

**BREASTSCREEN AOTEAROA**

**AN INDEPENDENT REVIEW**

**MAY 2002**

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# **SUMMARY AND RECOMMENDATIONS**

## **I SUMMARY**

On the basis of the conclusion of a recent World Health Organisation expert review of the evidence, a breast screening service is justified in a country such as New Zealand with a high mortality from breast cancer. Despite a number of factors that make the organisation and administration of efficient public health screening programmes difficult in New Zealand, BreastScreen Aotearoa, (BSA), is developing into a coherent well-monitored national service.

The quality of the screening process is high and it is provided in a consistent way across all Lead Providers that is likely to maximise the benefit and minimise the harm. The systems in place to safeguard against poor performance are comprehensive, and, although it is never possible to guarantee 100% "safety", the danger of an incident comparable to earlier screening failures in New Zealand is remote.

The principal constraint on BreastScreen Aotearoa as a whole is the lack of a national population register and public health information system. As a result the proportion of eligible women who are participating in the programme is unknown, although estimates based on census data suggest that it is still well below the 70% needed to achieve a 30% reduction in the number of breast cancer deaths.

The present system for recording details of the pathology and treatment of screen-detected cancers is inadequate, and this has so far prevented an assessment of how well the screening programme is progressing towards its target of reducing deaths. This difficulty can be easily resolved with the co-operation of pathologists and surgeons in BSA.

Although all categories of staff working in many different aspects of BSA are obviously dedicated to their work, there is opportunity for more communication between the Lead Providers, the Independent Monitoring Group and the National Screening Unit, to emphasise the fact that this is a national service and all are working towards the same aim.

Although economic aspects of BSA were not included in this review, it appears to be expensive in its use of health service resources, not least because of the numerous safeguards to ensure its excellence. The number of lives which it is anticipated can be saved is not great and therefore it will be important in the future to keep cost-benefit considerations under review.

## II RECOMMENDATIONS

These are listed in the order in which they occur in the main report, which follows the organisation, provision, and monitoring of BSA through from start to finish. The recommendations are not in any order of priority.

### **Configuration of Screening**

**1.** Consideration should be given to establishing an additional Lead Provider to serve women living in North Harbour and Northland regions, and relieve the very large workload of Breast Screen Auckland and North. (para 3.6)

### **Women eligible for screening**

**2.** The Advisory Group for Population-based Screening Programmes should look again at the criteria for women's eligibility to be screened and assessed in BSA. (para 4.4)

### **Population Register**

**3** The National Screening Unit should participate in the current Ministry of Health Working Party on Development of a National Health Index Population Register, and should exert continuing pressure on the Ministry and New Zealand Health Information Service to implement the Register rapidly. (para 5.7)

### **Internal Quality Control of Radiology**

**4** The Clinical Directors of each Lead Provider should submit an annual return to the National Screening Unit showing the number of film review meetings attended in the year by each radiologist, regardless of whether he/she works in the main centre or a sub-contracted site. (para 6.4.2)

### **Quality Control of Surgery**

**5.** The information given to women about where they may receive free treatment should identify by name those surgeons who are participating in the RACS Audit. (para 7.4.1)

**6.** The NSU should offer differential treatment payments to DHB's for BSA women treated by surgeons participating in the RACS Audit. (para 7.4.2)

### **Final Pathology Record**

**7.** The Lead Pathologist in each Lead Provider should not only complete synoptic forms about his own specimens, but also obtain synoptic forms from colleagues in other laboratories who have examined specimens from women with breast cancer diagnosed by BSA. (para 7.6.2)

### **Treatment Record**

**8.** The RACS Audit form should be adopted for use as the treatment record for BSA, and incorporated into its information systems. (paras 7.6.4 and 9.9)

**9.** The Lead Surgeon in each Lead Provider should not only complete RACS forms about his own patients, but also obtain RACS forms from other colleagues who have treated women diagnosed by BSA. (para 7.6.5 and 9.9)

### **Independent Monitoring Group**

**10.** The frequency of routine IMG reports should be decreased to 6-monthly and their format altered to include more graphics, 95% confidence intervals round estimated proportions, and an SDR for each Lead Provider once a year. (para 8.4.4)

**11.** For Lead Providers which have sub-contracted sites to do both screening and assessment of the same women, results for the main site and for each subcontracted site should be analysed separately by the IMG once a year. (para 8.4.6)

**12.** Epidemiological members of the IMG should attend unidisciplinary meetings at which professionals of the Lead Providers meet to discuss common interests and problems. (para 8.4.8)

**13.** The NSU should examine the role of the non-epidemiological members of the IMG. (para 8.4.10)

**14.** The approval for the Interval cancer identification work to go ahead which was given, on behalf of all the regional Ethics Committees by the Otago Ethics Committee, should not be restricted to a 3-year approval but should apply for the whole duration of BSA. (para 8.5.2)

### **Audit of Quality Standards**

**15.** The NSU should continue to audit each Lead Provider once every two years. In order to streamline the process, every item in the audit tool template, (including any that arise from revision of Quality Standards), should be limited to items where non-compliance might pose a moderate or high risk to the programme and to women participating in it. (para 9.8)

### **Information System**

**16.** The current BSA data-base should be closely integrated with the NHI Population Register as the latter is being established. The three software packages supporting the operational needs of BSA should continue but should develop modifications to allow communication between them about individual women. (para 10.6.5)

### **Workforce**

**17.** Medical Radiation Technicians should be paid on a consistent pay-scale for their sessions in BSA, regardless of which Lead Provider they work for. (para 11.3)

### **Corporate Identity of BSA**

**18.** The Chairperson of each Unidisciplinary Group should, supported by the NSU, organise the agenda of 6-monthly meetings open to others of the same discipline working in BSA, and the Unidisciplinary Group as a whole should produce reports on any issue requiring revision of the Quality Standards. (para 12.3)

**19.** A 2-Day meeting, open to all working in BSA, should be organised by the NSU once a year. (para 12.5)

### **The National Screening Unit**

**20.** The QMAA division of the National Screening Unit should work more closely with the Independent Monitoring Group in particular, as well as with newly appointed Consultant Clinical Advisers. (para 13.8)

### **Additional Recommendations arising from the Gisborne Inquiry Report**

**21.** The legal rights of access to information held on the cancer registry, by appropriately qualified people engaged by the Ministry of Health to evaluate screening programmes still need to be clarified.

**22.** Ethics Committees need to develop a policy on the balance between protection of the health of the public and the privacy of the individual.

## **1. INTRODUCTION**

**1.1** The benefit of mammography screening is a reduction in the risk of death from breast cancer among women in the eligible age-range. Over the past 40 years there have been a number of scientifically conducted trials in each of which women have been randomised to a study group who were offered screening or to a control group who were not. Meta-analyses of the results of these trials have shown that women aged over 50 when first screened are 30% to 40% less likely to die from breast cancer than women in the control group. This conclusion was challenged two years ago by statisticians from Denmark, who questioned the validity of previous trials, and concluded that benefit was unproven and that a much larger trial, individually randomising hundreds of thousands of women was still needed, in order to reach a clear conclusion on whether mammography screening saves any lives. In response to this hypothesis the World Health Organisation assembled a group of 25 experts in evaluation of screening to re-examine existing evidence. Their conclusion, to be published in a forthcoming monograph from the International Agency for Research on Cancer, is that the original estimate of a 30% to 40% reduction in risk of death from breast cancer is correct, and that therefore in populations where many women die from breast cancer a screening service is a valid public health measure. (*IARC Scientific Publications, Prevention Series, International Agency for Research on Cancer, Lyon, France, in press*).

**1.2** Hence New Zealand's decision to provide a national breast screening service, BreastScreen Aotearoa, is upheld by current evidence.

**1.3** The three principal factors influencing how much benefit can be obtained in any population are the proportion of the eligible population who are screened, the sensitivity of the screening test (mammography) in detecting invasive cancers at a stage when the cancer is still curable, and the adequacy of the treatment provided for screen-detected cancers. A fourth possible but unproven benefit is the detection and treatment of pre-invasive ductal carcinoma in situ, (DCIS). This is unproven because although there is evidence that some cases of DCIS, particularly those with histological high grade malignancy, progress to invasive cancer and their removal would thus be of benefit, there may be others that would not become invasive within the woman's lifetime. Thus while screening reduces a woman's risk of dying from breast cancer by about 35%, it may at the same time increase a woman's risk of being diagnosed with in situ breast cancer.

**1.4** The principal human costs of the screening programme arise from the fact that like all screening tests mammography inevitably gives both false positive and false negative results. Women with false positive results have to go through the anxiety and inconvenience of being recalled for assessment, many have to undergo needle biopsy and a few open biopsy with consequent pain and morbidity. Women with false negative results undergo the stress associated with thinking they are clear of cancer and then finding they are not, and possibly some women may delay seeking diagnosis for a breast symptom because they assume they are clear. Anger at finding an interval cancer may lead some women to sue for compensation. As mentioned above, the identification of DCIS may also cause harm by treating a woman as a breast cancer

patient when she might not otherwise have developed invasive disease. There are very substantial financial costs to the health service in providing screening, unlikely to be compensated by reduced costs of treating advanced cancers. And for many women there are financial costs in attending for screening and assessment.

**1.5** In the main part of this report the performance of Breast Screen Aotearoa, (BSA), in its efforts to maximise the benefits and to minimise the costs is reviewed, together with the systems in place for auditing and monitoring the programme. My conclusions are based on a wealth of documents relating to BSA which I was sent in advance of my visit, together with the impressions gained by visiting the screening centres and meeting with about 40 different groups of people concerned in one way or another with BSA.

## **2. BACKGROUND**

**2.1** Following two pilot programmes, which had taken place in Waikato and Otago and Southland between 1991 and 1996, a decision was made in 1995 to provide a national breast cancer screening service in New Zealand. The service, Breast Screen Aotearoa, (BSA), provides free two-yearly mammography for all New Zealand women between the ages of 50 and 64. Between 1996 and 1998 preparatory work was done to develop a set of interim quality standards and a national monitoring and evaluation system. Regional Health Authorities tendered for selection of appropriate providers of mammography screening and six Lead Providers were identified, located in centres which would cover the whole geographical spread of the population. They entered into contracts with the Health Funding Authority in late 1998 and are thus now entering their fourth year of screening. Separate funding was made available to Hospital & Health Services, (now District Health Boards) to refund them for the costs of treating women whose breast cancer was diagnosed by BSA. Separate contracts were also given to nine independent service providers across the country to provide health education and assist in recruitment of Maori and Pacific Island ethnic groups.

**2.2** Between 1996 and 2000 successive changes to the New Zealand system of health care funding meant that the Regional Health Authorities were replaced by the Transitional Health Authority which was replaced by the Health Funding Authority whose functions have now been taken over by the Ministry of Health. These changes, often accompanied by changes in key staff, have not contributed to the stability of a new service in its infancy. Under the present organisation the contracts for BSA and for the National Cervical Screening Programme, (NCSP), are held by the National Screening Unit (NSU) within the Public Health Directorate of the Ministry of Health. The NSU not only funds the providers of screening but is also responsible for ensuring the quality of BSA and NCSP, for implementing any improvements deemed necessary and for developing both programmes to meet future needs. (See Section 13 below).

**2.3** An Advisory Group for Population-based Screening Programmes advises the Ministry of Health and the NSU on policy issues related to breast and cervical cancer screening.

