. Specifically, it details overarching policy on DM, its advantages and disadvantages, regulatory requirements, specifications for digitisation of prior mammograms, staff training, possible impacts on subcontracted breast screening sites and mobiles, and evaluation of DM policy (NSU, 2006a).

The *Digital Mammography Policy Implementation Plan (2006b)* is a companion document to the DM Policy. The Plan details key aspects of the implementation processes (e.g. information system and staff training requirements; processes for transitioning to DM including planning and work flow considerations) and gives Lead Providers specifications of the equipment deemed suitable for current use, estimates of cost, resources, constraints and assumptions for implementation of DM across New Zealand. Additionally, the Plan estimates a rollout scenario for the implementation of DM by BSA Lead Providers.

Together, the Plan and associated policy give Lead Providers “...operational directives in order to purchase and implement digital mammography within BSA, whilst ensuring connectivity and integration of the equipment to maximise the benefits from the technology” (NSU, 2006b, p3).

Underlying the Policy and Plan is the NSU's endorsement of the use of DM for women enrolled in the BSA programme. This endorsement is based on overseas research, which shows essentially equivalent results for the effectiveness of FSM and DM in detecting breast cancer. The NSU anticipates that implementation of DM for all Lead Providers of BSA will be complete between the years 2011-2013.

The NSU's policy is clear in its aim to ensure a national approach to the implementation of DM and recommends that Lead Providers opt for digital technology when the time comes to replace existing FSM equipment. The Policy and associated Plan provide specifications for the type of DM equipment that should be used and these specifications will serve as the cornerstone to ensuring compatibility of DM systems between providers. For example, the DM Policy and Plan provide specifications for:

- The standards to which equipment must comply (e.g. Digital Imaging Communication of Medicine standard (DICOM) Standards);
- Minimum bandwidth requirements for image transfer (100Mb/s or “Fast Ethernet”);
- The type of image compression that may be used (e.g. when Lossy images can/cannot be used);
- The radiologist workstation, including megapixel size of images and type of monitor;
- Megapixel quality of MRT workstation monitors;
- Standardisation of displayed images through Default Display Protocols;
- Picture Archiving and Communication Systems (PACS) that integrate with existing PACS used within BSA (e.g. Sectra PACS);

- Integration requirements between the Radiology Information System (RIS), the PACS and the modalities; ¹⁶
- The DM modalities that can be used (e.g. Sectra Microdose, GE Senographe 2000D, etc);
- The digitisation of women's prior films; and
- Adherence to the interim DM quality standards (NSU, 2007c).

Standardisation of these factors will enable Lead Providers to link in with one another via telemammography so that images can be read in more than one location. This has been identified as a key benefit of transitioning to DM technology as it will help to address current radiologist workforce shortages that have impacted negatively on the delivery of the BSA service (NSU, 2006b). Teleradiology and broadband are discussed further under a separate heading below.

At present, Lead Providers using DM technology are required to comply with the *ACR Technical Standard for Digital Image Data Management* (American College of Radiology, 2002). These standards provide guidance on how to manage digital image data, including staff training issues. The ACR standards are set to be supplemented with Standards from RANZCR, which is currently developing Teleradiology Standards through the Quality Use of Diagnostic Imaging (QUDI) Programme. Requirements for staff training in DM are currently guided by the Mammography Quality Standards Act, which requires that MRTs and radiologist undergo eight hours of training in DM prior to undertaking DM exams (NSU 2006a; 2006b).

QA of digital images is of paramount importance as failure of quality control has been shown to reduce image quality which in turn may lower breast cancer detection rates. The effectiveness of quality control is dependent on the conduct of routine procedures with results being charted and compared to set standards. A position paper of the Australasian College of Physical Scientists and Engineers in Medicine (ACPSEM) provides detailed recommendations for performance evaluations of DM systems as well as recommendations for their QA testing (McLean et al, 2007).

The DM Policy and Plan specify processes that Lead Providers must follow in transitioning to a DM service. For example, if seeking funding for the purchase of new DM equipment, Lead Providers are required to undertake financial analysis of the implications of the transition to DM, present this in a business case to the NSU, and use a project management model for integration/implementation of DM. A lead time of seven years has been planned for a managed approach to the national implementation of DM. Ongoing technological advancements are anticipated during this time, as well as reduction to costs associated with current digital technology. As such, it is anticipated that lessons learned from early stage implementation may be applied to ongoing implementation processes.

As discussed in the Implementation Plan, providers may approach DM implementation in one of three ways: the '*big bang*' approach (all fixed sites and mobile screening units at once; a *gradual implementation* (fixed sites first with gradual replacement of worn out FSM machines, and then mobile units); or; *parallel implementation* (fixed sites first, with the possibility of Lead Provider taking over subcontracted services, or collaboration and guidance for subcontractor to implement digital mammography) (NSU, 2006b, p6). Irrespective of the approach taken, the Policy emphasises the need for careful and ongoing planning around DM implementation in order to minimise risks such as incompatible hardware/software that would disrupt national data sharing.

The DM Policy will be reviewed based on assessments of whether the policy is consistent with and maintaining the aims, operation and quality of BSA. As outlined in the Policy document, criteria for evaluation of BSA DM Policy will include but not be limited to:

¹⁶ The PACS has been likened to a library, and the RIS to a librarian, which searches and retrieves images stored in the PACS.

- Changes in the operational environment resulting from transition to DM;
- Lessons learned from implementation processes;
- Effects of DM on recruitment and retention of staff (e.g. MRTs and Radiologists);
- Use of telemammography;
- Effects on programme quality as determined by data on efficiency, specificity and sensitivity; and
- Perspectives of service users.

As DM is an emerging technology, the BSA DM policy is set to be revised in 2008/2009. Alongside further policy developments, ongoing attention will need to be paid to telehealth and broadband issues related to the transmission of digital images.

3.2.4 TELERADIOLOGY AND BROADBAND

The transmission of digital images through teleradiology has been used in New Zealand for some time and has recently been advanced by the development of RIS to collect referral data and its integration with DICOM images and PACS. Through the integration of these systems, medical images may be recorded in rural centres and then reported to urban radiologists via teleradiology.

An important advantage of DM over FSM is that it enables telemammography, which allows for transfer of images from one screening site to another, where radiologists are available to conduct image assessment through telecommunication channels and/or store images to DVD (NSU 2006a; NSU 2006b). Although teleradiology has been in use for some time in New Zealand for other forms of radiological assessment, it has only recently been used with mammography as mammography is the last of the radiology modalities to change to digital technology. In light of the intent to roll out a national approach to the implementation of DM, consideration needs to be made of the ICT required to support it.

Historically, a lack of telecommunications infrastructure to carry out services that require high bandwidth has negatively impacted on opportunities for telemedicine. This has been most apparent in areas such as rural settings where the need for telecommunications is greatest. At a minimum, telemammography requires broadband, which is consistently connected, high-speed, high capacity telecommunications technology. Although broadband services extend to approximately 93% of New Zealand, service uptake has been slow due to system limitations and system costs, with cost being the major barrier to uptake in rural areas.

A significant move to make broadband services more widespread throughout New Zealand (including rural areas) has come through the Provincial Broadband Extension Project (PROBE), an initiative that aims to ensure that the needs for supply of and access to broadband services for educational and economic developments are met and no longer monopolised by a few key service providers. PROBE is a multi-agency initiative led by the Ministries of Education and Economic Development. It is hoped that PROBE, working in tandem with the Primary Health Care Strategy, which addresses rural health care needs, will become significant drivers of telemedicine in New Zealand.

A stocktake of ICT supporting telehealth in New Zealand indicated that the way forward for future telecommunications developments would be to put primary focus on the use of videoconferencing for telehealth and to acknowledge other telehealth services including teleradiology. Based on the findings of the stocktake, a generic service delivery for telehealth was devised, which would also complement overarching objectives of the Health Information Strategy for New Zealand (HIS-NZ) (Ministry of Health, 2005).

The HIS-NZ is a policy document that reports on developments within the health sector and provides a plan for improving and enabling national information sharing. The Plan assumes the

involvement of the Ministry of Health, the Accident Compensation Corporation (ACC) and the DHBs, who have a role in development of district and regional communication networks.

The New Zealand Digital Strategy (2005) builds on other ICT approaches and was released by the Ministry of Economic Development following a whole-of-government approach to its development. The Digital Strategy is identified as a framework for encouraging better utilisation of ICT by both private and public sectors.

The NSU is collaborating with the Health Information Strategy Action Committee to ensure the maximal use of telemammography by BSA providers. According to the DM Implementation Plan, this work will be undertaken over a period of five years (from 2006), as the existing Health Network is upgraded to the Next Generation Health Network (NSU 2006b).

As previously highlighted, ACR technical standards provide the current basis for guidance on transfer and management of digital images and these standards will be supplemented through the QUDI programme currently being developed by RANZCR. As part of the QUDI programme, an interim report on the literature related to quality use of diagnostic imaging (Qs7ii) has been released and serves to identify issues associated with the development of teleradiology standards. Specifically, the report details 14 key issues to consider in teleradiology (e.g. communication and data compression, patient confidentiality, reporting environment, data security, etc). A key finding of this report is that it is generally difficult for the literature to keep pace with rapid advancements in digital imaging equipment and techniques. As a result, any standards for teleradiology will need to be flexible and provisions will be needed for continual refinement and amendment (Swain & O'Keefe, 2006).

3.3 RESEARCH CONTEXT

The following paragraphs provide a brief overview of relevant DM research including clinical effectiveness, workforce and cost implications.

3.3.1 CLINICAL EFFECTIVENESS

There is little research on the impact that DM screening has on breast cancer mortality rates, as most of this outcome-based research has been based on FSM. However, some research with proxies of mortality (e.g., tumour size, cancer stage) has been undertaken to test the effectiveness of DM screening.

Recent research has examined the relative effectiveness of FSM and DM to detect breast cancer. These studies were all prospective in nature (i.e., followed women over time and screened them prior to any cancer symptoms). The most widely cited of these are the Oslo I and II studies and the DMIST study.

Oslo I (Skaane & Young, 2003) was conducted using paired comparisons of FSM and DM on a sample of 3,683 women aged between 50-69 years. Findings showed no real advantage to either FSM or DM in detecting breast cancer in a sample of 3,683 women.

Oslo II (Skaane & Skjennald, 2004) involved 25,263 women who were randomised to undergo either FSM or DM. The cancer detection rates for each type of screening were 59% and 41% respectively. The differences between these rates were not statistically significant. However, it was noted that DM was associated with greater cancer detection in women 50-69 years. The recall rates were significantly higher for digital than for FSM in this study.

ACRIN-DMIST¹⁷ (Pisano et al, 2005) compared the relative effectiveness of DM and FSM by having asymptomatic women (N=49,528) undergo both types of screening. The results of this trial, which is the largest clinical trial of DM to date, showed no clear advantage for DM. However, there were subgroups of women for whom DM worked better. These subgroups included women who: were less than 50 years old; were pre- or peri-menopausal; and had denser breasts. In converse, women who did not comprise these subgroups were better served by FSM, however, these latter findings were indicated only by a trend in the data and were thus not significant.¹⁸ The study employed five different digital imaging systems but found no evidence of a difference in diagnostic accuracy with the type of machine.

Additional studies examining the relative effectiveness of FSM and DM have included the Colorado Screening Trails I & II (Lewin et al., 2001; 2003). The Colorado I study used paired FSM and DM breast screens to determine the relative effectiveness of each in detecting breast cancer. Across a sample of 4,945 women aged 40 and above, results showed no significant differences between the technologies in cancer detection. The follow up study, Colorado II, used similar research methods but with a larger sample of women (N=6,736). Again, this research revealed a lack of significant difference in breast cancer detection rates by film versus digital methods. However, DM was associated with fewer technical recalls than film-based methods.

In addition to differences in the rate of cancer detection and recall rates, research has suggested that the two technologies relate to different levels of anxiety in women undergoing screening. According to Parikh (2005), DM's rapid image processing reduces women's anxiety and discomfort, as well as radiation dose with some equipment. Despite these reported benefits of DM over FSM for screening, research has not shown any advantages of DM for diagnostic mammography (see Muttarak, 2007).

For further reviews on some of the above studies as well as additional literature on the relative benefits of FSM and DM in detection of microcalcifications and lesions, as well as other clinical applications of DM such as tomosynthesis (3D image capture) refer to Young & Kitou (2005).

3.3.2 POTENTIAL WORK FLOW IMPACTS

Research highlights relative work flow advantages of DM over FSM (Daus, 2004). For example, Legood and Gray (2004) comment on the potential for increased MRT productivity due to a more streamlined work flow. Some research has found that utilisation of DM technology can translate to a 20-25% increase in MRT productivity (Berns et al, 2006; Daus, 2004).

MRT time savings have been attributed primarily to the elimination of film processing (Berns et al, 2006). Elimination of film processing and QA for chemicals and film processors may also have flow on benefits such as a reduction in occupational health and safety issues, including chemical sensitivity and repetitive strain injury (NSU, 2006a, 2006b).

Other MRT work flow advantages identified in the literature include more rapid image acquisition, the ability to repeat images immediately with the woman still in the x-ray room, and potential for fewer technical recalls and repeat assessments.

Potential work flow benefits of DM for radiologists include opportunities for telemedicine including remote image reading and peer review which could help mitigate impacts of radiologist workforce shortages.

¹⁷ ACRIN-DMIST: The American College of Radiology Information Network (ACRIN) – Digital Mammography in Screening Trial (DMIST).

¹⁸ The results of this trial are important for the BSA programme in light of its Age Extension and the fact that 26.6% of women who undergo screening fall into the 45-49 age group (NSU 2006b).

DM also has the potential to produce time savings for administrative/clerical tasks such as the storage, retrieval and transport of hard copy films, and hanging of films for reading. However, there are additional processes of digitising images of prior exams and printing hard copies when requested.

Although DM has the potential to improve efficiency of breast screening, cautions have been noted with regard to the work flow implications of transitioning to DM. For example, it has been found that radiologists may take more time viewing images (Berns et al, 2006; Daus, 2004). This is because the image magnification, orientation, brightness and contrast can be manipulated, allowing the radiologist more viewing options than with FSM. However, this may also confer a time saving if it reduces the need to recall women to obtain additional images.

Although DM eliminates film processing and associated QA tasks, Parikh (2005) notes that the QA process for DM is complex compared with that of FSM. QA tests unique to FFDM include contrast-to-noise ratio, signal-to-noise ratio, artefact evaluation, and soft-copy workstation evaluation. Each manufacturer has specific QA requirements and these can impact in terms of a slow learning curve, increased time commitment, and interference with clinical work flow.

Other factors can erode efficiency of DM if systems are configured suboptimally. For example, Berns et al (2004) identified technical problems and time delays in the transfer and retrieval of images that delayed the interpretation of digital cases.

3.3.3 COST AND BENEFIT IMPLICATIONS

Compared to FSM, the costs of DM are characterised by higher capital costs, which may be offset by operating efficiencies. Due to the higher initial costs, high screening volumes are required for DM to breakeven against FSM. The following paragraphs provide an overview of the establishment and ongoing costs (and cost savings) of DM compared to FSM, based on a literature scan. Section 6 explores the costs of DM at BSWN.

ESTABLISHMENT COSTS

Establishing a DM service requires investment in two key technologies: image capturing equipment, and information and communications technology (ICT) to store, transmit and display the images. Other establishment costs include changes to facilities, and staff time spent in planning, implementation and training.

Cost analysis by the NSU notes that one FFDM machine costs 2.3 to 3.5 times more than a FSM system (comprising a FSM machine, a roller viewer, a film loader with a set of cassettes, and a film processor) and that total annualised equipment costs for a DM system are from 1.9 to 2.3 times higher than for a FSM system. Therefore, a breast screening facility needs to perform a substantial volume of mammograms and run a DM system close to full capacity to justify the expenses (NSU, 2007b).

Depending upon the initial state of readiness of the breast screening site to transition to DM, establishment costs of ICT may include hardware and software for PACS, DICOM, RIS interface, reading workstations, digitiser, laser printer, broadband infrastructure, as well as technical and project management support to install and configure the systems and ensure they operate effectively as a unified system. A typical mammogram, incorporating a minimum of four images, requires 35-216 Mb of memory for each woman screened (Dershaw, 2004). Consequently, the storage and transmission of DM images requires substantial computer memory and bandwidth. Appendix C details the ICT infrastructure required for DM and how this has been configured at BSWN.

Changes to facilities will vary depending upon the nature of the existing workspace. However, key changes may include reconfiguration of the layout of waiting/changing rooms, x-ray rooms and QA workspaces to take full advantage of the potential productivity gains from DM, and elimination/reduction in darkroom and storage space. However, darkroom space may still be

needed if the service continues to operate some FSM equipment, and storage needs are likely to reduce gradually over some years due to the ongoing retention of prior mammograms and paper files.

The transition to DM will inevitably require an investment in staff and potentially external contractor time including management, financial, clinical and technical staff. These will vary from site to site in terms of their detail, but are likely to include processes similar to those described in section 4 with regard to BSWN.

ONGOING COSTS

Ongoing costs for DM and FSM include costs such as workforce, maintenance, consumables, storage/transport, and the annual cost of capital (e.g. depreciation and interest).

Overseas research suggests that the workforce costs of DM can potentially be lower than those of FSM, depending upon service and staffing configurations. For example, some overseas research has suggested a 20-25% increase in MRT productivity and savings in clerical/administrative support time. However, these efficiencies may not be realised immediately, as business processes may be refined over time and some additional tasks (such as digitising of prior films) may be involved in the transition period.

Some staff/contractor costs may increase in a DM environment. For example, physicist time may increase due to the additional maintenance and QA required in a DM environment. A Canadian study assumed an increase from 0.1 to 0.35 FTE (NSU, 2007b).

Maintenance costs such as an equipment maintenance contract and IT support may be higher for DM. Maintenance costs of a FFDM machine have been modelled by the NSU at 1.8 to 2.9 times higher than those of a FSM machine (NSU, 2007b). Maintenance contracts can be negotiated as part of the purchase price of most major equipment, effectively fixing the cost of maintenance in the first 2-3 years.

The costs of consumables, storage and transport should reduce with DM if images are stored and retrieved electronically, due to the removal of films, chemicals and paper files from the process (some sites overseas make hardcopy printouts of DM images using a laser printer, which erodes these cost savings) (Legood & Gray, 2004). However, storage costs may take some time to reduce due to the ongoing storage of prior films. DM also brings new consumable costs including software renewal and general overheads such as electricity consumption (NSU, 2006b; Parikh, 2005).

Parikh (2005) argues that more research is required to evaluate the hypothesised cost-efficiencies of DM accounting for a fully digitised system and for clinical experience and outcomes, and that this cost modelling needs to be an ongoing process in light of relatively rapid changes in technologies and increased possibilities for system integration.

COST-EFFECTIVENESS

Cost-effectiveness analysis is one of a number of different approaches to measuring value for money. It examines both the costs and the consequences (or effectiveness) of alternative courses of action (Drummond et al, 1997). Effectiveness is measured in natural or physical (rather than monetary) units, with the outcome measures being relevant to the objectives of the intervention or programme (e.g. cancers detected; life years saved). When comparing the relative value for money of DM compared to FSM, however, it is valid to compare the cost per woman screened, as the relative clinical effectiveness of DM and FSM in detecting breast cancer is essentially equivalent.

A recent study commissioned by the NHS Breast Screening Programme in the UK compared the relative cost-effectiveness of FSM versus DM for use in breast cancer screening and assessment. Two different DM machines were trialled alongside FSM machines at two different breast screening sites. Costs associated with the machines such as consumables, equipment, storage

and staff time (e.g., administration, processing time, radiologist review time) were examined. The research did not provide a full cost analysis of a PACS system as consideration of the range of factors associated with its costs were beyond its scope (e.g., consideration of image size, image compression, existing PACS system and updatability, web server requirements, mobile versus stationary screening centre, etc.) (Legood & Gray, 2004).

The main findings from this study were that cost savings in image storage for DM would not be maximised unless a fully digital screening system was implemented, including digitisation of patient information via a RIS and digitisation of prior patient screens. Some of these factors, while contributing to increased costs for DM over FSM in the initial phases of DM implementation, may decrease over time as systems become more integrated and embedded (Ibid).

The research also found that the total annual cost of screening 10,000 women per year was less for FSM than DM with maximum estimates of £113,700 versus £192,946 respectively. This maximum cost for DM was based on an assumption of no printing of hard copy digital images, and in the case of DM the estimated costs did not account for equipment replacements (e.g., detectors). However, the study indicated that over time it was likely that the cost of DM would level off and be comparable to FSM (Ibid).

In New Zealand, the NSU has recently undertaken cost modelling of the transition from FSM to DM, as part of the development of policy and planning for the implementation of DM in BSA. The analysis included capital equipment costs, and costs of maintenance and consumables. It excluded broadband image transfer costs for DM and corresponding courier costs for FSM. Sensitivity analysis included varying assumptions with regard to productivity gains in equipment capacity and MRT time (NSU, 2007b).

The NSU's modelling produced a baseline estimate of total annual costs for FFDM equipment per 10,000 women screened of \$284,143, with a minimum estimate of \$247,913 and maximum estimate of \$323,210. In comparison, the baseline estimate for the cost of FSM equipment, consumable and semi-consumable items per 10,000 women screened was \$172,226, with a minimum estimate of \$159,041 and maximum estimate of \$217,985 (Ibid).

The NSU's analysis found that to screen total BSA eligible population at a 70% coverage rate using FFDM over seven years would require at least \$34.32 million initial investment into DM equipment as compared to \$13.34 million if invested into completely new FSM equipment. To enable Lead Providers to cover their operational expenses with FFDM equipment, total funding would need to be increased by 12% to 17% relative to current funding levels (Ibid). This would cost the NSU from \$5.8 million to \$6.5 million extra per annum in payments to Lead Providers.

The DM Implementation Plan outlines the equipment costs for each technology and presents a comparative view based on the cost modelling, which demonstrates the higher costs of DM (NSU 2006b). In analysing costs for the development of a business case, the NSU recommends that Lead Providers consider the following key factors that help to offset costs of DM:

- Increases in volumes of women screened;
- Changes to work flow and how these may impact upon screening times;
- Impact on mobile van movements that will be much faster due to increased screening volumes at mobile sites; and
- Intangible benefits such as fewer technical recalls, less anxiety for women, etc.

Other cost modelling for DM has been undertaken by the National Health Service Breast Screening Programme (NHSBSP) in the United Kingdom (UK) and has been made available to the NSU as an Excel spreadsheet for cost modelling. The tool is intended as an aid and includes the following costs: Image profile (e.g., actual/estimated operational volume and efficiency); Material costs (e.g., per image); Facilities; and Resources (e.g., per exam). These costs are 'rolled up' into a summary of expenses and are broken down by annual, per exam and per image calculations (NSU 2006b). These cost workups are meant to assist Lead Providers in the New

Zealand context to plan for and implement DM based on evidenced based and sound modelling techniques.

3.3.4 TRANSITIONING TO DM

BSWN did not transition to DM; rather, the technology was adopted as part of the implementation of BSWN as a new Lead Provider. Nevertheless, a staged approach was followed (see section 4).

Other Lead Providers each have a choice of converting to DM gradually or in one hit. The benefits of a gradual transition include the spreading of initial costs over several years and the ability to adjust to the technology slowly (Zuley, 2004). Daus (2004) notes that many mammography facilities worldwide have chosen to make a gradual transition to DM. A gradual transition may involve starting out with one digital unit, identifying any *“delays, kinks and psychological glitches”*, and developing solutions before acquiring additional equipment (Daus, 2004). The main disadvantage of a gradual approach is that the provider has to maintain two work flows for MRTs and radiologists (Zuley, 2004). Making an immediate conversion to DM may realise work flow benefits more quickly, but reduces scope to manage implementation costs and risks.

Zuley (2007) makes a number of recommendations for facilities transitioning to DM. These include the following:

- Analyse the existing FSM situation, taking note of existing equipment, infrastructure, capacity and work flow. This will help determine what type of digital equipment will be the most logical choice, and an appropriate pace of conversion.
- Assess ICT requirements including PACS, RIS, workstations, storage, bandwidth, and what is required to integrate these and ensure their compatibility with the DM equipment.
- Use a transition team that includes someone from every department affected by the transition, to work together and discuss what details need to be taken into account. This will help to avoid or minimise integration and work flow problems after installation. The team approach is also helpful in assessing current work flow and patient capacity and identifying opportunities for improving these in the transition to DM.
- Set goals for the facility, in order to guide decision making about the transition to DM. *“After the goals are identified, understanding the digital options and how each choice will affect the goals will be easier”*.
- Consider what types of acquisition technology, workstations and other components are the most appropriate, and how these relate to facility layout and work flow. As part of this, determine how prior films will be handled in the new environment (e.g. will they be digitised or viewed in their analogue form), and what storage capacity is needed and how this can best be met.

4

PROCESS FINDINGS

This section provides a description and assessment of the decision making and implementation processes associated with the implementation of DM at BSWN. In considering these processes, it is important to understand the wider project context in which DM was implemented. Decisions about DM and decisions about the development of the service as a whole were inextricably related.

Prior to the establishment of BSWN, both WDHB and NDHB provided diagnostic breast services but neither DHB provided any screening or assessment services as part of BSA. Therefore, the establishment of BSWN was essentially a green field development. Accordingly, decision making and implementation encompassed all aspects of service development of which the decision to go digital was just one part.

This influenced the decision to go digital. Because BSWN was being wholly developed as a new service within WDHB and NDHB, a decision needed to be made whether to develop all facilities and processes to accommodate FSM or to design everything from the outset for DM. Mammography equipment has a life of approximately eight years, and hence had the decision been made to install FSM equipment, it was unlikely that a business case could have been made for changing to DM for another eight years.

4.1 OVERALL PROJECT STRUCTURE

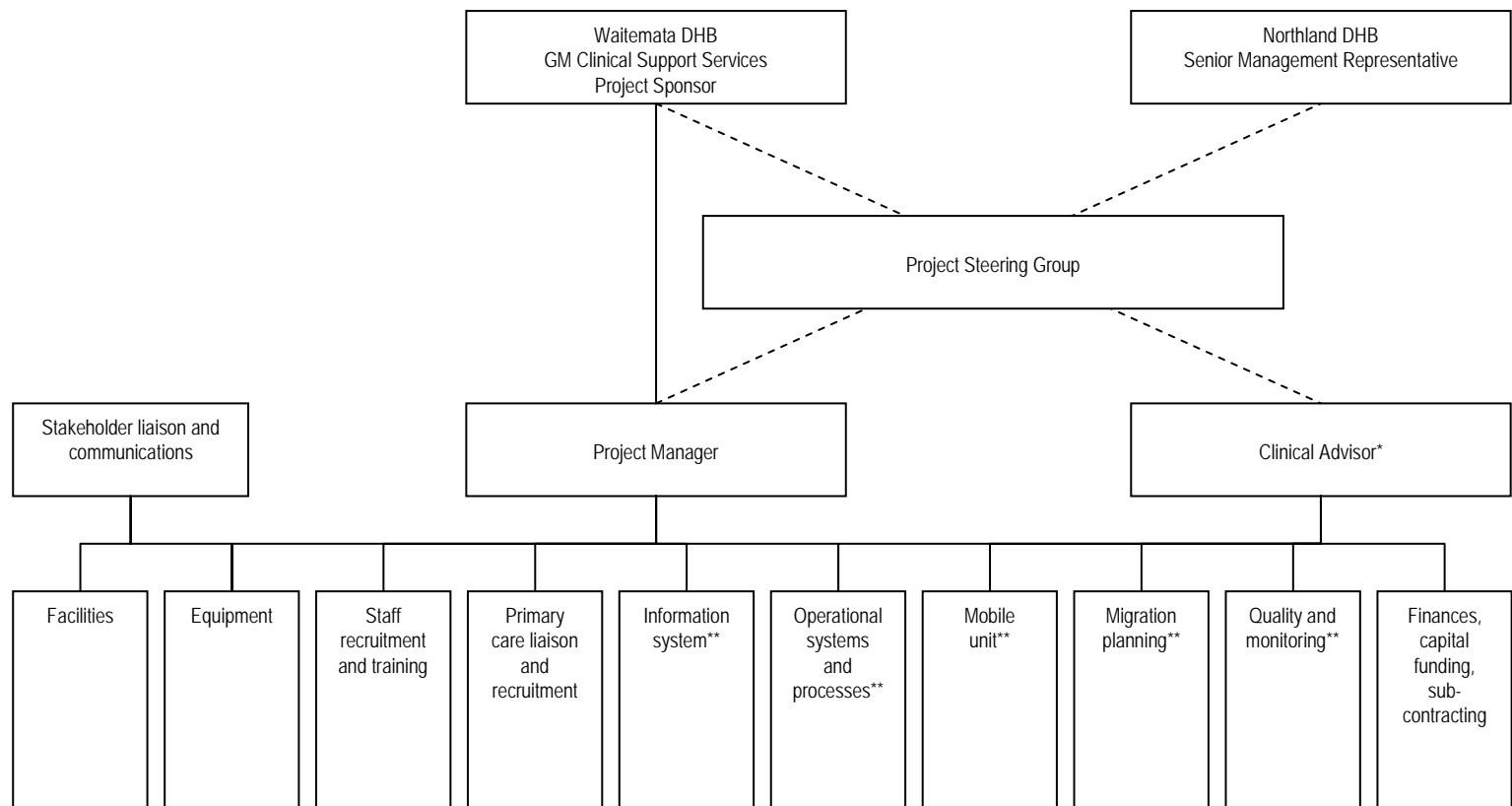
The organisational structure for the BSWN implementation project is shown in Figure 4.1 on the following page. A high level project plan (BSWN, 2005a) and overall Gantt chart were developed for the BSWN implementation project including identifying key milestones, interdependencies between projects and a critical path. Throughout the duration of the planning and implementation project, regular milestone progress was prepared for the project Steering Group. In addition, an issue and risk register for the project was maintained, and issues and risks were raised at each Steering Group meeting.

BSWN covers a large and complex region, and the new programme was established within a relatively short time frame. Therefore, planning and the early stages of implementation often needed to occur in parallel. The high level project plan acknowledged that ideally, the implementation phase of a project would not commence until the planning stage was complete. However, some aspects of implementation needed to begin during the planning phase in order to ensure their completion in time for BSWN's go-live date of 1 February 2006 (WDHB, 2005a).

Accordingly, the overall project and each sub-project had both planning and implementation tasks. These two streams of work were managed carefully to ensure that new information identified via planning could be immediately reflected in implementation.

WDHB appointed a Project Manager who was responsible for the overall coordination of the activities involved in establishing BSWN including all planning, decision making and implementation of DM. The Project Manager reported to the Project Sponsor (General Manager, Clinical Support Services at WDHB) who had overall management responsibility for the project.

Figure 4.1: Project Structure for BSWN Implementation including DM



* The role of clinical advisor was undertaken by a number of different people through the planning and implementation phase.

** Indicates BSWN region-wide sub projects which were managed by WDHB in collaboration with NDHB. The other sub-projects were managed separately by WDHB and NDHB for their respective districts. All of these were linked together and project staff in NDHB and WDHB worked closely together on all related aspects. For example, equipment requirements were combined for additional purchasing power and managed via healthAlliance. A wide range of clinical, technical, cultural staff and operational staff were involved at all levels of the overall project.

Source: WDHB, 2005a. This report does not identify individual participants by name, hence job titles have been used in this diagram and in the explanatory text below.

The role of clinical advisor to the project was undertaken by a number of different people through the planning and implementation phase. The clinician who provided much of the early clinical advice to the project had never worked in breast screening, and so was hesitant to accept the full mantle of 'clinical advisor'. Clinical advice was also provided by radiologists from the WDHB Radiology Department who had previous or present breast screening and/or diagnostic breast cancer expertise.

During August/September 2005, negotiations were underway with a radiologist in the UK with experience in a DM screening environment regarding the permanent Clinical Director position for BSWN. This radiologist agreed to contract some of his time to provide clinical advice to the digital team to ensure that if he did accept the permanent position, he had been involved in the decision making processes around DM.

The project Steering Group was established in March 2005. The role of the Steering Group was to:

- Review and provide comment on relevant documentation;
- Approve all project plans and other documentation for the implementation project;
- Receive monthly reports from the Project Manager on progress with design and implementation and provide input and advice as appropriate;
- Monitor agreed project milestones and agree actions required in the event that milestones were not being met;
- Ensure that relevant staff in their respective organisations were in a position to contribute to the project;
- Provide advice on key issues as they arose during the course of the project;
- Monitor the implementation budget;
- Receive risk reports from the Project Manager and agree risk mitigation strategies; and
- Contribute to and sign off bi-monthly updates for key stakeholders and other communication initiatives.

The Project Manager reported to this steering group. Membership of the Steering Group consisted of two members from WDHB (the Project Sponsor and a Public Health Physician) and two members from NDHB (Portfolio Manager, later replaced by GM Clinical Support Services, and a representative of Te Tai Tokerau MAPO (WDHB, 2005a).

The implementation project was divided into ten sub-projects covering various aspects of the overall establishment of BSWN:

- **Facilities:** Identify need for new/refurbished facilities at all sites; plan and design new facilities; building/refurbishing;
- **Equipment:** Identify equipment requirements; prepare specifications; procurement/tendering processes; order and install new equipment. This sub-project was later divided into clinical and non-clinical equipment sub-projects;
- **Staffing recruitment and training:** Appoint Clinical Director and Programme Manager; advertise, appoint and train all new staff;
- **Primary care liaison and recruitment:** Set up working liaison arrangements with primary care providers; develop and document health promotion and recruitment strategies; book first appointments prior to first screening day;
- **Information systems:** Confirm new IT system to be used; scope all aspects of IT and requirements for service; plan for migration of data from BSAN; install and test IT systems; accreditation by NSU. This sub-project expanded considerably once the decision to go

digital was made, as this sub-Project Manager had responsibility for all IT components of digital, e.g. PACS, interface issues, digitising priors, etc;

- **Operational systems and processes:** Identify and document all operational systems and processes; establish all operational systems and processes;
- **Mobile unit:** Specific planning and implementation work for the establishment of BSWN's mobile unit including detailed route planning;
- **Migration planning:** develop plans for all aspects of migration of data, files, etc to BSWN from BSAN;
- **Quality and monitoring:** implement quality and internal monitoring plans;
- **Finances, capital funding, sub-contracting:** Submit capital funding applications; identify and confirm sub-contract mammography providers (WDHB, 2005a).

Of central importance to this evaluation are the two sub-projects focused on equipment and information systems respectively. The decision to go digital also had direct impact on a number of other sub-projects such as facilities, staff recruitment and training, operational systems and processes, quality and monitoring, and finances/capital funding, as discussed elsewhere.

Each sub-project had an identified project leader and its own project plan. Leadership of many of the sub-projects changed over time. The overall Project Manager was also the sub-project leader for a number of the sub-projects. Once the equipment sub-project was split into clinical and non-clinical equipment sub-projects, the overall Project Manager took responsibility for the clinical equipment sub-project. Once the BSWN Programme Manager commenced employment, she assumed responsibility for a number of the sub-projects.

Collectively, the Project Manager and project leaders formed the "project team". In many respects, the project team operated as a virtual team, with individuals working from different locations on different arrangements. The whole team held face to face meetings as required to discuss specific issues or planning and implementation challenges. Between these meetings, teleconferences and smaller meetings of sub-groups took place to work on specific issues (WDHB, 2005a).

Each project leader developed a sub-project plan for their area of responsibility. This included detail of all activities to be managed by that project leader and linkages between sub-projects. Project leaders reported to the Project Manager for all project activities. In addition, DHB staff reported to their line manager (and contractors reported to the Project Sponsor) for contractual matters (Ibid).

NDHB established a similar project structure for the NDHB implementation, including appointing a Project Manager to oversee all project work streams in Northland. The NDHB Project Manager worked closely with the overall Project Manager, and individual WDHB sub-project leaders worked with the NDHB Project Manager and/or relevant staff on the ground where appropriate (for example, to coordinate bulk purchasing arrangements).

As the service's operational team was appointed and as each new BSWN staff member came on board they became involved and included in the sub-project relevant to them. Prior to 1 February 2006 when the service went live, there was a staged hand-over from the project team to the operational team (Ibid).

4.2 DIGITAL PROJECT STRUCTURE

The early stages of consideration of whether to go digital were managed by the overall Project Manager, working directly with relevant staff.

The initial Capital Expenditure Proposal to the WDHB Board, in May 2005, sought approval for capital expenditure and lease agreements based on FSM. On 15 July 2005, the WDHB Chief

Executive and the Chair of the Board met with the Project Sponsor and agreed that the BSWN project team should prepare a revised business case based on using digital technology from day one.

A dedicated Digital Working Group (DWG) was subsequently established to work on all aspects of the planning and implementation of DM. This group included a range of staff who had extensive experience in planning and implementing a PACS environment, establishing the required quality infrastructure and training staff. The group comprised mammography radiologists, MRTs, IT and PACS specialists and equipment procurement staff. An external medical physicist and MRT advisor were also contracted by WDHB, specifically to work with this group. The NDHB Project Manager attended meetings.

The overall Project Manager managed the work of the DWG. The group met at least weekly, with additional meetings being called as and when required for particular tasks (for example, preparation of tender documents, presentations from prospective vendors). The DWG's first meeting was held on 2 August 2005.

The DWG established links with DM implementation teams in New South Wales, Victoria and Tasmania to share documentation and experiences wherever possible.

Following extensive consideration and discussion with NDHB, a staged process of DM implementation was agreed which enabled DM implementation at Whangarei to capitalise on learning from the DM implementation at Takapuna, and likewise for DM implementation at Waitakere to benefit from learnings from implementation at Takapuna and Whangarei, as outlined below:

- **Stage 1:** Effective 1 February 2006: Implementation of DM at the Takapuna screening and assessment site, including two DM machines (one with stereotactic capability), a mammography PACS system and two MRT PACS workstations, two radiologist reading workstations, film printer, digitiser;
- **Stage 2:** Effective April 2006 (later moved to July 2006): Implementation of DM at the Whangarei screening and assessment site, including one DM machine¹⁹ (with stereotactic capability) (later changed to two DM machines), two MRT PACS workstations, two radiologist reading workstations, and film printer.
- **Stage 3:** Effective July 2007: Implementation of DM at Waitakere screening site (one DM machine and one MRT PACS workstation);
- **Stage 4:** Effective potentially in 2007/08 financial year (now planned for 2010): Implementation of a mobile DM unit; and
- **Stage 5:** Working with BSWN sub-contractors to support them in conversion to DM if/when appropriate.

Following the 15 July decision of the WDHB CEO and Board Chair to consider a revised business case for BSWN based on the above staged approach to implementation of DM, there were a series of letters, discussions and meetings between BSWN and the NSU which culminated in a formal proposal being sent by BSWN to the NSU on 24 August 2005, formally seeking approval from the NSU for BSWN to be established as a pilot for FFDM within BSA (BSWN, 2005b).

In that proposal, BSWN acknowledged that the decision to implement DM at BSWN would mean that it would be the first Lead Provider to do so, and the significance of this for BSA and other Lead Providers. BSWN noted that it was fully committed to the national BSA programme and to ensuring it work as closely as possible with other Lead Providers and the NSU. In that context, BSWN was

¹⁹ NDHB has two DM machines. One of these was purchased for BSA work. Operationally, both machines are used for screening and assessment on some days of the week, and on other days are used by the diagnostic service.

keen to ensure that the digital developments could be structured in such a way as to provide maximum gain to the NSU and other Lead Providers in due course. To that end, BSWN signalled a preference to formalise its digital planning and implementation as a BSA pilot (BSWN, 2005b).

