SCREENING MAMMOGRAPHY SERVICES

a report by the

NATIONAL

HEALTH

TECHNOLOGY

ADVISORY

PANEL

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SCREENING MAMMOGRAPHY SERVICES

A REPORT BY THE

NATIONAL HEALTH TECHNOLOGY ADVISORY PANEL

Any comments or information relevant to the subject matter of this report would be welcome. Correspondence should be directed to:

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EXECUTIVE SUMMARY

. This report is a survey of information and opinion on equipment, training and quality control in screening mammography and has been prepared to assist the Breast Cancer Screening Steering Committee established under the auspices of the Australian Health Ministers' Advisory Council.

. There is substantial consensus as to appropriate specifications for mammography and film processing units.

. Quality control requirements for screening mammography units are well established.

. The Royal Australasian College of Radiologists (RACR) has made recommendations for a national screening program. The Panel supports the College's proposal to introduce accreditation for mammographic screening clinics.

. Workforce requirements for a national program may present difficulties.

. The Panel suggests that:

- recommendations on screening and diagnostic mammographic equipment and film processing detailed in this report are used as a basis for decisions by the Breast Cancer Screening Steering Committee;

- specifications for equipment are kept under review;

- the Steering Committee hold discussions with the RACR and the Australian Institute of Radiography on issues related to training of radiological staff for mammography, and the availability of suitably qualified persons;

- the Steering Committee consider the RACR proposals for a national data base and establishment of a network of screening clinics, and develop these areas in association with the College;

- appropriate quality control mechanisms are put in place, and administered by the RACR in association with the organisation responsible for the national data base;

- a study is undertaken to provide governments with clear information on the cost effectiveness of a national mammography program.

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INTRODUCTION

At their conference in 1987, Health Ministers agreed that a subcommittee should be established under the auspices of the Australian Health Ministers' Advisory Council (AHMAC) to provide a mechanism for development of a national strategy for the detection of early breast cancer and cervical cancer. The NHTAP was invited to participate in the work of the subcommittee and asked to provide advice on technological aspects of mammographic services. Other groups associated with the subcommittee would be responsible for developing approaches to various other aspects of screening services and for organising pilot projects funded by Commonwealth and State governments. Responsibility for the mammography screening work was subsequently passed to a Breast Cancer Screening Steering Committee.

This report has been prepared as a survey of available information and expert opinion on equipment, training and quality control in screening mammography. The report is intended to assist the Steering Committee in its development of pilot projects and evaluation methods, and to provide suggestions for a possible future national breast cancer screening program. The Panel has drawn especially on the advice of the Royal Australasian College of Radiologists (RACR) which has recently announced proposals for a program to coordinate a national mammography screening service (1).

Screening mammography is applied to asymptomatic women with the aim of detecting malignancies in the early stages before they become symptomatic. Diagnostic mammography is used when the presence of a malignant lesion is suspected on the basis either of symptoms or a screening mammogram.

Overseas data have established that use of mammographic screening can significantly reduce deaths from breast cancer, which is the most common type of malignancy in women in Australia (1). Benefit has been clearly demonstrated for screening of women aged 50 or over in two major trials, the Breast Screening Project of the Health Insurance Plan of New York (2) and the Swedish Breast Screening Project (3). Evidence is emerging that women in the 40-50 year age group will also benefit from such measures (4).

However, for mammographic screening to realise its full potential, scrupulous attention must be paid to all aspects of the process. Tabar and Dean have noted that

the final product (mammogram) can be no better than the weakest link in the chain (5). It will be important for any Australian mammography program to take account of established criteria for X-ray equipment, film processors, training, methods of reading, procedures for recall, quality control and maintenance of a suitable database.

EQUIPMENT

Mammography requires a specially designed X-ray unit. A screening mammography unit may not need to achieve the level of performance necessary for a diagnostic unit. However, it must be designed to allow a high throughput.

There appears to be substantial agreement within Australia on appropriate specifications for screening and diagnostic mammography units. These are based on the suggestions and practice of Tabar and are summarised in Table 1.

A number of units which meet these specifications are on the market and can be made available in Australia. In most cases regular servicing could readily be provided in major cities, but might present problems in country areas. Costs of screening units are in the region of $A90,000-125,000. Diagnostic units may cost from $A110,000 to 190,000. Film processors are an additional cost, at around $14,000 per unit. Information on some of the mammography units available in Australia is given in Table 2.