**2.4** There have been three much-publicised failures in cancer screening in New Zealand, two concerning screening for cervical cancer and one concerning Breast

Screen Aotearoa. In the first, which came to light in the 1980s, women with abnormal cervical smears had been left untreated in a misguided attempt to research the natural history of the disease. Several developed invasive cancer and some died. This was the subject of a public inquiry, the Cartwright Report, in 1988, following which the whole screening programme was more systematically organised and a national cervical screening register was established. But the programme still lacked performance standards and quality control measures. The second failure which was detected in 1999, arose because a cytopathologist, working in isolation over several years under-reported cervical intra-epithelial invasion, with the result that again some women went on to develop invasive cancer and some died. The Report of the Ministerial Inquiry into the Under-reporting of Cervical Smear Abnormalities in the Gisborne Region, published in 2001, concluded that the whole New Zealand cervical cancer screening programme was inadequately monitored and lacked sufficient quality assurance. It made a number of recommendations for improvement, some requiring legislative change. Implementation of the Gisborne Inquiry recommendations is now in hand and is being closely monitored by an external reviewer from the UK.

**2.5** The third episode, reported in the Health Care Otago Report, occurred in the Otago and Southland breast screening programme, (Breast Screen Health Care) in 2000. Due to inadequacies in the information system, a repeated clerical error led to some women with mammographic abnormalities being allocated to routine repeat screening in two years rather than to immediate assessment. When this came to light past films were reviewed and two women with breast cancer were found to have been missed by the screening programme because of similar errors. An external review revealed several other aspects of the service needing tighter quality control.

**2.6** These much-publicised failures of cancer screening have led to concern about whether the new Breast Screen Aotearoa service is adequately organised, audited and monitored in order to minimise the risk of errors at all stages, and whether it is on line to meet its target of reducing breast cancer deaths by 170 per annum after 5 years. Specifically it was also felt that some of the Gisborne Inquiry recommendations were also relevant to BSA. The present review was therefore commissioned in order to get an independent opinion from outside New Zealand on the organisation, audit and monitoring of BSA at this relatively early stage in its development, to assess its ability to meet its target of reducing deaths from breast cancer, and to recommend any improvements which are needed.

### **3. CONFIGURATION OF SCREENING SERVICES**

**3.1** When the development of a national breast screening programme was announced in 1995, the Regional Health Authorities invited tenders for six Lead Providers of screening. The decision to limit the number to six was presumably made in order to balance the benefits for quality control of a centralised system with the need to have screening centres reasonably accessible to a widely spread population. The size of population to be covered by each does not seem to have been an issue, and there is an almost five-fold difference in the number of women in the target population between the largest, Breast Screen Auckland and North (BSAN) with 104000 women, and the smallest, Breast Screen Health Care (BSHC) covering Otago and Southland, with a population of 22,000. The remainder are Breast Screen Midland, (BSM), covering the

Waikato area and the Bay of Plenty, with a population of 48,000, Breast Screen Coast to Coast, (BSCC), covering Hawkes Bay, Palmerston North and New Plymouth, with a population of 41,000, Breast Screen Central,(BSC) covering the Wellington area with a population of 33,000, and Breast Screen South,(BSS) covering Canterbury and Westland) with a population of 54,000.

**3.2** In order to make screening accessible for as many women as possible, all the Lead Providers operate a mobile mammography unit to visit towns with small populations for a defined period of weeks in each screening round. They also sub-contract screening, and assessment, to mammography services which exist in other clinics or hospitals within their catchment areas, but distant from the main site.

**3.3** Four of the Lead Providers, BSM, BSCC, BSC, and BSHC are in the public sector, their contracts being held by their local District Health Board, and two, BSAN and BSS are private. The BSAN contract is held by a private breast clinic, and that of BSS by a not-for-profit company set up in partnership by a general practitioner IPA and a private multidisciplinary breast clinic. There is also a mix of public and private provision in the sub-contracted units.

**3.4** The funding arrangements for BSA were not within the remit of this review, and I am unclear whether there is parity between the Lead Providers in terms such as allocation of resources per woman in the target population, or whether each was funded on an ad hoc basis according to their estimates of what it would cost to deliver the service to their own population.

**3.5** The Lead Providers vary not only in their size of population but also in their geographical catchment area and ethnic mix. These factors create particular problems for large Lead Providers in achieving adequate coverage and in managing distant sub-contracted screening sites, while at the same time providing high quality screening for the more local population in the main LP site. The size of population served by Breast Screen Auckland and North implies (with 70% coverage) 36,500 screens a year, larger than any of the 95 screening programmes in the UK. The audit of BSAN, (see Section 9 below), concluded it appeared to be fragmented, rather than being a single cohesive service, and highlighted some of its problems in communicating effectively with all its sub-contracted sites.

**3.6 Recommendation. Consideration should be given to establishing an additional Lead Provider to serve women living in North Harbour and Northland regions, and relieve the very large workload of Breast Screen Auckland and North.** (para 3.6)

#### **4. ELIGIBILITY OF WOMEN FOR SCREENING BY BSA**

**4.1** Breast Screen Aotearoa provides screening every two years for all well women aged 50 to 64 who are citizens of New Zealand. Work is currently in progress to assess the resources needed to extend the programme up to age 69. Within the age-range, certain categories of women are *not* eligible. These are

- Women who are pregnant
- Women with "significant" breast symptoms or signs
- Women who have had a mammogram within the previous year
- Women who have had breast cancer diagnosed within the previous 5 years.

**4.2** Apart from the pregnancy category which is excluded because of the risk of radiation to the foetus, the assumption is made that these exclusions are women who should be, or are being adequately managed by other parts of the health care system. Before attending for screening women fill in a questionnaire which includes questions about these aspects of their eligibility. If they have symptoms they are told to consult their general practitioner who will initiate diagnostic investigations. If they have had a mammogram outside the programme within the past year, they are asked to contact the screening clinic again one year after the date of that mammogram. If they turn up to the screening clinic and say then that they are aware of a breast abnormality, they may have mammograms taken, but if these are normal they do not go on to a full assessment but are told to discuss their symptoms with their GP. I am not certain of the extent to which all Lead Providers, or indeed to which all reception and MRT staff within one centre, follow these definitions of eligibility. There is also an obvious problem in assessing whether a symptom is "significant".

**4.3** My personal view is that, except for pregnancy, all women who contact BSA, and who have not been screened by BSA within the previous 2 years, should be accepted for screening. General practitioners should be discouraged from referring women with symptoms but if a woman turns up for screening and then admits to an abnormality she deserves a full assessment including clinical examination, even if the screening mammograms are negative, because it is known that there are a small number of cancers which are mammographically occult. If such a woman is just told to consult her GP there is no guarantee that she will do so, or even that she has a GP, and if she subsequently is diagnosed with breast cancer she may accuse the screening clinic of not investigating her adequately. The presence or absence of symptoms can be routinely recorded and results in symptomatic women analysed separately from the symptom-free majority. It may also be unwise to turn away a woman who has had mammography outside BSA within the previous year, firstly because nothing is known about the quality of that mammography, and secondly because the rejection may deter her from returning to BSA in the future.

**4.4 Recommendation. The Advisory Group for Population-based Screening Programmes should look again at the criteria for women's eligibility to be screened and assessed in BSA.**

## **5. POPULATION COVERAGE**

**5.1** Estimates of the number of lives which can be saved in New Zealand by BSA are based on the assumption that 70% of eligible women will participate in the screening programme. But coverage of the population is a major problem for BSA and will continue to be so unless some action is taken as a matter of urgency. In the first 2-year round of screening only 55% coverage was achieved implying that the benefits of screening for breast cancer were denied to nearly half the population. During the third year coverage has improved up to 61% (as at November 2001) but 3 of the 6 Lead Providers are still below 60%.

**5.2** There are, however, problems in the way that coverage is measured, arising from the fact that no population register is available to BSA. The number of eligible women can only be estimated from Census data updated by estimates of population change in post-Census years.

**5.3 Recruitment of women into the programme** has used a number of methods in parallel.

**5.3.1 Health promotion.** Information for the public about the programme is provided by a highly professional health promotion strategy, developed within the National Screening Unit. Carefully designed and tested media advertising is timed to saturate a locality shortly before screening is brought to it. Each Lead Provider is contracted to employ health promotion staff to work in the community to educate and raise awareness of the programme, and to liaise with health promotion departments in Public Health Departments, and with women's groups in the area.

Although I did not see breast cancer mortality rates broken down by ethnicity, I was informed that although Maori women have a lower incidence of breast cancer they have a high mortality rate. This emphasises the necessity for bringing the programme to Maori women, but for cultural and socioeconomic reasons recruitment is difficult. The fact that the screening process itself has to be done in such a clinical, high-tech environment presents a real challenge for acceptance within the natural holistic culture of Maori society. The Pacific Island population has the additional disadvantage of many language barriers. Maori and Pacific Island provider development staff in the National Screening Unit work with Independent Service Providers in the Maori and Pacific Island communities. The Independent Service Providers have identified key community leaders and contract with them to inform and educate the population, for example by holding meetings in Maori marae or in Pacific Island churches. The coverage for Maori women as of mid- 2001 was only 49%, and for Pacific Island women 45%.

**5.3.2 Free Telephone Line.** The Health Promotion strategy is backed up by a free telephone line which women can call to make an appointment to be screened. The relevant number is widely publicised in each Lead Provider's catchment area.

**5.3.3 General Practitioners** and other primary care workers are a very important source of recruitment, particularly if they have age-sex registers of their population of patients, to identify eligible women and invite them to be screened. Independent Primary Care Associations, (IPAs) which hold age-sex registers covering many GPs

in their area, are also potentially a very useful means of aiding recruitment. The Lead Provider, (BSS), with the greatest success in recruitment, reaching 76% of its estimated population by November 2001, has a contract with a very large IPA which covers a high proportion of its GPs, and the Lead Provider itself employs a worker to visit and recruit the remaining GPs in its catchment area. Each GP's list of eligible women is sent to the Lead Provider. Letters of invitation to each woman, together with a provisional appointment date, are sent out from the Screening Centre accompanied by a supporting letter from the GP.

One might wonder why the same system of recruitment by GPs is not more widely used by the Lead Providers with lower recruitment rates, and the NSU has recently started a project to examine this in more detail. But it is clear that there are differences in the organisation of primary care across the country, as well as in GPs' perceptions of the programme, which may act as barriers. For example, not all GPs have age-sex registers or have contracts with IPAs. There is one large IPA in Auckland which actively promotes breast screening outside the BSA parameters, by recommending clinical examination and reduced price private mammography routinely for all women over the age of 40 on its GP's lists. This has led some GPs to insist that they will only refer a woman to BSA after they have clinically examined her (for which she must pay).

Although the Quality Standards require each Lead Provider to have an identifiable staff member who contacts each GP or Primary Care Provider at least once every six months, this contact is not necessarily face-to-face but could be merely a newsletter. There is also a requirement to inform the GP about the result of every screen, so that over time GP awareness of the programme is bound to increase. It is clear that there is a need for more education of general practitioners and IPA's about the evidence on which BSA is based, including the age groups in which trials have shown that mortality can be reduced by screening, and the relative sensitivities of mammography and clinical examination in detecting early cancers. One possible means of increasing GPs knowledge of breast screening could be the use of health promotion staff, who are already well-informed about all the relevant issues, to extend their role from educating the public to educating primary care staff at all levels. However education sessions for primary care staff are a feature of BSC, but this Lead Provider had only achieved 57% coverage by November 2001

Contracts between the NSU and the Lead Providers include a fee, specifically for recruitment, of \$8 for each woman screened for the first time and \$5 for each routine repeat. But there is no check on whether these fees are actually used for recruitment. The system of payment of GPs in New Zealand, depending as it does largely on private fees, means that GPs require adequate financial recompense for all they do, including administrative matters such as compiling age-sex registers and identifying eligible women. I got the impression that BSS, which has achieved the highest coverage has spent considerably more money on recruitment through its GPs than any other Provider, but I learned of no estimate of the true cost involved. In other areas a few GPs have demanded payments which at least superficially seemed excessive in relation to the cost of their staff time in recruiting women. Support of GP's for BSA is very important, and it is essential that they understand their role and receive appropriate compensation for it.