The NSU advised BSWN, in a letter dated 2 September 2005, that *“the NSU will not consider funding, additional to the implementation funding already provided, for the operational components of this project, for example the purchasing of equipment, acceptance testing, training and quality assurance. As explained previously, this is because the decision to implement digital mammography nationally has not yet been made”*.

At a subsequent meeting between the Project Sponsor and the BSA Clinical Leader, the NSU designated the BSWN digital development as a BSA pilot. Although additional funding was allocated internally within the NSU for evaluation of the pilot, there was no further funding made available to BSWN to implement digital beyond the funding of the IS project, including RIS/PACS integration.

4.3 KEY STAGES IN DECISION MAKING AND IMPLEMENTATION OF DM

Key stages and milestones in the planning and implementation of BSWN, of relevance to the concurrent implementation of DM, are summarised in the following paragraphs.

August 2004:

- NSU recommends to the Minister of Health that breast screening services in Auckland and Northland be reconfigured by contracting with two new Lead Providers (WDHB for the Waitemata and Northland regions and CMDHB for the South Auckland region).

January 2005:

- WDHB engages a Project Manager to manage all aspects of planning and establishment of the BSWN service.
- High level project plan (including sub-project structure) prepared (BSWN, 2005a).
- Around this time NDHB also appoints a Project Manager to coordinate aspects of implementation that were specific to Northland.

March 2005:

- Formation of the project steering group and confirmation of working arrangements between NDHB and WDHB for all aspects of the project as well as functional relationships between the Project Manager, clinical advisor, steering group, and Project Sponsor.
- Revised version of the high level project plan signed off by Steering Group at its inaugural meeting.

April 2005:

- Agreement on the high level configuration of BSWN including the location of assessment centres.
- The need to consider digital technology is first mooted in an *Issues and Options* paper (Peel and Herbert, 2005). This paper, developed following extensive consultations with WDHB and NDHB teams, sets out the basis for decisions to be made over the service delivery model including options for meeting required volumes. Paper is supported by analysis including 10-year master volume projections by Territorial Local Authority (TLA) area; projected impact of volumes on staffing, equipment and mobile unit requirements; benchmarking against other service providers to further inform configuration, service structure, staffing requirements, etc. Paper notes that decisions are required about the extent to which DM would be implemented at Takapuna and Whangarei, including a need for more detailed planning and financial analysis and consideration of training requirements, issues of some films being digital and others being hard copy, and

requirements for screening and assessment to be done using the same mammography machine.

- At this stage, the results of the international ACRIN trials into DM had not been announced. The Clinical Leader of BSA indicated that use of DM equipment within BSA could only proceed if the DMIST trial results (to be reported in November 2005) indicated clinical equivalence or better for FFDM versus FSM. One option considered at this stage was to purchase FSM equipment that could later be converted to Computed Radiography (CR)²⁰ digital technology rather than purchasing Digital Radiography (DR) technology from the outset.
- Project Manager presents the Issues and Options paper to the steering group and key internal stakeholders, works through the issues and reaches agreement on the way forward. Agreed service delivery model is documented in detail and sign-off obtained from management on service delivery model.
- Appointment of project leaders (some DHB staff and some contractors) for each sub-project and development of draft sub-project plans.
- Comprehensive cost model for all steps and stages of the programme developed based on volumes projected via the Issues and Options paper.
- Confirmation of major equipment requirements based on assumptions that all equipment would be FSM initially but that CR digital equipment would be purchased for Waitakere in 2007/08 and the mobile unit would be converted to CR technology in 2008/09.
- Identification of capital funding requirements for 2005/06, 2007/08 and 2008/09, and preparation of full business case based on projected capital requirements and revenue and operating costs based on projected volumes from the costing model (see above).
- NDHB appoints an independent consultant to take over the role of project management for Northland.

May 2005:

- Business case submitted to the May meeting of the WDHB Board, with a capital expenditure proposal demonstrating that income earned from the programme would cover the cost of borrowing to fund capital. The submission (WDHB, 2005b) was based on FSM but noted that a key technical requirement for the future of BSWN would be the provision of DM and that all equipment purchased would be capable of being converted to CR digital technology at a later date (assuming the results of the ACRIN trials were favourable). The paper also noted that telelinking the Northland and Waitemata sites would provide optimal clinical management and team building opportunities and would assist the service to be at the forefront of BSA developments, but that further planning work was required to ascertain the extent to which current technology could be implemented in the multidisciplinary screening arena.
- WDHB Board approves capital expenditure of up to \$2.97 million for purchase of clinical equipment, IT software and hardware (including contingency sums) and the signing of a Lease Agreement for six years.
- Project Manager holds liaison meetings with staff, contractors and potential sub-contract providers to assist in identifying all implementation requirements and to confirm the assumptions made in the issues and options paper, the service delivery model and the business case.

²⁰ CR uses conventional x-ray equipment to capture an image, but stores the image to a cassette-based imaging plate which is subsequently removed from the x-ray machine in the same way as a film cassette. When processed, a digital image is produced.

June 2005:

- Appointment is confirmed for the Programme Manager Position, for an August 2005 start.

July 2005:

- Charge MRT at WDHB Radiology Department has meeting with Project Manager and urges a reconsideration of the decision to settle for CR digital technology and then only at Waitakere and on the mobile. He had heard that the results of the ACRIN trials were very favourable for DR technology but less convincing for CR digital technology.
- Project Manager makes contact with BreastScreen NSW in Sydney to find out what digital developments were being planned in the NSW programme.
- Charge MRT at WDHB meets with the NSW State Radiographer and other key people while in Sydney, and discusses digital developments.
- Project Manager raises the possibility of making a decision to implement DR digital technology from day one with the Project Sponsor, and prepares a paper of key information collected to date.
- Project Sponsor meets with WDHB CEO and Board Chair. Agreement reached that the project team should proceed to investigate the possibility of going digital from day one and that a revised business case should be prepared based on this and submitted to the Finance and Audit sub-committee of the Board. Subsequent discussions held with NDHB who agreed to follow a parallel approach with its developments and business case.
- Project Sponsor sends a letter to NSU advising that *"There is now a unanimous view within both DHBs that our new breast screening sites should be established with digital mammography"* (22 July 2005).
- Visit arranged by Sectra (one of the digital suppliers) to visit WDHB and give a generic educational presentation on digital technology and the status of digital usage for screening mammography worldwide. NSU representatives attend this briefing.
- Dedicated Digital Working Group (DWG) established. The DWG took the lead in the scoping and procurement processes for planning, purchasing and implementation of all digital equipment and IT configurations and requirements.

August 2005:

- DWG starts weekly meetings.
- NSU representatives meet with CEOs and related staff from the three Auckland/Northland BSA providers.
- BSWN receives a letter from NSU, inviting BSWN to prepare a formal proposal to pilot DM within BSA and outlining the key points to be included in such a proposal.
- WDHB submits a proposal to the NSU seeking approval to formally designate BSWN as a pilot site for the implementation of FFDM within BSA.
- Contact made with a number of people internationally to gather more information regarding digital developments for screening mammography.
- Project Manager and Finance Manager prepare revised business case based on projected costs and savings associated with going digital.

- The Finance and Audit Committee of the WDHB Board approves the revised business case including the capital expenditure for digital technology (22 August 2005).²¹

September 2005:

- Ratification obtained from the Regional Capital Committee and approval from the National Capital Committee for the required borrowing for WDHB capital expenditure.
- RFP for a range of digital equipment requirements is issued on GETS website (18 August 2005). Due to time constraints, this RFP had a relatively short turnaround time. To expedite the process and ensure fairness to all prospective vendors, the procurement officer contacted all known equipment suppliers directly to advise them of the RFP, and a fast track system was put in place to respond to questions from suppliers about the RFP.
- DWG develops comprehensive evaluation criteria for the selection of the digital equipment.
- All proposals evaluated and shortlisted by the DWG. Shortlisted suppliers come on site to give presentations and answer questions.
- Decision made to send a team to Europe to evaluate the shortlisted DM machines and PACS systems in working situations.
- NSU writes to WDHB in response to the proposal to pilot DM, stating that if additional funding were to be made available it would be limited to funding for an evaluation, because NSU had not yet made a decision to implement DM nationally.
- Meeting held between BSA Clinical Director and the Project Sponsor and Programme Manager at BSWN. NSU advises it is not willing to consider funding BSWN as a pilot site. NSU offers to consider an application for additional IT establishment funding to ensure PACS developments for BSWN are able to be rolled out to other Lead Providers as they go digital.
- ACRIN trial results available, showing positive findings for DR digital equipment, and less conclusive results for CR digital technology for screening mammography.
- Conversation between Clinical Advisor BSWN and Clinical Leader BSA to confirm NSU approval in light of ACRIN results.
- Draft changes made to facility design as information comes to hand about requirements for DM equipment. Modifications to plans continue to be made up until November 2005, to reflect specific requirements of the equipment finally selected.
- Facility construction plan is signed off based on an assumption that Takapuna site will be digital from day one.

October 2005:

- Digital evaluation team members visit five countries in Europe to assess DM and PACS equipment in operation. Evaluation findings are fed back to the rest of the DWG in New Zealand via a teleconference (including a link in from NDHB team) at the end of the five days of assessments, to expedite decision making processes.
- DWG makes final decision to go digital.
- DWG with healthAlliance (hA)²² decide that Sectra PACS is the preferred system. Project Sponsor gives approval to proceed with negotiations with Sectra regarding price, contract terms and conditions, and a project plan for implementation. The PACS decision was

²¹ WDHB has advised that the same paperwork went to the Finance and Audit Committee as went to the National Capital Committee and Regional Capital Committee. This document was provided to the evaluators (WDHB, 2005b). A separate business case was processed by NDHB. NDHB did not have to get National Capital Committee approval to borrow capital funds because the DHB had funds on hand to purchase capital.

²² hA is a shared service company, jointly owned by Counties Manukau and Waitemata DHBs.

made ahead of decisions regarding DM machines as it had a longer lead-in time for its establishment.

- Project sponsor formally advises Sectra that they are the preferred supplier for the PACS based on the agreed price and subject to finalising terms and conditions of the contract.
- Endorsement of selected PACS system obtained from Regional Information Services Strategic Planning (RISSP) Governance Group – the Auckland regional DHB IT group that has to endorse all new IT developments.
- hA holds preliminary price negotiations with shortlisted vendors of DM machines to ensure the selected range of equipment can be obtained within the budget approved by the Board. NDHB project team is included in all aspects of negotiations to ensure synergies in decisions regarding modalities between Takapuna and Whangarei sites.
- Workshop held to start to work-up and document the operational business processes for DM environment.
- NSU approves additional establishment funding to cover the cost of developing an interface between the PACS and Soprano Breast Screening (SBS) database.
- Facility development work is prioritised so that areas of the facility likely to change as a result of final decision regarding DM and selection of equipment are developed last. Minor modifications made to plans after September 2005 sign-off, once specific requirements of each item of selected equipment are known and to reflect learnings from European site visits regarding optimal facility arrangements for DM working environment.
- Requirements for enhancements to SBS developed in conjunction with Orion and development begins.

November 2005:

- Contract signed between WDHB and Sectra for PACS.
- Drafting underway of Operational Policies and Procedures manual for BSWN including all clinical and operational aspects related to DM environment.
- Project Sponsor makes decision to order Siemens DM machine (11 November 2005) and Sectra DM machine (14 November 2005). Contract negotiations commence with these suppliers.
- Final changes to mammography rooms, air conditioning requirements, etc. at Takapuna site to reflect decisions regarding modalities.
- Contracts negotiated for all sub-contractor screening sites following RFP process.
- PACS system is delivered, installed, and testing begins.
- Weekly meetings held between BSWN IT Project Manager, BSWN Radiologists and Orion development team to review development progress and direction. This continual review and enhancement process was a key factor in the successful delivery of the enhancements.

December 2005:

- National Radiologists Unidisciplinary Group (UDG) consider the requirements for digital training (1 December 2005) and decide that radiologists require a minimum of eight hours of training with application specialists for FFDM/RIS/PACS – i.e. overseas training is not required.
- Training programme for January 2006 is developed, and schedules for all relevant staff are adjusted so they can attend required training. Arrangements made with medical physicist, IT specialist and radiologists to conduct the training.
- Contracts finalised with Siemens and Sectra, orders placed and arrangements made to air freight machines to Auckland.

- Arrangements made for medical physicist to be on hand to test and accredit Siemens machine (January 2006) and Sectra machine (February 2006) immediately they are installed.
- Data transfer into SBS completed and BSWN database goes live.
- Test version of the new interface between SBS and PACS up and running. All systems fully functional. Interface with the digitiser also working. Awaiting arrival of DM machines to organise connectivity with these.

January 2006:

- Siemens mammography machine delivered, installed, tested and accredited.
- All other equipment also delivered, installed and tested, with exception of Sectra mammography machine. Agreement reached with Sectra that delivery of their machine would take place in February so that BSWN would receive a newly released model.
- Digital training provided to BSWN staff.
- PACS interface with Siemens mammography machine established.
- Hard copy films from BSAN start arriving and BSWN starts digitising prior films.

February 2006:

- Screening starts at the Takapuna site (1 February 2006).

March 2006:

- NDHB sign-off for DM at Whangarei.

June, 2006:

- Mammography machine delivered to Whangarei site.
- All acceptance testing, accreditation, calibration and QA tests are completed for the Whangarei machine.
- ICT interface between WDHB and NDHB established. Refer to Appendix C for discussion of the issues that were encountered in establishing this interface.

July 2006:

- Screening starts at the Whangarei site.

July 2007:

- DM screening starts at the Waitakere site (full implementation processes for Waitakere not included in the timeline above).

4.4 THE DECISION TO GO DIGITAL

As the timeline above indicates, the decision to go digital was made in a number of stages, including:

- WDHB and NDHB confirmation of a unanimous view within both DHBs that their new breast screening sites should be established with DM (July 2005);
- Finance and Audit committee of WDHB Board of Directors approval of a revised business case based on digital technology for WDHB sites (August 2005);
- National Capital Committee approval of WDHB's proposed financing for digital equipment and the associated business case (September 2005); and
- The final decision to order DM equipment for Takapuna (PACS and mammography machines and related equipment) following evaluation of vendors' proposals and international site visits (October 2005).

- NDHB sign-off for DM at Whangarei (March 2006).

The DWG, a team of clinical and other experts who evaluated overseas literature (including the DMIST report), presentations from vendors, and overseas site visits, made recommendations to management during all steps and stages of the decision making process. The final decisions, based on recommendations from the DWG, were made by management (Project Sponsor, CEO or Board depending upon levels of delegated authority). Decisions were made in stages to ensure tendering and purchasing could proceed as sufficient information was on hand regarding each aspect of digital equipment. In parallel to the equipment tendering and purchasing process, WDHB was negotiating with the NSU to secure additional funds for the IT interface between the new PACS system and the SBS interface.

The following paragraphs summarise the decision making process including the DWG, key considerations in the decision to go digital, and the key benefits and risks considered as part of the decision making process. Subsequent sections discuss the equipment selection process and other critical stages in the DM implementation process.

4.4.1 DIGITAL WORKING GROUP

The DWG played a critical role in the decision making process once the capital expenditure for digital technology was approved by the Finance and Audit sub-committee of the WDHB Board. The DWG comprised three radiologists, two MRTs, the BSWN IT Project Manager, the WDHB PACS administrator, a medical physicist, and the Project Manager.

The capital procurement analysts from hA worked closely with the DWG throughout all stages of the planning, tendering and procurement of digital equipment. The NDHB Project Manager was invited to all meetings and kept well informed throughout the process. There was also an open invitation to other NDHB staff to attend any of the DPG meetings.

More than half of the group were already working in a digital radiology environment at WDHB. One of the radiologists had prior experience in implementing a PACS system so brought an understanding of critical success factors and potential pitfalls.

The group met once a week during August, September and October 2005, for approximately 1-1½ hours per meeting. The Group debated and scoped all aspects of equipment and IT configurations, identified equipment requirements, prepared specifications, evaluated tender submissions, undertook site visits, developed recommendations on the preferred vendors, oversaw acceptance testing once the selected equipment had been installed, and ran the digital training programme.

The DWG formed themselves into two subgroups (DM machines, and PACS) to manage the analysis of tender responses, supplier presentations/demonstrations, evaluation of equipment options, and acceptance testing. Both subgroups had radiologist representation. The DM machine subgroup also included MRTs and the medical physicist, while the PACS subgroup included the IT and PACS experts.

Feedback from BSWN indicates that critical success factors for the DWG included:

- Its composition, including clinical staff, IT experts and a medical physicist (stakeholders said it was important to involve all of these people from the outset of the planning and procurement process for DM);
- A significant time investment, with all team members dedicating time to the process away from their day-to-day workloads, at a minimum of 2-3 hours per week (including meetings and preparation/other activities) and considerably more time than this during the tender evaluation process;
- A willingness by all DWG members to ensure rapid turnaround of draft documentation and other information requiring comment between meetings;

- Prior knowledge of a digital radiology environment; and
- A commitment to work as a team, drawing on one another's strengths and respecting each other's area of expertise.

A strength of the process was the use of the weekly meetings as a forum for discussing equipment needs, configurations, functionality and associated issues, and extensive use of email between meetings to ensure the process kept moving at an optimal pace. As a result of this process, individual and collective thinking was able to evolve, and this had positive impacts in terms of designing an efficient work flow and ensuring the initial purchasing decisions placed the service configuration on a sound long-term footing. For example, while radiologists initially had a preference for viewing prior films in their analogue state using a light box, this changed following site visits and discussion of options within the group, and the final consensus was that the digitising of priors was preferable in terms of both ergonomics and work flow.

The DWG benefited from having an IT Project Manager who was experienced in the digital radiography environment, had excellent technical knowledge, brought creative problem solving skills and was an effective lay communicator. These attributes meant that he played a critical role in managing: communications between the clinical group members, the WDHB IT department, and IT vendors to ensure the RIS and PACS systems were appropriately configured; and the relationship between IT staff at WDHB and NDHB in resolving firewall and connectivity issues between the Whangarei site and WDHB, as discussed in Appendix C.

A BSWN stakeholder noted that none of the overseas screening sites that the DWG members visited in Europe, and no other sites that they were aware of (aside from perhaps Sweden) has ever managed to achieve full connectivity between RIS, PACS and DM machines from the outset; anecdotally, many are still struggling after a year or more to achieve what the IT project Manager at BSWN was able to achieve in a matter of months. This is a significant area of success for BSWN and marks BSWN as a site that other providers (in New Zealand or overseas) preparing to convert to DM should seek to learn from.

4.4.2 KEY CONSIDERATIONS IN THE DECISION TO GO DIGITAL

Because BSWN was a green field development, decision making focused on considering the relative costs and benefits of DM and FSM rather than the transition from FSM to DM as other Lead Providers would have to consider.

In order to start screening from 1 February 2006, the first of the mammography equipment needed to be ordered by October 2005. Hence there was a very small window of opportunity for WDHB and NDHB to decide whether to purchase FSM or DM equipment knowing that if the decision was made to purchase FSM equipment, there would be little chance of obtaining Board approval to replace this with DM equipment during the useful life of the FSM equipment (approximately eight years). The DHBs were also aware that if they elected to establish the new programme with DM equipment, they would be one of the first screening programmes in the world and the first in New Zealand to do this.

In considering these options, BSWN evaluated the potential benefits of DM over FSM within the context of:

- The service configuration planned (i.e. two assessment centres, working together as one team);
- The challenge of recruiting and retaining key staff;
- The capital and operating costs of the various options;
- The capacity of each option to maximise resources (equipment and human); and
- The geography of the region (i.e. large rural areas with some women having to travel long distances to be screened) (BSWN, 2005b).

Because there was a deadline for making the decision, risk management was also a key consideration, and stringent risk management processes were put in place. Right up until the point that the contract was signed for the PACS system, BSWN kept open the option of not proceeding with DM but rather reverting to an FSM decision.

The risk management was influenced by the NSU's decision not to support BSWN to pilot DM within BSA. The WDHB management were cognisant of the risks of proceeding without the support of the funder, and factored this into its decision making.

Broader factors also influenced decision making. The issues and options paper (Peel and Herbert, 2005) set out the service objectives used in assessing the various service configuration options (including DM as well as broader considerations such as the number, location and capacities of sites). These service objectives included:

- Allowing eligible women to be screened as close to where they live (or work) as possible. When women have a choice of sites to access near where they work and live there is evidence that this increases participation rates;
- Ensuring that women who had previously been screened by BSAN would be able to be re-screened within 20-24 months of the date of their previous screen;
- Maintaining or improving levels of access, coverage, and participation rates;
- Providing screening capacity sufficient to ensure newly enrolled women could be screened with minimum delay;
- The ability to cope with forecast population increases for the next ten years;
- Financial viability;
- Meeting all BSA quality standards;
- Efficiency and effectiveness for clinicians and other staff working at BSWN; and
- Ensuring operational processes appropriate to support service delivery.

WHY DID BSWN DECIDE TO GO DIGITAL?

In summary, BSWN believed that the implementation of DM at BSWN was justified on a number of grounds:

- Digital radiology was being systematically introduced into mammography (including breast screening programmes) worldwide, and was considered to be the way screening mammography was heading. Indeed, all of the people spoken to internationally and from within New Zealand during the planning process, recommended that any service setting up in a green fields manner at that time would be sensible to start off with DM equipment;
- DM was in line with the existing WDHB radiology environment, which was by this stage fully digital (both in terms of staff expertise and IT infrastructure available) and the strategic direction of NDHB's radiology service;
- BSWN had an experienced and skilled implementation team and support team of clinicians, MRTs, IT technicians and Project Managers to manage the risks at all stages of implementation;
- DM offered a number of benefits over FSM for the BSWN service in terms of its configuration, geography and requirement to attract new staff to a new service; and
- It was considered potentially financially unsound to invest in new FSM equipment (including mammography machines and all related processing equipment) and the facility developed to support FSM when this technology was likely to become redundant well before the end of its expected life.

It was also recognised that by BSWN making a decision to go digital, there would be a range of subsequent benefits to the BSA programme overall and to individual Lead Providers when they eventually make the decision to convert to DM.

KEY BENEFITS OF DM IDENTIFIED BY BSWN

The key benefits of DM over FSM that were identified by BSWN and influenced the decision to go digital are summarised below, based on BSWN's August 2005 proposal to the NSU (BSWN, 2005b), various other BSWN planning documents, and stakeholder feedback. The extent to which these benefits have been realised to date are discussed in section 5 (impact findings).

Integration of two sites

A major anticipated benefit was the ability to have close integration between the WDHB and NDHB clinical teams, through the electronic transmission of images between sites. As BSWN anticipated, this connectivity has enabled:

- Ready exchange of images for double and third readings, affording protection against quality compromise arising from geographic isolation and from the same radiologists always being first and second reader on the same films;
- High quality and accessible MDT meetings, with images viewed by staff at both sites simultaneously, significantly reducing clinical isolation and QA risks; and
- The option for radiologists to obtain a second opinion during assessment if required.

Historically it had been found that it was difficult to ensure a MDT providing assessment services as part of BSA didn't become isolated from the rest of the programme being provided from Auckland. It was recognised that these same issues would present challenges for BSWN and would need to be managed through: clear processes and protocols detailing film reading arrangements; clinical pathways for assessment; rostering of staff to assessment clinics; and commitment to weekly reading volumes. The issues and options paper (Peel and Herbert, 2005) noted:

To minimise the risk of repeating problems of the past it will be essential that the clinical, management and administration teams in Waitemata and Northland work closely together to create one overall regional team, to provide support and assistance to one another where required, to ensure consistency of service provision and to ensure the quality of care delivered in Northland matches that delivered in Waitemata. The Clinical Director and Programme Manager roles will be critical in ensuring this wider regional approach and to linking the two teams together. In addition, there are a number of other regional positions that will have oversight of both Waitemata and Northland services including the Lead Pathologist and Surgeon, Data Manager, and Quality Manager.

Stakeholders universally considered that the two sites had been successfully integrated and had a positive working relationship. ICT issues encountered in linking the two sites are discussed in Appendix C.

Staff recruitment, retention and safety

It was anticipated that DM would increase attractiveness of BSWN as an employer for both MRTs and radiologists, which would therefore aid recruitment. This has been the case, with MRTs successfully recruited into the service from overseas as well as within New Zealand commonly citing DM as a key reason for applying to work at BSWN. Furthermore, BSWN had eight fully accredited radiologists when the programme started and a further six in the process of completing training requirements to become accredited.

DM was also expected to improve staff retention due to their having involvement in a leading edge technology as well as improved safety (see section 5.5).

These were important issues for BSWN as a green field development, as all staff needed to be recruited into the service. At the time the issues and options paper was prepared in April 2005 (Peel and Herbert, 2005), there were no MRTs on staff at NDHB or WDHB who had expressed an interest in working for the new screening service. Moreover, there was and continues to be a shortage of suitably skilled breast radiologists and MRTs, both within BSA and overseas.

It was also anticipated that BSWN staff would amass considerable experience in planning and implementation of DM, clinicians would develop skills specific to their discipline, and the administration team would develop and bed down a range of operational processes to support the DM environment. Therefore, BSWN predicted that it would be in a position to provide support, advice and guidance to other Lead Providers when they convert to digital technology.

Likely cost advantages

Digital units are more expensive than plain film to purchase initially, but this is partly offset by equipment that is not required (e.g. film processors, multi-viewers, silver recovery units, etc). Operational cost savings also accrue through the elimination of film and chemical costs, and reduced costs of storage, transport and handling of films. In addition, if DM resulted in better staff retention then there would be less ongoing cost of recruiting and training new staff. Cost impacts are discussed further in section 6.

Quality advantages

The potential quality advantages of DM over FSM are detailed in section 3.1.2 and include:

- Potential for better contrast resolution and more latitude of exposure (this may make DM better for imaging dense breasts, which has particular implications given the reduction in age of first breast screening to 45 years);
- Potential for fewer screening technical repeats or technical recalls for magnification views of microcalcifications;
- Potential lower radiation dose with some machines; and
- Elimination of the risk of films being lost or damage or quality degraded.

Stakeholder feedback indicates that these advantages have been realised at BSWN. Furthermore, DM technology provides opportunities for ongoing quality improvements within the life of the existing technology. Although the purchase of DM equipment effectively locks the service into a fixed level of quality of image capture, the technology for image enhancement post capture is continually improving.

In addition to the quality advantages of DM over FSM, stakeholders saw significant disadvantages in terms of the available FSM technology. Worldwide, there were seven manufacturers of DM technology and three FSM equipment manufacturers, only one of which had a presence in New Zealand. According to stakeholders, the dominant FSM manufacturer in the New Zealand marketplace was offering limited equipment options, and the technology on offer was not widely supplied internationally and had known performance issues.

Maximising resource capacity

BSWN anticipated gains in resource capacity from:

- Increased throughput of women, enabling more women to be screened on each machine. Thus, it was anticipated that DM would maximise opportunities for increasing capacity and would eliminate the need to purchase additional machines at some sites

where capacity would be reached on plain film machines within 4-5 years of implementation;

- Potential for significant time efficiencies through the use of a DM unit with stereotactic and hookwire capacity, resulting in a reduction in the time of an unpleasant procedure for the patient, and increased throughput at an assessment session, reducing the need for more radiologist and MRT time;
- The ability to provide cover between Northland and Waitemata radiologists by reading images in Takapuna and Whangarei; and
- Post-processing of digital images, including image magnification, thereby obviating the need for additional magnification views in some cases.

Many of these gains have been realised, with further efficiencies likely in the future with further integration of screening processes with the RIS. Refer to section 5 for further discussion of the gains and limiting factors.

CHALLENGES, ISSUES AND RISKS OF DM IDENTIFIED BY BSWN

BSWN also identified a range of challenges, issues and risks associated with the implementation of DM. These are summarised below, based on BSWN's August 2005 proposal to the NSU (BSWN, 2005b), the High Level Project Plan (BSWN, 2005a), various other BSWN planning documents, and stakeholder feedback. Many of these issues and risks reflected the fact that BSWN was the first BSA Lead Provider to implement DM, and was therefore less able to learn from previous implementations. These risks were mitigated through the lessons learned from overseas site visits as well as WDHB's experience in a digital radiology environment. The following discussion indicates how these risks might vary for other Lead Providers.

Limited number of approved FFDM units available

Key risks identified by BSWN are listed below. The incremental approach to implementation reduced the risk of only being able to choose from a limited number of machines. DM technology is continually advancing so these limitations may no longer apply.

- Some of the technology available was limited to 100 microns resolution while others were down to 50 microns.
- Some options were limited on plate size (18 x 24cm) while others were able to provide a larger plate size (24 x 30cm) which was a recognised requirement for some New Zealand women. Other manufacturers used non-standard plate sizes, which has implications for image display.
- One product had significant dose reduction benefits, but used higher kVps which raised questions from a physics perspective about how the claimed contrast resolution could be achieved.

Potential vendor incompatibility

Compatibility of modalities and the various components of the ICT infrastructure were recognised as critical success factors for the implementation of DM, but were subject to many unknown factors. To mitigate these risks, strong contractual obligations were placed on modality providers, PACS and RIS vendors to "guarantee" seamless integration, including significant financial penalties for a failure to provide this integration, in recognition of the productivity costs that would be associated with such failure. BSWN's successful implementation of these components and the learning that has occurred alongside, serves to reduce the risk to other Lead Providers. Nevertheless, this remains a significant risk for other Lead Providers to manage as they implement DM.

In the first instance, limiting the number and type of digital modalities reduces some of the potential variability in the system. However, with continual advances in the field of digital mammography, and different manufacturers emerging as either CR or DR leaders, together with the desirability of engaging more than one vendor from a competitiveness point of view, it seems inevitable over the course of a staged digital conversion to be investing in units from a number of manufacturers. This risk is amplified for BSA as a whole given the longer timeframe for conversion of all Lead Providers to DM.

Thought should also be given to the potential incompatibility of sub-contract providers deciding to go digital but purchasing equipment that is not compatible for their BSA Lead Provider. For example, Lead Providers should ensure their sub-contracts include provisions to mitigate this risk.

BSWN identified risks associated with DICOM incompatibilities and a lack of proprietary approaches to image processing and data transfer, resulting in different matrix sizes being used for image display, different annotation formats, and other associated anomalies. This was addressed through the careful review of DICOM Conformance Statements from both the PACS vendors and the DM vendors. Also, the presentation state abilities of the PACS vendors was carefully reviewed and evaluated during the vendors' presentations.

The PACS system needed to be compatible not only with modalities purchased as part of the initial implementation, but also with other modalities including ultrasound and possibly MRI in the future. This is an important consideration for any other Lead Provider transitioning to DM.

Issues needed to be considered on a nationwide basis as well as for BSWN, to allow for ease of transmission of images between Lead Providers in the future. The PACS system had to be capable of supporting a range of DICOM interfaces, to allow bi-directional and automated interaction with other PACS systems. Differences in image processing and data transfer between FFDM manufacturers and PACS archiving were recognised as risks to this future functionality in terms of both image transfer and retrieval, and subsequent comparable image display. Clearly defined image processing rules need to be established up front and enforced on all vendors. This means each exam set, from any modality vendor, can be consistently displayed alongside another exam set (whether digital from another vendor or digitised film). It was not seen as feasible to consistently present three sets of processed images for a single exam, as well as unprocessed data from one vendor and not from another. This is an important consideration for any other Lead Provider transitioning to DM.

Image interpretation and manipulation

There are significant variations between alternative systems in terms of post processing and image display and image hanging protocols. These features combine to raise significant issues regarding the ability to rapidly and automatically "hang" series of studies for review when prior and current mammograms may have been obtained with different DM modalities. The images may not "hang in standard fashion". In addition:

- The "look" of images obtained by different DM modalities may also be quite different, making comparison of images over time more difficult; and
- Significant time may be spent on image manipulation and adjustment to make studies comparable, and if this were combined with non-seamless RIS integration, the time for reading a normal study could be significantly increased.

These issues suggested significant risks in image interpretation and also in screen reporting productivity. BSWN mitigated this risk through a gradual implementation, initially using FFDM for screening less than one-third of the BSWN eligible population and assessment only, in order to moderate and monitor the effect of this risk on radiologist workforce demands and radiologist retention.

These issues are worthwhile for other Lead Providers to consider in their conversion to DM, including the strategy of staged implementation to manage risks associated with radiologist work flow.

Reading productivity

Overseas studies revealed a risk of digital conversion slowing radiologist work flow, particularly in the short term. Unless there is very strong integration between the digital mammogram source and the reading workstation, and very strong integration between the reading workstation/PACS and the RIS, there are risks that radiologists' mammogram reading productivity can be significantly reduced.

As discussed above, BSWN mitigated this risk through a gradual implementation, with the staged implementation of DM ensuring that increased volumes of digital reading were not created until all digital reading processes and acceptable reading rates were achieved. Other Lead Providers should consider similar strategies when converting to DM.

Film/digital "hybrid" environment issues

It was acknowledged that whichever configuration option was used (DM or FSM), there would be a mix of both film and digital examinations to manage for some time, including a mix of digital and film sites (until such time as all sub-contract providers can justify the capital investment to convert smaller practices to DM) and an ongoing need to compare digital images with analogue priors.

Inevitably, this would result in some capital investment in old technologies and some ongoing administrative costs related to film handling, especially in the first few years. As a result, all potential savings from a DM environment would not be fully realised until all sites (including all sub-contract sites) became digital. Implications for other Lead Providers are included in the discussion of financial impacts of DM (section 6).

Training

BSWN acknowledged the need for comprehensive training for all members of the MDT to ensure there is no compromise of QA in the processes of migrating to a DM environment. It was noted that this issue applied particularly to radiologists and MRTs who had no previous exposure to working in a digital radiology environment.

Most of the radiologists working at the Takapuna site had the benefit of work experience in a PACS environment at WDHB and were thus familiar with similar work flow processes. Staff were given training in the new equipment, ICT and reading environment (see section 4.5.2).

Image storage

DM significantly increases electronic storage demands, with each examination potentially in the order of 200Mb. Any Lead Provider converting to DM must plan for these increased storage demands.

It was estimated that the implementation of digital imaging across the BSWN region would double WDHB's imaging storage requirements from 1.5TB (terabytes) per annum to 3.0TB per annum. For BSWN, this risk was well managed and future-proofed for further developments (e.g. tomosynthesis) by hA's development in 2005 of a Medical Archiving Solution (MAS) with storage capacity of 200TB.

Evidence

One of the identified risks of DM was that there were initially no conclusive clinical trial results. Mammography is one of the last areas of radiology to convert to digital technology internationally. There had recently been a move internationally to trial and evaluate the performance of DM in the screening setting, but the available results at the time were inconclusive. Accordingly, some members of the DWG initially had reservations about implementing DM before such clinical evidence became widely available.

BSWN contacted the DMIST researchers and learned that initial results from the DMIST study were due to be released in October 2005. These results were favourable (see section 3.3.1) and (together with the international site visits) influenced the decision to go digital.

BSWN's enquiries also found that screening programmes in Australia and other countries were beginning the process of converting to digital technology. NSW had conducted trials of the quality of both CR and DR technologies and were confident that both modalities provided very acceptable levels of image quality. NSW, Victoria and Tasmania had all either purchased or were in the process of purchasing some DM equipment for their screening programmes.

The NHSBSP in the UK had set up a National Digital Steering Group and was in the process of coordinating evaluations of each type of digital equipment. BreastCheck, the Irish National Breast Screening Programme, had recently installed some DM equipment and related PACS. DM was also widely being used in the USA and in the Swedish breast screening programme.

BSWN found that the FDA had approved six FFDM machines for use in mammography facilities and assessment of other makes and models was well advanced.

4.5 EQUIPMENT AND IT SELECTION

The DWG, in partnership with hA, managed the equipment selection process as outlined above, including preparing RFP documentation and evaluation criteria, undertaking the tendering process, conducting international site visits, and selecting the preferred vendors. The following paragraphs provide further detail on these processes.

4.5.1 DETERMINING EQUIPMENT REQUIREMENTS

Equipment requirements for each site were determined prior to establishment of the DWG, and flowed from the volume projections, agreed service configuration, and related analysis presented in the Issues and Options paper. Having agreed the number and location of screening sites (and mobile unit) to provide screening services, the equipment requirements for each site were scoped on the basis of each site's respective role in the overall BSWN service and projected service volumes for each site.

Analysis of the number of machines required was informed by benchmarking against screening volumes per mammography machine at BSA Lead Provider sites and through observation of screening volumes and DM work flow models at international screening sites and information obtained from the Tasmanian screening site where a DM machine had been installed.

The DWG scoped the requirements for the PACS and RIS and for connectivity between BSWN sites, as detailed in Appendix C.

4.5.2 TENDER SPECIFICATION

The tender specification prepared by the DWG included both DM equipment and ICT infrastructure, and invited vendors to bid for the supply of either the full suite of technology required or individual components. An objective of the tendering process was to identify and consider different options for the technology (including CR and DR). Therefore, the RFP invited proposals for a wider range of equipment than was actually purchased.

The RFP included the following list of DM equipment:

- FFDM systems (up to two for Takapuna and one for Whangarei) including mammography machines (gantry with x-ray and digital detector, high voltage (HV) generator and acquisition workstations), fully digital in design and capable of screening and diagnostic examinations including stereotactic guided biopsy procedures;

- CR systems (up to two for Takapuna and one for Whangarei) including mammography machines, plate reader, QA/review workstations and ID monitor, and cassettes;
- Stereotactic devices for the FFDM and/or CR systems (one for Takapuna and one for Whangarei);
- PACS system including: PACS software and hardware; three radiologists' review/reporting workstations; QA functionality/workstation; installation of the system to the point of verifying storage connection, interface with the RIS and interfaces with modalities; and comprehensive applications field support, user training and manuals; and
- Laser printers for mammography (one for Takapuna and one for Whangarei) (hA, 2005).

The RFP also signalled the possibility of another machine subsequently being purchased for the Waitakere site. This prospect of a possible future sale was signalled as a possible negotiating tool to try and leverage prices down for the initial equipment purchases.

Due to the concurrent use of FSM for (initially) 70% of BSWN's mammograms (i.e. all mammograms performed by sub-contractor sites and the mobile unit), the RFP also included mammoviewers (two for Takapuna and two for Whangarei), together with film view accessories to magnify views and subtle abnormalities on plain films, and high-intensity lights (Ibid).

The tender process excluded first and second-tier storage and related hardware as BSWN was able to make use of WDHB's existing storage area network (SAN) and hA's newly established MAS. Also excluded were the database/administration workstations for the RIS which were sourced separately. Digitisers were not included in the tender process but were subsequently purchased once the decision was made to digitise prior films.

The RFP document also provided a brief background on the BSA programme and BSWN, and a comprehensive description of the required functionality from the DM and PACS equipment.

RFP SUBMISSION FORMS

The DWG and hA prepared detailed RFP submission forms which vendors were required to complete, enabling collection of consistent information from each vendor in terms of compliance against the required functionality, and facilitating comparison of options. With the benefit of experience, these submission forms were revised for the subsequent Waitakere tender. Copies of the RFP submission forms used for both the Takapuna and Waitakere tenders are attached at Appendix D. The Waitakere forms represent the most recent submission forms for DM modalities from BSWN, while the Takapuna forms include submission details for other equipment including the PACS, stereotactic equipment, etc.