As a mammography unit must be able to visualise relatively small differences in density in soft tissue, high contrast resolution is required. The target material in the X-ray tube will have a significant influence on contrast resolution. Molybdenum, used with a beryllium window and a molybdenum filter, is the preferred target as it gives higher contrast images. The Panel has been advised that a tungsten tube with palladium and rhodium filters can also produce good results (Tucker, personal communication).

A diagnostic unit requires an X-ray tube with two focal spots, one for routine mammography and the other for microfocus magnification. For screening mammography, magnification may not be required, in which case only one focal spot of size 0.3-0.6mm^2 (preferably 0.3-0.4mm^2) would be necessary.

A mammography unit should have a well designed, reliable, compression device for positioning the breast prior to X-ray exposure. It is highly desirable for this device to be motorised and foot controlled, (with a

control on either side of the unit) and to have adjustable compression force with automatic compression release when exposure is terminated (5). Draft U.K. proposals have suggested that there should be provision to overide the automatic release facility so that compression can be maintained if required (Tucker, personal communication).

Smooth control of the compression device is important - too rapid movement can cause anxiety. Vigorous compression is, however, essential to obtain a good quality image and to reduce radiation dose. The U.S National Council on Radiation Protection and Measurements (NCRP) has noted that the compression device should be stiff and parallel to the film surface (6).

Coned down compression is needed for studies of specific regions, and should be provided on diagnostic units. A moving grid can enhance contrast resolution and is necessary on a diagnostic unit. It can be particularly useful in the examination of dense breasts, but increases radiation dose.

There seem to be differing views on whether microfocus magnification, coned down compression and a moving grid are needed on a screening unit. On the basis of advice received, the NHTAP is inclined to the view that they are not required for screening purposes as:

- screening is expected to be directed to older women who are less likely to have dense breasts (if screening is extended to women under 50, the case for a grid will be stronger);
- radiation dosage should be minimised in screening examinations;
- screening examinations would be expected to be short and to follow a well established routine without special studies on particular individuals, in order to maintain a high throughput.

FILM PROCESSING AND READING

The RACR considers that film screen mammography should be used rather than xeromammography, which imparts a higher radiation dose (1). A specially designed film/screen combination and a dedicated processor are required. While conventional X-rays are obtained with double emulsion film exposed with two intensifying screens, single emulsion film exposed with one intensifying screen is used in mammography. It is important to use a film processing technique suitable

for single emulsion film. If a processing technique suitable for conventional X-rays is used, the film will be underdeveloped (5).

Tabar has noted the tendency to compensate for poor picture quality by use of a grid. This practice, which increases dose to the woman being examined, cannot be justified. The use of the grid should be reserved for women whose breasts are difficult to compress and/or those who have dense glandular tissue (5,6). For processing single emulsion mammography film Tabar has recommended 42-45 seconds in the developing fluid at 35^{o}, with a fluid replenishment of 400-410 mL per metre of film. If a 90 seconds processor is adjusted to these parameters, exposure values must be correspondingly reduced.

The Panel has been advised that there is a trend towards recording two views for all women at the initial mammographic examination. There is evidence that two view mammography increases the certainty of diagnosis and decreases the incidence of false positive readings (7). The reduction in false positives is seen as especially significant in avoidance of anxiety in women who are unnecessarily called back. Such anxiety may be difficult to erase through reassurance following further views.

A suggested approach is that two views would be taken at the initial examination to establish a baseline, with the number of views in subsequent examinations depending on the breast pattern. If the breasts are fatty, subsequent screening mammograms should be done with a single oblique view. If the breasts are dense, continued screening using two views would be appropriate. (Hare and Wilson, personal communications).

The Panel has been advised that there may be advantages in using motorised viewing devices, with multiple screens, for reading films. Such devices should be especially suitable for larger, busier mammography centres and could save time and costs. Films can be loaded and unloaded by non-medical staff, leaving the radiologist free to view the mammograms, if necessary in comparison with film from previous examinations. Tabar is able to view films from 300 patients in about 2 hours using such a device. A range of machines is available, with costs varying from about $12000 - 25000. (Baker, personal communication.)