**5.3.4 Routine Rescreens.** The second Lead Provider to reach the 70% target, BSHC, is one of those which took part in the pilot study when 75% coverage resulted from a combined approach using both general practitioners and the Electoral Roll (discussed further below) to recruit women. This Lead Provider's catchment population did not increase between the pilot phase and the start of BSA, with the result that its screening activity now comprises mainly routine rescreens, except for the youngest age-group. Invitations for rescreening are sent directly to women, and coverage is steady at around 72%.

**5.4 Development of a national age-sex register for health purposes.** The success of BSS, in reaching nearly 80% coverage, confirms a wealth of evidence that individual invitation, combined with a provisional appointment, and a letter of support from a known health worker, is more successful than even the very best package of health promotion, (which aims to educate not to recruit). But invitation implies that an accurate register, containing each woman's name, date of birth, and current address must be available. Clearly GPs' age-sex registers are a good model but, within the present primary care system in New Zealand, are not ideal for the BSA programme as a whole for a number of reasons. They are not universally available. Taken as a whole they may contain duplicates because a woman may consult as many different practices as she chooses and thus appear on more than one register. When a woman leaves a practice, for example when she moves to a different part of the country, her record does not go with her. And, many different computer systems may be used by GPs and IPAs to store their registers.

One single national computerised age-sex register would provide the answer. It would be of benefit to the whole population for many different public health services, ensuring equal access for all. It would also enable eligible groups to be invited to participate in programmes such as immunisation or screening, which is particularly important among those who might not otherwise be aware of their entitlement. As far as BSA and cervical screening are concerned it would have many advantages. Firstly it would provide a means of individually inviting every eligible woman when her screen was due. Secondly the date of each invitation and, for those who accepted, date of screening and summarised information of the outcome in terms of routine recall, referral for assessment, diagnosis of breast cancer, or other reason for exiting the programme, could be added, thus building a national database of every eligible woman's screening history. For women who moved to a new area this would give her new Lead Provider the date on which she was next due to be invited, as well as providing information on the true population coverage of BSA. Thirdly, some knowledge of reasons why women did not wish to participate (e.g. because they were having private mammography, or because they were already being followed up after an earlier diagnosis of breast cancer) could be investigated. Fourthly, it would assist the Lead Providers in scheduling their screening sessions, which would be of particular value for their mobile units which at present often have to guess at the number of "new" women who may attend either by dropping in or by calling the Freephone number.

**5.5** There are a number of different possibilities for compiling such a national population register.

**5.5.1. Primary care register.** If the system of payment for general practitioners were to change to a capitation fee rather than a fee for service, a population register for every GP would necessarily follow. Because its main function would be to pay the GP for each person on his list, the same person could not appear on more than one GP's list. When a person changed from one practice to another the register would be updated to show the move.

The report of the Gisborne Inquiry stated that it was official policy in New Zealand to change to a capitation fee system and that this would be complete for the whole country by 2003. But I understand that this will certainly not happen. Capitation fees are being introduced very gradually, implemented at first only for selected low income groups of the population, and it will take ten years or more before the change is complete. So this is not a satisfactory option for BSA.

**5.5.2 Electoral Roll.** Registration on the New Zealand Electoral Roll is compulsory and it is estimated that 98 – 99% of women aged 50 to 64 are registered, although the proportion among Maori women is lower. It is probably the most complete population register available. The Electoral Roll is updated every three years and may also be updated to show changes of address in the intervening period if a person notifies the Post Office of a change of address. The Register contains date of birth as well as name, (the only identifier of gender) and address. In the pilot studies of breast cancer screening the Electoral Roll was used and achieved over 70% participation. But its use was only possible because the Electoral Act permits the use of the Roll for the purposes of research that relates to a scientific matter or to human health. Use of the Roll for a service, as opposed to a research study, would not be permitted without a change in the law. Before embarking on the work involved to draft new legislation it is important to clarify exactly how the Roll would be used and what would be its advantages and disadvantages.

Each successive update of the Roll at 3-yearly intervals would need to be matched against the register of women known to each Lead Provider to update their information on who is still in their catchment population, who has moved away, and who has newly entered, either by moving in or by attaining the age of 50. The Electoral Roll has the disadvantage that it cannot recognise changes of name, for example by marriage, in successive updates of the Roll. Nor can it guarantee a nationally unique identifier since it is possible for two women to share both name and date of birth. It does not permit the addition of other information such as National Health Index Number, let alone a summary of each screening episode. Thus while its use would have great advantages for recruiting new women into their first screen, there are limitations to its use in compiling and maintaining an ongoing Breast Screening Register.

**5.5.3 National Cervical Screening Register.** A national register of women participating in the national cervical screening programme exists. This is said to cover 70% of women between the ages of 20 and 70, thus including the BSA age range. But within the overall participation rate there may be differences in particular age-groups. Access to this register is governed by Section 74A of the Health Act which states that no information on the register which identifies a woman may be disclosed without the consent of the woman. And similarly, for Maori women the Kaitiaki regulations prohibit disclosure without the consent of a Kaitiaki Committee.

Although the register is held within the NSU, it is unclear whether the NSU itself could seek to obtain the consent of women and Kaitiaki Committees, to their identification details being given to the relevant Lead Provider of BSA so that they could be invited to participate. In any case it would be of limited value because it is likely that the 30% of women not on the NCSR would be those same women who are hard to reach in BSA.

**5.5.4. The National Health Index System.** Starting in 1978 a National Health Index Number was allocated to every person in New Zealand who contacted a public hospital or other public health agency, (and to every child born in New Zealand). GP consultations, which are part of private health care, do not qualify as public health contacts. Women now in the BSA age range who have had any contact with public health providers over the past 24 years will have an NHI number. It is thought that the great majority of the population is on the NHI database but many people do not know that they have an NHI number. Even though all hospitals have access to the central database of NHI numbers if a woman does not know her NHI number when she contacts a hospital or other health agency she may be allocated a new one; thus duplicates may occur. A further problem is that there are instances where the same number has been allocated to more than one woman.

The central database of NHI numbers is held by the New Zealand Health Information Service, (NZHIS). Each number is linked to the individual's name, date of birth, sex and address at last contact with any health agency. A major exercise is now under way to clean up this register, identifying and removing duplicates, and correcting numbers allocated to more than one person. If this exercise can be completed quickly it offers the possibility that the NHI system could be used as a population register for BSA. It would however have the limitation of out of date addresses in an unknown proportion of the population.

A further barrier to its use for inviting women is the way that the Privacy Act and Health Privacy Code may be interpreted. This states that any person's health information can only be disclosed to a different health agency from that which collected it if the disclosure is directly related to the purpose for which it was collected. The term "purpose" in this connection could be taken by some to mean that the NHI number was only to be used in connection with a specific episode of health care for which the individual was consulting when the number was first allocated. Alternatively it could be interpreted in a much wider sense, as in the now defunct 1995/96 Guidelines for Regional Health Authorities which stated that the purpose of registration was to help with the co-ordination and provision of services, particularly preventive services. A current ruling on this issue, incorporating the views of the Privacy Commissioner, is still urgently required.

**5.6 Which Population Register offers most?** Although in the short term the Electoral Roll might seem to offer a one-off way of quickly recruiting more women into the programme, it does not offer a long-term solution. Even if legislation permitted its use for recruitment it could never be integrated into a wider health information system as a whole. It would have to be repeatedly used in an ad hoc way, matching it against the records held by each Lead Provider.

The National Health Index Population Register on the other hand could be developed despite its present inaccuracies, and could be used, *inter alia*, for a single national Breast Screen Aotearoa register. It would be important to build into it a system for up-dating changes of address and a link with general practitioners as well as other health agencies. A cross-Directorate Working Party within the Ministry of Health and New Zealand Health Information Service is already working on this, pressured by the need for a system to measure immunisation rates. The manager of the Information section of the NSU, and indeed the Group Manager of the NSU itself, are eminently well-qualified to contribute to the development of the NHI Register and have the skills energy and commitment to push it forward quickly, and should therefore be involved in the Ministry Working Group.

**5.7. Recommendation. The National Screening Unit should participate in the current Ministry of Health Working Party on Development of a National Health Index Population Register, and should exert continuing pressure on the Ministry and New Zealand Health Information service to implement the Register rapidly.**

**5.8 Public Attitudes towards Population Registers for Health Purposes.** The secrecy, prohibiting use of the cervical screening register in particular, seems to have resulted from a recommendation of the Cartwright Inquiry into under-treatment of women with cervical intra-epithelial neoplasia. The resulting Code of Health and Disability Consumers' Rights very properly protects consumers from being the subjects of *research* without informed consent. But in so doing it also seems to have created a climate of opinion in which the offer of a preventive *service* is regarded with extreme suspicion, fearing that a paternalistic medical profession is taking away people's freedom of choice. As a foreigner, I found the level of concern about protecting privacy extraordinary, even some health professionals I met expressing the view that they would suspect an invitation to be screened, (which they are at liberty to ignore or refuse), to be an invasion of their privacy. This attitude, assumed to be in the public interest by guarding individuals' rights, has the converse result of lessening the public's chance of benefitting from preventive services.

In taking forward the development of any register for use in public health programmes like BSA, it will be very important to include the views of the public. If the popular feeling remains " Privacy at all costs", then it must be recognised that one of those costs is ineffective and inefficient public health systems. But if the public, as represented for example by women's groups and by Maori community leaders can be convinced of the benefits of using a population register, opinion at large will realise that excessive concern with privacy issues is harmful to health.

## **5.9 Accessibility and Acceptability of Screening**

**5.9.1** A further factor influencing the up-take of screening is its accessibility to the eligible population.. Unlike cervical screening which can be done in a local facility already known to the woman, mammography, because it requires specialised equipment and the specialised skill of Medical Radiation Technologists, (MRTs), has to be centralised in specialised units. There are great advantages in centralisation for quality assurance and cost, which presumably is the underlying reason why it was decided that the service should be delivered by only six Lead Providers. But in a large country with a thinly spread population they have to contend with the problem

of enabling women to reach the screening units. This is done by a combination of sub-contracted fixed screening sites, usually in hospitals serving communities far from the Lead Provider's main centre, and by the use of mobile screening units which are towed to different localities and remain there for a set period of time judged to be sufficient to screen the local population. I had the impression that, surprisingly, the need to travel long distances for screening was less of a problem in very rural areas where people are accustomed to driving to town, than in outer suburban areas where people on low incomes may not have a car and have to rely on public transport. This seems to be a particular problem for many Maori and Pacific Island women. The siting of the main Lead Provider Units in Auckland and Wellington, which have the lowest coverage rates, are not ideal from the point of view of accessibility by public transport.

**5.9.2** The immediate environment of the screening unit may also be important. It is generally accepted that a service for well women should be provided in a non-clinical environment, where they do not mix with patients attending hospital. Two of the six Lead Provider Units have adapted erstwhile private houses, which provide the ideal environment, although one of them, BSCC, is too small. Two others are located in radiological clinics in buildings on the campus of a general hospital but physically separate from it. The remaining two are inside general hospitals. One of these, BSC, is close by the main entrance and women who see the notice for Breast Screen Aotearoa can reach it without mixing with patients at the hospital's main reception desk. The second, BSHC, is in a very unsatisfactory environment, on the first floor of the hospital, sharing facilities with the Nuclear Medicine Department, which one supposes could deter some women. Nevertheless it must be acknowledged that this unit which was one of the pilot programmes, has overall achieved the target of 70% coverage and the bulk of its work is now mainly rescreens. It also has one sub-contracted fixed screening site, and one mobile so it is possible that coverage may be higher for the latter two, and lower for the main site. Two years ago this Lead Provider was given additional funding to convert premises on the ground floor of the hospital with a separate entrance, which would provide a much more suitable environment. But the District Health Board which administers the funding has so far not managed to vacate the premises as promised, to allow the conversion to proceed. There seems no sense of urgency in this DHB to use the money for its intended purpose. The NSU should consider taking sanctions against this DHB, for example by not funding the DHB's overhead costs for administering the screening centre.