4.5.3 TENDERING PROCESS

The tendering process comprised:

- Initial evaluation phase: Tenders were received from four PACS vendors, four CR vendors and five FFDM vendors. The DWG evaluated these proposals against the selection criteria (see section 4.5.4 below). The process involved "screeds of reading – about six inches of paper for each provider". Responses were separated between two sub-groups (DM machines and PACS) so that individuals in those teams could concentrate on the areas that matched their expertise, and to facilitate a quick and efficient process. A total of four FSM vendors and two PACS vendors were short-listed;
- Detailed evaluation phase (including due diligence process) to become fully conversant with the proposed solution: Short-listed vendors were invited to make formal presentations to the DWG, provide additional follow-up information as required, and to nominate international screening sites where DWG members could observe the equipment in operation and interview local screening staff (see section 4.5.5);

- Vendor selection phase: The DWG identified the preferred vendors based on the due diligence process and international site visits;
- Negotiation phase: Contract negotiations with preferred vendors; and
- Agreement phase: Contract signing with the preferred vendors; orders placed for new equipment.

The final decision to go digital was made as an integral part of the above processes. The detailed evaluation phase enabled the DWG to reach a point where all key parties were confident that the advantages of DM outweighed any possible disadvantages and that the quality and operational issues of DM could be managed in such a way as to not compromise the new service. The contract negotiation phase was the final point of confirmation that equipment could be purchased within the budget approved by the respective DHB Boards.

4.5.4 SELECTION CRITERIA

The DWG developed vendor selection criteria and a scoring and ranking system for the equipment included in the tender process. The over-riding objective of the selection criteria was to find the most cost-effective solution for the supply of mammography equipment by addressing the following issues and opportunities:

- A supply strategy which helps BSWN to meet its business outcomes;
- Cost-effectiveness;
- Administrative efficiency;
- Time of the essence;
- Quality products and services;
- The basis for ongoing improvement; and
- Effective use of technology.

Accordingly, initial tenders were assessed and evaluated in regard to the following evaluation criteria:

- Ability to satisfy business requirements (including the ability to deliver by February 2006);
- Geographical support and representation;
- Confirmation of strong administrative and reporting systems and the ability to interface with BSWN processes and systems;
- Evidence of a sound organisational and financial structure;
- An acceptable pricing structure, including overall cost and value for money;
- Ability to meet commercial requirements and demonstrate long term stability in relation to ownership, business plans and policies, company size, company expertise and references;
- A planned approach to transition and implementation;
- Use of technology;
- Flexibility to evolve and develop to meet changing business and technology needs;
- Product fit for purpose;
- Ongoing service costs;
- Provisions for warranty;
- Training and in-service; and
- Experience and quality of staff.

The detailed evaluation and due diligence phase considered each of these criteria in greater detail and focused on evaluating the performance of the equipment in a real-life setting and determining the compatibility of the individual components to work as a system.

4.5.5 SITE VISITS

The aim of short-listing was to identify approximately two vendors for each of the PACS and DM machines and then to observe the short-listed equipment in action in a high volume screening site before making a final decision. Site visits were considered to be critical in the context of the risks associated with selecting poor equipment.

Vendors nominated and negotiated access to the reference sites. Options for suitable reference sites were limited because DM was still at an early stage, the DWG wanted to observe both DM equipment and PACS including the integration of these, and sites had to be identified at short notice. Other Lead Providers will have access to a far greater choice of sites comparable to the New Zealand screening environment, including BSWN and other sites within Australasia.

Site visits were completed in six countries in a five-day period by three members of the DWG: a radiologist, an MRT, and the medical physicist. In addition, the UK radiologist who provided clinical advice to BSWN at the planning stage joined the team at some sites to provide his expert advice, and the BSWN Programme Manager also visited some sites to look at work flows but was not involved in equipment selection.

Generic questions were prepared which were addressed at each site visit (Appendix E). Priority questions and additional specific questions were also identified in planning for each visit. Due to the short timeframe for decision making, delegates emailed key findings and issues back to the Project Manager while overseas, with full report back to the team occurring immediately following completion of the site visits.

The following sites were visited:

- **Paris:** General Electric (GE) Senographe NGD large plate FFDM system;
- **Utrecht, Netherlands:** Hologic FFDM;
- **Erlangen, Germany:** Siemens factory;
- **Luxembourg:** AGFA PACS;
- **Malmo, Sweden:** Siemens FFDM and Opdima Stereotactic system; and
- **Helsingborg, Sweden:** Sectra PACS.

Overall, the site visits validated that "without a doubt, we are doing the right thing going digital. Everyone I spoke to stated they would do the same if they were setting up a new unit..." (notes from team feedback following site visits, 25 October 2005).

Speaking from hindsight, members of the DWG considered that the international site visits were an important feature of a successful decision making process, and had played a critical role in the decision to go digital as well as the selection of equipment. They noted that it was particularly helpful to be able to observe and discuss different equipment in operation as well as different screening practices and work flows. They recommended that other Lead Providers:

- Consider conducting site visits as part of their decision making processes;
- Visit comparable sites with well-established screening processes;

- Observe work flow patterns;²³
- Conduct discussions with a variety of staff including clinical, technicians and administrative staff, in order to learn of possible pitfalls;
- Involve their medical physicist in equipment selection in order to assess key performance and QA parameters of each machine.

In particular, the Helsingborg site provided conclusive evidence of an efficient process in a digital screening environment, and played a critical role in convincing the 'sceptics' within the DWG that DM was a viable and attractive option for BSWN. Helsingborg was the only site found where DM equipment was being used with a full PACS system in a breast screening service comparable to BSA services including the use of double blind reading and batch reporting. The DWG had already determined that BSWN should adopt a fully integrated PACS in order to realise work flow efficiencies, and the visit to Helsingborg influenced BSWN's decision to go digital by demonstrating that digital screening could be done efficiently. The other sites visited were printing digitally acquired images and thus were continuing to use manual hanging, reading and filing processes.

At the time, Sweden's was the world's only digital breast screening programme (DM provided in other sites was not part of a screening programme). The programme had consistent presentation across modalities (despite individual sites selecting their own equipment), and consistent reporting processes across all radiologists and sites. The programme digitised prior films.

On the day of the Netherlands site visit, the screening service's film processor had failed and all women were being screened using the digital equipment. This happenstance proved valuable for the visiting DWG representatives as it demonstrated the efficiency the productivity gains that were possible: "they were keeping up".

The visits were also valuable in revealing lessons that the sites had learned during their implementation which they were able to pass on to BSWN. For example, the Malmo site had learned that stereotactic biopsies were best performed in a centre with high patient numbers and an experienced team. This site had also experienced initial detector problems which had subsequently stabilised (this is consistent with experience at Takapuna where both modalities had initial detector problems).

In addition, UK visits were made to Cardiff University, Coventry and London. Although not part of the equipment evaluation process, these visits provided opportunities to observe work flows and benefit from the local experience at these sites. For example, Cardiff University's hospital diagnostic service indicated that the service had experienced significant equipment failure and maintenance issues during the first six months of operation, including replacement of three detectors. The initial problems seemed to have been ironed out, following three upgrades. A representative of the service commented, "you need to know there will be excellent back-up support".

In Coventry, a trial was being undertaken on the digitisation of prior plain films for comparative reading purposes. This was a critical operational activity for BSWN and the Coventry visit provided the opportunity to learn how to minimise staff time in this process and maximise quality outcomes.

4.5.6 KEY CONSIDERATIONS IN SELECTING THE EQUIPMENT

SEAMLESS INTERFACE BETWEEN COMPONENTS

A key issue emphasised in the RFP was the requirement for the various components of the DM screening environment to be fully compatible and work seamlessly. To minimise the risk of problems arising with acceptance testing, compatibility and interfaces between components of

²³ NSU recommends that other Lead Providers only include visits to sites that are completely soft copy reading from digitally acquired images, as this is now mandated in the NSU digital standards.

the DM environment, and to maximise opportunities for a national network of BSA providers, the tender document stated:

The over-riding requirement for BSWN in purchasing digital modalities, PACS and supporting equipment for breast screening is to establish a non-proprietary system at all levels and interfaces, i.e. the modality(ies), PACS, RIS (SBS) and storage servers. To that end BSWN intend contractually holding vendors responsible for:

- *Individually ensuring connectivity and functionality for goods and services supplied by them*
- *Collectively ensuring connectivity and functionality of the system as a whole.*

Vendors shall identify any modalities, PACS, supporting equipment they know their equipment cannot interface with. Unless vendors state otherwise, BSWN will assume there are no known interface issues (hA, 2005).

FFDM OR CR

BSWN considered both FFDM and CR solutions. The equipment RFP (hA, 2005) invited proposals from vendors of both types of modality. The DWG formed the view that FFDM was the preferred option for reasons of greater throughput, suitability for assessment/biopsy work, and to ensure consistency in machine type between sites.

MODALITIES EVALUATED

The DWG shortlisted four vendors, and evaluated five mammography machines. Of these, three had the potential to support an efficient, high volume screening work flow while the latter two had assessment capabilities as well as the ability to provide additional (albeit slower) screening capacity.

Following evaluation of these options, WDHB purchased the Sectra MDM and Siemens FFDM with Opdimia Stereotactic system. Many factors were weighed up in making this decision, in line with the criteria summarised in section 4.4.4 and in Appendix D. According to stakeholders, the following factors were significant in influencing the equipment selection:

- **Service and support:** None of the vendors had established, robust support in New Zealand at that time. Some vendors were proposing to provide support from an overseas base, which the DWG viewed as inadequate. Others were variously proposing to employ a local support person or to contract support to a local third party. The decision to purchase two different modalities also afforded some risk management as these would be less likely to simultaneously be affected by technical issues.
- **Plate size:** It was anticipated that approximately one quarter of the women attending screening would require a large plate size in order to produce a four-image study. Using a smaller plate size for these women would require additional views at screening and assessment (and therefore extra radiation exposure and disadvantages for reading). Therefore, at least one of the machines had to have a large plate available. One modality did not have a large plate available.
- **Image appearance:** The Siemens and Sectra modalities provided images that more closely resembled the films to which radiologists were accustomed, as preferred by the DWG. The GE and Hologic modalities that were available at that time produced images that were darker and higher in contrast.
- **Detail of images:** There is ongoing debate in the literature about the ideal pixel size for DM. The DWG had a preference for small pixel size (more detailed) images and considered that the Siemens and Sectra modalities offered the most suitable image detail to BSWN's requirements. Image detail was also debated in relation to the digitising of priors, as

sufficient detail is required to identify lumps and microcalcifications. Usually a larger pixel size is acceptable for priors as the original films can be accessed if needed.

- **Spectrum used and radiation dose:** Using a different detector provides the opportunity to change the characteristics of the radiation source. The Siemens and Sectra modalities used a different target-filter combination to the other modalities which enabled them to use a lower radiation dose. The maximum dose for screening in New Zealand is 1.5 mGy per exposure (as performed on a phantom of standard thickness at a standard compression, set by the National Radiation Laboratory). BSWN set a threshold of 1.3 mGy for its equipment. The Hologic modality delivered a 1.8 mGy dose. Subsequently, new ACPSEM criteria have been released stating that DM must be of a higher standard than FSM in both image quality and radiation dose.
- **Image quality/dose combination:** The differences between the Siemens and Sectra specifications meant that the Sectra modality was expected to provide the best image quality/dose combination for screening purposes.
- **Assessment:** One of the DM modalities was required to have the capability to perform stereotactic biopsies. As up to 80% of biopsies are benign, it is important to minimise the intrusiveness of the procedure. DM technology also provides the opportunity to conduct stereotactic biopsies more quickly, as discussed elsewhere. The Siemens FFDM and Opdim stereotactic system provided the preferred stereotactic capability, with the main trade off being a slow exposure time (long preparation phase).

Whangarei subsequently went through a full RFP process and made its decision to purchase two Siemens machines. Connectivity and consistency of images were key factors influencing this decision.

4.6 OTHER SUB-PROJECTS

The processes described above relate to the decision to go digital and the selection and capital funding of DM equipment and ICT hardware and software. The decision to go digital also influenced other BSWN implementation sub-projects in important ways. The following paragraphs provide an overview of the wider considerations impacted by the implementation of DM.

4.6.1 FACILITIES

The facilities sub-project involved all aspects of establishing facilities for BSWN including identifying needs for new and/or refurbished facilities at all sites, planning and designing the new facilities, and overseeing any building/refurbishing work.

Because BSWN was a green fields development, the facilities project included selecting facilities on the basis of their location and the suitability of existing buildings (including consideration of the extent and cost of any modifications required).

The implementation of DM technology influenced the design of the Takapuna facility in the following ways:

- No darkroom or film processor space was required (processing facilities at North Shore hospital are to process the films from the mobile unit);
- To provide an efficient work flow including the ability to work three schedules with two DM modalities, the facility layout included a sub-waiting room with changing cubicles and the overall layout was designed to provide a circular flow from reception to sub-wait room to mammography room to changing room to exit and to enable assessment clinics to be run concurrently with screening sessions;
- The mammography room and the MRTs' digital QA station were also placed in close proximity to facilitate an efficient work flow. Similarly, the PACS reading station was located in proximity to the assessment area;

- Air conditioning systems were required that would produce very high airflows relative to the size of the mammography rooms (up to 70 changes per hour) due to the high heat output of the DM machines. Digital units are more temperature-sensitive than FSM units, and temperature needs to be kept within a very narrow range at all times, with only a maximum of 3 degrees Celsius variation in room temperature. If the temperature varies by more than this amount, an alarm is activated signalling that the machine requires re-calibration;
- The Sectra DM machine requires supply of three-phase electricity, which needed to be installed in the facility (the Siemens machine uses single phase power);
- One of the machines (Sectra) required reinforcing of the floor to support the weight of the machine (950kg). However, this is unlikely to affect other Lead Providers as a new model has subsequently been released which is lighter;
- The width of doorways and corridors needed to accommodate the installation of the machines.

4.6.2 STAFFING RECRUITMENT AND TRAINING

All BSWN staff had to be recruited including leadership positions and all clinical, technical and administrative staff. The staffing recruitment and training sub-project oversaw this process, as well as the training of all new staff. Recruitment of MRTs and radiologists was difficult due to shortages in both professions, and involved both national and international searches. The opportunity to work in a digital screening environment was attractive and assisted in recruiting the required staff. Once the Programme Manager started work, she systematically took over responsibility for recruitment and training from the Project Manager.

All staff needed initial training in operational systems and processes specific to BSWN. As the implementation of DM at BSWN pre-dated the development of national DM policy, it was necessary for BSWN to negotiate what the training requirements would be and then ensure all staff received the training prior to go-live. It was recognised that MRTs and radiologists operating in the DM environment and reading digital mammograms would need some training in the new modalities. BSWN also acknowledged the need for comprehensive training for all members of the MDT to ensure there is no compromise of QA in the processes of migrating to a DM environment. The Radiologists JDG made a decision at their December 2005 meeting regarding digital training requirements.

Some staff, such as WDHB radiologists, brought prior experience in digital radiology in a PACS environment and in training staff in a new digital environment. MRTs brought screening mammography experience but had no prior experience using digital equipment. Training therefore needed to cater to a range of prior knowledge and experience while ensuring all staff were familiar with local processes and equipment.

Enquiries were made regarding international DM training opportunities, either by sending staff overseas or bringing overseas trainers to New Zealand. Predominantly, the training was provided at BSWN sites and included:

- Training in the PACS environment (for radiologists, MRTs, and administrative staff): Sectra provided comprehensive training on the PACS. Trainers from Sweden, using a clear training outline, worked with small groups of MRTs/radiologists or administrative staff and individualised the training to the needs of each group;
- Training (and associated manuals) for MRTs in the use of the DM modalities including QA tasks and machine-specific issues such as positioning of detector plates on the Sectra modality: Delivered on site by the vendors as part of their service contracts with BSWN, negotiated as part of equipment selection;
- Training for radiologists in reading mammograms in a digital environment: BSWN established its own programme for radiologists. Initially, the programme comprised four hours of theory and four hours practical. It has subsequently been amended to reduce the

theory component and increase the practical component, which now includes 200 dummy reads and review of cancer cases. The NSU is issuing guidelines which reflect this change of practice. The PACS/RIS system is set up to allow trainee reads on current cases.

The standard eight-hour training programme that BSWN ran for its radiologists who were going to read digital films and do assessments and for the MRTs prior to commencement consisted of:

- A three hour classroom session of:
 - Introduction to digital physics and technology (led by Medical Physicist);
 - Learnings from the site visits in Europe (led by Radiologist);
 - SBS functionality and how it will interface with FFDM and PACS (led by BSWN IT Project Manager); and
 - PACS hanging protocols (led by Radiologist).
- Minimum two hours training in the use of Siemens FFDM and Opdima Stereotactic;
- Minimum two hours training in the use of Sectra PACS, reading workstations, MRTs and digitising QA workstations, delivered on site by the Sectra PACs and MDM trainers.

Individual training packages were arranged around this standard package. Radiologists who were going to be reading DM images but not doing assessments did:

- Three hour classroom session (as above);
- Four hours training on DM reading workstation (DS5/mx.net) delivered on site by the Sectra PACS trainer; and
- One hour classroom session on Sectra PACS for Breast Imaging delivered on site by the Sectra team.

In addition to the above, those radiologists who were also doing assessment did:

- Approximately one day's training in the use of Siemens FFDM and Opdima Stereotactic delivered on site by the Siemens trainer; and
- Training on mammotome used in conjunction with Opdima.

The MRTs all did:

- Three hour classroom session (as above);
- One hour classroom session on Sectra PACS for Breast Imaging delivered on site by the Sectra team;
- One hour training on DM reading workstation (DS5/mx.net) delivered on site by the Sectra PACS trainer;
- Four hours training on Sectra QA workstation (DS5/qa.net) delivered on site by the Sectra PACS trainer;
- Approximately one day's training in the use of Siemens FFDM and Opdima Stereotactic delivered on site by the Siemens trainer;
- Training on mammotome used in conjunction with Opdima; and
- Training on Sectra MDM.

In addition, the Lead MRT spent time in Tasmania familiarising herself with working on a DM machine. One of the MRTs, the WDHB main radiology department PACS administrator, and the IT Project Manager all received two days PACS administrator training provided by the Sectra trainer.

The BSWN Data Manager received:

- Three hour classroom session (as above);
- One hour classroom session on Sectra PACS for Breast Imaging delivered on site by the Sectra team;
- Two days super user/system administrator training, including scanner, IDS5/qa.net and IDS5/mx.net; and
- Two days administration training with Sectra.

The administrator who had the role of digitising the prior films also had specific training in the DM environment, including:

- Three hour classroom session (as above);
- One hour classroom session on Sectra PACS for Breast Imaging delivered on site by the Sectra team; and
- Some specific PACS system training with the Sectra trainer.

Radiologists noted that converting to DM requires “learning how to read in a different fashion”. Cancers can be more subtle on DM images, and it takes at least a year to become familiar with cancers on DM. There can be additional challenges where radiologists combine DM screening work with film-based radiology work elsewhere.

MRTs noted that time constraints had presented a challenge for training, as training had to be completed quickly, two weeks prior to the commencement of screening (the period between when the equipment was set up and when screening started), and involved becoming familiar with two different modalities. Other Lead Providers would need to allow time for staff training outside of their normal work and plan for service continuity during this time.

Other Lead Providers should ask vendors to provide sufficient details of trainers and training either as part of the RFP or contract negotiation processes. Ideally, implementation time frames should include allowance for resolution of emergent issues but this was not possible within the available timeframe for BSWN's implementation.

4.6.3 OPERATIONAL SYSTEMS AND PROCESSES

As part of establishing BSWN, a sub-project was established with extensive input from external consultants and selected members of the DWG to identify, document and establish all operational systems and processes for the new service. These systems and processes were influenced by the decision to go digital as this affected work flows associated with acquiring and reading mammograms, QA, and assessment clinics as discussed elsewhere.

Clinical staff helped to design the layout of the facility, and mapped the layout to the screening pathway so that the facilities would be appropriate to the work flows. Consideration of specific operational processes related to DM commenced as a natural part of the DWG's debating and scoping of equipment configurations. The processes for DM continued to be developed as the equipment was installed, training undertaken and staff familiarised themselves with the new equipment and the collective DM environment. The clinical advisor seconded from the UK brought significant experience in managing digital mammography sites, and played a key role in assisting local clinical leaders to develop digital work flows and processes.

As one example of the operational processes influenced by equipment specification decisions, the DWG considered two alternative approaches for the reading of prior films, based on approaches being used by overseas programmes for DM. In the first of these approaches, providers were digitising all prior films. This became the preferred option and was subsequently implemented at BSWN. Digitised priors at BSWN provide a first point of reference for the reader, with prior films being accessible as required.

The alternative approach involved plain films being hung on a multi-viewer that would operate on a belt system above the reading workstations. With this method, the reader has the digital image on the screen in front of them and the prior plain films on a viewer above. This option was considered and was ultimately rejected by BSWN because: it is less efficient, requiring manual hanging; it means the priors would still have to be transported between sites for second readings; and is ergonomically inferior because film-screen viewers have different light characteristics to digital viewers, leading to delays and possible quality risks associated with readers' eyesight accommodating when switching between viewers.

4.6.4 QUALITY AND MONITORING

A robust QA programme is critical for the initial stages of equipment selection as well as installation, calibration and testing, and as an ongoing process at all steps in the image chain. BSWN worked with the NSU to develop the required modifications to the NP&QS to include necessary processes (including image acquisition, processing, review, storage and distribution) and targets for the DM environment, and to trial their implementation (BSWN, 2005b).

As part of the procurement process, vendors of DM machines and PACS systems were asked to include full details in their responses of how all required QA processes could be undertaken on their equipment. The evaluation of vendor responses and the supplier presentation and demonstration process were used to fully assess each modality and PACS system's ability to ensure full compliance with all QA testing requirements (Ibid).

Physics acceptance testing included initial testing as well as 6- and 12-monthly testing. This included:

- kV accuracy and reproducibility;
- Beam quality assessment (HVL measurement);
- Radiation output;
- Mammography unit assembly evaluation;
- Evaluation of focal spot performance;
- Collimation assessment;
- Breast entrance exposure, Mean Glandular Dose, and reproducibility;
- Artifact evaluation;
- Phantom image quality tests;
- Flat field test;
- Signal to noise ratio;
- Modulation Transfer Function; and
- Contrast to Noise Ratio (Ibid).

It is essential that the QA phantoms and software packages are included as part of the purchase of the equipment. The tender specifications required vendors to provide details and cost of the CDMAM phantom, as this phantom provides a good measure of performance and easy cross-reference to several European papers and the European Standards (BSWN, 2005b).

With regard to ongoing support, BSWN established and documented MRTs' QA tasks (see section 5.6) and provided assistance and training in these.

4.7 LESSONS FROM DECISION MAKING AND IMPLEMENTATION PROCESSES

BSWN experienced a range of challenges during the planning and implementation of DM. Many of these were directly related to being the first Lead Provider to adopt these new technologies and having a very short timeframe in which to make decisions, plan, purchase, implement and train staff in the new DM environment. Lead Providers will benefit from the progress that has been made in these issues in the two years since. Key issues are discussed below, and lessons for other Lead Providers are identified.

PLANNING, DECISION MAKING AND IMPLEMENTATION PROCESSES

Participants found that the decision making processes for DM at BSWN (including the decision to go digital and subsequent decisions regarding equipment and work flows) were robust and have resulted in the implementation of an effective and efficient breast screening service.

It is recommended that any Lead Provider deciding to implement DM look to do that in a staged transition approach rather than changing all fixed, mobile and subcontracted sites to DM in one 'big bang' approach. A staged approach to implementation has a number of benefits including opportunities for learning and refining processes and minimising any temporary adverse workforce impacts such as slower reading times.

Part and parcel of deciding to go digital is acceptance of a dynamic service environment in which the provider is continuously looking at ways to improve effectiveness such as software upgrades and work flow improvements. In comparison, FSM is more static.

Planning and implementing a transition to DM requires significant project management, clinical, technical and other multi-disciplinary input and a time investment from those involved including time dedicated away from day to day work to be involved in a digital project.

BSWN reported that a critical success factor in their successful planning and implementation of DM was in establishing the right multi-disciplinary team of experts from the outset. The key members of this team for any Lead Provider to have are:

- At least one radiologist with expertise in and a passion for DM;
- An IT specialist with a proven track record of being able to successfully bring together technical solutions that meet complex clinical, QA and operational process requirements and in ensuring technical connectivity in complex environments;
- A medical physicist who is knowledgeable in the area of digital mammography and able to dedicate significant amounts of time to working with the project; and
- At least one MRT who is able to work with the team to ensure all primary user requirements are adequately considered.

Other critical components reported by BSWN include:

- DM influences facilities requirements including the layout and function of rooms, air conditioning and electricity requirements, and possibly reinforcement of building structures depending upon the type of equipment used.
- Staff training is a key feature of successful implementation. Allow time for staff training within their normal work and plan additional staffing for service continuity during this time. It also behoves Lead Providers to ensure prospective vendors are able to provide training of appropriate quality and timeliness.
- A supportive GM, CEO and Board;
- Dedicated time of a business analyst, procurement personnel and legal/contracting expertise;
- Identification of clinical champions who will work with the project but also champion the case for DM with the other clinicians;
- Contingency planning that recognises throughput on DM (both in taking and reading mammograms) will be slower at the outset so Lead Providers converting to DM should book minimal appointment slots until all aspects of installation have been approved and completed. This will result in less disruption to work flow, clinics and clients;
- Learning from other programmes, both in New Zealand and overseas, that have already done planning and implementation for DM; and
- Maintaining a risk register at all times during the project so mitigation strategies can be found for all new risks as they become known.

It is anticipated that other Lead Providers would have considerably longer lead in time for planning, decision making and implementation of DM than BSWN. A longer lead-in time will in itself reduce many of the risks.

INFORMATION AND COMMUNICATIONS ARCHITECTURE

The over-riding consideration in implementing the ICT infrastructure for DM was ensuring the compatibility of its various components including the PACS, RIS, storage servers and modalities, as well as maximising opportunities for future consistency and connectivity between providers (see Appendix C). Lead Providers should ensure contractual arrangements for DM implementation place responsibility on vendors for seamless integration.

As detailed in Appendix C, several unanticipated ICT issues were experienced, including:

- Initial network speed issues between the PACS at North Shore Hospital and the workstations at BSWN's Takapuna site, which took six months to resolve with the addition of an on-site image server;
- Security issues in devising an architecture to manage the transfer of images between Whangarei and the PACS, due to Windows networking protocols, which were resolved by extending the North Shore Hospital network to the Whangarei site rather than linking the two networks together;
- Upgrading the uninterruptible power source (UPS) units for the DM machines in response to power outages that had led to machines losing power without being able to follow the proper shut-down procedure.

BSWN found that one digitiser was insufficient to cope with the volume of work and the addition of a second digitiser at the Takapuna site has improved efficiency for the imaging clerk.

Other Lead Providers considering a transition to DM should seek IT guidance from an established DM screening site with a similar PACS configuration.

EQUIPMENT PROCUREMENT PROCESSES

Key success factors and lessons from BSWN's equipment procurement process suggests that other Lead Providers should:

- Conduct site visits as part of their decision making processes, involving: visits to comparable sites with well-established screening processes; observing work flow patterns; and conducting discussions with a variety of staff including clinical, technicians and administrative staff, in order to learn of possible pitfalls;
- Involve a medical physicist from the outset in equipment selection in order to assess key performance and QA parameters of each machine;
- As part of the due diligence process, ensure that full details are provided against all requirements and criteria including sufficient evidence/plans for the provision of prompt and readily available service support;
- Pay particular attention to negotiating an effective service contract including availability of technical expertise in New Zealand and storage of spare parts in New Zealand or Australasia to ensure timely access, escalation and penalty clauses. Also agree minimum response times for service and whether evening and/or weekend cover is necessary and available;
- Note that BSWN's RFP evaluation criteria (section 4.4.4) and submission forms (Appendix D) provide a potential model or starting point for the development of submission forms for future tendering processes.

There will be opportunities for significant savings and other efficiencies to other Lead Providers if they are transitioning to digital at the same time. BSWN discovered that the DM vendors were prepared to make substantial discounts if WDHB and NDHB undertook to order more than one of their machines. Hence, collective bulk buying opportunities will be possible, similar to those used by Lead Providers when the programme was initially established.

VENDOR PLANNING AND INSTALLATION PROCESSES

BSWN experienced implementation issues. Other Lead Providers should pay particular attention to:

- Sufficient input and planning with engineers and trainer prior to installation, to ensure awareness of Lead Provider schedules and needs; and
- Allowing sufficient time to thoroughly test equipment before the go-live date and before final payment is made to the vendor. Speed issues are critical to reading and assessing.

QUALITY STANDARDS FOR DM

At the time of implementing DM at BSWN, quality standards had not yet been developed for DM for Australia and New Zealand. The NSU required BSWN to implement the digital standards maintained by the FDA in the United States. These included eight hours training for radiologists and MRTs and vendor-specific QA standards. In addition, the NSU specified that:

- Only the readers who were already experienced in screen reading (within BSA or the United Kingdom) could become digital readers at start-up;
- A radiologist, MRT and physicist who were experienced in mammography should be involved in all decision making regarding equipment purchases and implementation; and

- Only equipment that was FDA approved or in use in European screening programmes could be purchased.

BSWN initially had to develop its own protocols from the FDA standards. The NSU has now issued *Interim Digital Mammography Standards for Full Field Digital Mammography and CR Systems* (2007) as an addendum to the NP&QS. Now that these standards are in place, they will serve to provide more direction to other Lead Providers and simplify the transition to DM.



IMPACT FINDINGS

This section discusses the impacts of DM as experienced by BSWN stakeholders. It begins by presenting an overview of the key impacts on overall screening processes. This is followed by discussion of the impacts on various aspects of the screening business including appointment scheduling, workforce utilisation, recruitment and retention of staff, occupational safety and health, quality assurance, maintenance, integration of screening sites and MDT meetings, and impacts for women. The section concludes by summarising the advantages and disadvantages of DM and lessons for other Lead Providers.

5.1 SCREENING PROCESSES

DM screening processes differ from FSM processes in a number of ways. The process maps in Appendix F detail these differences at each stage of the screening process. Key differences in DM screening compared to FSM are:

- There is greater automation of the screening work flow through the PACS worklist system, including tracking of each woman through the screening process from arrival at reception through to the final screening/assessment outcome, the linking of images and data for electronic storage and retrieval, and the assigning of studies to workstations/users. The processes implemented at BSWN take work flow automation further than the systems observed overseas by BSWN representatives, through the linking of the RIS (SBS) and PACS. Without this link, the full potential benefits of DM are not realised.
- Prior film images collected from previous screening rounds and/or film-based screening sites are digitised at digital screening sites, for women attending DM screening and for women recalled to assessment.
- The registration form (“green form”) recording demographic, interview and screening details is scanned into the PACS and stored electronically with the woman’s images and electronic data. The form is coloured green to reduce glare at reading workstations.
- The use of a sub-waiting room, where the woman changes before entering the x-ray room, provides the opportunity to increase work flow per machine by making more efficient use of the x-ray room. Data entry can be completed at a QA workstation in a separate room, allowing the next examination to commence (with a different MRT) immediately. This work flow enables the Takapuna site to operate three screening schedules across two x-ray rooms.
- The MRT remains in the room with the woman throughout the examination. MRTs are able to QA each image as it is taken, and take any repeat views if needed due to movement or artefacts. The woman is able to leave immediately upon completion, with less likelihood of a technical recall for repeat views.²⁴
- There is no film processing involved, no darkroom/processing room required, and no chemical handling or storage.

²⁴ BSWN data for women screened between 1 February 2006 and 1 February 2008 shows a technical recall (TR) rate of 0.07% for digital, 0.10% for fixed film and 2.15% for mobile film.

- After leaving the x-ray room, the MRT completes QA at the QA workstation. 'Hanging' of digital images is performed automatically by the PACS using programmed hanging protocols and is checked/corrected by the MRT during QA. The images are then immediately available for retrieval at any reading workstation with no manual hanging of films required.
- Images are accessed electronically by reading and assessment radiologists. Reading can be shared between radiologists working at different sites. Radiologists are able to 'double read' remotely and assessment clinics can be run with one radiologist instead of two.
- Electronic images can be sent to treatment providers. Hard copy images are laser printed if needed for other radiology or treatment providers.
- Stereotactic equipment with DM enables biopsies to be taken more quickly, making more efficient use of radiologist and MRT time and minimising patient discomfort.²⁵
- Multidisciplinary meetings are more sophisticated, using digital technology including videoconferencing with remote sites.
- DM screening technologies and processes are continually evolving, and BSWN is investigating and implementing refinements to its screening processes on an ongoing basis.

As BSWN is not fully digital (FSM is still used by sub-contracted providers and for the mobile unit which collectively perform 30% of BSWN's mammograms), the full benefits of DM are yet to be realised. Moreover, there is a transitional period of two years following conversion to digital, in which prior analogue films need to be retrieved from storage and digitised, after which the imaging clerks' workload should reduce. There will also be an ongoing residual workload associated with digitising priors transferred from other Lead Providers or private providers using FSM technology.

5.2 SCHEDULING

The weekly schedules of screening appointments for each site were developed with the intention of offering screening services at a range of popular times, with extra appointments being offered at the busier times. Experience has been that the early morning, late afternoon/evening and Saturday appointments are the most popular. The schedules also incorporate weekly QA testing (approximately one hour each week), MDT meetings, and, where applicable, set-up and conduct of assessment clinics (up to 24 women per week, including 6 stereotactic biopsy appointments available per week), and checking of mobile films.

The schedules continue to be revised and fine-tuned on an ongoing basis by the Lead MRT and programme manager, with MRT input.

The DM work flow at Takapuna provides the ability to work three screening schedules across two machines, providing increased volumes per machine. Until recently, appointments were scheduled at 15 minute intervals. The current schedule (implemented 1 December 2007) has two women every 10 minutes to achieve the desired screening numbers and maintain smoother work flow. Thus, the Takapuna site can screen 12 women per hour with two machines (or 6 per machine). In comparison, appointments for FSM screening, and appointments at Waitakere where there is one DM machine, are 15 minutes apart with a single schedule, for an output of 4 women per machine per hour.

²⁵ Most BSA sites already have stereotactic equipment so this is not an additional benefit of DM for these sites.

5.3 WORKFORCE UTILISATION

The following paragraphs consider the impact of DM on the utilisation of the screening workforce including MRTs, radiologists, imaging clerks, IT support, and medical physicist.

5.3.1 MRTs

The DM work flow at Takapuna enables three MRTs to work three screening schedules using two x-ray rooms. This provides increased volumes per machine. However, experience at BSWN to date has been that individual MRT volumes have remained similar to those in a FSM environment. The current appointment schedule (implemented 1 December 2007) allocates 10 minutes per woman for screening appointments. Previously, three women were screened per 15 minutes. From 1 December, four women are screened every 20 minutes. As detailed in Appendix F, this length of time reflects:

- Clinical practice considerations, including establishing rapport and trust with each woman in order to achieve good compression, taking care in positioning the woman to acquire a high quality image, acknowledging and addressing any discomfort or anxiety, responding to questions, and allowing the woman to see the images where requested. Additionally, some women are scheduled for a double appointment, including first appointments, women with breast implants, and women with a cognitive or physical impairment.
- Cultural issues, including working with women who speak limited English, attending to specific cultural needs, and balancing efficiency considerations with the need to ensure women are given time to prepare themselves, ask questions and do not feel “rushed”.
- Occupational Safety and Health (OSH) considerations associated with positioning women and machinery and with operating switches which are manageable at current volumes but may be exacerbated if output per MRT were increased.
- The current SBS configuration which requires data entry and scanning of the green form as part of the image QA process after the MRT has left the x-ray room. This is currently being reviewed with the intention of improving the flow of the data entry process and eliminating paper processes associated with the green form, as discussed below.
- The use of green forms is currently being reviewed (see below), with the intention of improving the efficiency of the data entry process and elimination of paper processes associated with the green form.
- An increased role for MRTs in the QA programmes for DM machines, which impacts on their available time for conducting screening. MRTs at BSWN also evaluate the technical quality of mammographic images, a step which is left out of the screening process in some overseas screening programmes (e.g. Sweden).

Additionally, the effective output of the breast screening service has been affected by frequent maintenance issues including equipment breakdowns during the first 18 months (see section 5.7).

For comparison of MRT throughput in digital and analogue screening sites, BSWN provided data on screens per MRT-hour at two DM sites (Takapuna and Waitakere) and three FSM sites (collectively), for a week in February 2008. During this period:

- The Takapuna digital site performed 286 screens in 85.5 MRT-hours, for an average 3.35 screens per MRT-hour;
- The Waitakere site performed 243 screens in 81 MRT-hours, for an average 3.0 screens per MRT-hour; and
- The three FSM sites performed 48 screens in 16.25 MRT-hours, for an average 2.95 screens per MRT-hour.

Time of arrival and the completion time of paperwork are recorded in SBS for each woman screened. However, recorded departure times are not accurate as they indicate when the MRT

marks the appointment as departed, not when the woman leaves the screening service. Therefore this data cannot provide a reliable indication of digital screening times. The time each image is exposed is also regained in the PACS. As previously mentioned, the PACS QA of images together with scanning of the MRT form and data entry are a significant portion of the complete exam.

The Lead MRT also conducted an informal evaluation at the Waitakere site, and advised that acquisition time per woman varied between 4 minutes and 27 minutes, with the majority being completed within 4-5 minutes. Data and QA time varied between 1-7 minutes, averaging 4 minutes. The Waitakere site has some time limitations as there is only one machine and the modality has a slower acquisition and display time than one of the Takapuna machines.

The most significant near-term opportunity to enhance the MRT work flow at BSWN is the current review of the SBS configuration. Under the present arrangement, the MRT writes notes on the green form while taking mammograms, then conducts data entry and scanning of the form as part of the subsequent QA process, resulting in double-handling of data. Moreover, data entry fields in the computer system do not match the layout or content of fields on the green form, and this causes further inefficiencies due to the need to locate fields on the system and re-interpret information for data entry.

The current review is aimed at enabling direct data entry and eliminating the use of the green form through improved integration of the RIS with the acquisition workstation. This would shorten the exam time as the full process would be completed by the time the woman leaves the x-ray room. It was estimated that this might save up to five minutes per woman, enabling appointments to be scheduled ten minutes apart instead of the current 15 minute intervals.

From 1 December 2007, the Takapuna site has moved to a system in which work flow has changed to 10-minute appointments and the MRT performs 2-3 exams in succession then completes the paperwork and QA for this group of exams.

5.3.2 RADIOLOGISTS

A key driver of the decision to go digital at BSWN was the ability to integrate the Takapuna and Whangarei based clinical teams. The ability to electronically transmit images between sites has successfully widened the pool of clinical expertise, including sharing of double blind reading between the two sites. It is now standard practice for Takapuna based radiologists to perform second reads for images taken in Whangarei, and for Whangarei radiologists to perform second reads on an equivalent number of images acquired in Takapuna. This process has been implemented smoothly and the two sites have a positive working relationship.

The ability to read images in real time also enables assessment clinics to be performed with one radiologist present at the assessment and another available to provide a second opinion during assessment by viewing the images remotely.

The linking of the two sites has also paved the way for high quality and accessible MDT meetings, with images being viewed by staff at both sites simultaneously through the use of videoconferencing technology. This significantly reduces clinical isolation and QA risks without the need for radiologists to travel between sites, and facilitates working relationships.