QUALITY CONTROL

To ensure that screening is carried out with acceptable accuracy, quality control mechanisms are required for the performance of the mammography unit and the film processor as well as for the interpretation of the mammograms. In-house checks can be carried out on the equipment. The X-ray unit should be tested every six months and the film processor every day. The quality of film interpretation will to some extent be checked by the use of two radiologists for reading, but some form of external check would also be desirable, perhaps once a year. This is a matter for further discussion with the RACR.

The NCRP has summarised U.S quality assurance requirements for mammography and cites recommendations of the FDA National Centre for Devices and Radiological Health on elements that should be incorporated into a quality assurance program (Table 3).

It would be highly desirable for quality control of mammograms and operator performance to be eventually linked to a national data base, which could be used to provide important feed back on results obtained by individual screening centres. (Croll and Wilson, personal communication).

PERSONNNEL AND TRAINING REQUIREMENTS

The introduction of a national breast screening program in Australia would add substantially to the workload of radiological services and require specially trained personnel, both radiologists and radiographers. Workforce requirements will depend on the volume of screening examinations, which in turn will depend on the age group selected for screening, the interval between examinations and the compliance rate. In an earlier review Ilbery noted that the mounting of a universal mammographic screening program is daunting to medical manpower (8).

The RACR has suggested that women between 40 and 74 years should be screened, and has estimated that if the interval between examinations averages 20 months and the compliance rate is 70%, 4,300 screening examinations would be required every working day. The NHTAP has estimated that if screening is restricted to women in the 50-74 year age group, screening is undertaken every two years, and the compliance rate is 80%, 2700 examinations would be required per working day. Significant additional workforce would be required to meet either estimate.

The RACR has noted that radiological manpower is a significant problem and considers that a radiologist with special training in the field must oversee all stages of image production. Mammograms must be examined by a radiologist with special training in the field and preferably double read by a second radiologist, with both persons reading together if a lesion is suspected (9).

The Panel is aware that there are strong reservations on the part of the RACR with regard to training non-radiologists to carry out readings. The NHTAP has been advised that mammography raises particular difficulties in relating images to physiology and anatomy. It has been suggested that interpretation of mammograms should not be undertaken by a person without radiological training - it is difficult for the non-expert to relate film readings to physiology. There might also be a problem with dropout of non-radiologist readers.

Consideration may need to be given to whether an adequate number of radiologists would be prepared to undertake screening mammography, given that the work may be regarded as tedious. It may be desirable in many cases for it to be undertaken on a part-time basis, in association with diagnostic work. This might help prevent boredom and errors resulting from failures to maintain concentration.

Representatives of the RACR have advised that radiologists undertaking mammography would require intensive training for about one month, and ongoing training for perhaps another 6 months. Existing mammography clinics could well provide centres for training. It has been suggested to the Panel that 100 to 150 additional suitably trained radiologists would be needed in Australia for a national screening program.

A national screening program would require radiographers trained in mammography. To encourage maximum participation in the program the radiographers should be women. The number required could be between 200 and 400. A 2-4 week training course in mammography would be required for radiographers with no experience in this area. The NHTAP understands that there is a shortage of radiographers in Australia, and it is not clear whether the need for female mammographers could be met.

The RACR considers that a key to a successful national program is adequate training and is in favour of a deliberate approach using established centres of expertise as a nucleus (Wilson, personal communication).

The Panel suggests that the Steering Committee discuss these issues with the RACR and the Australian Institute of Radiography with a view to developing an agreed approach to training of required radiological staff.

DISTRIBUTION AND ORGANISATION OF SCREENING FACILITIES

The Panel notes that the RACR proposals envisage 10-12 large, dedicated screening clinics in Australia, servicing up to 1200 cases per day between them, with about 120 small centres, each dealing with 20-30 cases a day, providing the major part of population screening. The large centres may well develop out of the pilot project sites (1). A minimum case load of 20-25 per day could be required to maintain adequate competence (Wilson and Croll, personal commmunication). The possible role of mobile imaging units may also need to be considered. It has been suggested to the Panel that equivocal readings obtained at smaller centres should be followed up initially by providing the film to a centre of excellence for appraisal before any re-examination. Patients should be recalled to the centre at which they were first examined.

The Panel understands that many existing mammographic units in Australia are of a suitable standard for screening purposes. The Panel considers that the success of any national scheme will depend on an effective network being put in place to support the smaller screening clinics, the provision of adequate on-going training for radiologists and mammographers and feedback to them on the clinical results in the context of the overall program.