**5.9.3** I did not visit any of the sub-contracted fixed screening sites so cannot comment on the suitability of their environments. I was impressed with the one mobile unit I visited, where the welcoming friendly attitude of the receptionist and the MRT more than compensated for the necessarily cramped surroundings.

**5.9.4** Staff attitudes are another aspect of the acceptability of the service. The front line staff for breast screening are telephonist/receptionists and MRTs. From the brief superficial observations I was able to make, both these categories of staff were excellent in their interaction with women. They were cheerful, friendly, spoke in a calm reassuring manner, and gave correct and honest information about the screening process and its limitations. I had the impression that those whom I met enjoyed their jobs and got much satisfaction from them. The acceptability of the service to the great

majority of women who attend is confirmed by the audits which have so far been completed. (See Section 9 below)

## **6. QUALITY OF SCREENING**

**6.1** The quality of taking screening mammograms and the quality of interpreting them are the determinants of sensitivity and specificity. Quality is routinely monitored by the Independent Monitoring Group and by the system of auditing standards, which are discussed in Sections 8 and 9 below. My visits to each of the Lead Providers were necessarily short and could not assess quality issues. Rather their purpose was to meet the people providing the service and gain a general impression of how the screening and assessment processes were functioning. The following notes summarise my understanding of how screening is conducted in each of the six Lead Provider centres. Although describing the process in what some may feel as unnecessary detail, they are included so that readers can assess whether my understanding of how BSA is functioning is correct.

**6.2 Technical quality** of the mammographic and processing equipment, and ultrasound equipment used in assessments, can also affect sensitivity, and regular quality checks are mandatory to ensure that physical performance and radiation protection standards are met. A team of six medical physicists take responsibility for regular detailed inspections throughout BSA, and the MRTs test some parameters routinely. Not having knowledge of physics I am unable to comment on this aspect of BSA except to note that the standards for optical film density and mean absorbed glandular radiation dose have been met in the Lead Providers which have thus far been audited. I was however told of one incident in which a mammography machine in one of the sub-contracted sites was not adequately meeting the standard in pre-BSA tests and was not retested prior to its use in BSA. This was known to the physicists but initially they took no action to report to the Lead Provider, demonstrating that even in this highly technical field human failures may occur.

**6.3 Taking Mammograms.** This is the responsibility of Medical Radiation Technologists, (MRTs). If the mammogram does not include the whole breast, or if the film is of poor technical quality, it is possible that some cancers may not be visible. Two views, mediolateral oblique and craniocaudal, are taken of each breast routinely both for first screens and for repeats. This practice, rather than a single oblique view has been shown to increase both sensitivity and specificity. So far as I could judge, the performance of the MRTs was of high quality, although some Lead Providers were not quite meeting the target for a low rate of repeat mammograms taken for technical reasons. MRTs are obviously conscious of the pain caused by compression of the breast and I had the impression from those I observed that they minimise the period of compression and deal sympathetically with the women.

**6.4 Reading of screening mammograms.** This poses particular skills, different even from the reading of private mammograms of symptomless women. In the latter case the radiologist has the opportunity to read the films while the woman is still present, to take further views or ultrasound if necessary, and to talk directly to the woman. In the case of screening, however, the radiologist has to make a decision just on two films of each breast. The team of radiologists working in each Lead Provider unit are well trained in mammography interpretation, having had to undergo a formal

testing system set up by the Royal Australasian College of Radiologists, and having to meet a standard volume of reading at least 2000 screening mammograms each year.

The verdict on each woman is recorded independently by two radiologists, each of whom enters his/her recommendation for further action into the computerised record system. If no abnormality is present the verdict is "routine recall" for repeat screening in two years. If further imaging, clinical examination, or tissue diagnosis is required to diagnose a suspected abnormality the verdict is "refer for assessment", and additional descriptive details of the abnormality are also entered.

Because it is recognised that interpreting mammograms is a difficult skill, a system of double reading by two radiologists, independently of each other, is observed throughout BSA. If both agree on the verdict the appropriate action is taken. If they disagree then further consultation is required. This differs between different Lead Providers, most referring the case to a third radiologist, but others relying on discussion of the films by the two radiologists to reach a consensus.

**6.4.1 Internal quality control for individual radiologists.** The Clinical Directors of each Lead Provider have set up systems of ensuring that all radiologists working in the Centre are able to compare their film reading with each other. Some of the Clinical Directors arrange internal meetings to review films on a weekly basis, others less frequently. The film reviews focus particularly on any interval cancers that are known, and on the outcomes of cases referred to assessment. In addition each Lead Provider is paired with another, and every month each sends to its partner a set of ten films so that their interpretation can be compared. At least one Lead Provider, BSHC, has set up a formal protocol for acting on any disagreements but I am uncertain whether this applies to all.

The BSA Quality Standards specify that a radiologists' meeting for the whole Lead Provider region should be held at least once every 3 months. But in two of the Lead Providers, (BSAN and BSCC) I had the impression that they were not actively involving radiologists in sub-contracted sites to participate in these exercises, while in others there were obviously very close working relationships between main centre and sub-contractors. The frequency of radiologists' film review meetings is audited every two years, but this may not be sufficient.

**6.4.2 Recommendation.** The Clinical Directors of each Lead Provider should submit an annual return to the National Screening Unit showing the number of film review meetings attended in the year by each radiologist, regardless of whether he/she works in the main centre or a sub-contracted site.

## **6.5 Assessment of Women with Suspected Abnormality**

**6.5.1** Appropriate care is taken in informing women that they need to return for assessment. In most cases it is the task of the Breast Care Nurse to telephone the woman, while at the same time introducing herself and reassuring the woman that she will be there to support her at the assessment clinic. The Breast Care Nurses whom I met were dedicated to supporting women throughout the diagnostic process.

**6.5.2** The radiologists who read the screening mammogram record details of the suspected lesion and recommend the further imaging which is required. This may be further mammographic views and/or ultrasound. A clinical examination of the breasts may also be performed. In the majority of cases these investigations prove negative and the woman is informed that she can now return to routine rescreening in two years' time.

**6.5.3** Sometimes the radiologist is still slightly concerned, even after these further tests, but not sufficiently so to recommend biopsy, so recalls the woman for a repeat assessment visit after some months. In the past the Independent Monitoring Group noticed that some of these "extended assessments" were being repeated over a long period of time and that a number of them eventually progressed to a diagnosis of cancer. Therefore a new standard has recently been introduced, stipulating that the radiologist is permitted to recommend that a woman be recalled to only one further assessment clinic visit in either 6 or 12 months. If the lesion is stable or has regressed she is recalled for bilateral mammography 24 months after the last screen and is then put back into the routine rescreening category. Otherwise a biopsy should be performed at the second assessment visit. These extended assessment verdicts should comprise less than 1% of all assessments

**6.5.4** Whenever the assessment tests indicate a lesion needing a pathology diagnosis, the radiologist, or the surgeon if he/she is present normally performs either a fine needle aspiration or a needle core biopsy, under ultrasound or stereotactic X-ray control unless the lesion is palpable. Both fine needle aspiration cytology or core biopsy are permitted within BSA. Until a few years ago fine needle aspiration cytology which provides a cellular, as opposed to a tissue diagnosis was the preferred method, and some pathologists who are skilled at cytology still prefer it. But the development of needle core biopsy, in which a narrow core of tissue is removed from the lesion, to be examined histologically, is preferred by most pathologists because it enables a more specific diagnosis to be made. In a small number of cases needle aspiration or core biopsy are inadequate or impossible, or show possibly significant lesions such as atypical ductal hyperplasia, and the woman then has to undergo open biopsy under general anaesthetic. After the biopsy the woman is told when the result will be available and is given the option of returning to the clinic or being told the result by her GP – an option offered because some women live very far away from the Assessment Centre.

**6.5.5 Multidisciplinary Meetings.** For every woman who has a pathology procedure the final diagnosis is decided by a multidisciplinary meeting which reviews the histology/cytology alongside the mammographic films. Ideally the disciplines present at these meetings should include the Lead radiologist, the radiologists who read the screening films, the Lead pathologist, the Lead surgeon, the Breast Care Nurse, and MRTs. In order to minimise the time a woman has to wait for her result, these multidisciplinary meetings should be held as close in time as possible to the assessment clinics.

In some Lead Providers a "Results clinic" is held immediately after the multidisciplinary meeting, at which the women can be told their diagnosis. This may be done by the surgeon or the radiologist, and in every case the Breast Care Nurse should also be present. In the case of women found to have breast cancer, one of the

supposed duties of the Lead Surgeon is to discuss treatment options with the woman, but this is an impossible requirement because at this stage he/she does not have information on stage, grade, ER status, etc., on which options for extent of surgery and adjuvant therapy depend. All that can be done is to inform the woman of the range of treatments which *may* be suitable for her and to inform her of the hospitals where she may be treated. The Breast Care Nurse will normally provide ongoing support and liaise with the treatment hospital chosen by the woman.

In general the multidisciplinary meetings seemed to be running satisfactorily, although I felt that to hold a meeting only once every two weeks, (the maximum interval set down in the Quality Standards) means keeping some women in anxiety for too long. In practice, four of the Lead Providers hold multidisciplinary meetings at least weekly, one fortnightly, (BSAN), and one (BSCC) does not hold a multidisciplinary meeting as such but substitutes for it a meeting between Clinical Director and Lead Pathologist the day after a specimen has been sent for histology. This has the advantage of letting the woman know her diagnosis, (normally told by the Clinical Director), very quickly, but misses out on the benefits of a full discussion of the case and its management by all the disciplines concerned, thus losing the opportunity for continuing education, as well as having a possible effect on clinical management. This Lead Provider is shortly to have its 2-yearly audit, and I would expect that this issue will be dealt with as a result of the audit report.

Assessment clinics and multidisciplinary meetings are held at some of the sub-contracted sites but I did not visit any of these. The Clinical Director in each Lead Provider centre is supposed to organise a multidisciplinary clinical meeting with all relevant professions from all assessment centre sites within the region at least once every six months. It was clear from some of the Clinical Directors I spoke to that they had a very close working relationship with their sub-contracted clinical colleagues, but with others I received the impression that relations were not close and in some cases strained. The Audits should always include details of multidisciplinary meetings between the main centre and sub-contracted sites.

## **6.6 Measuring the performance of the Screening and Assessment process**

There are a number of indicators of how well the screening process is performing; the detection rate of cancer, the stage distribution of screen-detected cancer, the sensitivity of screening and the specificity of screening. These are all being measured in BSA by the Independent Monitoring Group. (See Section 8 below).

**6.6.1 The detection rate of cancer.** In the first round of screening, when women are being screened for the first time, breast cancers which are prevalent in that population will be detected. Some of these cancers may be relatively large and on the verge of being symptomatic while at the other end of the spectrum others will be very early in their development. Hence the detection rate will be higher than the normal incidence of cancer in the absence of screening. In subsequent rounds, the rate of detection will approximate to the normal incidence but should contain a high proportion of very early cancers. In all Lead Providers, the rate of detection in the first (prevalent) round has met the expected level, at >6 cancers per 1000 women screened. The overall rate in BSA as a whole in the first half of 2001 was 8.1 per 1000. In subsequent rounds,

again all Lead Providers have has met the expected target of >3 per 1000 women screened. The rate for BSA as a whole in the first half of 2001 was 5.7.