A second benefit of the DM environment for radiologist work flow is the increased flexibility in the reading process. Film-based mammograms are loaded into a viewer and are viewed sequentially as they are wound on and are then viewed in the opposite sequence for second reads. Radiologists typically have to set aside a block of time (approximately 2-2½ hours) for film-based reading and have to complete the full viewer at one sitting. In contrast, the DM system enables radiologists to read studies in any order. Generally, second reads are called up first, followed by first reads.

Further, as it is not necessary to read a whole viewer at one sitting, radiologists are able to use smaller chunks of time for reading which provides opportunities for radiologists (who often

combine screening work with hospital and/or private practice work) to make more efficient use of their time.

Reading capacity is constrained by the number of workstations (rather than film viewers) available. The Whangarei screening site found that the addition of a second workstation greatly improved work flow flexibility by enabling two radiologists to read simultaneously.

For DM reading, there are more viewing options as well as additional requirements such as four-quadrant magnification, which are more time consuming than for films. There is wide variation between reads and between radiologists in the time per read. BSWN found (consistent with overseas findings) that reading times for DM were initially substantially slower than for FSM. With radiologists now familiar with DM reading, the time per read has stabilised to an average of 37% longer than FSM.²⁶

DM enables significantly reduced times for stereotactic biopsies. These can be performed within 30 minutes whereas the procedure typically took an hour or longer using FSM equipment. This is because positioning the needle in the breast tissue is guided by a series of still x-ray images which are now acquired digitally, obviating the need to process a series of films during the procedure.

Overall, BSWN has found that radiologist FTE requirements for DM are equivalent to those in a FSM environment. BSWN does not foresee any significant reduction in radiologist FTE unless Computer-Aided Detection (CAD) is adopted in the future. This technology can bring efficiencies without necessarily involving full automation of first reads; CAD can be used by readers to facilitate more rapid identification of potential microcalcifications.

5.3.3 IMAGING ASSISTANTS

Imaging assistants (or 'film hangers') are still needed in a DM environment. However, their role changes with the conversion to DM. New duties include digitising of priors and data entry into the PACS to support the digital work flow. This is more complex than traditional film hanging and requires a higher degree of expertise and competence. Film hangers who are experienced in a FSM environment can learn and become competent in their new role over a period of 3-4 weeks ('on the job'), working with an experienced digital imaging assistant.

Initially, imaging assistants have been required to digitise all prior images. BSWN experience has been that the FTE complement of imaging assistants for digitising of priors and completing data entry in a DM environment is roughly equivalent to that required for the manual hanging of analogue films. Thus, there is no time saving in the first two years of digital screening. The addition of a second digitiser at Takapuna has improved efficiency for the imaging clerk. A reduction in clerical workload is anticipated as BSWN approaches its two-year anniversary of digital screening, as a greater proportion of priors will be digital. Although the workforce implications have not yet become clear, it is anticipated that this may reduce the overall clerical workforce required by 1FTE (out of a total of 16FTE across all BSWN sites for 32,000 screens).

During the transition to DM, some analogue film hanging may also be required if the service is not fully digital. At BSWN, analogue films are sent to Takapuna from sub-contracted sites and the mobile unit, for reading using a film viewer. There will also be an ongoing residual need to digitise priors, both due to the remaining analogue services and the transfer of files from other Lead Providers and private providers.

In addition to the changes discussed above, a darkroom technician is not required in a DM environment. Thus, the Takapuna, Whangarei and Waitakere sites no longer employ a darkroom

²⁶ This is based on BSWN data showing an average reading time of 64 seconds for all digital reads performed at BSWN in 2007 and an average 47 seconds for all film reads at BSWN in 2007. Average reading times varied between individual radiologists (from 53 to 78 seconds for digital and from 35 to 78 seconds for film). Only one of 13 radiologists had a faster average reading time for digital than film.

technician. Analogue films from the mobile unit are either processed at a private practice in Whangarei, or at BSCM. The mobile mammography machine is calibrated to both processors as necessary.

5.3.4 IT SUPPORT

Additional IT support is needed in a DM environment, reflecting the increased use of IT in the screening work flow. This includes the new role of a PACS administrator. As the ICT infrastructure for DM involves a number of separate components and suppliers (see Appendix C), it is very important that the PACS administrator be familiar with digital radiography business processes in general, and the ICT system at the screening site in particular, and be able to correctly diagnose problems and call upon the appropriate outside support. This process is assisted by automated alerts built into the system but still requires a high degree of technical knowledge.

Additionally, the data transmission requirements for DM are substantial, and standard Internet Service Provider (ISP) routing networks can adversely affect transmission speeds. Excellent IT support has contributed significantly to the success of DM at BSWN by identifying and implementing solutions to network speed issues as these were encountered.

5.3.5 PHYSICIST

In a DM environment, MRTs play a more extensive role in the QA programmes for each machine (see section 5.6 below). However, this has not led to a corresponding reduction in time for the medical physicist. Although BSWN expected the need for ongoing services of a physicist (post installation and acceptance testing of the DM equipment) for one day every 2-3 months, the reality has been that 4-5 days per month has been required during the first 18 months of the service.

This has largely resulted from maintenance issues (see section 5.7). There are relatively few medical physicists accredited to provide services to BSA. They are in high demand, and often work to tightly planned schedules. Lead Providers and physicists need to be aware that physicist services may be required urgently and unexpectedly due to equipment failures.

The increased physicist involvement also reflects the dynamic environment of DM, in which systems and processes are continually being adjusted and refined as learning takes place. The physicist has also been involved in the training of MRTs in QA programmes at the new Waitakere digital site. BSWN anticipates that the physicist role will gradually subside to an equivalent level to that of FSM.

5.4 WORKFORCE RECRUITMENT AND RETENTION

As anticipated, the implementation of DM has made BSWN an attractive employer for both MRTs and radiologists. In particular, it has been a key reason stated by New Zealand and overseas applicants expressing interest in MRT positions. Moreover, it is easier to recruit graduate MRTs to a digital screening service as few new graduates have film experience.

DM has also been found to enhance job satisfaction through the opportunity to work with leading edge technology and the elimination of film and chemical handling at DM sites, and because MRTs can remain present with the woman during the screening process.

A disadvantage of being the first Lead Provider to move to DM has been a lack of available relief/locum MRTs and readers. As further Lead Providers adopt DM, this problem should ease.

5.5 OCCUPATIONAL SAFETY AND HEALTH

For MRTs, the OSH benefits of DM include:

- Improved ergonomics, with positioning of the machines being motor-assisted, and 'one-touch' positioning from the keypad from cranio-caudal (CC) to medio-lateral oblique (MLO) or latero-medial (LM) views, rather than manual; and
- Elimination of film, cassette and chemical handling from the work flow.

As with FSM, there are physical stressors associated with positioning women (e.g. twisting, weight bearing) that are the main cause of musculoskeletal problems for MRTs, and require adherence to safe movement technique and taking regular breaks. BSWN has also purchased special stools which help to improve the ergonomics associated with this activity. It was argued that there could be OSH risks if throughput were increased in a way that resulted in MRTs performing these activities at shorter intervals. The work flow observed in Sweden counters these risks by rotating MRTs between duties and incorporating stretching exercise breaks into the work flow.

As a result of these considerations, it was argued that throughput volumes *per machine* can be increased through careful attention to the work flow but volumes *per MRT* should only increase slightly.

For radiologists, it was noted that workstation ergonomics are important in terms of monitor and equipment positions, posture and duration of use (as with any work that involves extended periods of time at a computer). Lighting considerations are also important. A DM reading monitor emits less light than a film viewer which places less strain on the reader's eyes (this is also helped by the ability to adjust the brightness and contrast of the display). It also means that the reading room must be equipped with blackout curtains and these must be drawn for reading.

BSWN also provides separate reading rooms for each reader so that they are able to work undisturbed.

5.6 QUALITY ASSURANCE

QA processes for DM equipment differ from those for FSM, especially with regard to the MRT role in the QA programme. With FSM, MRTs are involved in routine phantom testing each morning, and processor sensitometry. Other tests such as compression testing and visual/mechanical checks are similar to DM. FSM also requires six-monthly film contact testing on all cassettes.

Similar to FSM, the QA processes undertaken by MRTs for DM include the following, as detailed in the *Interim Digital Mammography Standards for Full Field Digital Mammography and CR Systems* (NSU, 2007c):

- Daily and weekly phantom tests for image quality and artefact evaluation, with daily exposures of the phantom stored to the PACS (FSM QA includes daily phantom exposure to measure optical density);
- Daily monitor cleaning and inspection of viewing conditions (FSM QA includes daily cleaning and inspection of darkroom);
- Monthly visual and mechanical inspection of all moving parts;
- Monthly repeat rate analysis to determine repeat rates attributable to a range of equipment faults and positioning errors;
- Six-monthly compression tests;
- Six-monthly automatic exposure control (AEC) thickness tracking tests; and

- Ongoing maintenance and fault logging as required.

In addition to the processes listed above, the QA processes undertaken by MRTs for DM include the following which do not have an equivalent process in a FSM environment:

- Weekly calibration of detector and shutdown of machine;
- Weekly QA of reading and acquisition monitors against a test pattern (TG18-QC);
- Weekly laser printer image test and monthly laser printer artefacts tests;
- Weekly stereotactic accuracy confirmation tests prior to first use, on each day a procedure is carried out (most BSA sites already have stereotactic equipment so already undertake this QA);
- Monthly full-field artefact evaluation; and
- Quarterly image receptor homogeneity test.

Overall, BSWN estimated that MRTs spend an average of approximately two hours per week on DM machine QA. This is comparable to the time requirements in a FSM environment.

The specific QA processes and requirements are different for each machine. BSWN MRTs commented that establishing new QA programmes with new DM equipment is an extensive process which is made more complicated by inconsistent terminologies used by different manufacturers. It is important to allow time for MRTs to be trained in the QA programme for each modality.

As with FSM, as part of the QA programme for DM equipment, the medical physicist is responsible for conducting a range of yearly tests related to radiation dose and image quality performance levels. The physicist is also involved in acceptance testing at machine installation and after equipment repairs and/or replacement of parts.

At the time DM was implemented at BSWN, quality standards did not exist for DM in Australia or New Zealand. Thus, BSWN initially had to develop its own standards, necessitating the development of a lot of documentation (manuals and forms). The NSU has now issued the Interim DM Standards (NSU, 2007c) as an addendum to the NP&QS. These interim standards are based on the position paper by the ACPSEM on Interim Recommendations for a DM QA Program (McLean et al, 2007). Now that these standards are in place, they will serve to provide more direction to other Lead Providers and simplify the transition to DM. QA processes for DM are continuing to evolve.

BSWN has recently been audited against the interim standards, and noted that the auditors had mixed experience themselves in DM. Thus there is a need to ensure that auditors increase their understanding of DM.

At BSWN, QA programmes are also undertaken for FSM as required for the mobile unit as it is an analogue system. This includes daily phantom testing plus recording of sensitometry results from the processing site.

5.7 MAINTENANCE

Maintenance includes scheduled maintenance on the modalities and IT systems, which are planned and incorporated into BSWN's business processes, and the servicing of equipment due to unforeseen malfunction or failure of one or more components.

The scheduled maintenance requirements for DM machines by an engineer include six-monthly checks. These have not yet been done as the engineers have been on site more regularly than this to date.

From an unscheduled maintenance perspective, the PACS proved stable, but multiple problems were experienced with both DM machines, particularly during the first 18 months of service. Although the risk of initial technical issues was anticipated based on the overseas site visits and was managed in the equipment selection phase, the issues experienced were more frequent and persisted for a longer duration than anticipated. Collectively, these equipment failures had a significant impact on BSWN's screening capacity from February 2006 through to mid-2007.

The equipment problems stemmed from two fundamental issues: DM is a new and evolving technology and can therefore be expected to break down more often than FSM equipment; and as BSWN was the first Lead Provider to adopt the technology, the local pool of expertise in servicing the equipment was developing from a small base.

EQUIPMENT FAILURES

BSWN has experienced multiple failures of x-ray tubes and detectors as well as a range of other, more isolated problems. Specifically:

- Five x-ray tubes have required replacement (one modality). In two of these cases the tube was replaced in an attempt to resolve grid lines; the problem was subsequently resolved by installing a UPS and some extra electrical insulation on part of the system. In comparison, FSM x-ray tubes generally last between 2-4 years.
- One detector and four detector coolers have required replacement (one modality). Detectors should normally last several years.
- Four detector coolers have required replacement (one modality).
- Two high voltage generators have required replacement (one modality).
- Failures due to a software upgrade not being compatible with the system. Contingency plans are now required prior to any upgrades.
- Other software failures requiring system shutdowns.
- Mechanical failures of equipment, e.g. a magnification table jammed in position.

As noted above, there have been multiple replacements of the tube, cooler unit and generator unit on one modality, together with a single replacement of the detector and workstation hard drive on that modality. A thorough investigative process by BSWN noted that the external power supply to the building was extremely variable and this was considered to be the likely root cause of the unreliability in component function. However, there has been a further tube replacement required since the power issue was resolved, so it is unlikely that the power issue was entirely responsible. Thus, the causes of the tube and detector failures have not yet been completely isolated. BSWN is unaware of whether other users of this equipment have experienced similar difficulties.

Although the equipment is sensitive to temperature and humidity variations, these are unlikely to be the cause of the failures as they are continuously monitored and kept within the acceptable range. The position of the air conditioning unit has proved critical in maintaining detector function. One vendor has recently moved the manufacture of its detectors in-house and it is anticipated that this may improve quality and reduce the failure rate. As a result of the early delays caused by x-ray tube and detector failures and the need to source these parts from overseas, the vendors have made a commitment to keep spares on hand.

Power failures (cuts and fluctuations) in Takapuna have also caused equipment outages. Once power is restored, there can be a two-hour delay for the machines to reach operating temperature. Power cuts can also damage electronic equipment by causing wear or acute damage to components or by causing data loss in machinery that could not be shut down in the recommended way. BSWN has upgraded its UPS units for the DM machines, to protect the equipment against power spikes and provide sufficient ongoing power to enable the mammography machines to be shut down properly in case of a power failure.

IMPACTS OF EQUIPMENT FAILURES

Equipment failure and the associated down-time reduce the overall capacity of the service and causes inconvenience for women whose appointments need to be re-scheduled. BSWN experienced frequent unscheduled machine down-time during the first 18 months of the service, and this had a significant impact on capacity during this time. For the year ending 30 June 2007, total machine down-time associated with these failures was 199 hours. At an assumed rate of 5 postponements per hour (provided by BSWN) this equates to 995 women affected (3.5% of targeted volumes). Although of great inconvenience to these women, it is likely that most re-scheduled.

The targeted number of screens for the 2006-07 year was 28,800 women. During that period, BSWN invited a total of 31,986 women. Of these: 28,216 attended screening (98% of target); 2,615 did not respond; and 1,155 did not attend. It is not clear how many of the women affected by machine down-time were re-booked and attended a subsequent appointment and how many were subsequently recorded as DNAs.

BSWN provided an example of downtime and lost productivity due to a failed software upgrade when no spare parts were held outside Europe: A mandatory software upgrade was scheduled for midday Friday 22 September 2006. Four screens were cancelled to allow for this upgrade. During the upgrade, a detector error occurred which prevented the upgrade from finalising. A new detector was ordered. It took 5 days for a detector to arrive from Europe. The detector was replaced on the evening of Wednesday 27 September. The machine was still not operational on Thursday 28 September. The upgrade was completed on Thursday evening. As a result, a total of 59 screens had to be cancelled (18% of bookings for the period). Spare parts are now held in New Zealand and Australia, allowing for 24 hour maximum delivery time.

BSWN has contingency plans in place for equipment failures (see Appendix G). Initial tasks involve contacting the service engineers, isolating the fault and determining the timeframe required to rectify it. Where necessary, bookings are re-scheduled. At Takapuna where there are two DM machines, it is sometimes feasible (depending upon the number of bookings and which machine is out of service) to maintain service provision with the one remaining machine.

SERVICE AND SUPPORT ISSUES

Access to technical support is critical to making DM work. The BSWN Programme Manager, Clinical Director and Lead MRT have invested time in managing relationships with the vendors, and the vendors have been working with BSWN including regular Issues Updates and three-monthly on-site meetings. Vendors have increased the number of engineers in New Zealand as increasing numbers of services have purchased digital radiology equipment. Other Lead Providers stand to benefit from the learning that has taken place, as the vendors' service and support capabilities in New Zealand have improved over the past two years.

A key lesson for other Lead Providers is the need to negotiate an effective service contract. This should include: components covered under warranty (e.g. x-ray tubes, detector plates); provision for storage of spare parts in New Zealand or Australasia to facilitate timely access; definition of first, second and third level faults; escalation and penalty clauses; minimum response times for service; and agreed parameters for evening and/or weekend cover.

5.8 INTEGRATION OF SCREENING SITES AND MDT MEETINGS

DM has proved successful in enabling the integration of screening processes between the Whangarei and Takapuna sites. As discussed elsewhere, the ability to transmit images and associated data electronically has effectively widened the pool of clinical expertise available to each site for reading and to obtain a second opinion during assessment clinics.

The use of videoconferencing facilities has also enabled BSWN to conduct high quality and accessible MDT meetings with images viewed by staff at both sites simultaneously. Weekly meetings of this nature would not be feasible if they required medical practitioners to travel this frequently between Whangarei and Takapuna.

The specific use of videoconferencing in enhancing integration between the two sites includes:

- A weekly operational/admin meeting between both sites (duration 1 hour) via videoconference. This would not occur if it were necessary to drive, and greatly enhances communication at management level;
- A three-monthly Clinical Governance meeting by videoconference. This would otherwise have to occur face to face and saves a minimum of 5 hours of travel 4 times a year;
- A three-monthly regional MRT meeting by videoconference. This also saves a minimum of 5 hours travel 4 times a year;
- Three-monthly meetings with a vendor which Northland attends by videoconference.

In addition, the Clinical Director and Programme Manager make a 3-monthly site visit to Northland and the Programme Manager visits Northland once a month as face-to-face meetings are considered more effective than videoconferencing for these meetings.

BSWN has invested in full High Definition Multimedia Interface (HDMI) LCD displays for high picture quality in videoconferencing. The image and sound quality is such that Waitakere-based staff may choose to join the meeting by video-conference rather than drive to Takapuna.

Photographic images of pathology slides are being transferred to Microsoft Powerpoint (as JPEG images) for presentation at the multi-disciplinary videoconference. Radiology images are viewed from the PACS system at Takapuna and sent by videolink to Northland in real time. This means that the mouse arrow can be seen at both sites, thereby facilitating discussion of a specific feature.

It is possible for both sites to each bring up the same images simultaneously on their PACS, but this is less satisfactory as the mouse arrow is not visible at both sites and there can be a time lag between sites getting the case ready for viewing. This option has been used when the video link is down and a teleconference has been held instead. The pathology images are also accessible by both sites from the DHB server, so this method is a useful backup option.

Similar videoconferences could be conducted between non-digital sites by scanning film-based images and putting them into a Powerpoint presentation with the pathology images.

5.9 IMPACTS FOR WOMEN

Impacts for women were identified through an anonymous survey which was administered to 50 women who attended screening at Takapuna on a selected week in October 2007. A total of 46 women responded to the survey (a response rate of 92%). The survey form (Appendix B) asked respondents whether they had noticed any differences between their current and previous screening, and if so, to list these differences. The question followed a free-text format for responses, with no prompting in regard to the possible differences women might experience.

Of the 46 respondents, 4 were aged 49 or less, 26 were aged 50-59 and 16 were aged 60 and over. For 7 of the women, this was their first attendance in the screening programme and they were therefore not able to comment on any differences between DM and FSM screening. The remaining 39 women indicated that they had previously undergone screening.

Of these 39 women:

- 30 (77%) noticed differences between their current and previous screening experience and 9 (23%) did not notice any difference;
- 24 (62%) commented that the screening process seemed quicker and/or that waiting time was reduced;
- 12 (31%) experienced less discomfort than on previous occasions (This is not an expected benefit of DM but one which MRTs noted is mentioned frequently. It may be attributable to a skilled MRT team rather than the DM technology), while 3 (8%) noted that there was still some discomfort or anxiety associated with the process;
- 7 (18%) noted that they had found the process "easier" (without specifying in what ways);
- 4 (10%) noted that they could see the image straight away; and
- No women identified any disadvantages of their DM screening experience compared to their previous FSM screening.

A range of complimentary comments were made about the quality and efficiency of service provided by BSWN. For example:

The Pupuke centre is much more efficient regarding time and procedure. Well organised. Personnel are friendly but efficient.

Right from the first phone call: Reception extremely polite and efficient – not a problem to change the time – no waiting – when I arrived, all forms ready to go – straight in and out within 15 minutes – a great service – well done – I am very impressed.

I appreciated the radiographer telling me of the change to digital.

MRTs also commented on their observations of impacts of DM for women. Consistent with the survey feedback, MRTs commented that women often perceive the process as faster, largely due to the elimination of waiting while films are processed – a process that previously required women to wait for 5-10 minutes before leaving the screening centre. The elimination of this waiting time has also been reported to reduce anxiety for women. However, with either DM or FSM there is a waiting period of up to ten working days before full results are available.

MRTs commented that a positive difference with DM is that the MRT stays in the x-ray room with the woman. It was noted that DM requires greater interpersonal skill for MRTs because they are staying with the women longer and because women often want to see their images. MRTs indicated that they show the breast image to most women when asked (except where there is an obvious abnormality) and avoid being drawn into any speculative conversation about results.

The ability to show the image is an advantage where it is necessary to repeat images, as technical problems such as blurring are usually obvious. This can also help to allay fears or anxieties.

One of the modalities (Sectra) uses a different shaped compression plate from FSM machines, and MRTs commented that some women could find this more difficult, especially if they are in a wheelchair.

5.10 ADVANTAGES AND DISADVANTAGES OF DM, AND LESSONS FROM IMPACTS

Table 5.1 below provides a summary of the advantages and disadvantages of DM, and lessons learned from BSWN's experience of the impacts of DM, based on the findings detailed earlier. The implications of these advantages, disadvantages and lessons for other Lead Providers are also summarised.

As clinical effectiveness aspects of DM are excluded from this evaluation, the advantages and disadvantages from a clinical perspective are not covered in this table. However, anecdotal advice from BSWN stakeholders accords with international research findings cited in section 3.3.

Table 5.1: Advantages and Disadvantages of DM

	Advantages	Disadvantages	Lessons for other Lead Providers
Work flows	<p>Increased volumes per machine.</p> <p>Greater automation of the screening work flow, through linking of SBS and PACS. All screening and assessment information is linked on the PACS, enabling easy retrieval. Clinicians can enter data as they go. Automated update of demographics. Less room for errors (e.g. linking films to wrong woman, incorrect film hanging, technical recalls).</p> <p>Easier transmission of the images for all purposes including reading, assessment, MDT meetings, remote sites, teaching, and treatment providers.</p> <p>No film processing – speeds up image acquisition.</p>	<p>New technology: big learning curve; rapid advances to keep abreast of.</p> <p>Network speed issues can cause delays in image retrieval, impacting on work flow efficiency.</p> <p>Need to print hard copy images when required for treatment providers/other radiology providers.</p>	<p>DM offers a number of advantages over FSM, but converting to DM won't all be plain sailing.</p> <p>Allow for down time.</p> <p>Don't expect to screen maximum screening volumes.</p> <p>There is still a lot of paperwork required.</p> <p>Need a supportive GM, Business Analyst and Clinical Team.</p> <p>DM screening technologies and processes are continually evolving. Implementing DM requires acceptance of this, and commitment to keeping abreast of technological developments and refining screening processes on an ongoing basis.</p> <p>Printing of hard copies or writing to CD also creates another process not previously necessary, except in a very small number of cases.</p>
Scheduling	<p>DM work flow provides the ability to work three screening schedules across two machines, providing increased volumes per machine.</p>	<p>No disadvantages were identified.</p>	<p>Build time into the appointment schedule for QA.</p>
MRT workforce utilisation	<p>Image is available for viewing almost immediately.</p> <p>No film processing tasks. MRT can stay in the x-ray room with the woman. Image QA and 'hanging' is automated and can be completed quickly.</p> <p>Future enhancements to improve direct data entry processes may bring efficiencies and enable increased volumes per MRT.</p>	<p>No disadvantages were identified.</p>	<p>Experience at BSWN to date has been that individual MRT volumes are similar to FSM, reflecting clinical practice considerations, cultural issues, OSH considerations, and QA processes (see Appendix F).</p> <p>DM requires greater interpersonal skills for MRTs because they stay in the x-ray room with the women and because women want to see their images.</p>

	Advantages	Disadvantages	Lessons for other Lead Providers
Radiologist workforce utilisation	<p>Ability to share reading across sites and provide cover for radiologists including for reading and 2nd radiologist at assessment clinics.</p> <p>Increased flexibility in reading process including ability to use smaller blocks of time for reading and flexibility to prioritise reading lists.</p> <p>Digital stereotactic equipment enables biopsies to be taken more quickly (most BSA sites already have this).</p> <p>Greater potential for addressing workforce deficiencies (e.g. cover for leave, vacant positions) in the future (e.g. through a national PACS network).</p>	<p>Reading times slower (especially initially) due to learning curve and more views.</p>	<p>Overall, BSWN has found that radiologist FTE requirements for DM are similar to those in a FSM environment.</p> <p>Reading capacity is constrained by the number of workstations. Sites need to provide sufficient workstations for flexibility, especially where radiologists alternate between screening work and other clinical roles.</p>
Imaging assistant workforce utilisation	<p>Workload for imaging assistants should reduce over the long term due to reduction in film hanging and handling of paper files.</p>	<p>Workload for imaging assistants remains similar to FSM initially due to ongoing handling of paper files and digitising of prior films.</p>	<p>There is a transitional period following conversion to digital, in which analogue priors are retrieved from storage and digitised. Thus, workforce efficiencies in relation to imaging assistants are subject to a two-year lag phase.</p>
Other workforce utilisation		<p>Additional IT support (including PACS administrator) is needed due to increased use of IT in the screening work flow.</p> <p>Greater input needed from medical physicist initially. This is expected to reduce over time to a comparable level to FSM.</p> <p>Physicist input was also required regularly with equipment part replacement requiring acceptance testing.</p>	<p>Excellent IT support is critical to the success of DM. This support is specialised because of the complexity of the DM environment, the need for seamless integration of components, and the substantial data transmission and network speed requirements.</p> <p>Excellent medical physics support is critical to the success of DM. Physicist services may be required urgently and unexpectedly due to equipment failures.</p>

	Advantages	Disadvantages	Lessons for other Lead Providers
Workforce recruitment and retention	<p>DM is beneficial in attracting radiologists and MRTs to the service and thus eases recruitment challenges somewhat. It is also easier to recruit graduate MRTs to a digital screening service as few new graduates have film experience.</p> <p>Ability to make up teaching files (for readers and MRTs) is useful for workforce development.</p> <p>DM enhances job satisfaction through the opportunity to work with leading edge technology and the elimination of film and chemical handling.</p>	<p>Re-training is required for staff to convert to DM.</p> <p>For the early adopters of DM, there is a lack of available relief/locum MRTs and readers. This should ease as further Lead Providers implement DM and the DM-experienced workforce increases.</p>	<p>Allow time for staff training and plan additional staff for service continuity.</p>
Occupational safety and health	<p>Improved ergonomics, motor-assisted machine movements, no heavy cassettes to move or lift.</p> <p>No chemical handling.</p> <p>DM workstations easier on readers' eyes.</p>	<p>Physical stressors associated with positioning women remain, and could be exacerbated if throughput per MRT were increased.</p> <p>The usual computer workstation ergonomic issues apply.</p>	<p>Due to OSH (and other) considerations, as throughput volumes <i>per machine</i> are increased through careful attention to work flow, volumes <i>per MRT</i> should only increase slightly.</p>
Quality assurance	<p>Once set up, QA programme should produce consistent, reliable results.</p> <p>No sensitometry or processor QA.</p>	<p>Broader MRT role in QA.</p> <p>Daily and weekly QA on DM modalities needs to be carefully planned to minimise downtime.</p>	<p>Each machine has specific QA processes and requirements. Establishing new QA programmes for DM equipment is an extensive process which is made more complicated by inconsistent terminologies used by different vendors.</p> <p>Allow time for MRTs to be trained in QA for each new modality.</p>
Maintenance		<p>DM is new technology, therefore less reliable. There is also less expertise in fixing it.</p> <p>The output of BSWN has been affected by frequent maintenance issues including equipment breakdowns during the first 18 months. Vendors are working together with BSWN to address this.</p>	<p>Access to technical support is critical to making DM work.</p> <p>NZ-based vendor capacity for service and support started from a small base and has increased through their work with BSWN. Other Lead Providers should therefore experience fewer problems in terms of the level of support provided.</p> <p>Negotiate an effective service contract, including: components covered under warranty;</p>

	Advantages	Disadvantages	Lessons for other Lead Providers
			<p>provision for storage of spare parts (e.g. x-ray tubes, detectors) in New Zealand or Australasia to facilitate timely access; definition of first, second and third level faults; escalation and penalty clauses; minimum response times for service; and agreed parameters for evening/weekend cover.</p> <p>Keep spare parts on hand.</p> <p>Ensure UPS units are suitable to protect equipment from power failures and enable machines to be shut down properly in case of power failure.</p>
Site integration and multi-disciplinary teams	<p>Easier to manage and integrate remote sites. Improved ability to service sub-sites and distant locations. Shared reading. Videoconferencing. SBS enhancements and PACS development for BSWN pave the way for other Lead Providers and for eventual national PACS network.</p>	<p>Network speed issues currently preclude the direct access of images off the PACS for MDT meetings. Images are currently copied into Microsoft Powerpoint presentations prior to each meeting.</p>	<p>Invest in full HDMI LCD displays for high picture quality.</p>
Impacts for women	<p>Elimination of waiting while films are processed. As a result, some women may perceive process as faster and/or experience reduced anxiety. Able to view images.</p>	<p>Sectra modality uses a different shaped detector plate from FSM machines which some women may find more difficult, especially if they are in a wheelchair. The detector plate may be more comfortable for others.</p>	<p>The change to DM is positive for some women and neutral for others. None of the women surveyed identified any disadvantages of DM screening compared to FSM.</p>



FINANCIAL IMPLICATIONS OF DM

This section provides analysis of the financial implications of DM. The purpose of this section is to enable the NSU to understand the financial implications (costs and savings) of introducing DM into the BSA programme. It may also inform the development of a framework to aid Lead Providers when considering the use of DM.

Financial implications of DM are explored under two key headings: implementation costs (costs associated with the initial setup of DM), and ongoing costs (costs associated with the provision of a DM service). Within each of these overarching categories, the analysis distinguishes capital costs (facilities and equipment), and operating costs (including the screening workforce, contractors, consumables, etc).

Following the discussion of the financial implications of DM, a high level analysis is provided of the cost per mammogram at BSWN in its first calendar year and its first full financial year of operation, and financial implications for the BSA programme are discussed.

6.1 ISSUES IMPACTING ON FINANCIAL ANALYSIS

The financial analysis draws on stakeholder feedback and financial data related to the implementation of DM at BSWN, with a focus on identifying findings that are generalisable to other Lead Providers and to BSA as a whole.

The analysis is premised on the principle that the specific costs of DM will vary between Lead Providers, whereas BSWN experience can assist qualitatively in:

- Identifying the main types of costs associated with establishing and implementing a DM service;
- Explaining how and why the costs of DM differ from the costs of FSM; and
- Exploring how and why DM costs may vary between Lead Providers.

Implementation costs for each Lead Provider will vary depending upon projected service volumes, the current and planned service configuration, the number of sites, the suitability of existing facilities for a DM work flow, the specific DM equipment selected by the Lead Provider, and other factors. As a new technology, DM equipment costs are likely to come down in the future. Therefore, BSWN's specific implementation costs are not necessarily a useful predictor of the implementation costs for other Lead Providers.

Moreover, BSWN's implementation costs were for a green field development. While some costs can be directly attributed to DM (e.g. the purchase of DM machines), other costs are jointly attributable to both the implementation of DM and the implementation of a new Lead Provider, and the influence of these two factors cannot be separated. For example, the fitout of BSWN's new accommodation fulfilled the dual purposes of converting the facilities to support the breast screening business generally, and incorporating the planned DM work flow. Much of the design and development process fulfilled both of these objectives concurrently, and the costs caused by the decision to go digital cannot be separated from the total fitout costs in a robust way.

Nevertheless, other Lead Providers can expect to incur the same general *types* of implementation costs, and it is instructive to review the main groups of costs incurred by BSWN and the possible implications for other Lead Providers. Any Lead Provider preparing a business case to move to DM would need to ascertain current costs for the specific capital items required.

With regard to the ongoing costs of providing a DM service, a further issue arises because BSWN's breast screening service is not fully digital. Between 1 February 2006 and 30 June 2007, approximately 52% of mammograms at BSWN were digital. From 1 July 2007, the proportion of digital mammograms increased to approximately 70% with the addition of DM at the Waitakere site. Screens performed by sub-contractors and by the mobile unit still use FSM technology. BSWN's financial records do not account separately for all of the costs associated with DM and FSM. However, the overall costs at BSWN represent a service in transition to DM and are therefore of some relevance to other services planning to make a similar transition.

As a result of these considerations, this section focuses primarily on qualitative discussion of the cost drivers for DM, and supplements this with a high level analysis of the costs at BSWN.

6.2 IMPLEMENTATION COSTS

6.2.1 CAPITAL

Table 6.1 summarises the main capital cost items associated with the implementation of DM, together with key differences in capital costs of DM compared to FSM. These are discussed further in the subsequent paragraphs.

Table 6.1: Capital costs of DM and differences from FSM

Conversion to digital mammography	Differences between DM and FSM
<p>Facilities</p> <ul style="list-style-type: none"> • Fitout for DM work flow (including sub-wait room; space for printers, digital archive/server, soft copy QA/review workstations, ongoing hardcopy storage). • Air conditioning for DM machines requires high airflows relative to size of rooms due to the high heat output of DM machines. • Possible connection of three-phase electricity depending upon the modality. • Possible reinforcing of floor to support weight of DM machine depending upon the modality (this is unlikely to affect other Lead Providers as new model is lighter). 	<p>Facilities</p> <ul style="list-style-type: none"> • Hard copy storage requirements should reduce over time with DM (initial two-year lag time while priors are digitised). • At BSWN all archiving is on site but other Lead Providers may face costs of outsourced archiving for analogue/hardcopy files. • Darkroom/processor space is not required once the service is fully digital, but may need to be retained on site during transitional period if some screens remain FSM (unless local hospital facility can be used as BSWN has done).

Conversion to digital mammography	Differences between DM and FSM
<p>Equipment</p> <ul style="list-style-type: none"> • FFDM modality or modalities and workstations. • Stereotactic biopsy device. • PACS and PACS workstations. • Software development (e.g. SBS modifications). • QA and reading workstation(s). • Infrastructure for image transmission (NSU has produced estimates of usage by Lead Provider). • Image storage (NSU has produced estimates by Lead Provider). • Laser printer(s). • Digitiser(s). • QA equipment including phantom, sensitometer, densitometer, image density reader. • Videoconferencing equipment. • UPS units. 	<p>Equipment</p> <ul style="list-style-type: none"> • FFDM modalities cost more than FSM. However, the higher cost per machine may be partially offset by greater throughput capacity per machine (this brings down the cost per mammogram). • Film processor (and associated equipment such as film cassettes, loaders and labellers) and viewers are not required once the service is fully digital, but may need to be retained during transitional period.

Facilities costs will vary with the individual characteristics of each site and whether the transition to DM is made all at once or in stages. For example, if a site is fully converted to DM, darkroom/processor space is no longer required and can be used for DM purposes as summarised in the table above.

If the site is able to increase its throughput as a result of converting to DM (e.g. by operating three schedules across two rooms) then the facilities and equipment cost per mammogram may be reduced.

Analysis by the NSU found that a DM machine costs 2.3 to 3.5 times more than a FSM machine, and total annualised equipment costs for a DM system would be 1.9 to 2.3 times higher than FSM equipment (NSU, 2007b). The precise equipment costs depend on a range of factors including the:

- Make and model purchased;
- Support contract (see section 4.7);
- Method of financing; and
- Duration of the agreement.

Additionally, savings may be achieved through Lead Providers negotiating bulk purchasing arrangements with DM vendors, as vendors may be prepared to make substantial discounts if multiple machines are purchased.

The ongoing cost of capital (discussed later) also depends on the method of depreciation used.

CAPITAL COSTS AT BSWN

WDHB's Capex report for BSWN shows capital expenditure of \$1.7 million associated with DM at Takapuna as follows:

- \$1.49 million for two FFDM modalities, stereotactic device, QA equipment, and QA and reading workstations. The costs of individual items cannot be disaggregated due to confidentiality agreements with individual vendors;
- \$89,000 for PACS and PACS workstations;²⁷
- \$77,000 for laser printer and digitiser; and
- \$43,000 for videoconferencing equipment.

Note that the above figures are for the Takapuna site only and exclude capital expenditures at Waitakere and in Northland. Nevertheless, they serve to indicate the level of capital investment that was required for the items listed.

Additionally, \$187,000 was spent on enhancements to the Orion Soprano Breast Screening (SBS) system to support the work flow and minimise clinical risk in a digital screening environment. This was funded by the NSU and is not included in the \$1.7 million above.

These costs did not include provision for establishing first and second-tier data storage as BSWN was able to utilise the existing Storage Area Network (SAN) housed at North Shore Hospital and Medical Archiving Solution (MAS), owned by hA. Other Lead Providers would need to investigate their existing DM image storage options and any possible additional storage requirements.

6.2.2 OPERATIONAL COSTS OF IMPLEMENTATION

Operational costs of implementing DM include:

- Time spent by a range of personnel in planning and purchasing of DM equipment;
- Travel, accommodation and incidental expenses for site visits to evaluate digital systems; and
- Training delivered to Radiologists, MRTs and other staff.

BSWN has advised that the financial costs associated with these tasks cannot be disaggregated from the costs of the implementation of BSWN overall. Moreover, such data would be of limited utility to other Lead Providers as these costs will vary depending upon a wide range of factors such as: the timeframe for implementation; the approach to transitioning from FSM to DM; the number of sites going digital; and the balance of in-house and externally contracted expertise required for the planning and implementation processes.

Nevertheless, other Lead Providers can expect to incur the same *types* of costs as they implement DM and there is therefore value in identifying the main cost items associated with the implementation of DM at BSWN to provide a framework for budget development by other Lead Providers.

²⁷ Costs have been rounded to the nearest \$1,000.

The estimated time spent in digital planning and purchasing at BSWN is summarised in Table 6.2. Details of the site visits made by BSWN are provided in section 4.5.5, and details of digital training at BSWN are provided in section 4.6.2.