ACCREDITATION OF MAMMOGRAPHY SERVICES

If widely dispersed centres are to be involved in the provision of mammographic services it will be essential to have some form of control to ensure that screening is undertaken only by those with adequate equipment and expertise. The RACR has proposed that it take on the role of accrediting facilities for screening mammography (1). Initial accreditation would involve assessment of equipment and expertise and adequacy of follow-up and ancillary services. Continuing accreditation would involve assessment of screening results.

The NHTAP notes that it should be possible to combine an accreditation system with a quality control mechanism. The College is at present conducting a survey of its members to obtain data on potential screening services, including equipment type and projected workload (Hare, personal communication).

The Panel supports the initiative taken by the RACR in this area, and considers accreditation to be an essential step in ensuring acceptable quality of services on a nationwide basis.

FOLLOW UP FACILITIES AND DATA BASE

The RACR has proposed that data from all screened women be held in a central agency. The data would incude results of screening, outcome as a result of positive screens and performance by individual screening facilities. Screening clinics would be obliged to provide data to the agency in order to gain accreditation (1).

The data base would be used to ensure follow up on positive or equivocal results and to direct notices of invitation to subsequent screening rounds. The RACR has prepared draft requirements for a central data collection agency for a breast cancer screening program (9).

The RACR has suggested that State cancer authorities are well placed to act as data agencies. The Panel supports this suggestion, but notes that there are organisational differences between these agencies and that individual registries may not have links for data exchange. It would seem highly desirable for data from State bodies to be handled centrally to provide continuity of coverage for individuals and to assist accreditation and assessment. Detailed consideration will be required as to how this might most effectively be achieved.

The Panel also notes that careful planning of strategies for operation and use of the data base will be required, and should desirably involve other professional bodies including the Royal College of Pathologists of Australasia and the Royal Australasian College of Surgeons. The Panel suggests the Steering Committee might usefully cooperate with the RACR in establishing an agreed approach to data acquisition and handling.

The College has noted that follow up/ancillary services must include:

- Full diagnostic mammography facilities (ideally in the same clinic) and desirably including ultrasound.

- Surgeons with a special interest in breast disease and with insight into the changing treatment modalities required for screening-detected abnormalities.

- Pathologists with a special interest in breast pathology and cytology.

- Specimen radiography with interaction between radiologist, pathologist and surgeon.

- Radiation oncologists (radiotherapists) with a special interest in breast disease (1).

PERFORMANCE AND COST CONSIDERATIONS

As noted above, in a national mammography program between 2,700 and 4,300 screening examinations might be required every working day. A target of 8 minutes per examination has been suggested (Wilson and Croll, personal communication). Assessment of cost of a national service would need to take into account the rate of call back, which might be between 5 and 10 per cent. The Panel has been advised that the false positive rate would be in excess of 6 per 1000 of all women examined in the first year of a screening service, after which it would be expected to drop back. The false negative rate might be of the order of 5 to 10 per cent. A target of biopsy of one benign lesion for each cancer detected has been suggested, but is unlikely to be achieved until several years' experience has been gained.

The cost of a a screening mammogram might be of the order of $30-40. Costs of diagnostic mammography and associated necessary procedures would be substantially higher.

The Panel suggests that a study be conducted to define the cost-effectiveness of a national mammography program. This should take account of capital and recurrent expenditure, associated procedures, operation of a data base, educational measures, decrease in morbidity and mortality, and treatment of women with early cancer expected to result from screening. Results from such a study would provide useful information to governments and place the substantial set-up and operating costs of a national screening program in an appropriate perspective.

BENEFIT - RISK CONSIDERATIONS

The Panel notes that while there are risks associated with screening mammography, due to exposure of women to low doses of ionising radiation, there is overwhelming evidence of overall benefit through the early detection and treatment of tumours. Benefits and risks of mammography have been clearly summarised by the NCRP (6).

The Panel also notes that there may be definite, if hard to quantify, psychosocial detriment to women for whom a false positive diagnosis is made through mammographic examination.

CONCLUSIONS

The Panel considers that adequate data exist to provide clear guidelines on the appropriate equipment for a screening mammography service and its method of use. One of the keys to a successful mammography program will be effective discussion between governments and professional bodies so that details of pilot projects and a national service can be agreed and necessary planning put in place.