**6.6.2 Stage Distribution of Screen-detected Cancers.** Size of invasive tumour, and nodal involvement are the two measures of stage used to assess screening performance. The Independent Monitoring Group will not analyse data on stage of cancers detected until it is available for 90% of cancers detected by that Lead Provider in a given time period. Due to difficulties which the Lead Providers have had in retrieving treatment data (see 7 Below) no information was yet available for BSA as a whole at the time of this review. The detail of stage of cancer detected, (including the differentiation between invasive and in situ), was only available for analysis from one Lead Provider, BSCC, which was meeting the targets.

**6.6.3 Standardised Detection Ratio.** A statistical technique for refining the overall invasive cancer detection rates to take account of differences in the ages of women being screened and to measure them against the rates obtained in the Swedish 2-Counties trial of screening (the "Gold-Standard") has been developed in the UK. It depends on estimates of what the age-specific incidence of breast cancer would be if no screening took place. Called the Standardised Detection Ratio,(SDR), it gives a score of 1 to a screening programme that is exactly matching the Swedish detection rate, less than 1 means it is not doing so well and more than 1 means that it is doing better. This technique can be applied to New Zealand, using the trend of incidence rates from the New Zealand Cancer Registry in the period before screening started to extrapolate what is the underlying incidence now in the absence of screening. This SDR is a useful, easily understood way of comparing one programme with others, and should be used in BSA as soon as sufficient data on invasive, as separate from in situ, cancers from all Lead providers are available. The SDR, as expected, is inversely proportional to the interval cancer rate, but cannot be accepted as a substitute for finding out the exact number and characteristics of interval cases.

**6.6.4 Sensitivity of Screening.** Sensitivity measures the performance of the screening process in detecting all the cancers that are present, and not giving any false negative results. In practice the only way of finding out about false negative results is by identifying all breast cancers which are diagnosed in screened women in the interval after a negative screen and before her next routine screen is due - so-called "interval cancers". The Independent Monitoring Group, working with the Cancer Registry, is just starting the process of identifying interval cancers (See 8. Below) but no information is yet available.

**6.6.5 Specificity of Screening.** Specificity measures the performance of the screening process in correctly clearing women who do not have breast cancer, and not giving any false positive results. It is calculated as the percentage of screened women without cancer who are allocated to routine recall on the basis of the screening mammograms. Women who are referred for assessment and who are found not to have cancer are regarded as having false positive results. The statistical analysis of specificity is conducted by the IMG at quarterly intervals and results are available at present for the second quarter of 2001. At this time the target of 93% specificity at the prevalent screen was only just being met in BSA as a whole,(92.7%) and in one Lead Provider, (BSHC) was below 90%.

(However this Lead Provider was doing comparatively few prevalent screens at this time, and it could be that this was a problem more apparent than real, due to small numbers. It would be useful to see the 95% confidence intervals around estimates such as this.)

In subsequent "incidence" rounds of screening, specificity is higher, aided by the increased knowledge given by the availability of earlier mammograms of the same women. All Lead Providers were above 96% specificity in "incidence" screening rounds.

Other ways of looking at specificity, which highlight the potential anxiety and morbidity caused to women by false positive results, are by measuring the proportion of women who are referred to assessment, the proportion who have to undergo needle biopsy and the proportion undergoing open biopsy. These are all routinely monitored within BSA, and are at acceptable levels.

## **7. QUALITY OF TREATMENT OF SCREEN-DETECTED CANCERS**

**7.1** An argument was put to me by a pathologist on one of the BSA audit teams that the responsibility of the screening programme ended at the point of diagnosis and that the quality of treatment was outside its remit. I disagree most strongly with this point of view. One need look no further than the episode which was the subject of the Cartwright Report where failure to treat screen-detected cervical abnormalities resulted in needless mortality and morbidity. It is essential that BSA follows up all the screen-detected cancers to ensure that they are adequately treated. But the diversity of surgeons and hospitals providing treatment creates some difficulties in obtaining routine information.

**7.2** When a woman is told by BSA that she has breast cancer she is given the option to receive free treatment in any public hospital, and is provided with a list of public hospitals in the area in which there are surgeons who care for patients with breast cancer. Or she may opt to be treated by a private surgeon in a private hospital of her choice, in which case she (or her personal health insurance) will have to pay. The surgeons involved in treating these patients in any one Lead Provider's area can number 10 or more, and similarly a large number of pathologists may report on the operation specimen. According to the woman's wishes the referral to a surgeon may be arranged by the woman's GP or directly by the Lead Provider. If radiotherapy or chemotherapy is required she will have to go for this to one of six oncology departments in New Zealand, all in public hospitals. In a large proportion of cases, the woman may be treated in a hospital with no BSA connection, and the Lead surgeon and the Lead pathologist in the Screening Centre where she was diagnosed may have no further part in her care. In practice in most Lead Provider centres the Breast Care Nurse takes responsibility for finding out where the woman is being treated, and for liaising with a hospital Breast Care Nurse there.

Concern was raised by several of those I met about the proportion of BSA-diagnosed patients who were being treated privately in Auckland, said to be around 50%. This was an issue when BSAN was audited in 2000. However the leaflet now given to these women by BSAN specifies fully and clearly the different public hospitals in which they can receive free treatment. Moreover BSAN now adopts a policy that the

referral to a surgeon can only be done after the woman has discussed the options with her GP.

**7.3** The budget for BSA as a whole allows for District Health Boards to be refunded by the NSU for the costs of treating women in their public hospitals, but since the treating clinicians there may not be aware which of their patients have come via BSA, it is not clear how often this funding is claimed. The impression was gained that BSA patients get "lost" among non- BSA breast cancer patients, and although this does not necessarily affect the quality of their care it certainly makes it difficult to retrieve information about their management.

**7.4** The revised Quality Standards for Treatment, (still in draft form), require the Lead Provider to ensure that women referred for treatment have access to a specialist multidisciplinary team, including oncologists and ideally within a designated breast unit, and that the team follows evidence-based guidelines on management of women with breast cancer. The Breast Section of the Royal Australasian College of Surgeons produces such guidelines, and has set up a system for auditing the treatments used by surgeons who voluntarily agree to send in structured forms about all their breast cancer patients. Where a patient who lives in a remote area opts to go to a "low volume facility" (less than 150 breast cancer cases treated per annum) that facility should develop formal links with a larger unit and collaboration with regional oncologists. One possible means of encouraging achievement of the target of providing evidence-based multidisciplinary treatment would be for the Lead Providers to emphasise to newly diagnosed breast cancer patients the advantages of treatment by a multidisciplinary breast team which participates in the Royal Australasian College of Surgeons Breast Cancer Audit.

**7.4.1 Recommendation** **The information given to women about where they may receive free treatment should identify by name those surgeons who are participating in the RACS Audit.**

**7.4.2 Recommendation** **The NSU should offer differential treatment payments to DHB's employing surgeons participating in the RACS Audit.**

**7.5 Availability of Radiation Therapy.** Several people I met raised the problem caused by the shortage of radiotherapy in New Zealand, which means that women with breast cancer may have to wait 3 months post-surgery for adjuvant radiotherapy to be started. This was felt to be a particular problem for women with DCIS, for whom local excision with adjuvant radiotherapy was prescribed, but among whom some (or their surgeons) were opting for mastectomy in order to ensure that treatment was completed promptly. The purpose of adjuvant radiotherapy is to kill off any malignant or pre-malignant cells that might be occult in the remaining breast tissue after local excision. At least one trial has shown that local recurrence of breast cancer in patients, treated for DCIS by local excision, is reduced in those who have adjuvant radiotherapy. But there are no data that I know of about the time interval between surgery and radiotherapy. Intuitively one may doubt whether many cells with occult malignant change will progress to invasive cancer within three months. Decisions about the optimum treatment for DCIS must await further randomised controlled trials, and it seems likely that different treatment regimes will be recommended for lesions with different markers of malignancy. In the meantime the shortage of

radiotherapy remains a problem for women with invasive cancer as well as those with in situ disease, but it is outside the remit of this review.

**7.6 Monitoring the Quality of Treatment.** Given the diversity of treatment sites it is not surprising that there has been considerable difficulty in retrieving information. Standard record forms have been drawn up, both for the detailed pathology of the excised cancer and axillary nodes, and for the type of surgery, radiotherapy, endocrine therapy and chemotherapy given as part of definitive treatment. But the pathologist, surgeon and oncologist concerned may be unaware he/she is supposed to complete a BSA record for a particular patient among many others. Moreover, even if aware, many pathologists and surgeons are unwilling to complete synoptic forms designed for computer entry, and prefer to depute this task to other staff to abstract data from their text record. The ease of collaboration between different pathologists is made more difficult by the intense competition between different private pathology laboratories.

**7.6.1 Final Pathology Record .** As already seen, one of the early criteria for judging the performance of screening is the detection rate of small invasive cancers, and node-negative cancers. This information is not available from the needle biopsy, and thus the Screening Centre has to find out the final pathology result, giving the type of tumour (invasive or in situ), size of tumour and nodal status. For breast cancers diagnosed in screened women up to the end of March 2001, only one Lead Provider, (BSCC), had reached the target set by the Independent Monitoring Group that treatment data should be available for 90% before the IMG would conduct an analysis by stage. Two LPs, (BSC and BSHC) were particularly behind. In the Lead Providers which are doing well, particularly BSCC this is entirely due to the efforts of the Breast Care Nurses who spend a large part of their time visiting a number of different hospitals and abstracting data from case-notes.

The detailed pathology record is increasingly recognised to be an important determinant of adjuvant therapy. In deciding how to treat an individual case information is not only needed about size and nodal status but also nuclear grade, vascular invasion, Estrogen and Progesterone Receptor status, and possibly other markers of malignancy in the future. In speaking to pathologists in the six Lead Provider centres, and in observing coding of breast cancer reports in the Cancer Registry, I was impressed at the completeness and organisation of written reports, which all contained the needed information. But there is still an unwillingness to report on synoptic forms. Although the Breast Care Nurses are doubtless well-trained and competent to abstract these data, this is not part of their job and should not be their responsibility. It would be preferable if the Lead Pathologist in each Lead Provider took responsibility for completing the record forms not only for the cases he/she reports on personally, but also for obtaining completed forms from colleagues in all hospitals to which women are referred. This would not only have the advantage of placing responsibility for the accuracy of the report on the person who makes the diagnosis, but also would give the Lead Pathologists a greater sense of involvement in BSA as a whole, particularly in terms of the stage at which cancers are detected. I felt that some, but not all, Lead Pathologists saw their role in BSA as ending after they have reported on the biopsy and discussed it at a multidisciplinary meeting.

**7.6.2 Recommendation The Lead Pathologist in each Lead Provider should not only complete synoptic forms about his own specimens, but also obtain synoptic forms from colleagues in other laboratories who have examined breast cancer specimens from women diagnosed by BSA.**

**7.6.3 Treatment Record.** A very detailed form has been drawn up by one of the Lead Surgeons in BSA to record clinical features, including the sites of any distant metastases if present, date(s) of treatment, the type and extent of surgery performed, and the adjuvant treatments prescribed. It also has one item, "Status one year after diagnosis" which if observed would delay submission of the data as well as being irrelevant to monitoring BSA. There has been some criticism from other surgeons that the form is more detailed than is necessary and that they have to fill in various similar forms as part of the audit of their work. An association of breast surgeons in Auckland already participates in a local breast audit, and many New Zealand surgeons are also members of the RACS Breast Section Audit mentioned above. Those who are members have declared their special interest in breast cancer and have agreed to submit completed forms for all their breast cancer patients to the Adelaide office of RCAS. In order to avoid duplication of effort and encourage closer involvement of surgeons in BSA, the RCAS Audit Form could be adopted for use in BSA, and incorporated in the Lead Providers' information systems.(See 10 below) Selected items, judged to be essential, such as characteristics of the tumour, and adjuvant therapies prescribed, could then be abstracted for the BSA data-base and transferred to the IMG for regular analyses.