Table 6.2: Estimates of time spent on digital planning and purchasing at BSWN

Role	Hours	Timeframe	Notes
Project Manager	420	July 2005 – March 2006	This is total of hours spent (for planning and establishment of BSWN <i>and</i> DM).
IT Project Manager	480	July 2005 – August 2006	Procurement processes, system design, upgrades implementation, integration, calibration. The IT Project Manager worked full time on BSWN implementation for six months. Establishing DM within an existing service would be significantly simpler. Moreover, access to reference sites with established DM work flows (such as BSWN) would facilitate more rapid planning and implementation.
Radiologist advisor (a)	120	July 2005 – January 2006	Extensive advice and input throughout the project. Reviewing proposals to NSU, Board papers, etc. Approx. 8 x DWG meetings @ 2 hours, 6 x 4-hour sessions of presentations from vendors and in decision making processes, 10 hours reviewing drafts of tender documents, reviewing proposals from vendors. Trip to Europe to evaluate short-listed digital systems.
Medical Physicist Advisor	187	July 2005 – April 2006	RFP preparation and vendor presentations 86 hours. Site visit and selection process 66 hours. Training, acceptance testing and installation problem solving 35 hours.
MRT Advisor	80	October 2005 – January 2006	Approx. 8 x DWG meetings @ 2 hours, 6 x 4-hour sessions of presentations from vendors and in decision making processes, 10 hours reviewing drafts of tender documents, reviewing proposals from vendors. Trip to Europe to evaluate short-listed digital systems.
Purchasing Advisor	80	July 2005 – January 2006	Work with DWG to develop digital specifications, manage tendering process, arrange vendor presentations, decision making, etc.

Role	Hours	Timeframe	Notes
MRT/PACS Advisor	70	July 2005 – December 2006	Extensive advice and input in early stages. Reviewing proposals to NSU, Board papers, etc. Approx. 8 x DWG meetings @ 2 hours, 6 x 4-hour sessions of presentations from vendors and in decision making processes, 10 hours reviewing drafts of tender documents, reviewing proposals from vendors.
Radiologist Advisor (b)	50	July 2005 – January 2006	Approx. 8 x DWG meetings @ 2 hours, 6 x 4-hour sessions of presentations from vendors and in decision making processes, 10 hours reviewing drafts of tender documentation, reviewing proposals from vendors.
Radiologist Advisor (c)	50	July 2005 – January 2006	Approx. 8 x DWG meetings @ 2 hours, 6 x 4-hour sessions of presentations from vendors and in decision making processes, 10 hours reviewing drafts of tender documentation, reviewing proposals from vendors.
PACS Administrator	30	July 2005 – January 2006	Approx. 4 x DWG meetings @ 2 hours, 3 x 4-hour sessions of presentations from vendors and in decision making processes, 10 hours reviewing drafts of tender documentation, reviewing proposals from vendors.
BSWN Manager	10	October 2005	Trip to UK to view digitising processes and Europe to view work flow.
Radiologist Advisor (d)	20	July 2005 – January 2006	Participation in some of the digital meetings and some of the purchasing processes.
TOTAL	1,597		

6.3 ONGOING COSTS OF SERVICE PROVISION

This section focuses on the costs of providing a DM service, post 'go-live' date. It is important to note that the costs of service provision are not constant over time. For example:

- BSWN did not go fully digital from the first day of operation. As already discussed, approximately 52% of mammograms were digital initially. From 1 July 2007, the proportion of digital mammograms increased to approximately 70%;
- The transition to DM involves a learning curve for all staff. As well, DM systems and processes are continually being adjusted and refined in response to technological improvements and ongoing learning about the DM work flow. Actual screens and expenditures at BSWN to-date do not take into account potential future efficiency gains such as increased MRT capacity associated with integrating the RIS with acquisition workstations (see section 5.3.1);

- There are lags associated with some efficiencies (e.g. imaging assistant input may take two years or longer to reduce below a level equivalent to FSM due to the digitising of priors);
- Equipment reliability issues affected screening volumes and costs at BSWN in the first 18 months of the service. Actual screening volumes in 2006 and in the first half of 2007 were impacted by unscheduled machine downtime (see section 5.7). Therefore the actual costs incurred to date may over-estimate the cost per screen over the longer term;
- BSWN also noted in its Post-Audit Evaluation Report for the period 1 February 2006 – 31 January 2007, that annual coverage in the first year was impacted by low annual coverage of the previous provider, NDHB delaying start up of the programme by five months, and insufficient capacity of private subcontracted providers in West Auckland. These factors can be expected to push up the average cost per screen in BSWN's first year of operation.

It is also important to note that the *net* costs of DM include cost savings from changes to the screening work flow (e.g. potentially higher screening volumes per machine than FSM) and the elimination of some costs associated with FSM (e.g. films, chemicals). The net effect of these costs and cost savings involves a complex interplay between a range of factors such as screening volumes, facility layout, type of DM modality in use, and so on. Consequently, the *net* costs/savings of DM relative to FSM will vary between Lead Providers and over time.

The following overarching principles govern the net cost of DM relative to FSM:

- The higher capital costs of DM compared to FSM mean that the fixed costs of service provision (costs that are incurred regardless of the number of mammograms performed) are higher for DM.
- The variable costs of DM (costs that vary with the number of mammograms performed) may be lower than FSM due to lower consumable costs. However, some other costs (e.g. maintenance) may increase in a DM environment.
- For both DM and FSM, the average cost per mammogram (the sum of all fixed and variable costs divided by the number of mammograms) reduces as screening volumes increase, because the fixed costs are spread across a greater number of mammograms.
- The higher capital costs of DM compared to FSM mean that the average costs per mammogram of DM are higher at low screening volumes. As screening volumes increase, a breakeven point may be reached where the average costs of DM are equal to those of FSM. High screening volumes per machine are required to reach this point.

The BSWN Lead Provider region has high numbers of eligible women, and can keep its DM machines busy full time. Other Lead Providers serving lower populations may not be able to operate a DM machine at close to its maximum capacity, or may have screening volumes that exceed the capacity of one DM machine but cannot justify the purchase of two machines.

It is beyond the scope of this evaluation to model the net costs/savings of DM relative to FSM under a range of scenarios. Instead, the following discussion considers each of the main cost components individually, and how each component differs between DM and FSM. Section 6.4 below then considers the aggregate effect of these differences by analysing the average cost per screen at BSWN.

6.3.1 CAPITAL

The ongoing cost of capital is a fixed cost – that is, the cost of a given capital configuration, once implemented, is incurred irrespective of the actual number of mammograms performed. Accordingly, the average capital cost per mammogram reduces as the total service volumes increase. BSWN has stressed that it is important to ensure business cases include realistic

assumptions about the screening volumes that will be provided (i.e. Lead Providers should not expect to screen maximum screening volumes).

The ongoing cost of capital for DM depends upon:

- The total capital required for implementation;
- What is included in the capital cost (e.g. this sometimes includes the maintenance contract for the first 2-3 years);
- The method of financing (e.g. how much if any is borrowed, at what interest rate and over what term); and
- The method of depreciation used.

As discussed in section 6.2.1, the total capital required for implementation of DM will vary between Lead Providers but in general is higher for DM than FSM. Therefore the ongoing cost of capital will also be higher in a DM environment.

Although digital units are more expensive than plain film to purchase initially, this is partly offset by equipment that is not required (e.g. film processors, multi-viewers, silver recovery units, etc). Operational cost savings also accrue through the elimination of ongoing film and chemical costs, and reduced costs of storage, transport and handling of films. In addition, if DM results in better staff retention then there would be reduced ongoing costs of recruiting and training new staff.

WDHB purchased DM equipment using borrowed funds. The Board approved this borrowing on the basis of a business case showing that the capital costs could be recovered through net operating cashflow. It should be noted that the original business case sought capital funding to establish BSWN as a Lead Provider. The decision to go digital (supported by further financial analysis) was made subsequently.

BSWN's DM machines are depreciated over seven years using a straight line depreciation method. IT equipment (including the PACS and workstations) are depreciated over a three year period (straight line). Thus, the ongoing cost of capital is highest in the first three years. If the serviceable lives of DM machines and/or ICT equipment exceed their depreciation periods, the cost of capital may reduce over time. Moreover, the up-front costs of upgrading or replacing existing equipment should reduce as the technology becomes more widely adopted and prices come down.

6.3.2 OPERATIONAL COSTS OF SERVICE PROVISION

WORKFORCE COSTS

As detailed in section 5.3, BSWN has advised that the workforce costs associated with providing a DM service have not, to date, differed significantly from those associated with a FSM service. This is significant because the combined costs of salaries and outsourced clinical services at BSWN comprise 73% of total costs (based on 2006/07 records). In summary:

- BSWN has found to date that the MRT staffing complement for DM is equivalent to that of a FSM environment. The DM work flow enables MRTs to work three screening schedules across two x-ray rooms, which increases screening volumes per machine but not significantly per MRT. Recent scheduling changes (from 1 December 2007) together with planned IT enhancements improving the integration of the RIS with the acquisition workstation are expected to increase throughput per MRT.
- Overall, BSWN has found that radiologist FTE requirements for DM are equivalent to those in a FSM environment. BSWN does not foresee any significant reduction in radiologist FTE unless CAD is adopted in the future. Reading times for DM are slower, especially at the start, but costs are unaffected as radiologists are predominantly paid per read.

- BSWN experience has been that the FTE complement of imaging assistants is roughly equivalent to that of FSM, reflecting the need for digitising of priors, especially during the first two years of a DM service. A slight reduction is anticipated beyond the two-year mark.

Therefore, the core workforce costs for DM at BSWN have to date been comparable to those of FSM, but efficiency gains may be made in the future, particularly with regard to the MRT work flow which should increase capacity per MRT.

OTHER OPERATIONAL COSTS

Other operational costs differ widely between DM and FSM, reflecting technological and work flow differences. The following table summarises the key areas of difference in operating costs between DM and FSM. These operational costs include a combination of fixed and variable costs.

Table 6.3: Other operating costs for DM

Cost group	DM costs	Cost drivers	Differences between DM and FSM
Contractors	PACS administrator (subcontracted to BSWN via North Shore Radiology). Medical physicist – more time.	Fixed cost for planned administration/ maintenance plus additional costs for unplanned maintenance.	PACS administrator only needed for DM, not FSM. More medical physicist input is required for DM than for FSM. This includes participation in RFQ processes, MRT training, vendor performance meetings, recalibrating machine for each detector.
Consumables	Ink and film for laser printer (images are only printed where requested by other Lead Providers or private providers). Biopsy consumables e.g. hook wires/ FNA needles.	Variable cost per mammogram printed. Less than 1% of mammograms are printed. There is a strict policy on printing to minimise time and costs. Following a recent revision of this policy, images are being put onto CD instead of printing in order to reduce costs.	Reduction in consumable costs as no chemicals are needed for DM.
Maintenance	Service contracts.	The first three years of servicing costs are built into the price of the modalities. However, unscheduled downtime can affect productivity and increase the average cost per mammogram.	Maintenance costs can be high for DM, especially initially (see section 5.7).

Cost group	DM costs	Cost drivers	Differences between DM and FSM
Spare parts	x-ray tubes. Detectors. Other spare parts (see section 5.7).	Currently, spare parts are covered by warranties. However, unscheduled downtime can affect productivity and increase the average cost per mammogram.	Cost of replacing parts outside of warranty may be higher for DM but should come down over the longer term.
Archiving/storage	Maintaining first and second tier digital image storage. Maintaining physical storage for analogue/ hardcopy files.	Fixed cost. At BSWN, first tier storage is provided via WDHb's Storage Area Network (SAN) and second tier storage is provided through a Medical Archiving Solution (MAS) owned by hA. Other Lead Providers would need to investigate their existing DM image storage options and any possible additional storage requirements.	Hard copy storage requirements should reduce over time with DM (initial two-year lag time while priors are digitised). At BSWN all archiving is on site but other Lead Providers may face fixed and variable costs of outsourced archiving for analogue/ hardcopy files.
Couriers	Significantly reduced costs due to digital image transmission.	Variable cost based on volume of analogue films transported. Images requested by other Lead Providers or by private providers are still delivered by courier.	DM images are shared electronically between sites, obviating the need for courier services.
Telecommunications	Data transmission costs. Other telecommunications costs, e.g. videoconferencing	Telecom charges based on data usage (including fixed and variable components).	Telecommunications costs increase with DM due to transmission of large image files. Offsetting savings through increased use of videoconferencing which reduces transport and associated down-time for participants.
General screening programme costs	Health promotion, appointment scheduling, service management, etc.	Principally fixed costs.	These costs are broadly equivalent under either DM or FSM.

6.4 AVERAGE COST PER SCREEN

This section explores the average cost per woman screened at BSWN, based on actual costs and screening volumes during:

- The first calendar year of operation for BSWN (1 February 2006 to 31 January 2007); and
- The first full financial year for BSWN (1 July 2006 to 30 June 2007).

These costs are then compared to the average costs per mammogram in the BSA programme.

It is important to acknowledge a number of important caveats and limitations to this analysis. It would not be valid to directly extrapolate BSWN average costs per woman screened against current national volumes to assess the implications for the BSA programme overall. As already noted, average DM costs would vary between Lead Providers depending upon screening volumes, service configurations, etc. The BSWN Lead Provider region has high numbers of eligible women and BSWN can therefore keep its machines busy full time. Other Lead Providers may require less than one machine, resulting in spare capacity and higher average costs per woman screened (or may need more than one machine but less than two, with similar implications).

It is also important to note that the apparent cost per screen varies between Lead Providers due to differences in accounting practices as well as differences in service profile. Therefore there is no readily available average cost per woman screened in FSM to use as a valid comparator. For this reason, we have also calculated the average rate of funding projected for the BSA programme for 2007/08 on the assumption that Lead Providers are able to break even at this level of funding.

Furthermore, as noted at the beginning of section 6.3, costs of service provision are not constant over time and there are sound reasons for anticipating a reduction in the average cost per screen at BSWN over the next few years.

Bearing these caveats in mind, the following table compares average costs at BSWN with average BSA costs. The average costs shown are all-inclusive – that is, they reflect total costs associated with providing a screening service including capital, workforce and operating costs, for management, administration, health promotion, provision of screening and assessment services, biopsies, etc.

In its first year of operation, BSWN provided 25,916 screens at an average cost of \$210 per screen. At the completion of its first full financial year (five months later), the number of screens had increased to 28,062 and the average cost had reduced to \$169 per screen.

In comparison, BSA data shows that in the previous (2005/06) financial year, the cost per woman screened for the eight BSA Lead Providers ranged from \$147 to \$199, and averaged \$176 for BSA as a whole. Estimated volumes and funding for 2007/08 suggest the average cost per screen for BSA this year will be \$188.

Table 6.4: Comparison of average cost per screen

Provider	Period	Total cost	Total women screened	Average cost per screen
BSWN	Actual: 1 Feb 06 – 31 Jan 07	\$5.45m	25,916	\$210
BSWN	Actual: 1 Jul 06 – 30 Jun 07	\$4.74m	28,062	\$169
BSA	Actual: 1 Jul 05 – 30 Jun 06	\$29.95m	170,319	\$176
BSA	Estimate: 1 Jul 07 – 30 June 08	\$38.23m	202,819	\$188

This analysis suggests that BSWN costs, although high initially due to various factors that impacted on screening volumes, are now at a level commensurate with BSA as a whole. This accords with the WDHB revised business case and supporting financial analysis for the establishment of a DM service, which established that the capital costs of DM could be recovered through net operating cashflow at existing BSA funding levels (WDHB, 2005b).



CONCLUSION AND RECOMMENDATIONS

This section provides a brief summary of key findings against the evaluation questions together with discussion of the implications of these findings for the managed introduction of DM into the BSA screening programme, and recommendations on the implementation and use of DM based on BSWN's experience to date.

As the first Lead Provider to implement DM, BSWN experienced a range of unique circumstances and challenges during the planning and implementation of DM. Other Lead Providers will benefit from the progress that has been made subsequently, including lessons that can be learned from BSWN's experience, the availability of BSWN as a reference site for other Lead Providers, and the development of national quality standards for DM.

7.1 PROCESSES

HOW WERE DECISIONS MADE ABOUT DM? WHO MADE THE DECISIONS?

The decision to go digital was made in a number of stages, including in-principle agreement within WDHB and NDHB that the new breast screening sites should be established with DM; Board approval of a revised business case based on digital technology; National Capital Committee approval of proposed financing for digital equipment, and the final BSWN decision to order DM equipment.

A Digital Working Group (DWG), a team of clinical and other experts, in partnership with hA, managed the planning and equipment selection process including evaluating overseas literature, preparing RFP documentation and evaluation criteria, undertaking the tendering process, conducting international site visits to observe the short-listed equipment in action in high volume screening sites, and selecting the preferred vendors. The group made recommendations to management during all steps and stages of the decision making process.

The final decision to go digital was made as an integral part of the above processes. The detailed evaluation phase enabled the DWG to reach a point where all key parties were confident that the advantages of DM outweighed any possible disadvantages and that the quality and operational issues of DM could be managed in such a way as to not compromise the new service.

WHAT CRITERIA/BASES WERE USED TO AID IN THE DECISION MAKING PROCESS?

Key considerations affecting the decision whether to go digital at BSWN included the planned service configuration (two assessment centres working together as one team), the challenge of recruiting and retaining key staff, the capital and operating costs of the various options, the capacity of each option to maximise resources (equipment and human), and the geography of the region (large rural areas with some women having to travel long distances to be screened).

Because there was a deadline for making the decision, risk management was a key consideration, and stringent risk management processes were put in place. Right up until the point that the contract was signed for the PACS system, BSWN kept open the option of not proceeding with DM but rather reverting to a FSM decision.

Processes and criteria involved in selecting the make and model of DM equipment are discussed under a separate heading below.

WHAT EVIDENCE DID BSWN GATHER TO HELP MAKE THE DECISION TO GO DIGITAL? HOW USEFUL WAS THE EVIDENCE FROM OVERSEAS?

One of the identified risks of DM was that there were initially no conclusive clinical trial results. Mammography is one of the last areas of radiology to convert to digital technology internationally. There had recently been a move internationally to trial and evaluate the performance of DM in the screening setting, but the available results at the time were inconclusive. Some members of the DWG initially had reservations about implementing DM before such clinical evidence became widely available.

BSWN contacted the DMIST researchers and learned that initial results from the DMIST study were due to be released in October 2005. These results were favourable (see section 3.3.1) and (together with the international site visits) influenced the decision to go digital.

BSWN's enquiries also found that screening programmes in Australia and other countries were beginning the process of converting to digital technology. NSW had conducted trials of the quality of both CR and DR technologies and were confident that both modalities provided very acceptable levels of image quality. NSW, Victoria and Tasmania had all either purchased or were in the process of purchasing some DM equipment for their screening programmes.

The NHSBSP in the UK had set up a National Digital Steering Group and was in the process of coordinating evaluations of each type of digital equipment. BreastCheck, the Irish National Breast Screening Programme, had recently installed some DM equipment and related PACS. DM was also widely being used in the USA and in the Swedish breast screening programme.

Site visits were undertaken in six countries as detailed in section 4.5.5. Generic questions were prepared which were addressed at each site visit (Appendix E). Priority questions and additional specific questions were also identified in planning for each visit. DWG members considered that the site visits had been an important feature of the decision making process and had played a critical role in the decision to go digital as well as the selection of equipment.

HOW WAS THE BUSINESS CASE DEVELOPED?

The need to consider DM technology was first mooted in an April 2005 *Issues and Options* paper prepared by the Project Manager and colleagues (Peel and Herbert, 2005). This paper, developed following extensive consultations with WDHB and NDHB teams, set out the basis for decisions to be made over the service delivery model.

Subsequently the same month, the Project Manager and Finance Manager projected full capital funding requirements for the three years to 30 June 2009 and prepared a full business case based on these requirements together with revenue and operating costs based on projected service volumes. This was submitted to the WDHB Board in May 2005. This initial business case was based on FSM assumptions but signalled that a key technical requirement for the future of BSWN would be the provision of DM.

In July 2005, the Project Sponsor, WDHB CEO and Board Chair agreed that the project team should proceed to investigate the possibility of going digital from day one and that a revised business case should be prepared based on this and submitted to the Finance and Audit sub-committee of the Board. Subsequent discussions were held with NDHB who agreed to follow a parallel approach with its developments and business case.

In August 2005, the Project Manager and Finance Manager prepared a revised business case based on projected costs and savings associated with going digital. This revised business case was approved by the Finance and Audit Committee of the WDHB Board.²⁸

WHY DID BSWN DECIDE TO GO DIGITAL?

In summary, BSWN believed that the implementation of DM at BSWN was justified because:

- Digital radiology was being systematically introduced into mammography (including breast screening programmes) worldwide, and was considered to be the way screening mammography was heading. Indeed, all of the people spoken to internationally and from within New Zealand during the planning process, recommended that any service setting up in a green fields manner at that time would be sensible to start off with DM equipment;
- DM was in line with the existing Waitemata District Health Board (WDHB) radiology environment, which was by this stage fully digital (both in terms of staff expertise and IT infrastructure available) and the strategic direction of the radiology service at Northland DHB (NDHB);
- BSWN had an experienced and skilled implementation team and support team of clinicians, MRTs, IT technicians and Project Managers to manage risks at all stages of implementation;
- DM offered a number of benefits over FSM for the BSWN service in terms of its configuration, geography and requirement to attract new staff to a new service; and
- It was considered potentially financially unsound to invest in new FSM equipment (including mammography machines and all related processing equipment) and the facility developed to support FSM when this technology was likely to become redundant well before the end of its expected life.

It was also recognised that by BSWN making a decision to go digital, there would be a range of subsequent benefits to the BSA programme overall and to individual Lead Providers when they eventually make the decision to convert to DM.

WHAT PROCESSES WERE USED IN PLANNING AND BUDGETING FOR THE IMPLEMENTATION? WHAT PROCESSES WERE USED IN IMPLEMENTING THE SERVICE?

The establishment of BSWN was essentially a green field development. Accordingly, planning and budgeting encompassed all aspects of service development, of which DM was just one component.

WDHB appointed a Project Manager who was responsible for the overall coordination of the activities involved in establishing BSWN including all planning, decision making and implementation of DM. The Project Manager reported to the Project Sponsor (General Manager, Clinical Support Services at WDHB) who had overall management responsibility for the project. The role of clinical advisor to the project was undertaken by several people through the planning and implementation phase.

The project was overseen by a Steering Group, consisting of two members from WDHB (the Project Sponsor and a Public Health Physician) and two members from NDHB (Portfolio Manager, later replaced by GM Clinical Support Services, and a representative of Te Tai Tokerau MAPO.

²⁸ WDHB has advised that the same paperwork went to the Finance and Audit Committee as went to the National Capital Committee and Regional Capital Committee. This document was provided to the evaluators (WDHB, 2005b). A separate business case was processed by NDHB. NDHB did not have to get National Capital Committee approval to borrow capital funds because the DHB had funds on hand to purchase capital.

The implementation project was divided into ten sub-projects covering various aspects of the overall establishment of BSWN. Two of these (equipment and information systems) were central to the implementation of DM. The decision to go digital also had direct impact on a number of other sub-projects such as facilities, staff recruitment and training, operational systems and processes, quality and monitoring, and finances/capital funding.

A high level project plan and Gantt chart were developed for the BSWN implementation project including key milestones, interdependencies between sub-projects and a critical path. Throughout the duration of the planning and implementation project, regular milestone progress was reported to the Steering Group. In addition, an issue and risk register for the project was maintained, and issues and risks were raised at each Steering Group meeting. Each sub-project also had an identified project leader and its own project plan. NDHB established a similar project structure for NDHB implementation.

Budgeting was undertaken by the Project Manager and Finance Manager. Key processes included the preparation of: the Issues and Options paper which included supporting analysis of 10-year volume projections by TLA and the projected impact of volumes on staffing and equipment; a comprehensive cost model for all steps and stages in the programme based on the projected volumes; and the business case and revised business case which included analysis of capital expenditures and ongoing revenues and costs, and demonstrated that income earned from the programme would cover the cost of borrowing to fund capital.

Implementation of DM was overseen by the Project Manager together with the DWG as discussed elsewhere.

WHAT PROCESSES AND CRITERIA WERE INVOLVED IN SELECTING THE DM EQUIPMENT?

To aid in selection of DM equipment, the DWG developed criteria and a scoring and ranking system. The over-riding objective of the selection criteria was to find the most cost-effective solution for the supply of mammography equipment. Accordingly, initial tenders were assessed and evaluated in regard to the following evaluation criteria:

- Ability to satisfy business requirements (including the ability to deliver by February 2006);
- Geographical support and representation;
- Confirmation of strong administrative and reporting systems and the ability to interface with BSWN processes and systems;
- Evidence of a sound organisational and financial structure;
- An acceptable pricing structure, including overall cost and value for money;
- Ability to meet commercial requirements and demonstrate long term stability in relation to ownership, business plans and policies, company size, company expertise and references;
- A planned approach to transition and implementation;
- Use of technology;
- Flexibility to evolve and develop to meet changing business and technology needs;
- Product fit for purpose;
- Ongoing service costs;
- Provisions for warranty;
- Training and in-service; and
- Experience and quality of staff.

Detailed RFP submission forms (Appendix D) were prepared which vendors were required to complete, enabling collection of consistent information from each vendor against required functionality and other evaluation criteria.

Short-listed vendors were invited to make formal presentations to the DWG, provide additional follow-up information as required, and to nominate international screening sites where DWG members could observe the equipment in operation and interview local screening staff.

The detailed evaluation and due diligence phase considered each of these criteria in greater detail and focused on evaluating the performance of the equipment in a real-life setting and determining the compatibility of the individual components to work as a system.

WHAT WERE THE STRENGTHS/WEAKNESSES OF THE DECISION MAKING AND IMPLEMENTATION PROCESSES? WHAT ARE THE MOST IMPORTANT FEATURES OF A SUCCESSFUL PROCESS?

Participants found that the decision making and implementation processes for DM at BSWN were robust and have resulted in the implementation of an effective and efficient breast screening service. Key issues and lessons from BSWN are listed under Recommendations below.

7.2 IMPACTS

HOW DOES THE SCREENING PATHWAY FOR DM AT BSWN DIFFER FROM THE SCREENING PATHWAY FOR FSM?

DM screening processes differ from FSM processes in a number of ways. Key differences at BSWN are detailed in process maps (Appendix F) and include:

- There is greater automation of the screening work flow through the PACS worklist system, including tracking of each woman through the screening process from arrival at reception through to the final screening/assessment outcome, the linking of images and data for electronic storage and retrieval, and the assigning of studies to workstations/users. The processes implemented at BSWN take work flow automation further than the systems observed overseas by BSWN representatives, through the linking of the RIS (SBS) and PACS. Without this link, the full potential benefits of DM are not realised.
- Prior film images collected from previous screening rounds and/or film-based screening sites are digitised at digital screening sites, for women attending DM screening and for women recalled to assessment.
- The registration form recording demographic, interview and screening details is scanned into the PACS and stored electronically with the woman's images and electronic data. The form is coloured green to reduce glare at reading workstations.
- The use of a sub-waiting room, where the woman changes before entering the x-ray room, provides the opportunity to increase work flow per machine by making more efficient use of the x-ray room. Data entry can be completed at a QA workstation in a separate room, allowing the next examination to commence (with a different MRT) immediately. This work flow enables the Takapuna site to operate three screening schedules across two x-ray rooms.
- The MRT remains in the room with the woman throughout the examination. MRTs are able to QA each image as it is taken, and take any repeat views if needed due to movement or artefacts. The woman is able to leave immediately upon completion, with less likelihood of a technical recall for repeat views.²⁹
- There is no film processing involved, no darkroom/processing room required, and no chemical handling or storage.

²⁹ BSWN data for women screened between 1 February 2006 and 1 February 2008 shows a technical recall (TR) rate of 0.07% for digital, 0.10% for fixed film and 2.15% for mobile film.

- After leaving the x-ray room, the MRT completes QA at the QA workstation. 'Hanging' of digital images is performed automatically by the PACS using programmed hanging protocols and is checked/corrected by the MRT during QA. The images are then immediately available for retrieval at any reading workstation with no manual hanging of films required.
- Images are accessed electronically by reading and assessment radiologists. Reading can be shared between radiologists working at different sites. Radiologists are able to 'double read' remotely.
- Electronic images can be sent to treatment providers. Hard copy images are laser printed if needed for other radiology or treatment providers.
- Multidisciplinary meetings are more sophisticated, using digital technology including videoconferencing with remote sites.
- DM screening technologies and processes are continually evolving, and BSWN is investigating and implementing refinements to its screening processes on an ongoing basis.

HOW DO THE WORKFORCE REQUIREMENTS FOR AN EQUIVALENT SERVICE VOLUME FOR DM COMPARE TO THE WORKFORCE REQUIREMENTS FOR FSM?

With regard to workforce utilisation, BSWN has advised the workforce costs associated with providing a DM service have not, to date, differed significantly from those associated with a FSM service. In summary:

- MRTs: BSWN has found that the MRT staffing complement for DM is fairly equivalent to that of a FSM environment. The DM work flow enables MRTs to work three screening schedules across two x-ray rooms, which increases screening volumes per machine but not per MRT.³⁰ Future IT enhancements improving the integration of the RIS with the acquisition workstation are expected to enable direct data entry and improve throughput per MRT.
- Radiologists: Overall, BSWN has found that radiologist FTE requirements for DM are equivalent to those in a FSM environment. BSWN does not foresee any significant reduction in radiologist FTE. Reading times for DM are slower, especially at the start.³¹ However, this has not affected costs as radiologists are either paid per read or in some cases salaried.
- Imaging assistants: There is a transitional period of two years following conversion to digital, during which prior analogue films need to be retrieved from storage and digitised. BSWN has found that the FTE complement of imaging assistants during this period is roughly equivalent to that of FSM. A slight reduction in imaging assistant FTE is anticipated beyond the two-year mark. There will still be an ongoing residual workload associated with digitising priors transferred from other Lead Providers and private providers using FSM.
- IT support: Additional IT support is needed in a DM environment, reflecting the increased use of IT in the screening work flow. This includes the new role of a PACS administrator. Excellent IT support has contributed significantly to the success of DM at BSWN by identifying and implementing solutions to problems such as network speed issues as these were encountered.
- Physicist: More intensive medical physicist support is needed both during implementation and in the first few years of DM operation. This is due both to maintenance issues, physicist

³⁰ Comparison of MRT throughput in digital and analogue screening sites at BSWN during a week in February 2008 found that an average 3.35 screens per MRT-hour were completed at the Takapuna digital site (across two machines), compared to 3.0 screens per MRT-hour at the Waitakere digital site (one machine) and 2.95 screens per hour for analogue sites (one machine each site).

³¹ BSWN data for the 2007 calendar year shows an average reading time of 64 seconds for digital reads and 47 seconds for film reads.

involvement in MRT training for QA programmes, and to the dynamic environment of DM, in which systems and processes are continually being adjusted and refined.

Overall, BSWN's experience is consistent with the research summarised in section 3.3 – i.e., that despite more streamlined work flows, efficiencies in a DM environment may not be realised immediately.

WHAT ARE THE ADVANTAGES AND DISADVANTAGES OF DM OVER FSM?

For BSWN, key advantages of DM are:

- Increased volumes per machine including the ability to work three screening schedules across two machines;
- Greater automation of the screening work flow, through integration of the SBS and PACS;
- Easier transmission of the images for all purposes including reading, assessment, MDT meetings, cover for remote sites, teaching, and treatment providers;
- Faster image acquisition, eliminating waiting times for women while films are processed, and enabling the MRT and the woman to view images almost immediately. As a result, some women may perceive the process as faster and/or experience reduced anxiety;
- There are no film processing tasks and the MRT can remain in the x-ray room with the woman;
- Image QA and 'hanging' is automated and can be completed quickly;
- DM is beneficial in attracting radiologists and MRTs to the service and thus eases recruitment challenges somewhat;
- Improved ergonomics including motor-assisted machine movements and no heavy cassettes to move or lift.

For BSA, key advantages of DM include benefits for individual sites as summarised above, plus the increased potential for addressing maldistribution of the radiologist workforce through a national PACS network. DM technology combined with carefully designed work flows can increase the capacity of equipment. BSWN's experience of the workforce impacts of DM to date suggests that DM is beneficial for staff recruitment and may assist in retention, but may not mitigate MRT workforce shortages by increasing the capacity of a given workforce, at least initially.

Key disadvantages of DM include:

- A steeper learning curve with the adoption of a new technology and the need to keep abreast of rapid advances;
- DM is new technology, and therefore less reliable. There is also less expertise in fixing it. The output of BSWN has been affected by frequent maintenance issues in the first 18 months. Vendors are working with BSWN to address this;
- Network speed issues can cause delays in image retrieval, impacting on work flow efficiency;
- Re-training is required for staff to convert to DM;
- Reading times are slower (especially initially) due to learning curve and more views;
- For the early adopters of DM, there is a lack of available relief/locum MRTs and readers;
- Additional IT support (including PACS Administrator) is needed due to increased use of IT in the screening work flow;
- Greater input is needed from the Medical Physicist, at least initially and in response to equipment failures; and

- Physical stressors for MRTs associated with positioning women remain, and could be exacerbated if throughput per MRT were increased.

WHAT DIFFERENT SYSTEMS OF APPOINTMENT SCHEDULING WERE CONSIDERED? HOW WERE THEY ASSESSED? WHAT SYSTEM IS USED, AND WHY?

The weekly schedules of screening appointments for each site were developed with the intention of offering screening services at a range of popular times, with extra appointments being offered at the busier times. Experience has been that the early morning, late afternoon/evening and Saturday appointments are the most popular. The schedules also incorporate weekly QA testing (approximately one hour each week), MDT meetings, and, where applicable, set-up and conduct of assessment clinics and checking of mobile films.

The schedules continue to be revised and fine-tuned on an ongoing basis by the Lead MRT and programme manager, with MRT input.

The DM work flow at Takapuna provides the ability to work three screening schedules across two machines, providing increased volumes per machine. Until recently, appointments were scheduled at 15 minute intervals. The current schedule (implemented 1 December 2007) has two women every 10 minutes to achieve the desired screening numbers and maintain smoother work flow. Thus, the Takapuna site can screen 12 women per hour with two machines (or 6 per machine). In comparison, appointments for FSM screening, and appointments at Waitakere where there is one DM machine, are 15 minutes apart with a single schedule, for an output of 4 women per machine per hour.

7.3 FINANCIAL IMPLICATIONS

DIRECT COSTS OF IMPLEMENTING AND OPERATING DM

Specific costs of DM will vary between Lead Providers. BSWN experience can assist qualitatively in identifying the main types of costs involved, explaining how the costs of DM differ from those of FSM, and exploring how costs may vary between Lead Providers.

Implementation costs include capital costs associated with facilities and equipment, and operational costs associated with time and expenses of the DWG and other implementation processes. DM implementation costs differ from FSM in that:

- FFDM modalities cost more than FSM,³² but the higher cost per machine may be offset by greater throughput capacity per machine (this brings down the cost per mammogram);
- DM requires additional IT infrastructure including PACS, first and second-tier data storage;
- Hard copy storage requirements should reduce over time with DM (there is an initial two-year lag while prior films are digitised); and
- Darkroom and processor space, and film processing equipment, are not required once the service is fully digital, but may need to be retained on site during the transition to DM.

WDHB's Capex report for BSWN shows capital expenditure of \$1.7 million associated with DM equipment at Takapuna, covering FFDM modalities, stereotactic device, QA equipment, QA and reading workstations, PACS and PACS workstations, laser printer, digitiser and videoconferencing equipment. Additionally, \$187,000 of NSU funding was spent on enhancements to the SBS system to support the work flow and minimise clinical risk in a digital screening environment.

³² NSU analysis found that total annualised equipment costs for a DM system would be 1.9 to 2.3 times higher than FSM equipment (NSU, 2007b).

Operational costs of implementing DM include:

- Time spent by the DWG and others in planning and purchasing of DM equipment (to an estimated total of 1,597 hours at BSWN);
- Travel and related expenses for site visits to evaluate digital systems; and
- Training delivered to Radiologists, MRTs and other staff. Details of training are provided in section 4.6.2, including approximately two days per MRT and two sessions including 200 dummy reads per radiologist.

Ongoing costs of service provision are not constant over time. For example:

- BSWN is not yet fully digital. Currently, around 30% of mammograms at BSWN are FSM;
- The transition to DM involves learning curves for all staff;
- DM systems and processes are continually being adjusted and refined in response to technological improvements and ongoing learning;
- There are lags associated with some efficiencies (e.g. imaging assistant input may take two years or longer to reduce below a level equivalent to FSM due to the digitising of priors); and
- Equipment reliability issues affected screening volumes and costs at BSWN in the first 18 months of the service.

The net costs of DM include savings from changes to the screening work flow (e.g. potentially higher screening volumes per machine than FSM) and the elimination of some costs associated with FSM (e.g. films, chemicals). The net effect of these factors will vary between Lead Providers and over time. The following overarching principles govern the net cost of DM relative to FSM:

- The higher capital costs of DM compared to FSM mean that the *fixed costs* of service provision (costs that are incurred regardless of the number of mammograms performed) are higher for DM.
- The *variable costs* of DM (costs that vary with the number of mammograms performed) may be lower than FSM due to lower consumable costs. However, some other costs (e.g. maintenance) may increase in a DM environment.
- For both DM and FSM, the *average cost per screen* (the sum of all fixed and variable costs divided by the number of mammograms) reduces as screening volumes increase, because the fixed costs are spread across a greater number of mammograms.
- The higher capital costs of DM compared to FSM mean that the average costs per mammogram of DM are higher at low screening volumes. As screening volumes increase, a breakeven point may be reached where the average costs of DM are equal to those of FSM. High screening volumes per machine are required to reach this point.

The ongoing cost of capital for DM depends upon the total capital investment at implementation, the method of financing, and the method of depreciation used. As the capital costs of DM are higher than FSM, the ongoing cost of capital is generally higher in a DM environment. WDHB purchased DM equipment using borrowed funds. The Board approved this borrowing on the basis of a business case showing that the capital costs could be recovered through net operating cashflow.

BSWN's DM machines are depreciated over seven years. IT equipment (including the PACS and workstations) are depreciated over a three year period. Thus, the ongoing cost of capital is highest in the first three years. If the serviceable lives of DM machines and/or ICT equipment exceed their depreciation periods, the cost of capital may reduce over time. Moreover, the up-front costs of upgrading or replacing existing equipment should reduce as the technology becomes more widely adopted and prices come down.

Ongoing operating costs include workforce and other costs. Although DM units are more expensive than FSM to purchase initially, there are operational cost savings which may tip the balance in favour of DM, especially where service volumes are high. Key areas of difference in operating costs between DM and FSM include:

- Consumable costs are lower for DM than FSM as no chemicals or films are needed for DM. A few (less than 1%) mammograms are printed, which incurs ink and film costs.
- Archiving/storage costs should reduce as a service transitions to DM and an increasing proportion of images and records are stored electronically.
- Courier costs are significantly reduced due to electronic sharing of digital images between sites. Telecommunications costs increase with DM.
- DM requires additional specialised staff including a PACS Administrator and an increased level of medical physicist input.
- Maintenance costs can be high for DM, especially initially. The first three years of servicing and unscheduled maintenance costs are covered within the price of the modalities, and the cost of replacing parts (e.g. x-ray tubes, detectors) are initially covered under warranty. However, unscheduled downtime can affect productivity.

BSWN has advised that the workforce costs associated with providing a DM service have not, to date, differed significantly from those associated with a FSM service. Therefore, the core workforce costs for DM at BSWN have to date been comparable to those of FSM. This is significant because the combined costs of salaries and outsourced clinical services at BSWN comprise 73% of total costs (based on 2006/07 records). Efficiency gains may be made in the future, particularly with IT enhancements improving the integration of the RIS with the acquisition workstation.

Other general screening programme costs (such as health promotion, appointment scheduling, and service management) are equivalent for DM and FSM.

AVERAGE COST PER MAMMOGRAM OF DM AT BSWN

In its first year of operation, BSWN provided 25,916 screens at an average cost of \$210 per screen. At the completion of its first full financial year (five months later), the number of screens had increased to 28,062 and the average cost had reduced to \$169 per screen.