The Panel commends the RACR for its proposal to accredit clinics for mammography screening, and sees this as a major step towards ensuring services of an acceptable quality.

The Panel suggests that:

- recommendations in this report on screening and diagnostic mammographic equipment and film processing are used as a basis for decisions by the Breast Cancer Screening Steering Committee;

- specifications for equipment are kept under review;

- the Steering Committee hold discussions with the RACR and the Australian Institute of Radiography on issues related to training of radiological staff for mammography, and the availability of suitably qualified persons;

- the Steering Committee consider the RACR proposals for a national data base and establishment of a network of screening clinics, and develop these areas in association with the College;

- appropriate quality control mechanisms are put in place, and administered by the RACR in association with the organisation responsible for the national data base;

- a study is undertaken, perhaps by the Australian Institute of Health, to provide governments with clear information on the cost effectiveness of a national mammography program.

TABLE 1: SUGGESTED SPECIFICATIONS FOR MAMMOGRAPHY UNITS

SPECIFICATIONS	SCREENING	DIAGNOSTIC
TARGET MATERIAL	Molybdenum	Molybdenum
FOCAL SPOT SIZE (mm^2)	0.3 to 0.6	0.4-0.6(regular) 0.1(magnification)
OUTPUT	max at least 100 mA (accuracy $\pm$ 10%)	max at least 100mA
FILTRATION	Beryllium window Molybdenum filter	Beryllium window Molybdenum filter
PHOTOTIMER	Essential	Essential
MICROFOCUS MAGNIFICATION	Not necessary	Essential (1.7-2.0 times)
MOTORISED COMPRESSION DEVICE WITH FOOT PEDAL (both directions)	Highly desirable	Highly desirable
STIFF SUPPORT TABLE (Distorting less than 1mm under full compression)	Essential	Essential
CONED-DOWN COMPRESSION DEVICE	Not necessary	Essential
MOVING GRID	Not necessary	Essential
CAPACITY/TIME	300 films/day	Not critical
FILM SIZE	18X24 and 24X30cm	18x24 and 24x30cm
DEDICATED SINGLE - EMULSION PROCESSOR	Essential	Essential

TABLE 2 : SOME MAMMOGRAPHY UNITS AVAILABLE IN AUSTRALIA

Model	Meets Screening Specifications	Meets Diagnostic Specifications*	Approximate Cost($A)
Akoma MXR-103	All but motorised compression	No	89,000
Akoma MXR-HF105	Yes	Yes	116,000
Philips Mammo-Diagnost UM	All but 24x30cm film	All but 24x30cm film	135,000
Philips Mammo-Diagnost U	All but 24x30cm film	No	123,000
Siemens Mammomat 2	Yes	Yes	181,000
Siemens Mammomat B	Yes	Yes	190,000
Thomson-CGR Senographe 500TS	Yes	No	104,000
Thomson-CGR Senographe 500/ 600T	Yes	Yes	127,000
Toshiba MGU- 03B	Yes	Yes	112,500

* Specifications given in Table 1

Corrigendum - Page 13
The distributors have advised that the cost of the Siemens Mammomat 2 was about $A130,000 as of March 1988. This machine supersedes the Mammomat B.

TABLE 3 : TECHNICAL ITEMS TO BE EVALUATED IN A QUALITY ASSURANCE PROGRAM

a) For the mammographic unit:
- representative entrance surface exposure
- type of target and filter
- half-value layer
- accuracy and reproducibility of kVp stations
- accuracy and reproducibility of timer stations
- linearity and reproducibility of mA stations
- reproducibility of X-ray output
- accuracy of source-to-film distance indicators
- light/X-ray field congruence
- focal spot size
- compression device design, including breast thickness indicator

b) For automatic exposure control devices:
- reproducibility
- kVp compensation
- minimum response time
- backup timer verification

c) For films, screens and cassettes:
- mammography film and screens
- screen condition
- light leaks
- artifact identification and control

d) For film processing:
- an index of speed
- an index of contrast
- base plus fog
- solution temperatures

e) For the darkroom:
- darkroom integrity
- safe light conditions

f) For view boxes:
- consistency of light output with time
- consistency of light output from one box to another
- view box surface conditions
- image masking and ambient light control

g) For the system as a whole:
- dose calculations
- phantom imaging retakes

Source: NCRP Report No. 85, Mammography - A User's Guide - p.76

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