**7.6.4 Recommendation The RACS Audit form should be adopted for use as the treatment record for BSA, and incorporated into its information systems.**

**7.6.5 Recommendation The Lead Surgeon in each Lead Provider should not only complete RACS forms about his own patients, but also obtain RACS forms from other colleagues who have treated women diagnosed by BSA.**

## **8. THE BSA INDEPENDENT MONITORING GROUP**

**8.1** In the planning stages of BSA it was recognised that there would be a need to monitor the extent to which the programme was meeting its targets, and to conduct regular audits of each Lead Provider's compliance with quality standards. Accordingly, in January 1999, the Health Funding Authority entered into a contract with the University of Otago to provide an Independent Monitoring Group for BSA. Membership of the Group comprises two epidemiologists and one data analyst who undertake the statistical work, and representatives of all the professional disciplines involved in BSA, who assist in interpretation of the findings.

The IMG devised a plan for providing quarterly reports to the HFA (now NSU) to each Lead Provider, and this has continued since October 1999. Originally it was intended that the IMG should also be responsible for 2-yearly audits of each LP, but following discussion with BreastScreen Australia, the HFA decided that it would take direct responsibility itself for arranging the audit teams.

**8.2 Statistical monitoring of Performance.** Every month the Data Manager in each Lead Provider submits to the New Zealand Health Information Service, (NZHIS),

details of each woman screened, comprising the national monitoring data-set which consists of standard items relating to the different targets of the screening process. NZHIS validates the NHI number of each woman. The list is held in encrypted form in the BSA database at NZHIS. NZHIS sends a copy of the entire database to the Information Section of NSU by secure electronic transport with the NHI numbers unencrypted. Here various consistency checks are made and any queries resolved with the LP Data Managers. At 3-monthly intervals, the corrected encrypted data-set is sent from NZHIS to the Independent Monitoring Group for analysis.

The analysis includes the cohort of women screened in any given quarter. A draft report on the analysis is sent to NSU, who then send it on to all Lead Providers for comment. A meeting of the full IMG is then held to consider the responses and agree a final report which is then made public.

The IMG Reports have proved very useful in the early stages of BSA in identifying deficiencies in data quality, improving understanding and improving consistency between Lead Providers which use different information systems. It enables LPs to compare their performance with others, and to see how performance changes over time. It has also identified areas needing improvement, the principal one being accurate knowledge of population coverage. It has also highlighted the difficulty in obtaining treatment data mentioned above, which means that, except for one Lead Provider, it is not yet able to analyse the size and nodal status of screen-detected cancers, one of the criteria for judging the success of the screening programme.

**8.3** The IMG is playing an absolutely essential role in BSA and is a strong safeguard against serious failures such as have occurred in the past. Nevertheless there have been some problems, chiefly centring around the way it is perceived by the providers of screening and to some extent by the NSU. The volume of work generated by the quarterly reports is very large, and the reports, consisting largely of black and white summary tables are far from user-friendly. The comparisons of how well each Lead Provider is doing in meeting its targets do not give any indication of the number of events on which percentages were based in each quarter. I therefore felt it would be useful to show both numbers of events and 95% confidence intervals around each figure so that one could judge how serious any deficiencies were. On the other hand I had the impression that some senior members of LP staff, not accustomed to reading statistical reports, had given up studying them as carefully as they should. Moreover the text, which inevitably high-lights areas requiring improvement was sometimes judged to be too disciplinary in tone, and this, coupled with the IMG's emphasis on its own ethical imperative, made it seem somewhat sanctimonious at times. There was also a feeling that the providers were being lectured by those who did not know what it was like "at the coal-face", and the IMG was not seen for what it is, a Group contributing to the quality of BSA as a whole and therefore on the same side as the providers. All of these deficiencies are minor compared to the value of the IMG's work, and can relatively easily be resolved by improvements in communication.

**8.4.1** In my view, now that the whole programme is securely established, quarterly reports are too frequent and occupy a large amount of professional time in the Lead Providers, the NSU and the IMG itself, which could well be spent on other priorities. Also, to obtain treatment data on women with breast cancer an interval of at least 6 months after screening is required. Apart from coverage of the population, which is

in any case calculated routinely by the Information Section of NSU, the other variables in IMG are subject to variation due to the relatively small numbers of events in any LP in any quarter. I do not consider that the safety of BSA would be seriously compromised by less frequent reporting.

**8.4.2** The format of the reports could also benefit from change, with more use of colour-coding for each LP and use of bar charts, histograms and graphs showing changes over time. Even with 6-monthly reporting, the number of some events in some LPs will be small and it would therefore be useful always to show 95% confidence intervals around each calculated percentage.

**8.4.3** Once the required data-flow of pathology information is adequate, the IMG could present invasive cancer detection ratios (SDRs) for each LP annually. Since the SDR depends on assumptions about the underlying age-specific incidence rate in the absence of screening, based on trends from the New Zealand Cancer Registry for a few years before screening, it is important that this should be done promptly. There may however be difficulties caused by the fact that the Cancer Registry showed an apparent increase in incidence in the early 1990's due to the fact that registration became a statutory obligation. It may be possible to adjust for this artefactual increase, for example by comparison with the increase in other cancers.

**8.4.4 Recommendation** **The frequency of routine IMG reports should be decreased to 6-monthly and their format altered to include more graphics, 95% confidence intervals round estimated proportions, and an SDR for each Lead Provider at least once a year.**

**8.4.5** Because sub-contracted screening and assessment sites are likely to have a smaller throughput of women, they may be more vulnerable to lower achievement. But at present their performance is only investigated at the 2-yearly audit of each Lead Provider. The performance of sub-contracted sites is not presented separately in IMG Reports from the main site of the Lead Provider. It is often not possible to do this because the screening films may be read centrally (e.g. when taken on a mobile), but the assessments done at a sub-contracted site. However where both screening films and assessments are done at a sub-contracted site for a defined number of women it would be useful for the performance of the sub-contracted site and the main site to be analysed separately by the IMG at, say, yearly intervals.

**8.4.6 Recommendation** **For Lead Providers which have sub-contracted sites to do both screening and assessment of the same women, results for the main site and for each subcontracted site should be analysed separately by the IMG once a year.**

**8.4.7** The initial emphasis on the *independence* of the monitoring group was, in my view, detrimental to establishing a good working relationship with the Lead Providers. Rather than being seen as an outside body it would be preferable for the IMG to be accepted as an integral part of BSA, in which the epidemiological skills of its key workers complement the clinical skills of the Lead Providers and managerial skills of the NSU, in ensuring the provision of a high quality service. A closer relationship could be fostered if the key workers in IMG attended the various unidisciplinary meetings (see below) arranged for Lead Provider staff categories. This would enable

discussion of problems, interpretation of data, and greater understanding of the complementary benefit of each others' roles.

**8.4.8 Recommendation Epidemiological members of the IMG should attend unidisciplinary meetings at which Lead professionals of the Lead Providers meet to discuss common interests and problems.**

**8.4.9** The role of the non-epidemiological members of the IMG is questionable. Originally the Group was convened with representatives of all the disciplines involved in BSA with the intention that they should form the Audit team. But in the event, that suggestion has now lapsed, and their role, despite their commitment and their knowledge of screening, seems confined to commenting on the statistical reports, in addition to comments from the Lead Providers themselves. They may more usefully be deployed as consultants to the NSU (see 12.5 below) or as members of the Advisory Group; (one of them already is).

**8.4.10 Recommendation. The NSU should examine the role of the non-epidemiological members of the IMG.**

## **8.5 Interval Cancer Protocol**

**8.5.1** It is greatly to be welcomed that the IMG is now able to start measuring the incidence of interval cancers, and incidentally of breast cancers in eligible women who were not screened in BSA. This is a most important aspect of BSA because it is the only way in which the sensitivity of screening can be directly measured. I question why it was regarded as necessary for this work to be judged by a research ethics committee, since it is not research but an essential service for monitoring the quality of BSA. It can do no harm to any woman but can benefit many. Moreover all women who participate in BSA sign a consent form specifying that their information will be used for monitoring the programme and may be given to the NSU or its agent (the IMG), and, if relevant, to the NZ Cancer Registry.

**8.5.2 Recommendation The approval for the work on identification of interval cancers to go ahead which was given, on behalf of all the regional Ethics Committees by the Otago Ethics Committee, should not be restricted to a 3-year approval but should apply for the whole duration of BSA.**

**8.5.3** Details of all women diagnosed with histologically verified breast cancer since 1995 and who were aged 50 to 69 years at diagnosis will be extracted from the NZ Cancer Registry and matched against the BSA Data-Base, held in the NSU. By comparing date of diagnosis with information about the date and outcome of each screen, the women can be subdivided into

- those whose cancer was screen-detected,
- those who were diagnosed within 2 years of a negative screen,
- those diagnosed more than 2 years after a negative screen,
- those diagnosed after a positive test but negative assessment,
- those diagnosed while on extended assessment,
- and those who had never participated in BSA.

The stage distribution of cancers in each of these groups will be compared, and compared with the stage distribution of breast cancers registered before the start of

BSA. (A minor easily correctable fault is that the current form for recording interval cancers omits any mention of nodal status, thus preventing accurate information on stage from being recorded).

It is important that the stage-specific incidence of breast cancers in women who have never participated in BSA should be included in this exercise, for this will show whether non-participants are at greater or lesser risk of dying from breast cancer, and hence get some information on the effects of the problem of non-participation. It may be impossible to look up their medical records because they will not have given permission for this audit, but the New Zealand Cancer Registry breast cancer data-set includes stage as written on pathology reports, and therefore NHI encrypted records could be used for this part of the exercise.

The incidence of interval cancers at different intervals after a negative screen will be estimated. The sensitivity of screening (ie proportion of cancers detected by screening in screened women), and the programme sensitivity (ie proportion of cancers detected by BSA screening in all New Zealand women aged 50 to 69) will be calculated for BSA as a whole and for each Lead provider in each round of screening. These calculations will indicate the progress of BSA towards meeting its target of reducing mortality and will highlight priority areas needing action. The details of all interval cancers will be sent to the relevant Lead Provider, so that the mammograms at the previous screen can be reviewed and compared with the mammograms at the time of diagnosis.

## **9. AUDITING THE QUALITY STANDARDS OF BSA**

**9.1** A comprehensive audit of each Lead Provider, together with its sub-contractors, is conducted every 2 years. Its aim is to assess compliance with the LP's contractual obligations, and the quality standards in force at the time, and to report back to the NSU on their overall performance, making any recommendations for improvement deemed necessary.

**9.2** Before each audit the NSU recruits a multidisciplinary team of auditors, requests a detailed pre-audit questionnaire to be completed by the Lead Provider, together with a quantitative report on how well the LP is meeting its statistical targets, and commissions a Customer Feedback Survey by an independent social research organisation. The main components of the audit itself are a Data Audit, a Service and Clinical Quality Audit, a Maori Cultural Audit and the Customer Feedback Survey results. A visit of the audit team, accompanied by NSU staff, to the Lead Provider is then arranged, of sufficient duration (2 to 3 days in practice), to allow a visit to each of the sub-contracted screening and assessment sites.

**9.3** For each of the audit components the auditors are required to follow an audit tool template, listing the things they should look for. In reporting their findings they are asked to grade each item into whether it is being fully complied with, partially complied with or not being complied with. For the latter group, they are also asked to grade the degree of "risk" to the safety of the programme into high, medium or low.

**9.4** Following the audit, the results are fed back in an extremely detailed report to the Lead Provider and the NSU. The BSA team in NSU then works with the Lead

Provider to ensure that any recommended measures are taken within a time frame appropriate to the degree of risk determined by the auditors.