In comparison, BSA data shows that in the previous (2005/06) financial year, the cost per woman screened for the eight BSA Lead Providers ranged from \$147 to \$199 and averaged \$176 for BSA as a whole. Estimated volumes and funding for 2007/08 suggest the average cost per screen for BSA this year will be \$188.

This analysis suggests that BSWN costs, although high initially due to various factors that impacted on screening volumes, are now at a level commensurate with BSA as a whole. This accords with the WDHB revised business case and supporting financial analysis for the establishment of a DM service, which established that the capital costs of DM could be recovered through net operating cashflow at existing BSA funding levels (WDHB, 2005b).

The following caveats must be noted:

- It would not be valid to directly extrapolate BSWN average costs per woman screened against current national volumes to assess the implications of DM for the BSA programme overall, due to the significant differences between Lead Providers as already noted which would affect the local costs of DM.
- In particular, the BSWN Lead Provider region has high numbers of eligible women and can keep its DM machines busy full time. Other Lead Providers serving lower populations may not be able to operate a DM machine at close to its maximum capacity, or may have screening volumes that exceed the capacity of one DM machine but cannot justify the purchase of two machines.

- Apparent cost per screen varies between Lead Providers due to accounting differences as well as actual differences in service profile and cost.
- As already noted, costs of service provision are not constant over time and there are sound reasons for anticipating a reduction in the average cost per screen at BSWN over the next few years.

7.4 RECOMMENDATIONS

BSWN's experience in the implementation of DM, its impacts post-implementation and the financial implications of transitioning to DM, highlights a number of pertinent lessons for other Lead Providers and BSA as a whole during the managed introduction of DM into the BSA screening practice. It is recommended that the NSU draw on the following lessons identified in this report to assist other Lead Providers in identifying factors to consider in their Business Cases and Implementation Plans for DM.

IMPLEMENTATION

Key issues and lessons from BSWN suggest that other Lead Providers considering the transition to DM should:

- Adopt a staged transition approach rather than changing all fixed, mobile and subcontracted sites to DM in one 'big bang' approach. A staged approach has a number of benefits including opportunities for learning and refining processes and minimising any temporary adverse workforce impacts such as slower reading times. Implement site-by-site. Mixed digital and analogue at a single site would make it difficult to maintain QA adequately.
- Plan for significant project management, clinical, technical and other multi-disciplinary input and a time investment from those involved including time dedicated away from day to day work. A critical success factor is establishing the right multi-disciplinary team from the outset.
- Pay close attention to ensuring the compatibility of DM components including PACS, RIS, storage servers and modalities. Ensure contractual agreements for DM implementation place responsibility on vendors for seamless integration.
- Note that BSWN's RFP evaluation criteria and submission forms provide a potential model or starting point for the development of tender evaluation tools for future tendering processes.
- Plan for contingencies, recognising that throughput on DM (both in taking and reading mammograms) will be slower initially. To minimise disruption to work flow, clinics and clients, a conservative approach should be taken to booking appointment slots until all aspects of installation have been improved and completed.
- Learn directly from other programmes, both in New Zealand and overseas, that have already done planning and implementation for DM. This should include site visits to comparable sites with well-established screening processes, observing work flow patterns, and conducting consultations with screening staff in order to learn of possible pitfalls.
- Seek IT guidance from an established DM screening site with a similar PACS configuration.
- Note that BSWN has gone further in terms of connectivity between RIS, PACS and DM machines than the overseas sites observed by the DWG, and is therefore a key reference site for other Lead Providers preparing to convert to DM, both to maximise effectiveness for Lead Providers individually and to minimise risks associated with incompatibility between Lead Providers.
- Involve a medical physicist from the outset in equipment selection in order to assess key performance and QA parameters of each machine.

- As part of the due diligence process, ensure that vendors provide full details against all requirements and criteria including sufficient evidence/plans for the provision of prompt and readily available service support.
- Pay particular attention to negotiating an effective service contract, including availability of technical expertise and storage of spare parts to ensure timely access; escalation and penalty clauses; minimum response times for service; and whether evening/weekend cover is necessary and available.
- Manage vendor service risks by ensuring good relationships with vendors, undertaking sufficient input and planning with engineers and trainer prior to installation, and allowing sufficient time to thoroughly test equipment before the go-live date and before final payment is made to the vendor.
- Maintain a risk register at all times during the project so mitigation strategies can be found for all new risks as they become known.
- Investigate collective bulk buying opportunities with other Lead Providers, as DM vendors may be prepared to make substantial discounts if multiple machines are purchased.
- Allow time for staff training and plan additional staff for service continuity.
- Allow time for MRTs to be trained in QA for each new modality. Establishing new QA programmes for DM equipment is an extensive process which is made more complicated by inconsistent terminologies used by different vendors. Each machine has specific QA processes and requirements.

IMPACTS

In considering the impacts of DM on screening work flow, Lead Providers should note that:

- DM offers a number of advantages over FSM, but converting to DM involves risks and may not be all 'plain sailing'. In particular, Lead Providers should allow for down time and should not expect to screen maximum screening volumes.
- DM screening technologies and processes are continually evolving. Implementing DM requires acceptance of this, and commitment to keeping abreast of technological developments and refining screening processes on an ongoing basis.
- Experience of BSWN to date has been that individual MRT volumes are similar to FSM, reflecting clinical practice considerations, cultural issues, OSH considerations, and QA processes. However, it is anticipated that throughput would increase if the MRT form were available in its entirety as data entry fields on the RIS.
- DM requires greater interpersonal skills for MRTs because they stay in the x-ray room with the women and because women want to see their images.
- Overall, radiologist FTE requirements for DM at BSWN are similar to those in a FSM environment.
- Reading capacity is constrained by the number of workstations. Sites need to provide sufficient workstations for flexibility, especially where radiologists alternate between screening work and other clinical roles.
- There is a transitional period following conversion to DM where analogue priors are retrieved from storage and digitised. As a result, workforce efficiencies in relation to imaging assistants are subject to a two-year lag phase.
- Excellent IT support is critical to the success of DM. This support is specialised because of the complexity of the DM environment, the need for seamless integration of components, and the substantial data transmission and network speed requirements.
- Excellent medical physics support is critical to the success of DM. Physicist services may be required urgently and unexpectedly if there are equipment failures.

- Keep spare parts on hand (including x-ray tubes and detectors) to minimise down time in case of equipment failure.

FINANCIAL IMPLICATIONS

BSWN experience is potentially useful in identifying the main types of costs involved in implementing DM and providing screening services in a DM environment, and how these differ from FSM. However, individual Lead Providers need to conduct a thorough analysis of the financial implications of DM taking into account local service configuration (current and planned), volumes (current and projected) and other relevant factors.

Average cost per woman screened at BSWN is commensurate with costs for BSA as a whole. It is important to note that the BSWN Lead Provider region has high numbers of eligible women and can keep its DM machines busy full time.

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APPENDIX A: INTERVIEW SCHEDULE

The following list of questions provides a guide to the topics we would like to discuss at your interview. We will not necessarily cover every question at every interview. Your feedback is sought in the areas that are most relevant to your knowledge and experience of the implementation of digital mammography at BSWN.

If you are unable to participate in a face-to-face interview, please type your responses in the space provided below and email this document back to us at: julian@hoi.co.nz, as soon as possible and by Friday, 14 September at the latest.

Evaluation of the Implementation of Digital Mammography at BSWN

Interview with (name, position/title):

Interviewer and date

PROCESSES

The Decision to 'Go Digital'

1. What was your role (if any) in the decision to go digital at BSWN?

2. How was the decision made to go digital at BSWN?

3. Who was involved in making the decision to go digital?

4. What criteria or rationale were used in the decision to go digital?

5. What evidence did BSWN gather to help make the decision to go digital? How useful was the evidence from overseas in terms of its application to the New Zealand context?

6. What were the strengths/weaknesses of the decision making process? (e.g. what worked well? What would you do differently?)

7. What are the most important features of a successful decision making process that other Lead Providers should consider?

8. Why did BSWN decide to go digital?

9. How was the business case developed?

Establishing Digital Mammography

10. What was your role (if any) in establishing the digital mammography service, once the decision to go digital was made?

11. What processes were involved in establishing the digital mammography service?

12. What processes were used in planning for the implementation?

13. What processes were used in budgeting for the implementation?

14. What processes and criteria were involved in selecting the type (make and model) of digital mammography equipment?

15. What processes were used in implementing the service (e.g. key phases, tasks and timeframes, approach to project management, key personnel involved)?

16. What were the strengths/weaknesses of these processes? (e.g. what worked well? What would you do differently?)

17. What are the most important features of a successful implementation process that other Lead Providers should consider?

IMPACTS

18. What is your role (if any) in the ongoing delivery of digital mammography services at BSWN?

19. How does the screening pathway for digital mammography at BSWN differ from the screening pathway for conventional mammography (i.e. what are the key differences in terms of stages in the process, personnel, and workflow)?

20. How do the workforce requirements for digital mammography compare to the workforce requirements for conventional mammography (for an equivalent service volume)?

21. Any other workforce issues?

22. Any potential risks for occupational safety and health (e.g. occupational overuse syndrome)?

23. Has the use of digital mammography made any difference to the delivery of mammograms?

24. What are the advantages of digital mammography over conventional mammography to BSWN and BSA? What are the disadvantages?

25. What lessons were learned that may assist the NSU to develop guidelines to aid other lead providers in deciding if digital mammography is the best mode for delivering mammography?

Thank you for your feedback, it is appreciated.



APPENDIX B: CONSUMER SURVEY

You are invited to take part in a short survey

Project Title: *Evaluation of the Implementation of Digital Mammography at Breast Screen Waitemata and Northland*

Project Contact: Arden Corter, Health Outcomes International

Telephone: 0800 464 695 / **Email:** arden@hoi.co.nz

You are invited to take part in a short, anonymous and voluntary survey about your perceptions of the breast screen you underwent today.

About the Study

This evaluation study is being conducted for the Ministry of Health. The aim of the study is to evaluate the implementation of the digital mammography service at Breast Screen Waitemata and Northland (BSWN). This includes women's perceptions of the digital screening service compared to the film screening they may have received in the past. The findings from the study will help other breast screening sites in New Zealand as they change from film to digital mammography.

Participation

We are inviting the first 50 women who attend the Takapuna screening site during the week of 8-12 October to take part in the survey.

All participation is voluntary, which means that you do not have to take part. Your participation is strictly confidential. We do not collect names or other personal details, and we do not identify individual participants in the study. Your participation in this study will not affect your future screening, health care or treatment.

Benefits, Risks and Safety

Benefits of participating include the opportunity for you to contribute your opinion to inform our understanding of the differences between digital and film-based breast screening from the women's perspective. We haven't been able to identify any risks associated with participating.

General

Further information on the study can be provided by contacting Arden Corter (project contact) on 0800 464 695 or by e-mail to arden@hoi.co.nz.

If you have any questions about the digital mammography service you received today, please contact BSWN on 484 0200.

Where to from here?

If you are willing to take part, please fill out the attached survey form and send it back to Health Outcomes International in the freepost envelope provided.

Thank you for your time!



Digital Mammography Survey

Thank you for volunteering to participate in this short survey.

Please answer the questions below, about your screening experience today. Once you are finished, please mail your survey form to Health Outcomes International in the freepost, addressed envelope provided.

1. How old are you? *(please tick appropriate box)*

- 49 and under 50 - 59 years 60 and over

2. Is this the first time you have ever had a breast screen?

- No Yes *(If you answered yes, your survey is complete. If no, please continue)*

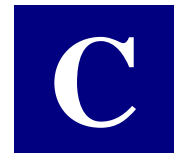
3. Did you notice any differences between the digital screening process and the film based screening you've had in the past?

- No Yes

4. If yes, please list the differences:

Thank you for taking the time to fill out this survey. We appreciate your participation.

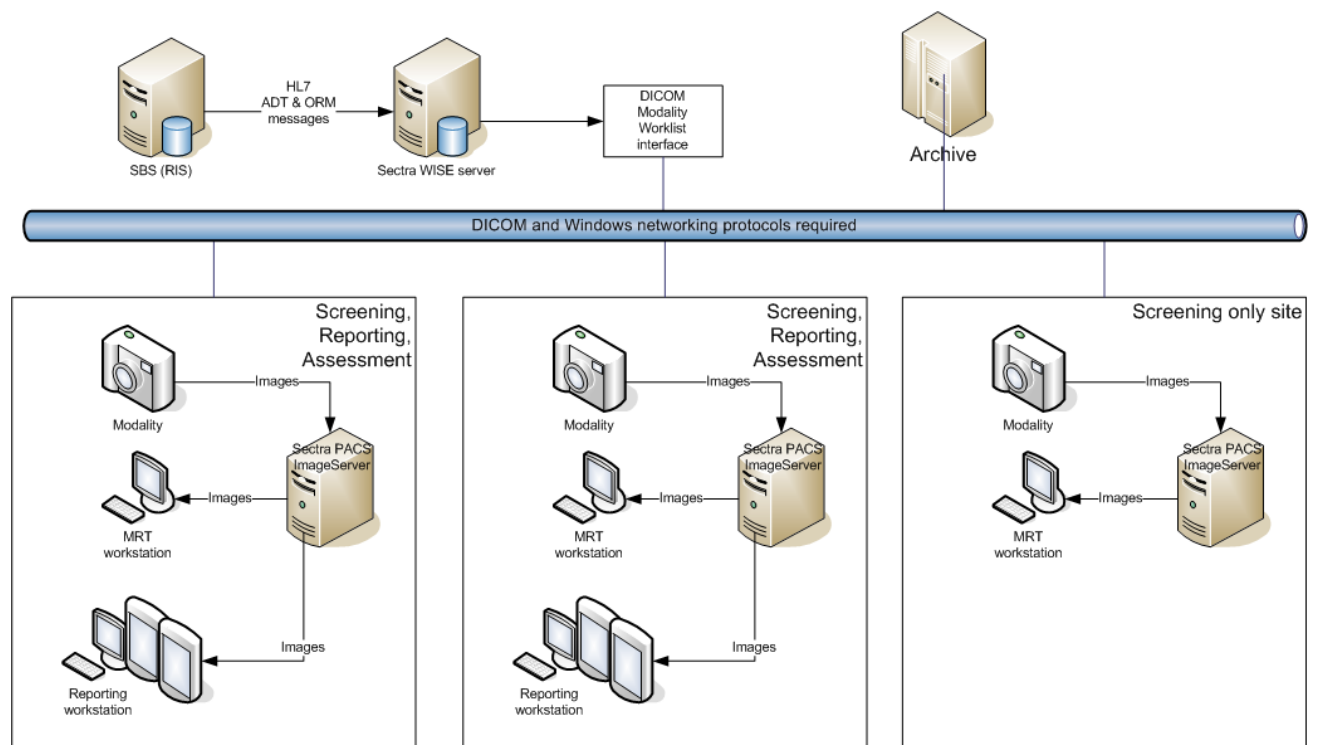
If you have any further questions about this survey, please contact Arden Corter at Health Outcomes International, on 0800 464 695 or by e-mail to arden@hoi.co.nz.



APPENDIX C: ICT INFRASTRUCTURE FOR DIGITAL MAMMOGRAPHY

Figure C.1 provides a diagram of the ICT configuration at BSWN. The paragraphs below outline the function of each component and discuss the issues faced by BSWN that led to this configuration being adopted.

Figure C.1: ICT Configuration at BSWN



Source: BSWN

PICTURE ARCHIVING AND COMMUNICATIONS SYSTEM

The Picture Archiving and Communication System (PACS) is the system at the centre of the digital screening ICT environment and manages “the acquisition, archiving and retrieval of digital images over a computer network, for diagnosis and review at dedicated workstations”.³³ It provides the central point of connection between the screening modalities, workstations and storage systems.

The BSWN PACS currently manages digital mammography images between Takapuna, Whangarei and Waitakere and, over time, will extend to the full BSWN region as other sites go digital. According to data cited in the equipment RFP (hA, 2005), the PACS was initially expected to handle an exam volume of 16,000-22,000 four-view mammograms per annum between Whangarei and Takapuna, and volumes will increase to 45,000 mammograms over time. In addition, up to 500 stereotactic guided biopsies are performed per annum.

BSWN purchased a Sectra PACS including hardware, software and related licenses, and workstations for QA and reading. The service agreement for supply of the PACS included installation of the system to the point of verifying storage connection, interface with the RIS and interfaces with modalities, as well as comprehensive applications field support, user training, and manuals. The PACS was the first component of the digital screening ICT infrastructure to be installed at BSWN.

In hindsight, it was commented that the DWG should have invested more time in investigating, evaluating and specifying hanging protocols (presentation of images on screen). In the event, BSWN was “lucky” and has ended up with a set of protocols that work effectively and efficiently. Hanging protocols have subsequently been specified in the NSU’s *Interim Digital Mammography Standards for Full Field Digital Mammography and CR Systems* (NSU, 2007c).

RADIOLOGY INFORMATION SYSTEM

The role of the Radiology Information System (RIS) is to store appointment and demographic information for BSWN. It drives the screening pathway (including the double blind reading work flow) and acquires all clinical data associated with the screening programme. The PACS takes bookings and other information from the RIS to form worklists (see below). The RIS and PACS exchange information using a Health Level 7 (HL7) interface, a standard accredited by the American National Standards Institute (ANSI) for the transfer of data between different systems in health care.³³

WDHB decided to use the Soprano Breast Screening (SBS) system as a RIS. SBS was an existing information system which had been in use for FSM for six years within BreastScreen Midland and is gradually being adopted by other Lead Providers, finally giving national coverage by 2008.

Modifications were required to SBS to interface it with the PACS and to make it function as a RIS. BSWN was clear that it wanted to go fully digital. The international site visits had demonstrated that efficiency gains and maximal quality and safety cannot be achieved through a “halfway solution”. BSWN received funding from the NSU for this purpose. The enhancements concerned the creation of DICOM worklists and providing the required worklist functionality to support the radiography, radiology and film scanning work flows.

Specifying and developing the required functionality required considerable input from clinical and IT staff at BSWN to ensure the flow logic and ‘rules’ supported the intended screening processes. Although recognised as crucial to system development, this process was described as “tedious meetings to explain banal processes”.

³³ <http://212.67.202.191/~pacnet/pacsnet/glossary/F.html>

These SBS enhancements undertaken by BSWN with NSU funding mean that the SBS functionality is now available to other Lead Providers.

DICOM MODALITY WORKLIST

The PACS uses worklists to manage work flows at modalities and workstations. Each worklist contains details of the women assigned to the appropriate modality/workstation for image acquisition, QA and reading.

The worklists for DM using the Digital Imaging and Communications in Medicine (DICOM) standard protocol, which is common to all manufacturers of medical imaging equipment. The standard provides "a method of linking a series of heterogeneous modalities, workstations and printers without the need for customised hardware to allow them to communicate and transfer images".

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The DICOM worklist transfers demographic information to the appropriate workstation (including National Health Index (NHI) and Study ID), which enhances clinical safety (ensuring the correct matching of women to electronic records) and time efficiencies (obviating manual entry of these details and facilitating the automatic retrieval of prior images).

The DICOM work flow requires that a radiology image be attributed to a patient on a worklist. The images are then stored against the patient in the PACS server. This is achieved through the HL7 interface. When a woman arrives for screening, SBS generates a HL7 message which registers the woman on the worklist. After the images have been taken, SBS maintains a list of the digital images that have been acquired, and this information is used in producing the reading worklists. After the radiologist has reviewed the digital images, they are removed from the cache and moved to long term storage (Orion Systems, 2005).

Because reading is performed by two independent radiologists, SBS generates a worklist for one radiologist, stores the reading result, and generates a worklist for another radiologist to perform the second reading. When the reading list is being created, SBS also generates a 'hanging list' of images to be located. The imaging clerk then prints the lists of films and retrieves them from film storage. The hanging list has sufficient information to enable tracking of films through the process (Ibid). At assessment clinics, the worklist includes 'slots' for the clinical workup and ultrasound data as well as digital images.

DIGITISER

BSWN ascertained from observation of overseas screening sites that digitisation of priors was the preferred method in terms of efficiency, ergonomics and quality. As part of this process, BSWN wanted to minimise data entry. Worklist functions were developed to achieve this. Changes to SBS enabled the creation of a backdated episode, to which digitised priors (and associated data, entered manually) could be attributed.

BSWN has recently acquired a second digitiser. This has enhanced efficiency as the imaging clerk can alternate between digitisers, reducing down-time associated with waiting for a scan to complete.

MODALITIES AND WORKSTATIONS

The mammography machines, ultrasound machines and workstations can be installed last. For the Takapuna site, BSWN purchased a Sectra FFDM and Siemens FFDM with Opdim Stereotactic system. The Sectra machine functions as the "workhorse" due to its more rapid image capture,

³⁴ <http://212.67.202.191/~pacsnet/pacsnet/glossary/F.html>

while the Siemens provides additional screening capacity as well as being used in assessment clinics due to the stereotactic biopsy capability. To ensure consistency in modalities linking to the PACS, NDHB purchased the same equipment as WDHB selected for its Takapuna site.

IMAGE SERVERS

The Whangarei site is connected to the PACS at North Shore Hospital via a dedicated Telecom 10 megabit per second (Mb/s) connection. This connection is too slow to allow reading workstations to access large (high resolution) images directly from the PACS. Therefore, the IT architecture included a local image server at Whangarei which would provide a cache of images on the worklist for more rapid access by workstations. Small (low resolution) images and examination data are accessed directly from the PACS as they are not impeded by the data transfer rate.

The Takapuna site is connected to the PACS via a 100 Mb/s connection. Initially it was anticipated that this would obviate the need for an image server at Takapuna. However, it transpired that due to a circuitous Telecom routing network between the two sites, data transfer between the PACS and Takapuna workstations was slow. A local image server was subsequently installed which eliminated this problem.

CONNECTIVITY BETWEEN WHANGAREI AND NORTH SHORE HOSPITAL

Initial problems were encountered in devising an architecture to manage the transfer of images between Whangarei and North Shore Hospital. The Sectra PACS has the requisite capabilities, but is dependent on Windows networking protocols. This raised security issues when it came to providing access to Whangarei which was outside the North Shore Hospital network. This was overcome by extending the North Shore Hospital network to the Whangarei site rather than linking the two networks together. Stakeholders noted that this solution may not be feasible for other Lead Providers to adopt.

IMAGE STORAGE

BSWN has access to two mechanisms for long-term reliable storage. First tier storage is provided via WDHB's Storage Area Network (SAN) housed at North Shore Hospital. The Medical Archiving Solution (MAS), owned by hA and replicated between North Shore and Middlemore Hospitals, provides second tier storage. These two storage mechanisms are able to meet the considerable data storage requirements required of DM in breast screening. Other Lead Providers would need to investigate their existing DM image storage options and any possible additional storage requirements.

UNINTERRUPTIBLE POWER SOURCE

One of the most significant challenges encountered by BSWN in adopting digital technology was the reliability and associated maintenance requirements of the mammography machines, as discussed elsewhere. Power outages in the Takapuna area were a factor that compounded these difficulties, and as a result, BSWN upgraded its UPS units for the DM machines. The UPS protects the equipment against power spikes and provides sufficient ongoing power to enable the mammography machines to be shut down properly in case of a power failure.

SEAMLESS INTERFACE BETWEEN COMPONENTS

The key issue in implementing the ICT infrastructure for DM was the success with which its various components could interface. At that point in time, the NSU had not produced specifications to ensure the compatibility of DM systems across Lead Providers, and both BSWN and the NSU were cognisant of the need to ensure maximum opportunities for future consistency and connectivity between providers.

The NSU took a keen interest in working closely with BSWN to ensure that any digital development work undertaken by BSWN provided the maximum opportunity for future developments in the other regional programmes.

Accordingly, the over-riding requirement for BSWN was to establish a non-proprietary system at all levels and interfaces including the modalities, PACS, RIS and storage servers. To that end, BSWN held suppliers of these components contractually responsible for: individually ensuring connectivity and functionality for goods and services supplied by them; and collectively ensuring connectivity and functionality of the system as a whole.

FUTURE ENHANCEMENTS

A BSWN stakeholder noted that none of the overseas screening sites that the DWG members visited in Europe, and no other sites that they were aware of (aside from perhaps Sweden) has ever managed to achieve full connectivity between RIS, PACS and DM machines from the outset; anecdotally, many are still struggling after a year or more to achieve what the IT Project Manager at BSWN was able to achieve in a matter of months. This is a significant area of success for BSWN and marks BSWN as a site that other providers (in New Zealand or overseas) preparing to convert to DM should seek to learn from.

BSWN is continuously looking at ways to improve effectiveness such as software upgrades and work flow improvements. Two areas where enhancements are likely in the near future are:

- Improving the integration of the RIS with the acquisition workstation. This would enable direct data entry by the MRT in the x-ray room and eliminate the use of the green form. Consequently, the average time per exam may be shortened significantly.
- Upgrading software (as it becomes available) to enable high quality pathology images to be included in the PACS. Currently pathology images are excluded from the digital work flow, but there is provision in the HL7 interface to include these in future. A related issue is the need for a reliable method for cross-referencing multiple lesions between radiology and pathology images.



APPENDIX D: RFP SUBMISSION FORMS

TAKAPUNA RFP FORMS

ATTACHMENT ONE

RFP SUBMISSION FORM

OVERVIEW

You must complete one copy of this section

To: healthAlliance

A - General Respondent Information

1. RFP FOR:	Supply of Mammography Equipment to Breast Screen Waitemata Northland	
2. RFP BY (Please insert legal entity):		
3. RESPONDENT'S CONTACT PERSON:	Name:	Phone:
	Title:	Fax:
	Address:	
4. RESPONDENT'S GST REGISTRATION NUMBER:		
5. PROFILE OF RESPONDENT:		
(a) SIZE: (Number of Personnel and type (Service, Sales, etc):		
(b) RELATIONSHIP TO MANUFACTURER (e.g Agent, Distributor):		
(c) NAME AND ADDRESS OF PARENT COMPANY:		
(d) LOCATIONS WHERE ORGANISATION IS REPRESENTED:		

B - RFP Response Summary

1. Respondent Acknowledges they have read and understood:	Read and Understood (please tick)
(a) Section One - HEALTHALLIANCE	
(b) Section Two - INSTRUCTIONS TO RESPONDENTS	
(c) Section Three - PROPOSAL EVALUATION	
(d) Section Four - PROPOSAL REQUIREMENTS	
(e) Section Five - COMMERCIAL REQUIREMENTS	

C - RFP Equipment Respondent is Proposing for:

Yes (Please tick)

Mammography Machine - Full Field Digital with/without stereotactic device	
Mammography Machine - CR with/without stereotactic device	
PACS	
Laser Printer for Mammography	
Mammography Digital Viewing Workstation	
Mammoviewers	
Vacuum Assisted Breast Biopsy Device	
Mammography Film View Accessories - screening & assessment	

The Respondent Proposals to healthAlliance to supply Equipment and Services on the basis of this RFP and in accordance with the terms and conditions of the RFP
SIGNED for and on behalf of the Tenderer

Name: _____
Position: _____
Date: _____

**ATTACHMENT TWO :
RFP SUBMISSION FORM -
Equipment**

You must complete one copy of this section for EACH type of equipment for which you are proposing

Equipment & Service Information	
Equipment Name	
Equipment Make	
Equipment Model	
Country of Manufacture	
What country will support services by provided from	
Experience	
Certification	
Medsafe Wand Registration	<i>Please attach evidence of registration</i>
CE / FDA / TGA Certification	<i>Please attach evidence of certification</i>
Other certificaion	<i>Please attach evidence of certification</i>
Reference Sites	
Is it possible to conduct site visits to a high volume unit using your equipment In September 2005	<i>For Mamography Machine responses only</i>
Please detail how this could be achieved	<i>For Mamography Machine responses only</i>

Contract Compliance	<i>Please confirm compliance or otherwise with the contract in Attachment 8</i>
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RFP Price (excluding GST)	<i>You must complete and append Attachment 3 for each type of Equipment you are proposing for</i>
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Term	Commencing: Expiring:
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Alternative Proposals	<i>Please attach and clearly title the details of any alternative proposals that you may wish to submit at the back of your response</i>
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Attachment Three Pricing Schedule

NB - You should complete one copy of this section for EACH type of Equipment for which you wish to submit a Proposal

1. Pricing Schedule :

DRAFT

1.1 Cost of Equipment

Part Number	Description	Cost NZ\$ (ea)

1.2 Cost of Options for the Equipment

Part Number	Description	Cost NZ\$ (ea)

1.3 Cost of Consumables for the Equipment

Part Number	Description	Qty per annum	Cost NZ\$ (ea)

1.4 Cost of Replacement Parts for the Equipment

Any part which is known to need replacement at any time during the reasonable working life or any part known to be prone to damage that a supplier has had to replace.			
Part Number	Description	Brief description of failure	Replacement frequency

1.5 Maintenance and servicing of the Equipment

Type of Maintenance or Servicing	Performed by supplier	Cost NZ\$
	WDHB / NDHB	
	Biomed	
	Staff	
	N/A	

1.6 Cost of Training and Maintenance Manuals for the Equipment

Type	Initial/Ongoing	Cost NZ\$
N/A		

Attachment Three Pricing Schedule

1.7 Any additional costs associated with the Equipment that BSWN should be aware of? For example, Delivery, Installation, and Assembly, etc.

What are the additional costs?	Cost NZ\$

1.8 Total cost of the Equipment

Year 1 NZ\$	Year 2 NZ\$	Year 3 NZ\$	Year 4 NZ\$	Year 5 NZ\$

**ATTACHMENT 4
R IMOGRAPHY DIGITAL VIEWING WORKSTAT**

MODEL NAME	Required Functionality	Scoring (tick one)				Vendor Comment / Explanation
		Complies	Partially Complies	Does not Comply	Not Applicable	
No.						
E1.00 Ability to Display						
E1.01 18 x 24 film size						
E1.02 24 x 30 film size						
E2.00 Illumination						
E2.01 Independent illumination control						
E2.02 Homogeneous illumination over whole viewing area						
E2.03 Adjustable light intensity – eg 10 increments						
E3.00 Autoselect						
E3.01 Ability to quick access any film						
E4.00 Two Belt Speeds						
E4.01 Low noise level at high speed						
E4.02 'Previous' and 'next' keys – one frame advance/reverse						
E5.00 Fold Down Desk						
E5.01 Optional fold down desk for dictation system/paperwork etc						
E6.00 Ability to Upgrade						
E6.01 Product to be supported by the vendor company for at least the next 5 – 7 years						
E7.00 Warranty and Servicing Requirements						
E7.01 The unit <i>shall</i> be covered by a warranty period of at least twenty-four (24) months from the date of system installation.						

**ATTACHMENT 4
MAMMOVIEWER**

MODEL NAME	Required Functionality	Scoring (tick one)				Vendor Comment / Explanation
		Complies	Partially Complies %	Does not Comply	Not Applicable	
No.						
F1.00 Ability to Display						
F1.00	18 x 24 film size					
F1.02	24 x 30 film size					
F1.03	Two or three bays – upper, middle and lower allowing: a). 8 on 8 (18x24cm) films (4 years) or b). 6 on 6 (24 x 30cm) films (3 years)					
F2.00 Capacity						
F2.01	1000 (plus) 18 x 24cm films					
F2.02	50 – 100 frames					
F2.03	50:50 frames for each film size					
F3.00 Autoselect						
F3.01	Ability to quick access any film					
F4.00 Shutters						
F4.01	Vertical manual shutters					
F4.02	Electronic horizontal shutters to close in to 18 x 24cm films					
F5.00 Illumination						
F5.01	Independent illumination control for all bays					
F5.02	Homogeneous illumination over whole viewing area					
F5.03	Adjustable light intensity – eg 10 increments					
F6.00 Two Belt Speeds						
F6.01	Low noise level at high speed					
F6.02	'Previous' and 'next' keys – one frame advance/reverse					
F7.00 Fold Down Desk						

**ATTACHMENT 4
MAMMOVIEWER**

F7.01	Optional fold down desk for dictation system/paperwork etc								
F8.00	Ability to Upgrade								
F8.01	Product to be supported by the vendor company for at least the next 5 – 7 years								
F9.00	Warranty and Servicing Requirements								
F9.01	The unit <i>shall</i> be covered by a warranty period of at least twenty-four (24) months from the date of system installation.								

**ATTACHMENT 4
VACUUM ASSISTED BREAST BIOPSY DEVICE**

MODEL NAME	Required Functionality	Scoring (tick one)				Vendor Comment / Explanation
		Complies	Partially Complies %	Does not Comply	Not Applicable	
G1.00 General						
G1.01	An 11 gauge biopsy device to perform vacuum assisted breast biopsies					
G1.02	Compatible for digital stereotactic guided biopsies					
G2.00 Warranty and Servicing Requirements						
G2.01	The unit <i>shall</i> be covered by a warranty period of at least twenty-four (24) months from the date of system installation.					

There are eight worksheets along the bottom, each labelled with the equipment type name:

Please do not change the format of the worksheets

Each request has a reference (e.g D1.01) please put the corresponding reference in front of your response on the line below

Provide your details in the section below each request in a different font type or colour (e.g red or blue)

If you are attaching additional information relevant to the section please put in a reference name/number so that it is easy to locate in your proposal folder

ATTACHMENT 5 FULL FIELD DIGITAL MAMMOGRAPHY MACHINE

A1.00 The Tube	
A1.01	List the focal spot size(s) offered, and maximal mA output for each focal spot.
A1.02	Detail the heat capacity and cooling requirements of the tube.
A1.03	Detail the technological advantages of the tendered system.
A1.04	Give exact tube and filter specifications.
A1.05	State the beam collimation/field size.
A1.06	Describe the diaphragms.
A1.07	List the automatic and manual exposure options.
A1.08	An electronic copy of the image shall be provided in DICOM format with the tender response.
A1.09	An important consideration in moving from a film/screen system to a digital system is the potential for patient dose reduction due to the higher quantum detection efficiency of most types of detector used for digital mammography, and in some systems, a significant reduction in scattered radiation. Where the vendor has more than one mode which affects patient dose, provide details of all modes with the corresponding images.
A1.10	State the number and spatial location of faulty pixels in the detector which are within the manufacturer's tolerance for acceptability.
A1.11	Define the term "faulty pixel" and the measurement conditions used to categorise such pixels, preferably using a method which can be reproduced at a clinical site.
A1.12	State the manufacturer's policy regarding detector replacement where additional pixels become faulty following installation and normal clinical use.

A2.00 The Generator	
A2.01	State the mAs capability of the generator.
A2.02	State kV range available.
A2.03	State the exposure technique factors (kVp, mAs, anode material, beam filter material, and HVL)
A2.04	State exposure time range.
A2.05	State the measured entrance surface dose in mGy
A2.06	State the calculated MGD to an ACR mammography phantom for an AEC controlled exposure in a system
A2.07	Please specify ventilation and air conditioning requirements and acceptable temperature range.

A3.00 Compression	
A3.01	State the compression force available with motorised and manual compression respectively.
A3.02	State the minimum duration of compression.
A3.03	List the available compression paddles.

ATTACHMENT 5 FULL FIELD DIGITAL MAMMOGRAPHY MACHINE

A4.00	Ease of Use and Ergonomics
A4.01	State the mechanism of gantry rotation (manual/motorised/automatic).
A4.02	State the vertical travel range of the gantry.
A4.03	State the maximum distance from compression plate to bucky.
A4.04	State the minimum system rotation axis to floor distance.
A4.05	State the Source to Image Distance.
A4.06	Detail overall space requirements and room dimensions for the entire system.

A5.00	Image Receptors
A5.01	Detail the image detector technology used.
A5.02	State the size of available image detector(s):
	* Largest receptor area, finest matrix;
	* Largest receptor area, optimal matrix (manufacturer's choice);
	* Regular receptor area (24x18cm or equivalent), finest matrix;
	* Regular receptor area, optimal matrix.
A5.03	State the limiting spatial resolution of the detector (Nyquist frequency).
A5.04	State the pixel pitch and fill factor of the detector (pixel size).
A5.05	State the DQE of the system with grid (attach DQE charts):
	* DQE versus lp per mm (at specified exposure and dose);
	* DQE versus dose diagram.
A5.06	State the modulation transfer function of the system with grid (attach charts).
	* FWHM (in lp per mm);
	* MTF versus lp per mm (specify exposure and dose).
A5.07	Detail the grid technology employed.
A5.08	List the magnification factors available.
A5.09	State the minimum amount of missed tissue at the chest wall.
A5.10	Detail the maximum acceptable number of defective pixels on the detector.
A5.11	Detail any ghosting or lag effects.
A5.12	Detail the minimum interval between consecutive exposures.
A5.13	Detail the cooling requirements of the detector.
A5.14	Dynamic range of detector as graph of OD versus exposure

ATTACHMENT 5 FULL FIELD DIGITAL MAMMOGRAPHY MACHINE

A5.15	Digital image depth (bits per pixel).
A5.16	ACR phantom score (specify a clinically relevant exposure and dose).
A5.17	Detail mean glandular doses:
	* Phantom glandular dose;
	* Screening patient population dose per view;
	* Dose at compression/magnification per view.
A5.18	Detail mean exposure durations:
	* Screening patient population - per screening view;
	* Per compression magnification view.
A5.19	The vendor shall state typical and maximum times from the completion of the x-ray exposure to:
	* Display of a preview image to confirm patient positioning etc
	* Display of the final fully processed image at the control workstation

A6.00	Acquisition Workstations							
A6.01	Detail image processing functionality of workstation.							
A6.02	Detail image storage capacity of acquisition workstation.							
A6.03	Detail the interval between exposure and display of fully processed image.							
A6.04	Detail the network requirements of the workstation							
A6.05	Detail remote fault diagnostics and software upgrade/patch capability.							
A6.06	Detail the acquisition workstation system requirements (CPU, memory, storage, operating system).							
A6.07	Detail separately the cost of non-proprietary workstation components.							
A6.08	Monitor: type, size, resolution, brightness and dynamic range.							
A6.09	Input and output devices (e.g. CD ROM burner) and time to burn images.							
A6.10	Operating system platform, warranty, update pathway.							
A6.11	Average time to perform daily functions: powerup sequence, daily QA sequence, image transfer times from end of exposure to on-monitor (per view), image transfer time to Reader's workstation (per view).							
A6.12	Features to arrange, modify, rotate, flip, window and centre images.							
A6.13	Features to label, annotate, measure images.							
A6.14	Ability to print images to DICOM printer and CD directly from the acquisition workstation							
A6.15	Details all options for hanging protocol on acquisition workstation							
A6.16	Number of mammograms that can be stored indefinitely in the acquisition workstation in event that the PACS connection fails							

ATTACHMENT 5 FULL FIELD DIGITAL MAMMOGRAPHY MACHINE

A6.17	Identify how this modality would operate in a mobile unit environment ie ability to obtain work lists and store images for once a day transfer with main site

A7.00	Standards
A7.01	Specify planned upgrade pathways for the unit.
A7.02	Specify modules under development for the unit that are planned for release.
A7.03	The vendor shall provide a list of HL7 messages that their system complies with.
A7.04	Vendors shall provide copies of their HL7 compliance statements.
A7.05	Vendors shall provide details of any other interface standards or data exchange mechanisms that their system is capable of.

A8.00	Warranty and Servicing
A8.01	State any additional warranty period on the image receptor.
A8.02	Detail the Maintenance Service Agreement options offered with this system.
A8.03	The quotation should include any alternative service contract options; for example up to 36 months following warranty period
A8.04	The current prices for a replacement detector and a x-ray tube shall be stated.
A8.05	The make and model of the detector and the x-ray tube shall be stated, together with the warranted and typically achieved lifetimes.
A8.06	Response times for all aspects of warranty/service agreement calls and repairs including initial response time (phone and site visit if required) and timeframes for full repair if replacement parts are required
A8.07	Details of the company's service/support team on the ground in New Zealand, including location and expertise in the equipment concerned

A9.00	Options
A9.01	Provide technical details and prices for any available optional enhancements to the FFDM system. This may include dual-energy subtraction imaging
A9.02	Detail all options available with this system, the availability and cost of accessories/attachments for the system:
	* Stereotactic biopsy attachment;
	* Hook needle localisation;
	* Tomosynthesis attachment/software.
A9.03	Laser printers will be required with adequate resolution to ensure the printed image reflects that displayed on the workstation. Identify those laser printers that are compatible with proposed system to ensure compliance with required image quality.

A10.00	Certification
A10.01	The date FDA approval obtained

ATTACHMENT 5 FULL FIELD DIGITAL MAMMOGRAPHY MACHINE

A10.02	If unit not yet FDA approved vendor shall provide details of when FDA approval is expected and status of current FDA trials

A11.00 Integration / Compatibility	
A11.01	Identify any required network connection to integrate with PACS or RIS.
A11.02	Identify any PACS that this modality(ies) cannot interface with
A11.03	Identify any potential difficulties, issues or risks with ensuring the required integration and proposed strategies for addressing these

A12.00 Technical Specifications	
A12.01	The vendor shall provide a full technical specification for the system.
A12.02	Where relevant, tolerances shall be stated

A13.00 Quality Assurance	
A13.01	The vendor shall state how often routine calibration must be performed in order to maintain the accuracy of all performance parameters within specification.
A13.02	Full explanatory documentation shall be included.

A14.00 Installation	
A14.01	Provide full details of any installation costs and timeframes

ATTACHMENT 5

COMPUTED RADIOGRAPHY (CR) SYSTEM FOR MAMMOGRAPHY

B1.00 The Tube	
B1.01	List the focal spot size(s) offered, and maximal mA output for each focal spot.
B1.02	Detail the heat capacity and cooling requirements of the tube.
B1.03	Detail the technological advantages of the system.
B1.04	Give exact tube and filter specifications.
B1.05	State the beam collimation/field size.
B1.06	Describe the diaphragms.
B1.07	List the automatic and manual exposure options.
B1.08	An electronic copy of the image shall be provided in DICOM format with the tender response.
B1.09	An important consideration in moving from a film/screen system to a digital system is the potential for patient dose reduction due to the higher quantum detection efficiency of most types of detector used for digital mammography, and in some systems, a significant reduction in scattered radiation. Where the vendor has more than one mode which affects patient dose, provide details of all modes with the corresponding images.
B1.10	State the number and spatial location of faulty pixels in the detector which are within the manufacturer's tolerance for acceptability.
B1.11	Define the term "faulty pixel" and the measurement conditions used to categorise such pixels, preferably using a method which can be reproduced at a clinical site.
B1.12	State the manufacturer's policy regarding detector replacement where additional pixels become faulty following installation and normal clinical use.

B2.00 The Generator	
B2.01	State the mAs capability of the generator.
B2.02	State kV range available.
B2.03	State the exposure technique factors (kVp, mAs, anode material, beam filter material, and HVL)
B2.04	State exposure time range.
B2.05	State the measured entrance surface dose in mGy
B2.06	State the calculated MGD to an ACR mammography phantom for an AEC controlled exposure in a system calibrated to the manufacturer's specification.
B2.07	Please specify ventilation and air conditioning requirements and acceptable temperature range.

B3.00 Compression	
B3.01	State the compression force available with motorised and manual compression respectively.
B3.02	State the minimum duration of compression.
B3.03	List the available compression paddles.

ATTACHMENT 5

COMPUTED RADIOGRAPHY (CR) SYSTEM FOR MAMMOGRAPHY

B4.00 Ease of Use and Ergonomics	
B4.01	State the mechanism of gantry rotation (manual/motorised/automatic).
B4.02	State the vertical travel range of the gantry.
B4.03	State the maximum distance from compression plate to bucky.
B4.04	State the minimum system rotation axis to floor distance.
B4.05	State the Source to Image Distance.
B4.06	Detail overall space requirements and room dimensions for the entire system.

B5.00 Image Receptors	
B5.01	Detail the image detector technology used.
B5.02	State the size of available image detector(s):
	* Largest receptor area, finest matrix;
	* Largest receptor area, optimal matrix (manufacturer's choice);
	* Regular receptor area (24x18cm or equivalent), finest matrix;
	* Regular receptor area, optimal matrix.
B5.03	State the limiting spatial resolution of the detector (Nyquist frequency).
B5.04	State the pixel pitch and fill factor of the detector (pixel size).
B5.05	State the DQE of the system with grid (attach DQE charts):
	* DQE versus lp per mm (at specified exposure and dose);
	* DQE versus dose diagram.
B5.06	State the modulation transfer function of the system with grid (attach charts).
	* FWHM (in lp per mm);
	* MTF versus lp per mm (specify exposure and dose).
B5.07	Detail the grid technology employed.
B5.08	List the magnification factors available.
B5.09	State the minimum amount of missed tissue at the chest wall.
B5.10	Detail the maximum acceptable number of defective pixels on the detector.
B5.11	Detail any ghosting or lag effects.
B5.12	Detail the minimum interval between consecutive exposures.
B5.13	Detail the cooling requirements of the detector.

ATTACHMENT 5
COMPUTED RADIOGRAPHY (CR) SYSTEM FOR MAMMOGRAPHY

B5.14	Dynamic range of detector as graph of OD versus exposure
B5.15	Digital image depth (bits per pixel).
B5.16	ACR phantom score (specify a clinically relevant exposure and dose).
B5.17	Detail mean glandular doses:
	* Phantom glandular dose;
	* Screening patient population dose per view;
	* Dose at compression/magnification per view.
B5.18	Detail mean exposure durations:
	* Screening patient population - per screening view;
	* Per compression magnification view.

B6.00	Cassette Reader
B6.01	Examples of pre-processing capabilities and processes
B6.02	Details of whether the reader is single or multi-plate
B6.03	Time taken to process a standard set of four mammograms
B6.04	Details of image plate and resolution modes
B6.05	Detail image processing functionality of reader

B7.00	QA Review Workstation
B7.01	Detail image storage capacity of review
B7.02	Detail the interval between exposure, reader and review of the processed image.
B7.03	Average time to perform review functions
B7.04	Detail the network requirements of the review workstation
B7.05	Detail remote fault diagnostics and software upgrade/patch capability.
B7.06	Detail the review workstation system requirements (CPU, memory, storage, operating system).
B7.07	Detail separately the cost of non-proprietary review workstation components.
B7.08	Monitor: type, size, resolution, brightness and dynamic range.
B7.09	Operating system platform, warranty, update pathway.
B7.10	Features to arrange, modify, rotate, flip, window and centre images.
B7.11	Features to label, annotate, measure images.
B7.12	Ability to print images to DICOM printer and CD directly from the review workstation

ATTACHMENT 5

COMPUTED RADIOGRAPHY (CR) SYSTEM FOR MAMMOGRAPHY

B7.13	Details all options for hanging protocol on review workstation
B7.14	Number of mammograms that can be stored indefinitely in the review workstation in event that the PACS connection fails
B7.15	Is the data displayed in a compressed format? If so please specify.

B8.00	Standards
B8.01	Specify planned upgrade pathways for the unit
B8.02	Specify modules under development for the unit that are planned for release
B8.03	The respondent shall provide a list of HL7 messages that their system complies with
B8.04	The respondent shall provide copies of their HL7 compliance statements
B8.05	The respondents shall provide details of any other interface standards or data exchange mechanisms that their system is capable of

B9.00	Warranty and Servicing
B9.01	State any additional warranty period on the image receptor.
B9.02	Detail the Maintenance Service Agreement options offered with this system.
B9.03	The proposal <i>should</i> include any alternative service contract options; for example up to 36 months following warranty period
B9.04	The current prices for a replacement detector and a x-ray tube <i>shall</i> be stated.
B9.05	The make and model of the detector and the x-ray tube <i>shall</i> be stated, together with the warranted and typically achieved lifetimes.
B9.06	Response times for all aspects of warranty/service agreement calls and repairs including initial response time (phone and site visit if required) and timeframes for full repair if replacement parts are required
B9.07	Details of the company's service/support team on the ground in New Zealand, including location and expertise in the equipment concerned

B10.00	System Configuration
B10.01	Describe the basic system hardware configuration
B10.02	Detail the total system power requirements
B10.03	Detail the total system footprint
	Detail the operating system parameters (temperature, humidity) of the system
B11.00	Options
B1101	Provide technical details and prices for any available optional enhancements to the CR system.

**ATTACHMENT 5
COMPUTED RADIOGRAPHY (CR) SYSTEM FOR MAMMOGRAPHY**

B11.02	Detail all options available with this system, the availability and cost of accessories/attachments for the system:
	* Stereotactic biopsy attachment;
	* Hook needle localisation;
	* Tomosynthesis attachment/software.
B11.03	Laser printers will be required with adequate resolution to ensure the printed image reflects that displayed on the workstation. Identify those laser printers that are compatible with proposed system to ensure compliance with required image quality.

B10.00	Certification
B10.01	The date FDA approval obtained
B10.02	If unit not yet FDA approved vendor <i>shall</i> provide details of when FDA approval is expected and status of current FDA trials

B11.00	Integration / Compatibility
B11.01	Identify any required network connection to integrate with PACS or RIS.
B11.03	Identify any potential difficulties, issues or risks with ensuring the required integration and proposed strategies

B12.00	Technical Specifications
B12.01	The vendor <i>shall</i> provide a full technical specification for the system.
B12.02	Where relevant, tolerances <i>shall</i> be stated

B13.00	Quality Assurance
B13.01	The vendor <i>shall</i> state how often routine calibration must be performed in order to maintain the accuracy of all performance parameters within specification.
B13.02	Full explanatory documentation <i>shall</i> be included.

B14.00	Installation
B14.01	Provide full details of any installation costs and timeframes

ATTACHMENT 5 PICTURE ARCHIVING AND COMMUNICATIONS SYSTEM (PACS)

C1.00	Radiologists and Readers Workstations
C1.01	Manufacturer, model, type, size and weight, power requirements
C1.02	Temperature range tolerated, ventilation clearance required on all sides
C1.03	Screen details: flat or curved (curvature radius), CRT or TFT, useful size
C1.04	Number of display pixels and matrix size (vertical or horizontal), pixel size
C1.05	Optical luminescence range (per pixel) in lux (or equivalent), its linearity
C1.06	Minimal guaranteed light intensity output (per unit surface), guarantee life
C1.07	Radiation emitted per screen per second towards reader: type and range
C1.08	Guaranteed minimal useful life at working light intensity
C1.09	Guaranteed minimal useful life at any level of light intensity
C1.10	Local availability of 'cold-spares' and guaranteed replacement time
C1.11	Display controller: operating system, memory, bus, clock speed, bus width
C1.12	Display quality assurance tools
C1.02	Number of images that can be stored locally on the PACS
C1.03	Detail actual local storage capacity and type
C1.04	Provide details of:
	Operating system
	Memory
	Power supply (detail UPS and RF filters if provided)
	Network interface (network speed, optical/copper)
C2.00	Server Hardware
C2.01	The respondent shall specify but not supply, additional server and/or archive equipment which will be required for satisfactory operation of the PACS

C3.00	System Licences
C3.01	Specify all license requirements to operate the system and all required interfaces
C3.02	Specifically, please detail all license options for different configurations, e.g. QA PACS workstation licenses or remote consultation licenses. Also please specify any additional licensing required to interface your system with other applications (eg any additional licensing for an HL7 messaging engine)

C4.00	Overall Software Functionality (including image acquisition)
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ATTACHMENT 5
PICTURE ARCHIVING AND COMMUNICATIONS SYSTEM (PACS)

C4.01	The vendor shall state the maximum time required to display a 4-view study in DICOM on the monitor screens, measured from the time that the study is selected in the patient list by mouse click
	*the PACS storage device
	*the radiologist's diagnostic workstation
C4.02	Management of DICOM work lists is required to support breast screening workflow including image acquisition, QA processes, identification of current and unreported studies and automation of independent double reading (and third reader where there is a discord between the 1 st and 2 nd readers' results). The DICOM work lists could be managed via the PACS or the RIS . Venders are asked to identify their recommended process for managing the double blind read (with third read for discordant results) process and the reader work-lists to ensure all studies are fully reported in a timely fashion, and that first and second reads of a study are performed by different individuals
C4.03	If the vendor is advocating that the mammography reading lists are to be managed via the PACS, confirmation is required that the system shall be able to support BreastScreen Aotearoa result coding and reporting for seamless interface of results back to SBS
C4.04	The extent to which the system intuitively sources prior examinations from archive for review
C4.05	How the system manages 'priors' including storage, ease of retrieval and hanging options for:
C4.06	Prior digital images
C4.07	Prior plain films that have been digitized
C4.08	Provide a diagram and full explanation of how the PACS would manage the DICOM work list and workflows from acquisition through to prompting reports (re films outstanding for reads), managing required 3 rd reads, and how read functionality between PACS and RIS/SBS will operate.
C5.00	Image Manipulation
C5.01	Detail times to perform most common operations (with study in local storage memory)
C5.02	The ability of the system to define a range or hanging protocols for current and prior images (according to radiologists hanging preferences)
C5.03	Details of the extent to which the system can facilitate consistency in the appearance and format and format of images coming from different modalities including options for viewing full size images
C5.04	The ability of the system to define custom user viewing environments (window level, hanging protocols etc)
C5.05	Extent and mechanism for magnification of views
C6.00	Display of image data and annotations
C6.01	Provide details of how the PACS system ensures true blind second reading whilst enabling any required third reader to examine any annotations/comments from the first and second readers

ATTACHMENT 5

PICTURE ARCHIVING AND COMMUNICATIONS SYSTEM (PACS)

C7.00	Output
C1.01	Laser printers will be required with adequate resolution to ensure the printed image reflects that displayed on the workstation. Identify those laser printers that are compatible with proposed system to ensure compliance with required image quality.
C8.00	Readers Interface to software
C8.01	Provide a diagram of the tool layout and individual key functions
C9.00	Integration and Modality Support
C9.01	Details of any cost variance associated with integration of potential modalities and RISs
C9.02	List of current supported DR and CR modalities
C9.03	Details of support for digital ultrasound
C9.04	Details of support for digital spot/stereotaxy
C9.05	Detail any current web interface availability
C9.06	Detail CAD options currently available for this system, proprietary or third party
C9.07	Identify any modalities this PACS cannot interface with
C9.08	Identify any potential difficulties, issues or risks with ensuring the required integration between the PACS, a range of modalities and the SBS and proposed strategies for these

C10.00	HL7 Network Connection
C10.01	The minimum recommended network connection (eg 100 Mb/s UTP, 1000 Mb/s optical fibre) <i>shall</i>
C10.02	Identify any required network connections to ensure integration between:
	mammography modalities
	the PACS
	the RIS/SBS
	reading workstations
	remote sites
	mobile sites
	1 st and 2 nd tier storage arrangements
C11.00	Backup
C11.01	Detail the backup archive media
C11.02	Time required for daily, weekly and monthly backup of the online archive based on stated annual volumes

ATTACHMENT 5

PICTURE ARCHIVING AND COMMUNICATIONS SYSTEM (PACS)

C11.03	Time to perform backup for a database that is 1/3 full, 2/3 full, 3/3 full
C11.04	Detail security and privacy protection mechanisms for archive units
C11.05	Detail the average and maximal time taken for daily maintenance functions

C12.00	Scalability
C12.01	Detail maximum study volume scalability
C12.02	The NSU are interested in the potential for one national PACS to support the national BreastScreen Aotearoa programme. Detail opportunities, limitations and issues relating to scalability of wider than the BSWN programme including the extent to which the PACS system is modular ie enables various modalities to be added on

C13.00	Quality Assurance
C13.01	Full details of all QA activities which the system supports
C13.02	Number of modalities that can be viewed on any one QA workstation
C13.03	Details of how CR QA activity is undertaken ie on the PACS QA workstation or the modality QA workstation

C14.00	Security and Privacy Protection Mechanisms
C14.01	Detail security and privacy protection mechanisms of the readers software

C15.00	Standards
C15.01	Attach DICOM conformance statement
C15.02	The Respondent shall provide a list of HL7 messages that their system complies with.
C15.03	Respondent shall provide copies of their HL7 compliance statements.
C15.04	Respondent shall provide details of any other interface standards or data exchange mechanisms that their system is capable of.

C16.00	Warranty, Reliability, Support & Maintenance
C16.01	State guaranteed uptime for reader's software
C16.02	Detail the planned upgrade cycle and product support pathway for the readers software
C16.03	Detail the planned upgrade cycle and product support pathway for the PACS application server software
C16.04	Details of the company's service/support team on the ground in New Zealand, including location and expertise in the equipment concerned
C16.05	Field support, guaranteed maximal response time for:
	Telephone/electronic response
	On-site response

ATTACHMENT 5
PICTURE ARCHIVING AND COMMUNICATIONS SYSTEM (PACS)

C17.00	Installation
C17.01	Provide full details of any supply timeframes and installation costs and timeframes
C17.02	Detail any potential issues, difficulties, and risks with installation, interfacing etc to ensure the system is fully functional by the required date and proposed strategies to address these
C18.00	Certification
C18.01	Has the PACS system been certified by the FDA for use with multiple vendor modalities in screening mammography?
C18.02	If the system has not yet FDA approved vendor <i>shall</i> provide details of when FDA approval is expected and status of current FDA trials

ATTACHMENT 5 LASER PRINTER FOR MAMMOGRAPHY

D1.00	Compatibility
D1.01	Identify those mammography systems the printer is known to be compatible with

D2.00	Specifications
D2.01	Image film sizes that can be printed
D2.02	Number of sorter bins/exit trays
D2.03	Number of film supply trays
D2.04	Pixel size (um)
D2.05	Imaging area for 20 x 25cm film
D2.06	Throughput - number of 20 x 25 films per hour
D2.07	Type of film/film base colour
D2.08	Film storage requirements (pre and post processing)
D2.09	Print Memory
D2.10	Density Correction
D2.11	Any additional accessories

D3.00	Warranty and Servicing
D3.01	Detail the maintenance service agreement options offered with this system

ATTACHMENT 5 MAMMOGRAPHY DIGITAL VIEWING WORKSTATION

E1.00	Capacity
E1.01	Details of number of films of various sizes that can be held at any one time

E2.00	Illumination
E2.01	Specification of luminance

E3.00	Autoselect
E3.01	Details of touchpad controls and/or footswitch for film retrieval

E4.00	Shutters/Shades
E4.01	Specifications of horizontal and vertical shades/shutters
E4.02	Any other features to control lighting and shade

E5.00	Installation
E5.01	Details of installation costs and timeframes

E6.00	Delivery
E6.01	Delivery details and delivery lead time details

E7.00	Service / Warranty
E7.01	Details of service and warranty conditions and any associated costs
E7.02	Details of service contract options, e.g. 36 months post warranty period

**ATTACHMENT 5
MAMMOVIEWERS**

Mammoviewers

F1.00	Illumination
F1.01	Any available accessories, e.g. high intensity light option

F2.00	Installation
F2.01	Details of installation costs and timeframes

F3.00	Delivery
F3.01	Delivery details and delivery lead time details

F4.00	Service / Warranty
F4.01	Details of service and warranty conditions and any associated costs
F4.02	Details of service contract options, e.g. 36 months post warranty period

ATTACHMENT 5
VACUUM ASSISTED BREAST BIOPSY DEVICE
Vaccum Assisted Breast Biopsy Device

G1.00	Functional Requirements
G1.01	Details of how the device attaches to different modalities
G1.02	Identification of any differences in operational functionality with different modalities

G2.00	Consumables
G2.01	Full details of all consumables required for this device
G2.02	Unit of Measure & Cost details of each consumable item
G2.03	Delivery lead time for consumables

G3.00	Delivery / Service / Warranty
G3.01	Details of service and warranty conditions and any associated costs
G3.02	Details of service contract options, e.g. 36 months post warranty period
G3.03	Equipment delivery lead time details

ATTACHMENT 5 FILM VIEW ACCESSORIES

H1.00	Equipment to magnify views and subtle abnormalities
H1.01	Detail the features and benefits of each of your proposed items
H2.00	High Intensity Light
H2.01	Detail the features and benefits of each of product

H3.00	Consumables
H2.01	Full details of all consumables required
H2.02	Unit of Measure & Cost details of each consumable item
H2.03	Delivery lead time for consumables

H3.00	Delivery / Service / Warranty
H3.01	Details of service and warranty conditions and any associated costs
H3.02	Details of service contract options, e.g. 36 months post warranty period
H3.03	Equipment delivery lead time details

WAITAKERE RFP FORMS

Score Sheet for Non-Price Requirements

RFQ Number :

RFQ Name:

DHB Location:

Evaluation Team Names

Scoring Model for all criteria except for 4.2a and 4.2b(i) Mandatory Requirements	
5	Exceeds
3	Adequate
1	Inadequate
0	Failure or Not Available

Scoring Model for 4.2b(i) Mandatory Requirements	
1	Complies
0	Fails to Comply

No.	Required Functionality: RFQ 4.2a, 4.2b(i), 4.2b(ii), 4.2(c), 4.2(d), 4.2(e), 4.6	Comment	Score	Siemens
4.2a	General Requirements (max Score = 12, scoring is 1 = complies, 0 = fails to comply)			
(i)	Medical devices must be registered with Medsafe on the WAND database (Web Assisted Notification of Devices)			
(ii)	All clinical products must be submitted with a completed PEHNZ (Product Evaluators Healthcare New Zealand) form (Attachment 6)			
4.2b(i)	Mandatory Requirements (max Score = 12, scoring is 1 = complies, 0 = fails to comply)			
1.00	Detector plate size nominal 24 x 30 cm			
2.00	Established hookwire localisation capability			
3.00	Established specimen radiograph capability			
4.00	Compliance with the Australasian College of Physical Scientists and Engineers (ACPSEM) position paper, Interim recommendations for a Digital Mammography Quality Assurance Program.			
5.00	An operational, non-prototype product which must be fully DICOM compliant			
6.00	Must integrate fully into Sectra PACS			
7.00	Must accept DICOM worklist from Orion Soprano Breast Screen RIS (SBS)			
8.00	FFDM product in operation at sites in recognised national screening programs and fully integrated into PACS			
9.00	Must supply contact information for radiologist, physicist, physicist, MRT from such sites			
10.00	Must have mean glandular dosage level for American College of Radiology (ACR) accreditation phantom (RMI156) less than 1.2 mGy in the standard contact dose mode.			
11.00	Must provide details of the machine mode (target, filter and focal spot size) used for the reference dose			
12.00	Guaranteed minimum uptime commitment of 97%.			
4.2b(ii)	Machine Specifications			
A1.00	The Tube, AEC and Generator Requirements			
A1.01	The tube focal spot size <i>shall</i> be sufficiently small that it is not a limiting factor in system resolution or MTF.			
A1.02	The output power of the unit <i>shall</i> be such that it enables shorter exposure times, better image quality and significant dose reduction.			
A1.03	The tube and filtration combination <i>shall</i> be designed for optimal mammography image quality with the digital detector.			
A1.04	There <i>shall</i> be a light centering device.			
A1.05	Using the same digital detector the system <i>shall</i> provide a magnification mode without a grid.			
A1.06	The system <i>should</i> automatically adjust the collimators to the field size appropriate for the selected compression paddle and <i>shall</i> allow manual over-ride of these initial settings by the MRT if required			
A1.07	A detector pixel <i>shall</i> be no larger than 100 x 100 um and <i>should</i> be closer to 50 x 50 um			
A1.08	The detector signal <i>shall</i> be digitized to at least 12-bit accuracy and <i>should</i> be digitized to at least 14-bit accuracy			
A1.09	The system <i>shall</i> be equipped with a high-frequency x-ray generator.			
A1.10	The system <i>shall</i> offer both automatic and manual exposure modes.			
A2.00	Compression Requirements			
A2.01	The system <i>shall</i> have motorised compression that should be able to be controlled by a footswitch.			
A2.02	The system <i>should</i> have the capacity to set automatic compression release on completion of exposure.			
A2.03	Compression <i>shall</i> be able to be manually adjusted.			
A2.04	There <i>should</i> be a compression release on the console.			
A2.05	The breast thickness and compression force <i>should</i> be displayed and easily seen.			
A2.06	A range of spot compression and magnification paddles <i>should</i> be included			
A2.07	There shall be hookwire localisation facility such that the breast can be imaged in 2 planes with the guiding needle in place.			
A2.08	There shall be facility for specimen radiography			
A3.00	Ease of Use and Ergonomics			
A3.01	The tube angulation <i>shall</i> be easily seen.			
A3.02	The system <i>shall</i> facilitate examination of clients with limited mobility (i.e. in wheelchair).			
A3.03	The vertical movement of the column <i>shall</i> be motorised.			

Category 1: RFQ Specifications

Product Proposed:

Item ID	Requirement	Score	Comment		
Required Functionality: RF-Q.4.2a, 4.2b(i), 4.2(c), 4.2(d), 4.2(e), 4.2(f), 4.2(g), 4.2(h), 4.2(i), 4.2(j), 4.2(k), 4.2(l), 4.2(m), 4.2(n), 4.2(o), 4.2(p), 4.2(q), 4.2(r), 4.2(s), 4.2(t), 4.2(u), 4.2(v), 4.2(w), 4.2(x), 4.2(y), 4.2(z), 4.2(aa), 4.2(ab), 4.2(ac), 4.2(ad), 4.2(ae), 4.2(af), 4.2(ag), 4.2(ah), 4.2(ai), 4.2(aj), 4.2(ak), 4.2(al), 4.2(am), 4.2(an), 4.2(ao), 4.2(ap), 4.2(aq), 4.2(ar), 4.2(as), 4.2(at), 4.2(au), 4.2(av), 4.2(aw), 4.2(ax), 4.2(ay), 4.2(az), 4.2(ba), 4.2(bb), 4.2(bc), 4.2(bd), 4.2(be), 4.2(bf), 4.2(bg), 4.2(bh), 4.2(bi), 4.2(bj), 4.2(bk), 4.2(bl), 4.2(bm), 4.2(bn), 4.2(bo), 4.2(bp), 4.2(bq), 4.2(br), 4.2(bs), 4.2(bt), 4.2(bu), 4.2(bv), 4.2(bw), 4.2(bx), 4.2(by), 4.2(bz), 4.2(ca), 4.2(cb), 4.2(cc), 4.2(cd), 4.2(ce), 4.2(cf), 4.2(cf), 4.2(ch), 4.2(ci), 4.2(cj), 4.2(ck), 4.2(cl), 4.2(cm), 4.2(cn), 4.2(co), 4.2(cp), 4.2(cq), 4.2(cr), 4.2(cs), 4.2(ct), 4.2(cu), 4.2(cv), 4.2(cw), 4.2(cx), 4.2(cy), 4.2(cz), 4.2(da), 4.2(db), 4.2(dc), 4.2(dd), 4.2(de), 4.2(df), 4.2(df), 4.2(dh), 4.2(di), 4.2(dj), 4.2(dk), 4.2(dl), 4.2(dm), 4.2(dn), 4.2(do), 4.2(dp), 4.2(dq), 4.2(dr), 4.2(ds), 4.2(dt), 4.2(du), 4.2(dv), 4.2(dw), 4.2(dx), 4.2(dy), 4.2(dz), 4.2(ea), 4.2(eb), 4.2(ec), 4.2(ed), 4.2(ef), 4.2(ef), 4.2(eg), 4.2(eh), 4.2(ei), 4.2(ej), 4.2(ek), 4.2(el), 4.2(em), 4.2(en), 4.2(eo), 4.2(ep), 4.2(eq), 4.2(er), 4.2(es), 4.2(et), 4.2(eu), 4.2(ev), 4.2(ew), 4.2(ex), 4.2(ey), 4.2(ez), 4.2(fa), 4.2(fb), 4.2(fc), 4.2(fd), 4.2(fe), 4.2(fe), 4.2(ff), 4.2(fh), 4.2(fi), 4.2(fj), 4.2(fk), 4.2(fl), 4.2(fm), 4.2(fn), 4.2(fo), 4.2(fp), 4.2(fq), 4.2(fr), 4.2(fs), 4.2(ft), 4.2(fu), 4.2(fv), 4.2(fw), 4.2(fx), 4.2(fy), 4.2(fz), 4.2(ga), 4.2(gb), 4.2(gc), 4.2(gd), 4.2(ge), 4.2(ge), 4.2(gf), 4.2(gg), 4.2(gh), 4.2(gi), 4.2(gj), 4.2(gk), 4.2(gl), 4.2(gm), 4.2(gn), 4.2(go), 4.2(gp), 4.2(gq), 4.2(gr), 4.2(gs), 4.2(gt), 4.2(gu), 4.2(gv), 4.2(gw), 4.2(gx), 4.2(gy), 4.2(gz), 4.2(ha), 4.2(hb), 4.2(hc), 4.2(hd), 4.2(he), 4.2(he), 4.2(hf), 4.2(hg), 4.2(hi), 4.2(hj), 4.2(hk), 4.2(hl), 4.2(hm), 4.2(hn), 4.2(ho), 4.2(hp), 4.2(hq), 4.2(hr), 4.2(hs), 4.2(ht), 4.2(hu), 4.2(hv), 4.2(hw), 4.2(hx), 4.2(hy), 4.2(hz), 4.2(ia), 4.2(ib), 4.2(ic), 4.2(id), 4.2(ie), 4.2(ie), 4.2(if), 4.2(ig), 4.2(ih), 4.2(ii), 4.2(ij), 4.2(ik), 4.2(il), 4.2(im), 4.2(in), 4.2(io), 4.2(ip), 4.2(iq), 4.2(ir), 4.2(is), 4.2(it), 4.2(iu), 4.2(iv), 4.2(iw), 4.2(ix), 4.2(iy), 4.2(iz), 4.2(ja), 4.2(jb), 4.2(jc), 4.2(jd), 4.2(je), 4.2(je), 4.2(jf), 4.2(jg), 4.2(jh), 4.2(ji), 4.2(jj), 4.2(jk), 4.2(jl), 4.2(jm), 4.2(jn), 4.2(jo), 4.2(jp), 4.2(jq), 4.2(jr), 4.2(js), 4.2(jt), 4.2(ju), 4.2(jv), 4.2(jw), 4.2(jx), 4.2(jy), 4.2(jz), 4.2(ka), 4.2(kb), 4.2(kc), 4.2(kd), 4.2(ke), 4.2(ke), 4.2(kf), 4.2(kg), 4.2(kh), 4.2(ki), 4.2(kj), 4.2(kk), 4.2(kl), 4.2(km), 4.2(kn), 4.2(ko), 4.2(kp), 4.2(kq), 4.2(kr), 4.2(ks), 4.2(kt), 4.2(ku), 4.2(kv), 4.2(kw), 4.2(kx), 4.2(ky), 4.2(kz), 4.2(la), 4.2(lb), 4.2(lc), 4.2(ld), 4.2(le), 4.2(le), 4.2(lf), 4.2(lg), 4.2(lh), 4.2(li), 4.2(lj), 4.2(lk), 4.2(lm), 4.2(ln), 4.2(lo), 4.2(lp), 4.2(lq), 4.2(lr), 4.2(ls), 4.2(lt), 4.2(lu), 4.2(lv), 4.2(lw), 4.2(lx), 4.2(ly), 4.2(lz), 4.2(ma), 4.2(mb), 4.2(mc), 4.2(md), 4.2(me), 4.2(me), 4.2(mf), 4.2(mg), 4.2(mh), 4.2(mi), 4.2(mj), 4.2(mk), 4.2(ml), 4.2(mn), 4.2(mo), 4.2(mp), 4.2(mq), 4.2(mr), 4.2(ms), 4.2(mt), 4.2(mu), 4.2(mv), 4.2(mw), 4.2(mx), 4.2(my), 4.2(mz), 4.2(na), 4.2(nb), 4.2(nc), 4.2(nd), 4.2(ne), 4.2(ne), 4.2(nf), 4.2/ng), 4.2(nh), 4.2(ni), 4.2(nj), 4.2(nk), 4.2(nl), 4.2(nm), 4.2(no), 4.2(np), 4.2(nq), 4.2(nr), 4.2(ns), 4.2(nt), 4.2(nu), 4.2(nv), 4.2(nw), 4.2(nx), 4.2(ny), 4.2(nz), 4.2(oa), 4.2(ob), 4.2(oc), 4.2(od), 4.2(oe), 4.2(oe), 4.2(of), 4.2(og), 4.2(oh), 4.2(oi), 4.2(oj), 4.2(ok), 4.2(ol), 4.2(om), 4.2(on), 4.2(oo), 4.2(op), 4.2(oq), 4.2(or), 4.2(os), 4.2(ot), 4.2(ou), 4.2(ov), 4.2(ow), 4.2(ox), 4.2(oy), 4.2(oz), 4.2(pa), 4.2(pb), 4.2(pc), 4.2(pd), 4.2(pe), 4.2(pe), 4.2(pf), 4.2(pg), 4.2(ph), 4.2(pi), 4.2(pj), 4.2(pk), 4.2(pl), 4.2(pm), 4.2(pn), 4.2(po), 4.2(pp), 4.2(pq), 4.2(pr), 4.2(ps), 4.2(pt), 4.2(pu), 4.2(pv), 4.2(pw), 4.2(px), 4.2(py), 4.2(pz), 4.2(qa), 4.2(qb), 4.2(qc), 4.2(qd), 4.2(qe), 4.2(qe), 4.2(qf), 4.2(qg), 4.2(qh), 4.2(qi), 4.2(qj), 4.2(qk), 4.2(ql), 4.2(qm), 4.2(qn), 4.2(qo), 4.2(qp), 4.2(qq), 4.2(qr), 4.2(qs), 4.2(qt), 4.2(qu), 4.2(qv), 4.2(qw), 4.2(qx), 4.2(qy), 4.2(qz), 4.2(ra), 4.2(rb), 4.2(rc), 4.2(rd), 4.2(re), 4.2(re), 4.2(rf), 4.2(rg), 4.2(rh), 4.2(ri), 4.2(rj), 4.2(rk), 4.2(rl), 4.2(rm), 4.2(rn), 4.2(ro), 4.2(rp), 4.2(rq), 4.2(rr), 4.2(rs), 4.2(rt), 4.2(ru), 4.2(rv), 4.2(rw), 4.2(rx), 4.2(ry), 4.2(rz), 4.2(sa), 4.2(sb), 4.2(sc), 4.2(sd), 4.2(se), 4.2(se), 4.2(sf), 4.2(sg), 4.2(sh), 4.2(si), 4.2(sj), 4.2(sk), 4.2(sl), 4.2(sm), 4.2(sn), 4.2(so), 4.2(sp), 4.2(sq), 4.2(sr), 4.2(ss), 4.2(st), 4.2(su), 4.2(sv), 4.2(sw), 4.2(sx), 4.2(sy), 4.2(sz), 4.2(ta), 4.2(tb), 4.2(tc), 4.2(td), 4.2(te), 4.2(te), 4.2(tf), 4.2(tg), 4.2(th), 4.2(ti), 4.2(tj), 4.2(tk), 4.2(tl), 4.2(tm), 4.2(tn), 4.2(to), 4.2(tp), 4.2(tq), 4.2(tr), 4.2(ts), 4.2(tt), 4.2(tu), 4.2(tv), 4.2(tw), 4.2(tx), 4.2(ty), 4.2(tz), 4.2(ua), 4.2(ub), 4.2(uc), 4.2(ud), 4.2(ue), 4.2(ue), 4.2(uf), 4.2(ug), 4.2(uh), 4.2(ui), 4.2(uj), 4.2(uk), 4.2(ul), 4.2(um), 4.2(un), 4.2(uo), 4.2(up), 4.2(uq), 4.2(ur), 4.2(us), 4.2(ut), 4.2(uu), 4.2(uv), 4.2(uw), 4.2(ux), 4.2(uy), 4.2(uz), 4.2(va), 4.2(vb), 4.2(vc), 4.2(vd), 4.2(ve), 4.2(ve), 4.2(vf), 4.2(vg), 4.2(vh), 4.2(vi), 4.2(vj), 4.2(vk), 4.2(vl), 4.2(vm), 4.2(vn), 4.2(vo), 4.2(vp), 4.2(vq), 4.2(vr), 4.2(vs), 4.2(vt), 4.2(vu), 4.2(vv), 4.2(vw), 4.2(vx), 4.2(vy), 4.2(vz), 4.2(wa), 4.2(wb), 4.2(wc), 4.2(wd), 4.2(we), 4.2(we), 4.2(wf), 4.2(wg), 4.2(wh), 4.2(wi), 4.2(wj), 4.2(wk), 4.2(wl), 4.2(wm), 4.2(wn), 4.2(wo), 4.2(wp), 4.2(wq), 4.2(wr), 4.2(ws), 4.2(wt), 4.2(wu), 4.2(wv), 4.2(ww), 4.2(wx), 4.2(wy), 4.2(wz), 4.2(xa), 4.2(xb), 4.2(xc), 4.2(xd), 4.2(xe), 4.2(xe), 4.2(xf), 4.2(xg), 4.2(xh), 4.2(xi), 4.2(xj), 4.2(xk), 4.2(xl), 4.2(xm), 4.2(xn), 4.2(xo), 4.2(xp), 4.2(xq), 4.2(xr), 4.2(xs), 4.2(xt), 4.2(xu), 4.2(xv), 4.2(xw), 4.2(xx), 4.2(xy), 4.2(xz), 4.2(ya), 4.2(yb), 4.2(yc), 4.2(yd), 4.2(ye), 4.2(ye), 4.2(yf), 4.2(yg), 4.2(yh), 4.2(yi), 4.2(yj), 4.2(yk), 4.2(yl), 4.2(ym), 4.2(yn), 4.2(yo), 4.2(yp), 4.2(yq), 4.2(yr), 4.2(ys), 4.2(yt), 4.2(yu), 4.2(yv), 4.2(yw), 4.2(yx), 4.2(yz), 4.2(za), 4.2(zb), 4.2(zc), 4.2(zd), 4.2(ze), 4.2(ze), 4.2(zf), 4.2(zg), 4.2(zh), 4.2(zi), 4.2(zj), 4.2(zk), 4.2(zl), 4.2(zm), 4.2(zn), 4.2(zo), 4.2(zp), 4.2(zq), 4.2(zr), 4.2(zs), 4.2(zt), 4.2(zu), 4.2(zv), 4.2(zw), 4.2(zx), 4.2(zy), 4.2(zz))					
A4.00	Image Receptor Requirements				
A4.01	All test tools, phantoms and software for quality assurance must be provided.				
A4.01	The active image area shall be nominal 24 x 30 cm format				
A5.00	Acquisition Workstation Requirements				
A5.01	The system shall support full integration with Sectra PACS via industry standard DICOM interfaces.				
A5.02	Access to the Quality Assurance system and image data shall be available.				
A5.03	Access to the number and location of defective pixels of the image receptor shall be available (pixel reconstruction map)				
A5.04	All test tools, phantoms and software for quality assurance shall be available				
A5.04	All image display monitors shall conform to the DICOM Part 14 GSDF.				
A5.05	The display monitors should be supplied with an internal luminance measuring system to check and adjust the luminance calibration.				
A5.06	Otherwise, the graphics card and display monitors shall be compatible with an external luminance measuring and optimization system, such as "VeriLUM" or equivalent.				
A5.07	The system shall send exposure, compression and dose information via DICOM to Sectra PACS				
A6.00	Standards Requirements				
A6.01	The unit shall comply with all required standards and regulations.				
A6.02	The installation of the equipment shall be to "Body Protector" standard, and a certification of compliance shall be provided by an independent qualified electrical engineer at the completion of the work.				
A6.03	Warranty and Servicing Requirements				
A7.00	Warranty and Servicing Requirements				
A7.01	The unit shall be covered by a warranty period of at least twenty-four (24) months from the date of system installation.				
A7.02	The vendor shall maintain the equipment under a service contract agreement				
A7.03	Warranty provision shall cover any costs for parts and labour to repair or replace defects of materials and/or workmanship on all components of the system.				
A7.04	The unit shall be covered by a comprehensive service contract covering applications support and regular preventative maintenance.				
A7.05	All parts for service and repair shall be held in Auckland NZ				
A9.00	Certification Requirements				
A9.01	The system shall comply with all relevant requirements for accreditation in mammography as specified in the Royal Australian and New Zealand College of Radiologists (RANZCR) Manual, (2002). Any references to film optical density are obviously excluded. It shall also comply with the ACPSEM Position Paper: Interim Regulations for a Digital Mammography Quality Assurance Program.				
A10.00	Integration / Compatibility Requirements				
A10.01	The system shall be compatible with and able to be integrated with Sectra PACS and SBS RIS system and the vendor is to be contractually bound for ensuring integration between their modality and the PACS is achieved				
A11.00	Technical Requirements				
A11.01	The system selected for purchase shall comply with this stated specification in every detail following installation and at any subsequent time while under warranty or service contract with the manufacturer's agent.				
A12.00	Quality Assurance				
A12.01	A complete set of test tools, phantoms and any other devices (e.g. CDMAM) including software necessary to measure the performance of the machine shall be supplied with the system and remain on the Takepuna site.				
A12.02	The vendor shall allow customer access to relevant QA software to meet the following requirements: a). Routine QA procedures performed by a MIRT (Medical Radiation Technologist) at recommended intervals to ensure that the system is operating normally b). Annual QA procedures performed by a QHP (Qualified Health Physicist) to ensure that the system complies with the Code of Safe Practice for the Use of X-rays in Medical Diagnosis, NRL C5, and in particular, facilitates the checking of AEC performance, dose measurement, and assessment of image quality as detailed in the relevant ACR Accreditation Manual				
A13.00	Installation				
A13.01	The system shall be fully installed and tested by x and interface with Sectra PACS system confirmed as fully functional by x				
A13.02	The vendor shall supply full site installation manuals before delivery of the equipment, and provide guidance regarding room layout and optimum position of services such as power supply, network connections, etc.				
A14.00	Training				
A14.01	A dedicated trainer will be provided to teach clinicians effective equipment use				
A14.02	A comprehensive "train-the-trainer" package will be provided for key support staff				
A14.03	Written training materials shall be made available				
A14.04	Video and/or interactive training materials are available				
A14.05	An expert trainer will be available to provide education and assistance to key personnel on the programming and use of the system both during the implementation phase and for the following 6 months				
A15.00	Support				
A15.01	On-call phone support will be provided 24 hrs a day				
A15.02	A minimum product warranty of 2 years will be provided				
A15.03	Technical service training will be provided to the facility's biomedical engineers				
A15.04	On-site support will be provided during the hours of Monday to Friday 8am-7pm & Sat 9am-1pm				
A15.05	A Service Manual including circuit diagrams & schematics will be provided				
A15.06	An Operator Manual will be provided with equipment				
A15.07	Specific equipment for biomedical testing shall be included				
4.2(c)	Reference Sites and Site Visit				