**9.5** The first audit of a Lead provider was completed in December 2000 and two more were completed in 2001. At the time of my visit, the remaining 3 were being planned. The detailed findings of the completed audits are too great to list here. Suffice it to say that the audits have identified a lot of areas needing relatively minor improvement and thus have proved useful both to the Lead Providers concerned and to the NSU in keeping up the quality of the whole of BSA.

**9.6** My initial impression was that the audits were hugely expensive in that they employed several highly qualified auditors, (some from Australia) to devote two to three working days to the visits, with accommodation included where necessary, and, presumably additional time spent in editing the report. The NSU staff also have to devote a large amount of time to organisation, to the visits themselves, and to writing the report. As I learnt more of the distribution of the screening and assessment sub-sites, however, I revised my opinion that the duration of the audits was unnecessarily long and therefore expensive. Apart from ad hoc visits by the BSA team in the NSU this is the only occasion when the sub-sites are assessed independently of the Lead Provider managerial and clinical staff, and it is necessary that this should be done at least once every two years.

**9.7** But it seems that the NSU may have difficulty in keeping up with the proposed schedule of three audits completed in every year. The amount of detail recorded in these first audits of each LP has been very great and, in general, has shown that the contractual obligations are largely being met. It may be possible for future audits to focus only on those areas in which non-compliance might pose a high or moderate risk. A pared down audit every two years is preferable to a detailed audit every three to four years.

**9.8 Recommendation.** **The NSU should continue to audit each Lead Provider once every two years. In order to streamline the process, items in the audit tool template, (including any that arise from revision of Quality Standards), should be limited to those where non-compliance might pose a moderate or high risk to the programme and to women participating in it.**

**9.9** At present there is no audit of the quality of treatment of women with breast cancer diagnosed by BSA. If, as recommended in para 7.6.5 above, the RACS Breast Cancer Audit form were used as a routine in BSA, this would sufficiently cover the need to audit treatment, albeit not in such great detail as the other aspects of BSA.

**9.10** The implementation of recommendations arising from the audit is the responsibility of the Lead Provider concerned, but is followed up by the NSU's BSA team. This provides a further safeguard to ensure that deficiencies in performance are corrected promptly. (Lack of follow up of audit recommendations has been identified as one cause of screening failures in the UK)

## **10. INFORMATION SYSTEMS IN BSA**

**10.6.1** In 1996 when tenders were sought for the six Lead Providers of mammography screening, specifications for developing a suitable information system were left to each applicant to develop and cost. The outcome was that four of the Lead providers (BSC, BSCC, BSS and BSHC) entered into a contract with one software company, and BSAN and BSM each contracted with a separate software company. As a result, there are three different and currently incompatible computerised systems in the Lead Providers. The systems have to fill several different functions ranging from scheduling staff, generating invitations, and scheduling appointments, to recording results and providing the minimum data-set for monitoring. The Independent Monitoring Group is particularly concerned about the problems that arise when a woman moves from one Lead Provider to another and appears on the records of both. They were also concerned by the slow development of fail-safe systems in BSM. In fact the facility for radiologists in sub-contracted sites to enter their findings electronically rather than manually, was only finally implemented the day before I visited BSM in late February 2002. The IMG continues to emphasise the need for a single information system for all Lead Providers, preferably integrated with a population register (see Section 5 above).

**10.6.2** As already seen, at monthly intervals the Lead Providers submit details of each woman screened to the New Zealand Health Information Service, (NZHIS), which validates the NHI number of each woman and, after the NSU has resolved any queries with the Lead Providers, adds the record to the BSA database. The national monitoring data-set included on this database consists of items of information required by the Independent Monitoring Group. Initially there were inevitable problems with abstracting the relevant details in a consistent way from the three different systems and each of the software companies had to make adjustments. However these problems are now largely resolved and fewer difficulties can be anticipated in the future.

**10.6.3** The need for a single national summary statistical database remains but this can be achieved without introducing a completely new software system to cover both operational needs of the Lead Providers and a statistical database. The current BSA data-base already provides the statistical database, while the three separate commercial software companies can continue to support the operational needs of the Lead Providers, thus avoiding the inevitable turmoil and expense of changing from one software system to a new one.

The BSA database is building up a cumulative record of each woman's screening history, and since it is held under NHI number has the additional advantage of being closely integrated with the NHI system and the NHI Population Register as it develops, (see 5.6 above). In future these systems could ensure that when a woman moves from one Lead Provider region to another, details of her last screen and due date of next screen could be abstracted from the BSA database and sent to her new Lead Provider. There may be a need, however, for the new Lead Provider to be able to access more detailed information images of from her previous Lead Provider, and this will necessitate some modification of their systems.

**10.6.5 Recommendation** The current BSA data-base should be closely integrated with the NHI Population Register as the latter is being established. The three software packages supporting the operational needs of BSA should continue but should develop modifications to allow communication between them about individual women. (para 10.6.5)

## **11. BSA WORKFORCE CONSIDERATIONS**

**11.1** The NSU has an ongoing project examining the need to recruit and provide ongoing education for all categories of BSA staff. The size of the eligible population of women and therefore the need for an increase in capacity of BSA, will increase in coming years due to the extension of the programme to cover women up to the age of 69, and at the other end of the age-range, women born in the "baby-boom" of the 1950s attaining the age of 50.

**11.2** The principal constraint in maintaining the workforce in BSA, let alone expanding it, is a shortage of Medical Radiation Technologists. This occurs across the whole of diagnostic radiology of which mammography forms only a very small part. The problem is poor remuneration, compounded by the fact that not all DHBs pay the same rate for the same job and some put screening MRTs on a scale where they cannot earn overtime. Most MRTs are only working part-time in BSA. The complement of MRTs in the private Lead Providers is more stable than those who are employed in the publicly-funded Lead Providers. If possible within the New Zealand health care system there should be a consistent pay-scale for MRTs working in BSA across all DHBs and the private sector, and the NSU could look into whether this is feasible. As far as I could judge, the training of MRT's in mammography was adequate.

**11.3 Recommendation.** Medical Radiation Technologists should be paid on a consistent pay-scale for their sessions in BSA, regardless of which Lead Provider they work for.

**11.4** Radiologists are the other major clinical profession involved in BSA. Their training, under a Royal Australasian College of Radiologists Mammography Group is extremely thorough and well monitored. There is at present no shortage of radiologists but some may be unwilling to take on mammography screening because of fear of litigation over interval cancers.

**11.5** A category of clinical staff who are keen to be involved in screening are Breast Physicians, of whom there are 12 in New Zealand. The New Zealand Division of the ASBP are currently affiliated with the New Zealand College Of General Practitioners. The exact role of Breast Physicians is ill-defined since they seem to act mainly as surgical assistants, while in Australia after training, they are also allowed to read mammograms, but the New Zealand branch of the Royal Australasian College Of Radiologists does not permit this. Although highly motivated I do not see any major role for them in BSA at present. This may change if a shortage of Radiologists willing to work in BSA develops.

**11.6** Another category of staff that may cause some concern is the Lead Provider Managers, among whom there seems to be a very rapid turnover.

## **12. CORPORATE IDENTITY OF BSA AMONG PROVIDERS**

**12.1** I received the impression that when the six Lead Providers were first identified they worked in isolation from one another, and to some extent in competition. While some competitive element is useful in promoting quality, the sharing of problems and solutions can be even more beneficial.

**12.2** A system of unidisciplinary meetings has been started, based on the meetings of Quality Reference Centre disciplines in the UK. At these meetings, the six Lead Radiologists, or the six Lead MRTs, or the six Lead Pathologists etc. have separate meetings to discuss issues arising in BSA in their particular field of interest. Apart from the Lead Provider Managers who have been meeting 6-monthly, these meetings have been slow to develop due principally to staff shortages in the NSU which has taken on the administrative task of organising them. The meetings would probably become more interesting and productive if the Lead Provider Leads themselves took on the impetus of determining agendas, and producing outputs, such as recommendations to updates of quality standards. It would also be useful to open up these meetings to others of the same discipline working in BSA. As examples, the radiologists might use these meetings, or part of them, to illustrate particular difficulties in mammogram interpretation; similarly the pathologists could organise slide reviews of borderline cases found in BSA, or the surgeons could discuss management of DCIS. The designated chairman of each Group should determine the subject(s) he/she wanted discussed. As mentioned above it would also be useful if one of the members of the IMG attended these meetings both to answer questions about interpretation of the statistical monitoring, and to keep abreast of current issues and future developments. The Clinical Director and the Manager of BSA in the NSU should also attend whenever possible.

**12.3 Recommendation** **The Chairperson of each unidisciplinary Group should be supported by the NSU, organise the agenda of 6-monthly meetings open to others of the same discipline working in BSA, and the Group as a whole should produce reports on any issues requiring alteration of the Quality Standards.**

**12.4** An annual meeting of all Lead disciplines together should also be organised at the time of publication of the annual report of BSA, preferably including a social function. This is not just put forward just as a "feel-good" proposal, but in the belief that a sense of corporate identity working towards a common goal can not only give peer group support but also improve the quality of service delivery.

**12.5 Recommendation** **A 2-Day meeting, open to all working in BSA, should be organised by the NSU once a year.**

## **13. THE NATIONAL SCREENING UNIT**

**13.1** Following the incorporation of the Health Funding Authority into the Ministry of Health in 2000, the National Screening Unit was formally established within the Public Health Directorate, with responsibility for cervical and breast cancer screening, (but not yet for other screening programmes). A period of rapid expansion followed, and the NSU now has six separate divisions with an establishment of 40 full-time

equivalent posts, although 8 are at present vacant. The six divisions are Information Services, Contracts and Finance, Maori Health Screening, Quality Monitoring and Audit, National Cervical Screening Programme, and BreastScreen Aotearoa. These report directly to the Group Manager, who is supported by a Clinical Director, a Communications Advisor, 2 Policy Advisors and a Personal Assistant. The budget also allows for part-time Consultant Clinical experts but these have not yet been recruited.

**13.2** While some of the present staff were previously working for the HFA, and others in the outposts of the National Cervical Screening Programme, many who have taken up new posts within the past 12 to 18 months were new to the field of screening and public health. I was uniformly impressed with their dedicated enthusiasm, with their quick grasp of the subject, and with their ability to work well as a team, under the exceptionally competent Group Manager.

**13.3** The reports of the Gisborne Inquiry and the Health Care Otago report have resulted in extreme media and political pressure being put on the NSU during the whole of its short life, and the Group Manager and other senior staff have had to spend a disproportionate amount of their time in answering parliamentary questions and in fending off media sniping. It was suggested to me by the Advisory Committee and others that the NSU might be less vulnerable to these pressures if it were not part of the Ministry of Health, but a stand-alone organisation, or attached to a Cancer Control Agency (which is proposed but does not yet exist). But, given that the NSU would still remain the only publicly-funded body managing both the national cancer screening programmes, I cannot see that a different location would necessarily lessen the demands, and another major organisational change might well have a destabilising effect. What the NSU needs most at present is a period of stability in which to settle down and have time to develop the skills it needs to maintain high quality breast and cervical cancer screening services.

**13.4** The resources allocated to the NSU are adequate (indeed generous by UK standards) but it has a very real problem in recruiting medically qualified staff. Until her recent resignation after three and a half years in the HFA and NSU, a Public Health Medicine consultant was Clinical Director of the Unit and was assisted by two junior public health medicine specialists and a registrar, all working in the Quality Monitoring and Audit division. The Clinical Director also acted as Manager of this division in addition to her other tasks. Principally due to her lack of time, no work had yet been done to recruit the Consultant Clinical Experts allowed for in the budget. The recent resignation of the Clinical Director necessitates an appraisal of the medically qualified staff employed in, or advising the NSU.