	Score	Comment
<p>Required Functionality: RFQ 4.2a, 4.2b(i), 4.2b(ii), 4.2(c), 4.2(d), 4.2(e), 4.5 Respondents are required to be able to provide a list of reference site(s) that are currently conducting screening services on their proposed product. It is preferable that the reference site(s) using the proposed product also has the product integrated into a non-proprietary PACS system. The reference site should be a high volume screening site (over 3000 screens per annum) and ideally had the digital mammography unit installed for more than nine months. As part of the evaluation process WDHB may elect to send up to three project team members to visit your reference site(s), the cost of travelling and conducting this reference site visit shall be the respondents responsibility.</p>		
<p>4.2(d) Delivery Dates The Equipment shall be fully commissioned at our designated premises in accordance with the dates below:</p>		
<p>Delivery Date: x</p>		
<p>Commissioning Date: x</p>		
<p>4.2(e) Service Level Supplier will be required to hold all FFDM spare parts in Auckland</p>		
<p>i</p>		
<p>ii</p>		
<p>iii</p>		
<p>iv</p>		
<p>Supplier will be required to provide on-site support during the hours of Monday Friday 8am to 7pm, and Saturday mornings 9am – 1pm. During the Implementation phase, and for the term of the service agreement, the Supplier will make available to the Customer a toll free number at which the Supplier can be contacted at any time to provide support to the Customer. The Supplier will be required to have in place an Auckland based factory trained engineer prior to the time of installation, and to provide ongoing service support for the machine at the Waitakere Hospital site. See also the draft support and service agreement where further service specifications are described. The final specifications will be agreed during negotiations. Respondents should also provide information in regards to how they propose to manage out of hours service calls. Out of hours time and material rates must also be stated.</p>		
<p>The DHB expects each item to be delivered within agreed timeframes and quality specifications.</p>		
<p>4.6 Transition and Implementation Vendors are required to confirm that qualified and experienced staff are available to us for the period (excluding statutory holidays) to complete installation and commissioning of Equipment as deemed necessary. A dedicated and experienced FFDM trainer shall be made available in the implementation phase and then for follow up training at 3 and 6 months from the date of the implementation</p>		



APPENDIX E: QUESTIONS FOR INTERNATIONAL SITE VISITS

The following questions were used by members of the Digital Working Group conducting international site visits.

QUESTIONS FOR ASSESSMENT VISIT: FFDM

1. Availability and screening experience with 24 x 30cm detector plate
2. Positioning smaller "18 x 24" size breast on 24 x 30cm detector plate
3. Pixel size
4. Image acquisition time
5. Lag
6. AEC exposure control + delay
7. Stereotactic biopsy capacity
 - a. Resolution/pixel size
 - b. Space to fit breast tissue
 - c. Space for mammotome
 - d. Plate protection
 - e. If stand-alone, how to maintain low usage tube
8. Compression plates
9. Needle localisation
10. Acquisition work station
 - a. Worklist management
 - i. Patient filtering
 - ii. Room specific
 - iii. Ability to select from other worklist
 - b. Fail safes for correct image
 - c. Ability to correct mistakes
11. DICOM integration
12. Environment
 - a. Cabling
 - b. Noise
 - c. Temperature/humidity
 - d. Warm up time
13. MRT work flow (screening)

- a. Patient cycle
 - b. Ergonomics
 - c. Previews
 - d. Checks
14. MRT work flow (assessment)
- a. Patient cycle
 - b. Ergonomics
15. Training
16. QA
- a. Calibration and testing
 - b. Frequency
 - c. Time taken
17. Image processing algorithms
- a. Can images be standardised to maintain "look" across different vendors
18. Clinical images
19. Detector stability and reliability
- a. Pixel loss + replacement
20. Reliability and experience in screening environment
21. Support

QUESTIONS FOR ASSESSMENT VISIT: PACS

1. RIS-PACS integration
- a. What are key issues?
 - b. What have been most difficult/challenging issues?
2. MRT worklist
- a. How is this created?
 - b. Does MRT pull by barcode or from menu?
3. Acquisition workstation (AWS)
- a. Can RIS sit on AWS along with images (for PGAR)?
 - b. Is it possible to achieve context synchronisation between images and RIS on AWS?
 - c. Can prior images be pulled from (other) PACS to AWS?
 - d. How long does MRT require per patient on AWS
 - i. Can one AWS serve two rooms without becoming rate limiting step?
 - ii. Can images be aligned by MRT so that paired images are properly matched for display?
4. Hanging protocols
- a. Is there a site-wide policy standardising these?
 - b. How was this chosen?
 - c. Is it vendor driven or user driven?
-

- d. Protocols for displaying studies with >4 images, e.g. repeats or overlapping views (large breast)
 - e. Protocols for displaying studies with prior studies
 - f. If images are repeated, can these be deleted?
 5. Image display
 - a. Is there a white band between images (or is there automatic "black border")?
 6. Blind reading
 - a. Discriminating between 1st, 2nd, 3rd read
 - b. Ensuring no reader can do more than one
 - c. Ability to reverse order of worklist
 - d. Ability to fix worklists (so that not partially read elsewhere)
 - e. Ability to completely hide annotations between 1st and 2nd read
 7. Prefetching
 - a. Does this pull to a secondary server, e.g. gateway server?
 - b. Or does this pull from long term archive to short term store, e.g. MAS to SAN?
 - c. Does RIS anticipate next patient on worklist and pull from SAN to workstation cache?
 8. Outlying sites
 - a. How are these handled?
 - b. MiniPACS?
 - c. Workstation with increased hard drive?
 - d. Redundant connections?
 - e. What sort of bandwidth is required?
 - i. Low bandwidth off peak?
 - ii. High bandwidth on demand?
 9. What happens if a "PACS disconnect" occurs?
 - a. Main/central site
 - b. Outlying site
 10. Time to load studies to workstation?
 - a. Booked with prefetched priors
 - i. Prefetched to secondary server
 - ii. Prefetched to STS
 - b. Unbooked
 11. How do sites with both film and digital modalities manage?
 - a. Digital screen and film assessment (and vice versa)
 - b. Diagnostic visit (film) and prior images digital
 12. Does RIS update PACS to "reported status" when study reading completed?
 13. QA and integrity reports
 14. Radiologist
-

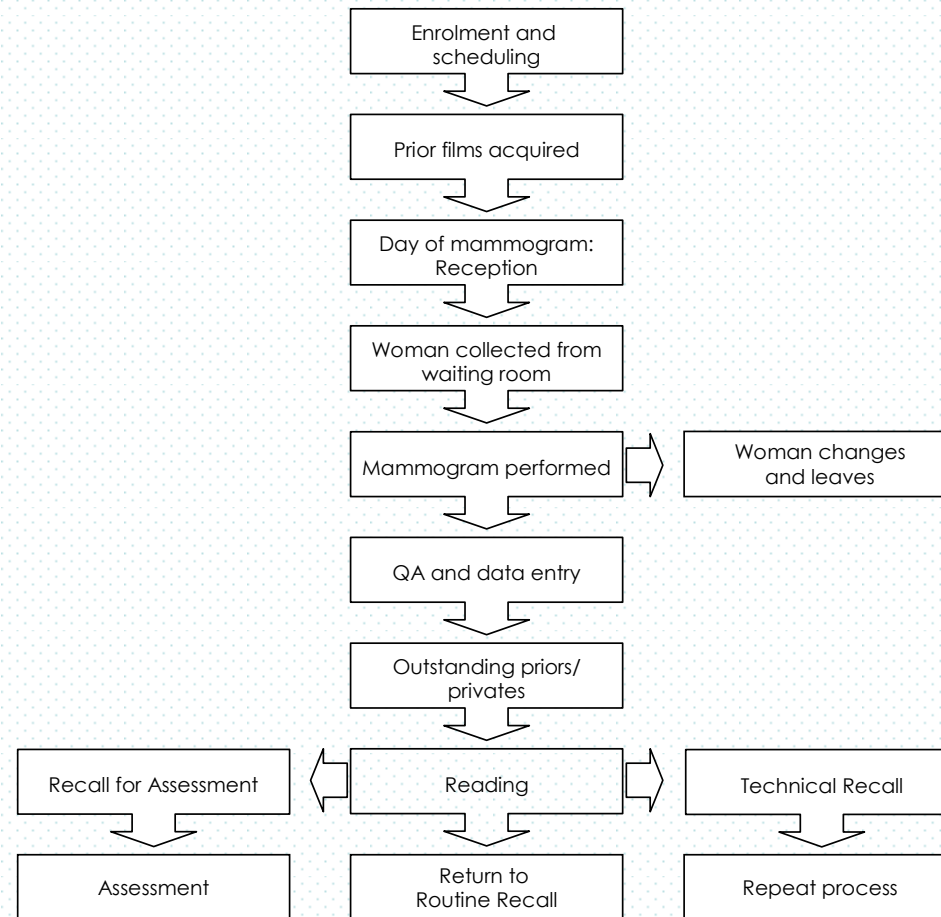
- a. Training
 - b. Satisfaction
 - c. Workflow
 - d. Productivity
 - i. Learning curve
 - ii. Long term screen reading speed
 - e. Ease of use of tools
 - i. Mouse vs keypad
 - f. RIS integration
 - g. Ability to individually configure hanging protocols
 - i. Are hanging protocols user or vendor defined?
 - ii. What do radiologists say about hanging protocols?
15. Digitising old films
- a. How is event created in RIS
 - b. Can correct DICOM mammography headers/tags be added
 - c. Can satisfactory automated hanging protocols be adequately achieved
 - d. Who + where is digitising done
 - i. Clerical
 - ii. Clinical (MRT)
 - iii. QA – can images be flipped, rotated, etc before archived?
 - iv. Can incorrect DICOM tags be corrected
16. Monitor specifications
- a. Warranty
 - b. Reliability
 - c. Pixel loss
17. Workstation
- a. Specifications
 - b. RIS integration – context synchronisation
18. Printed films
- a. Resolution
 - b. Film size
 - c. Format
19. Support and reliability
- a. Down time
 - b. Need for on-site engineering support
-



APPENDIX F: PROCESS MAPS

The attached process maps were prepared following interviews/workshops with staff (including MRT, IT and radiology input) and tours of the Takapuna (DM) and Orewa (FSM) screening sites. Draft process maps were produced which were reviewed by BSWN MRTs and radiologists, and were finalised following receipt of feedback from BSWN.

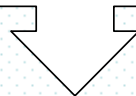
Overview of Process for Digital Mammography



Analogue

Enrolment and scheduling

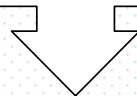
- Woman enrolls in BSA via GP or self-enrols.
- Receptionist registers woman in system (data entry) - may happen in parallel with appointment scheduling.
- Appointment scheduled, invitation letter generated.
- Woman confirms, re-schedules or is phoned until appointment confirmed in computer.
- Daily report generated for imaging clerk for retrieval of files.
- If priors need to be requested from a private provider or other Lead Provider, receptionist faxes request.



Digital

Enrolment and scheduling

- Woman enrolls in BSA via GP or self-enrols.
- Receptionist registers woman in system (data entry) - may happen in parallel with appointment scheduling.
- Appointment scheduled, invitation letter generated.
- Woman confirms, re-schedules or is phoned until appointment confirmed in computer.
- Daily report generated for imaging clerk for retrieval of files and digitising of priors.
- If priors need to be requested from a private provider or other Lead Provider, receptionist faxes request.



Comments

Key differences between analogue and digital mammography are underlined.

All enrolment and appointment scheduling is done in Takapuna via 0800 number. Schedules are then copied to satellite sites where applicable.

Analogue

Prior films acquired

- One week before day of mammogram, imaging clerk receives automated list of files required including names, bar codes.
- Retrieves paper files and films from storage/ transferred files from trolley.
- If woman is scheduled to visit a satellite site, files are couriered to that site.
- Files are grouped by days women are booked to come in for screening. Pile goes on desk for receptionist at 7:30 each morning.

Digital

Prior films acquired

- One week before day of mammogram, imaging clerk receives automated email list of files including priors required for digitising including names, bar codes.
- Retrieves paper files and films from storage/ transferred files from trolley.
- Imaging clerk digitises analogue priors and marks them on computer (so they drop off the worklist for digitising). Adjusts contrast of image as required to enhance clarity of image.
- Imaging clerk retrieves digital priors from medical archive system.
- If woman is scheduled to visit a satellite site, files are couriered to that site.
- Films are grouped by days women come in for screening. Pile goes on desk for receptionist at 7:30 each morning.

Comments

All paper files and films are shelved on site at BSWN's Takapuna site. Files (including prior films, green form, etc) are couriered to satellite sites for screening day then returned to Takapuna. No files are couriered to the Waitakere digital site.

The retrieval list follows the order in which the physical files are encountered on the shelving system, to enhance efficiency.

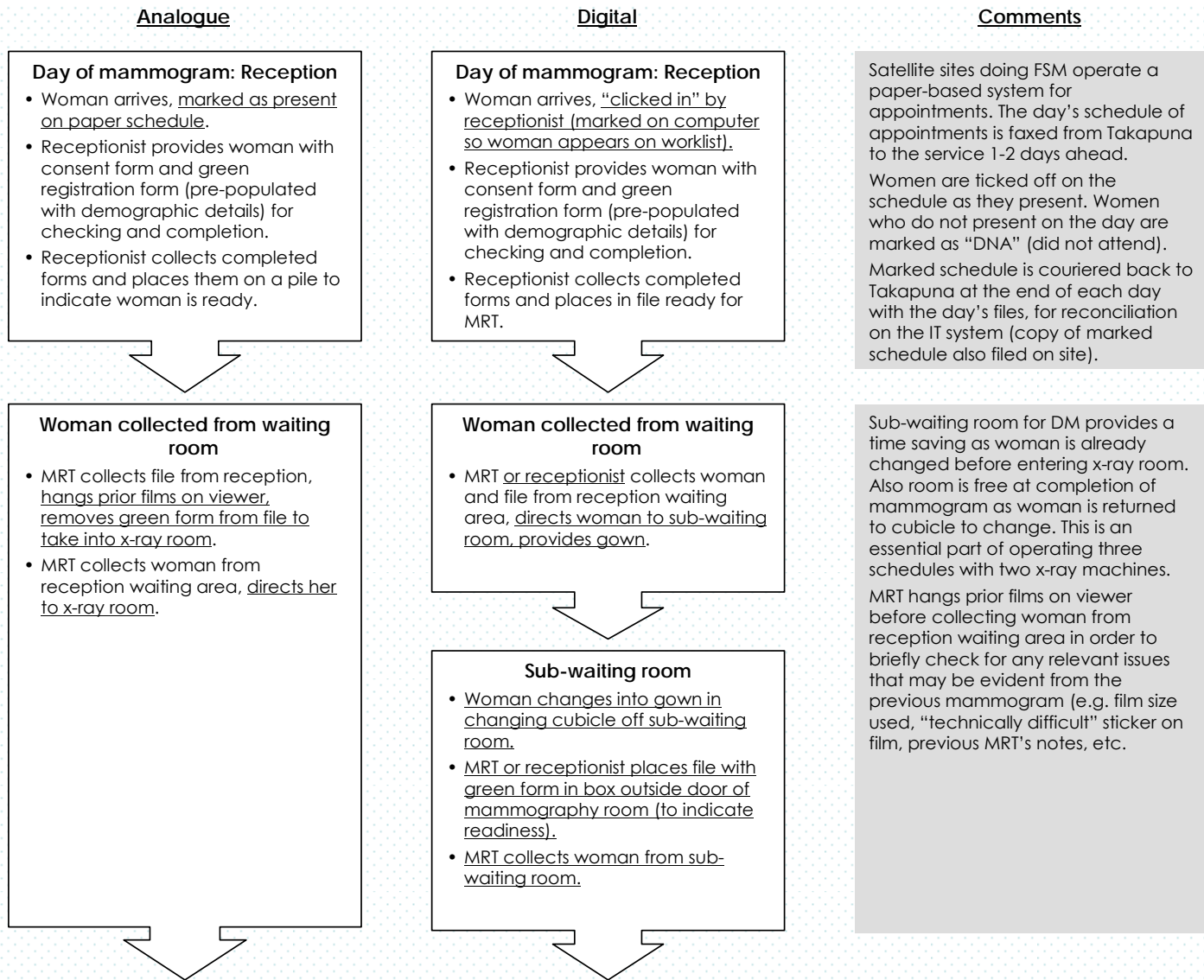
Transferred files arrive up to 2x/day by courier and are filed in a trolley in date order.

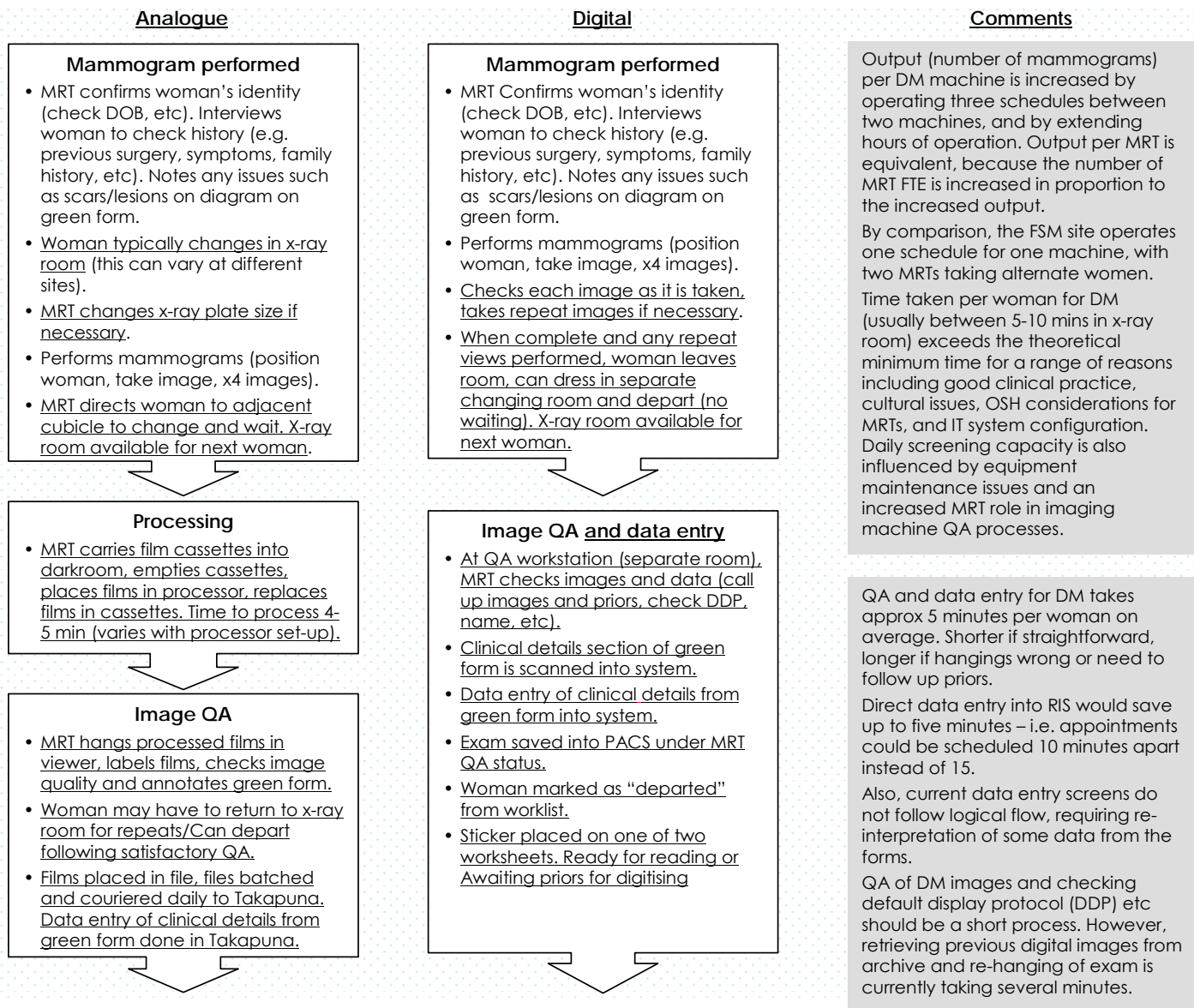
Digitised priors are stored on MAS (replicated between North Shore and Middlemore Hospitals). Retrieval of each image is slow due to bandwidth issues (currently being addressed).

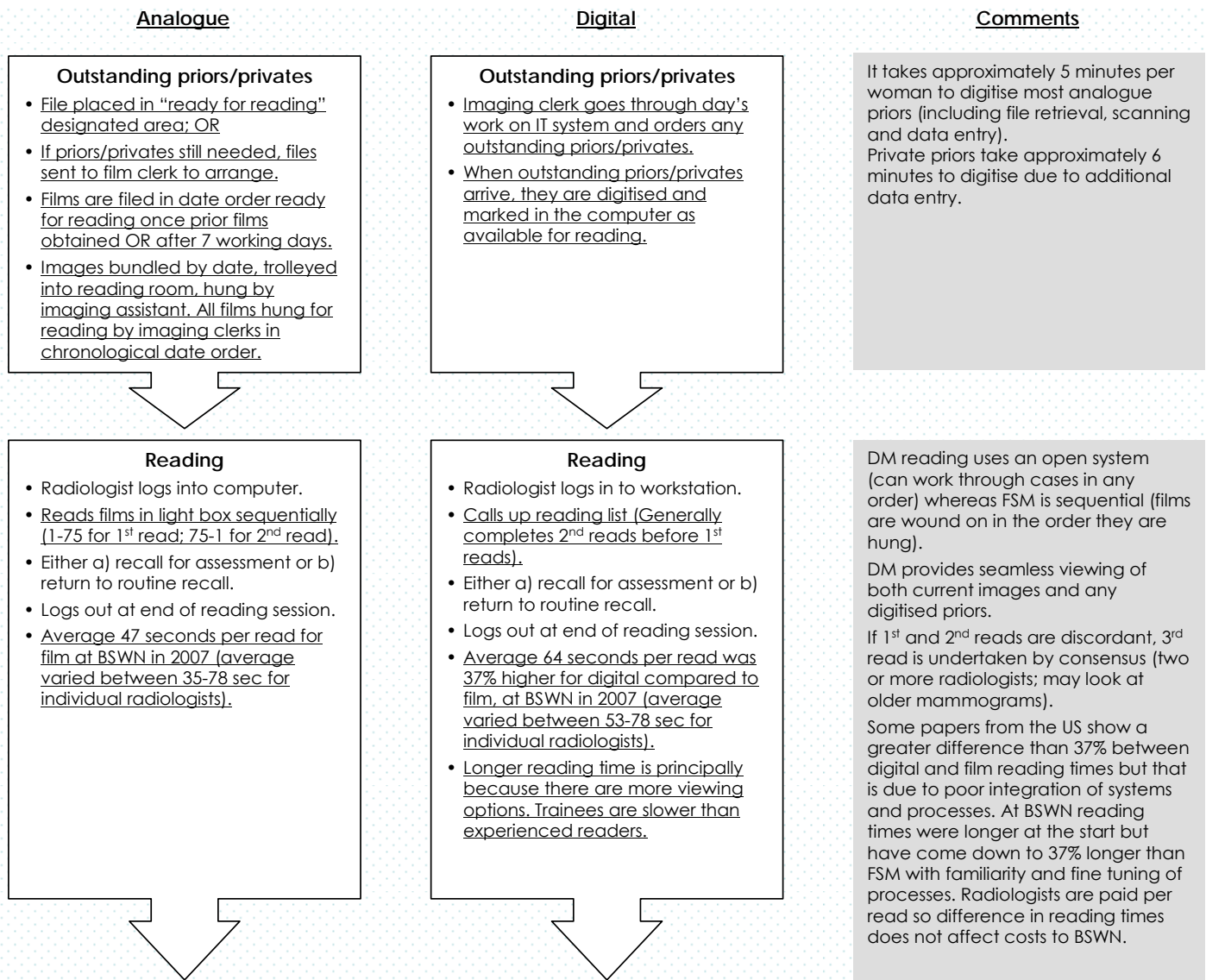
It takes approximately 5 minutes per woman to digitise most analogue priors (including file retrieval, scanning and data entry).

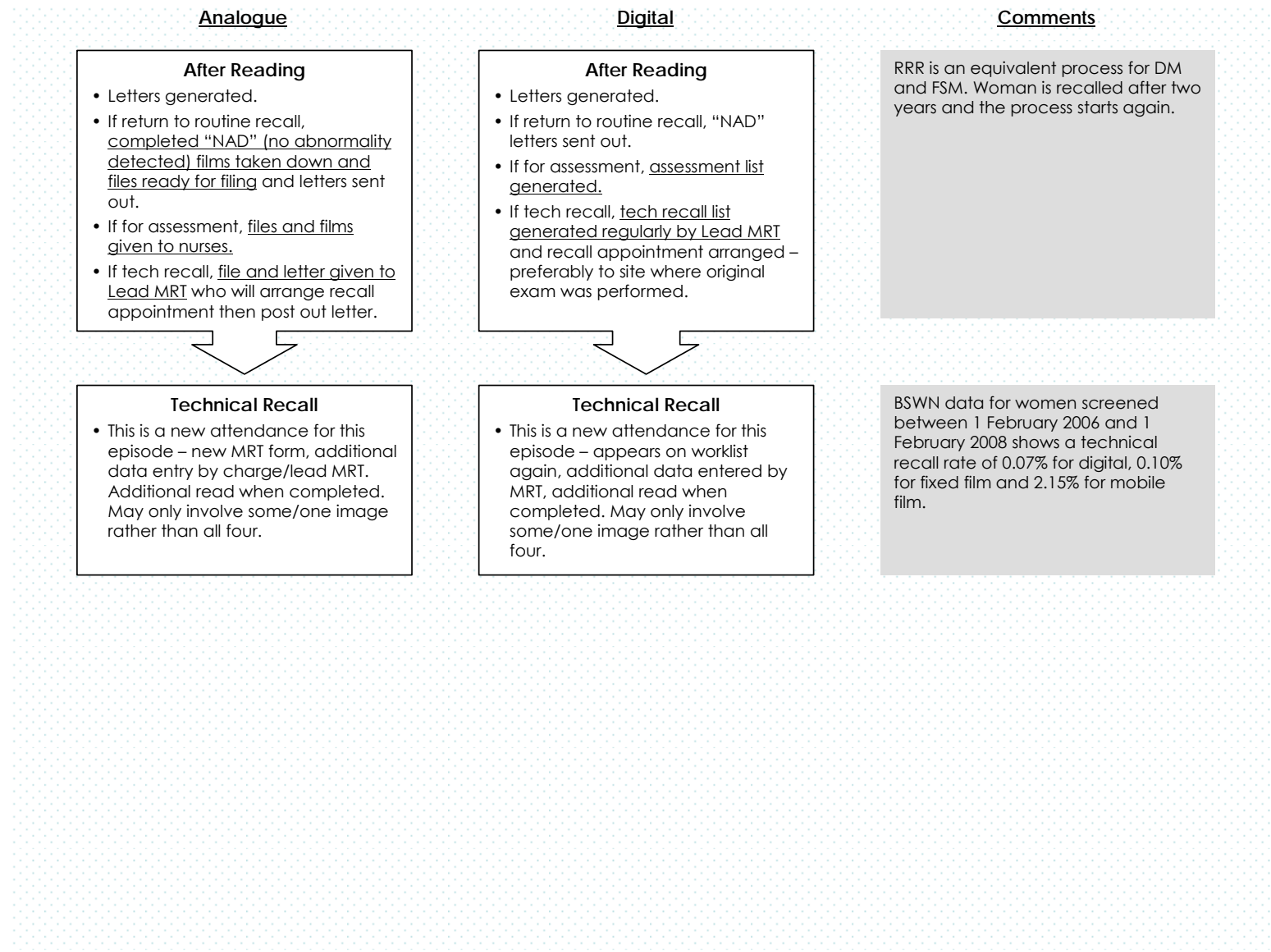
Private priors take approximately 6 minutes to digitise due to additional data entry.

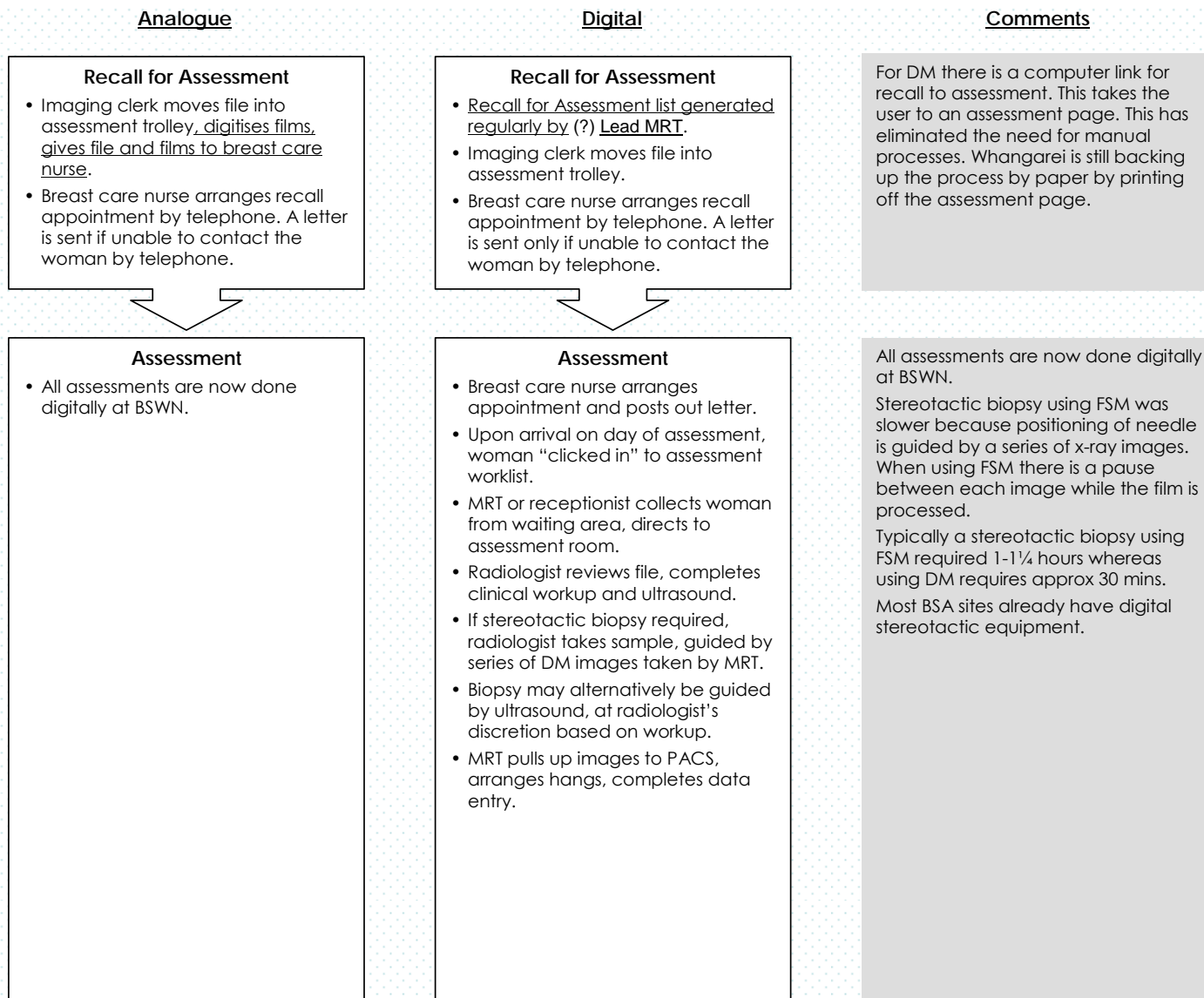
Number of priors requiring digitising is just starting to reduce (now at the 2-year mark).











TIME PER MAMMOGRAM WITH DIGITAL MAMMOGRAPHY

Digital mammography manufacturers have produced case studies of overseas sites where a mammogram is performed every four minutes. Time taken per woman at BSWN (scheduled at 15 minutes) exceeds the theoretical minimum time for a range of reasons including:

- Good clinical practice
- Cultural issues
- OSH considerations for MRTs
- IT system configuration
- Facility layout
- Equipment maintenance issues

Good clinical practice

A digital mammogram can be performed in 4-5 minutes at BSWN in “ideal” circumstances (e.g. where the woman has undergone digital screening before, is not anxious, has no questions, and is familiar with the sequence of steps).

Usually, however, a longer duration is needed (up to 10 minutes in the x-ray room) because it is important for the MRT to:

- Establish rapport with the woman in order to achieve good compression
- Answer any questions (e.g. some women may be nervous)
- Acknowledge and address any discomfort experienced by woman
- Reposition woman as required to acquire a high quality image
- Women often want to see images when digital (MRTs oblige but avoid in-depth discussion).

Additionally, some women are scheduled for a double appointment (30 mins). This includes:

- First appointments
- Women with breast implants
- Women with a cognitive or physical impairment.

Cultural issues

Some women require an interpreter (or speak little English and do not have access to an interpreter) and therefore require additional time for communication. This is an everyday occurrence at Takapuna.

Providing a culturally appropriate service requires attention to each woman's cultural needs. This potentially includes offering a karakia or other cultural support prior to conducting a mammogram.

The same basic cultural issues and needs are encountered in breast screening as any other healthcare service accessed by women from other cultures, and these must be attended to appropriately. It would be insensitive and potentially distressing for women to feel “rushed” through screening and not have time to prepare themselves, ask questions, etc.

There are cultural differences between New Zealand women and women in Europe. For example, women undergoing screening in Sweden find it acceptable not to be provided with gowns, and this translates into a time and cost saving.

OSH considerations for MRTs

Digital mammography is generally better ergonomically than analogue mammography (e.g. positioning of the machines is motor-assisted rather than manual).

However, there are potential repetitive movement issues such as shoulder and back care as well as issues associated with image acquisition (operation of thumb switch) which may become an OSH issue if output per MRT were increased. Sweden has addressed this issue through the use of a foot pedal in addition to the thumb switch so that the MRT can alternate between the two.

Sweden also has more MRTs per machine than BSWN which enables MRTs to alternate between the mammogram room and other duties. Each MRT performs five (or eight depending on the site) mammograms then spends an hour on other work such as reception duties. This enables a higher overall output per machine, but at higher cost due to the increased MRT FTE

IT system configuration

At BSWN, the MRT writes notes on the green form while performing the mammogram, then conducts data entry and scanning of the form as part of the subsequent image QA step.

In Sweden the MRT conducts direct data entry into the RIS while performing the mammogram.

This would save approx 5 mins per woman – i.e. appointments could be scheduled 10 minutes apart (note that this is an estimate and has not been trialled here).

The data entry fields in the computer system do not match the layout or content of fields on the green form. This causes inefficiencies in data entry due to the need to locate fields on the system and re-interpret information for data entry. BSWN is currently reviewing this format.

Facility layout

Facility layout can affect efficiency but is not a major issue at Takapuna.

The layout of the Takapuna facility is considered to be quite efficient. It provides a circular flow from reception, to the sub-waiting room, to the mammography room, to changing room, to exit.

The use of a sub-waiting room provides a time saving as the woman is already changed before entering mammography room – therefore total time per woman in the mammography room is reduced.

Flow may be improved if reception waiting room were more centrally located relative to the other rooms. However, this would be unlikely to generate a significant time saving.

Equipment maintenance issues

Frequent maintenance issues (including equipment breakdowns) were experienced during the first 18 months of the DM service, but have become less frequent. These had a substantial effect on output.

The QA schedule for digital mammography equipment has taken a lot of time to date developing and implementing, but is expected to now be more easily managed.