**13.5** It is not within my remit to find a solution to this current problem which only came to a head at the end of my review of BSA. I have every confidence in the ability of the Group Manager to resolve it, within the constraints of available medical manpower in New Zealand, and the available budget. The following suggestions are therefore put forward not as specific recommendations but as an indication of a possible way forward.

- The NSU as a whole needs support and advice from a senior public health physician, with both practical and academic experience of running and

monitoring preventive medicine services. It is unlikely that a sufficiently experienced person could be found to take on this role as a permanent full-time member of NSU staff, but such a person might be seconded as a consultant from a District Health Board for a defined number of sessions per week, or, as an interim measure, recruited from abroad for a defined period.

- The NCSP and BSA divisions could each have their own Clinical Director, employed directly by NSU for, say, a minimum of 5 sessions per week. These Clinical Directors would be experts in Quality Control within their own discipline, (mammography in the case of BSA).
- Consultant clinical advice from senior specialists in the cancer in question (breast surgery for BSA, gynaecology for NCSP) would be extremely valuable to advise on appropriate ways of monitoring treatment issues, and to maintain the high importance of the screening programmes within the profession. These advisers would not be needed on such a frequent basis, say one or two sessions per month.
- Public health specialists will continue to be required within the Quality Monitoring and Audit division. Their role will be to work closely with the IMG, and to work with the Providers to implement improvements to the service.

**13.6** The Quality, Monitoring, Audit and Analysis division of the NSU would, at least as far as BSA is concerned, benefit from closer collaboration with the Independent Monitoring Group, as well as with the Consultant Clinical Advisors when appointed. I had the impression that much time was spent in literature searches on specific topics, and insufficient time in going out to talk to specialists who probably already knew the answers - i.e. they were in danger of wasting time re-inventing the wheel.

**13.7** It is difficult for the professional members of the NSU to keep up-to-date with the large volume of current literature on breast and cervical screening. It was suggested to me that the NSU should hold regular journal club meetings to review recent papers and I was asked for advice on which journals the Unit should subscribe to. Apart from the obvious choice of the Journal of Medical Screening, it is difficult to recommend one journal over another as having most material relevant to the two screening programmes, since screening-related papers are likely to appear in public health journals, cytopathology journals, radiology journals, cancer journals, breast cancer journals and gynaecology journals, among others. Without close access to an academic library it would be extremely difficult for any member of NSU to cover all these. However the IMG at Otago University not only has easy access, but also an ongoing research interest in these subjects and therefore keeps up to date. Regular meetings between NSU and IMG to review current literature, as well as to discuss current projects would be extremely useful. Two-monthly Journal Club meetings between the NSU and the IMGs of both screening programmes could be held, alternating between breast and cervical cancer.

**13.8 Recommendation.** The QMAA division of the National Screening Unit should work more closely with the Independent Monitoring Group in particular, and with Consultant Clinical Advisers.

## 14. RELEVANCE OF THE GISBORNE INQUIRY RECOMMENDATIONS TO BSA

**14.1** The Terms of Reference of this Review specifically asked for an opinion on whether any of the Gisborne Inquiry recommendations, (See 2. Above), were relevant to BreastScreen Aotearoa. The Gisborne Inquiry made a total of 46 recommendations, most of them specific to the National Cervical Screening Programme and the possible failure of cervical smear reading in New Zealand, but some relevant to any screening programme including BSA. The latter group are summarised below.

*Gisborne Recommendation 11.7.* An annual statistical Report should be produced. The IMG Reports, which have been produced 3-monthly, are statistical reports on BSA. A more formal report covering the first full round of screening (i.e. 2 years) is in draft form. Subject to the minor revisions suggested in Section 8 above, the statistical monitoring of BSA is satisfactory.

*Gisborne Recommendation 11.9.* BSA has already set a minimum number of women to be screened by each participating radiologist each year.

*Gisborne Recommendations 11.11 to 11.13.* The National Screening Unit now meets these requirements, with the exception that the manager does not hold specialist medical qualifications in public health or epidemiology. Given the complexity of the Manager's role, in managing the funding of providers of screening, developing information systems, ensuring quality standards are met, managing improvements and changes to both programmes, responding to political and media questions, and more, I do not consider that this role is exclusively the province of a public health specialist. Public health advice is certainly needed, but the person in charge must first and foremost be a competent manager with ability to communicate effectively and strongly, not only with the National Screening Unit staff, but also with the providers of screening, the Groups who audit and monitor, and others with an interest in both programmes. I consider that the present manager has all the desired qualities.

*Gisborne Recommendation 11.16.* Although the BSA Independent Monitoring Group has obtained approval to link the records of women screened in BSA with the Cancer Registry, this was done under the guise of a research project, which it is not - it is a valid and necessary part of auditing the programme. (See 8.5 Above) **The legal rights of access to information held on the cancer registry, by appropriately qualified people engaged by the Ministry of Health to evaluate screening programmes still need to be clarified.**

*Gisborne Recommendation 11.20* Ethics committees require guidance on the application of the Privacy Act and the Privacy Health Information Code. **In addition to this recommendation they also need to develop a policy on the balance between protection of the health of the public and the privacy of the individual.**

*Gisborne Recommendations 11.26 to 11.27.* Interim Quality Standards were in place from the start of BSA, and these are now about to be replaced by a revised set. The need for Quality standards to be updated at intervals is recognised.

*Gisborne Recommendation 11.33.* The need for a population register is emphasised very strongly and is recognised by the providers of BSA screening as much as by the IMG and the NSU.

*Gisborne Recommendation 11.37.* Liaison with the Royal Australasian Medical Colleges. Within BSA the link with the RACR is strong, all participating radiologists having to pass its requirements for mammography reading. Liaison with the RACS and the RACP could be stronger. Many of the Lead Provider staff have spent some time in the Australian Breast Screening Programme, the UK Breast screening Programme, or both.

*Gisborne Recommendation 11.38.* The information provided to women registering in BSA is honest about the strengths and weaknesses of breast screening, and is reinforced by the MRTs and other staff they meet.

*Gisborne Recommendation 11.45.* A sample of users of BSA is questioned about their views as part of the 2-yearly audit of each Lead Provider.

## **15. CONCLUSIONS**

**15.1** There are a number of factors in New Zealand that militate against the organisation and administration of efficient public health screening programmes. Some of these are in the population as a whole, like the wide cultural differences between Maori and Pakeha perceptions of health services, the excessive concern about privacy in the public at large, and the level of media interest in women's screening which emphasises the failures and ignores the achievements. Others are structural within the health care system, such as the mix of public and private care, the lack of a single national health register, and repeated re-organisations of the Health Authorities and Ministry of Health.

**15.2** The way in which Breast Screen Aotearoa was planned and introduced reflects some of these constraints, but it is to its credit, and particularly that of the NSU (and before it the HFA), that it has developed into a coherent service across the whole country. The screening process itself is organised in a well controlled way, consistent across all Lead Providers, that is likely to maximise the benefit and minimise the harm.

**15.3** Its major constraint remains its apparent difficulty in recruiting a high proportion of eligible women, compounded by the fact that the exact proportion remains unknown due to the lack of a population register. The development of a population register for health purposes, to include a cumulative record of each woman's screening history, is essential.

**15.4** The training of Medical Radiation Technicians is adequate, and that of radiologists working in BSA is excellent, thanks to the accreditation process of the Royal Australasian College of Radiologists, and the Quality Standard that insists that BSA radiologists read a minimum of 2000 screening mammograms each year. The system of cranio-caudal as well as lateral oblique mammographic views being taken at every screen, coupled with the independent double reading of every screening film, ensures a high standard of radiological performance and guards against the danger of

a radiologist working in isolation. Although the system of internal quality control of radiological performance could be made more transparent, particularly with regard to sub-contracted units in some Lead Providers, there is no evidence that it is inadequate. The Lead Providers' computerised record systems have built in mechanisms for guarding against mistakes, and in particular the direct entry of results by radiologists prevents the sort of clerical errors that occurred in the early stages of BSHC, and more recently in the UK. In these respects the Lead Providers are at least as good as the longer standing programmes with which I am familiar in northern Europe.

**15.5** The current incompleteness of information on final pathology and treatment of women with breast cancer diagnosed by BSA prevents an assessment of how well BSA is doing in moving towards its goal of reducing breast cancer mortality. This results from a weakness in the arrangements for following the treatment pathway of women with breast cancer. This could and should be resolved by the Surgeons and Pathologists in each Lead Provider taking responsibility for finding out details of these women's diagnosis and treatment. In most Lead Providers this work is being done, on a voluntary basis, by the Breast Care Nurses in addition to their nursing role which they perform with skill and dedication.

**15.6** The Independent Monitoring Group has set up an extremely comprehensive system for routine monitoring and is designed to give early warning of any falling-off of performance. It is vital to the maintenance of a high quality screening programme but is expensive in time and resources, and could be made both more efficient and more acceptable to Lead Providers by some minor changes. The National Screening Unit works with Lead Providers to remedy any problems highlighted by the work of the IMG.

The routine monitoring coupled with 2-yearly audits of each Lead Provider makes the possibility of a sustained failure, such as occurred at Gisborne, extremely remote. But, as in any human system, these measures cannot entirely guarantee that adverse incidents will not occur; they should however ensure that any failure is rapidly recognised and corrected.

**15.7** There needs to be more communication between the numerous professional people in the Lead Providers, and between the Lead Providers, the Independent Monitoring Group, and the National Screening Unit.

**15.8** The National Screening Unit needs a period of stability without any more reorganisations, Inquiries or Reviews!

**15.9** Most of the recommendations of the Gisborne Inquiry Report which apply in modified form to BSA have already been implemented. But the role of Ethics Committees in monitoring and auditing public health services still needs to be clarified.

**15.10** The adverse effects on women screened are within acceptable limits, and are carefully monitored, but the most worrying disadvantage of BSA in my view is its cost to the health service. Although economic aspects were not included in this review, BSA appears to be very expensive in its use of health service resources, not least because of the numerous safeguards to ensure its excellence. The number of

lives which it is anticipated can be saved by BSA is not great, and therefore it will be important in the future to keep cost-benefit considerations under review, in the light of competing needs from other areas of health care.

## **16. ACKNOWLEDGEMENTS**

*This review was originally proposed by Professor David Skegg, and I am extremely grateful to him for giving me the opportunity to assess how BreastScreen Aotearoa is performing. It was a very enjoyable and interesting exercise, made more so by the enthusiasm and commitment of the numerous individuals and groups with whom I met. The programme of work was organised by the National Screening Unit, and especial thanks go to the Group Manager, Karen Mitchell, who guided me throughout and clarified many specific issues. Dr Julia Peters, the then Clinical Director, helped me to understand their concern about quality and explained the measures she had put in place to ensure the safety of screening. She accompanied me on my visit to the Independent Monitoring Group who were extremely helpful and convinced me of their determination to ensure that BSA was among the best screening programmes in the world. All staff in the various divisions of the NSU were exceptionally welcoming and friendly and my thanks go to all of them, but especially to Barbara Phillips and Jeannine Stairmand, who took me to visit most of the Lead Providers, and also enabled me to visit a marae. I was most warmly welcomed by the six Lead Providers and would like to thank the Managers, the Clinical Directors, the MRTs and reception staff I met, and the Lead Pathologists, all of whom gave up their time to discuss their work and concerns for BSA. Finally I must acknowledge the enormous amount of work put into this review by Esther Blomfield, who acted as my PA throughout. She had the unenviable task of scheduling 46 meetings and visits in the course of three weeks, couriered large quantities of papers to me beforehand, took excellent notes of most of the meetings, and always made sure that my every need was met. There are many others who participated in one way or another in this review, and I am grateful to all of them who helped to make my visit to New Zealand so enjoyable.*