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Factors in the Use of Breast Screening for Effective Secondary Prevention

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Abstract: Although Australia has set up a breast screening program in each State and a National Breast Cancer Centre, there is a lack of understanding of mammography over a wide range of the community, both women and men, about its objectives, limitations and requirements for effective secondary prevention of breast cancer. Therefore it seems desirable to examine the criteria for selection of a disease for screening as established by the World Health Organisation and discuss these criteria in their applications to screening for breast cancer. The presentation is made in the light of the Australian system and what each criterion realistically implies. With regard to the marginal cost per year of life saved calculated for a range of different screening strategies for age groups and screening frequencies it appears that the Australian strategy (age 50–69 biennially) compares very well with the most effective screening strategy.

Keywords: Breast screening, mammography, Australia

INTRODUCTION

The criteria for selection of a disease for screening have been established by the World Health Organisation as listed below. The following report discusses the case of breast screening in accordance with these criteria.

- The condition should be an important health problem;
- the condition should have a recognisable latent or early symptomatic stage;
- the natural history of the condition from latent to declared disease should be adequately understood;
- there should be an accepted treatment for patients with recognised disease;
- there should be a suitable test or examination;
- tests should be acceptable to the population;
- there should be agreed policy of whom to treat patients;
- there needs to be facilities for diagnosis and treatment;
- the cost of case funding should be economically balanced in comparison to the entire cost of medical care as a whole; and
- testing should be a continual process.

BREAST CANCER - A SIGNIFICANT HEALTH PROBLEM

Breast cancer is the second most common cancer amongst Australian women and the most common cause of death from cancer (29 per 100,000 in 1991 according to Australian Bureau of Statistics, 1993). Lifetime (0–74) risk of developing breast cancer is 1 in 16 and the likelihood of dying from breast cancer before 75 is 1 in 44 (Australian Cancer Society, 1993). Incidence of, and mortality from, breast cancer increases with age. The risk (Australian Cancer Society 1993) of developing cancer at age 30 is estimated as 1 in 2000, at age 50, 1 in 55, at age 74, 1 in 14. Established major risk factors include age, family history of breast cancer, prior breast cancer, benign breast disease, endogenous endocrine factors (eg age at menarche), age at birth of first child, age at menopause and radiation exposure. Other proposed but incompletely resolved risk factors include exogenous hormone exposure (eg oral contraceptive use), oestrogen replacement therapy and environmental factors including diet (Henderson 1997, Hoffman 1993). The main relative risk factors have

been tabulated relative to all cases (Hoffman 1993).

EARLY SYMPTOMATIC STAGES AND THEIR SIGNS (DIRECT AND INDIRECT)

Breast cancer has an early non-palpable, detectable stage arising mainly in milk ducts (and sometimes lobular neoplasia may be associated with intraductal carcinomas) where calcium hydroxyapatite deposits from transformed and necrotic epithelial duct cells can be revealed as the earliest useful indication by soft X-rays used in mammography. Expert radiologist diagnosis is needed for interpretation between these signs of benign and malignant lesions. Mammographic screening is capable of detecting cases through both "direct" and "indirect" signs. "Direct signs" include palpable mass, nipple discharge, nipple or skin retraction, erythema and dimpling. "Indirect signs" include the presence of characteristic microcalcifications (Wolfe 1990, Thomas et al. 1993), often the early sign of possible tumour.

As methods of detection continue to improve such as in imaging, better film and other technologies to aid mammography, there has been further accumulation of experience with minimal breast cancer and improved effectiveness in recent years. The most appropriate measure for assessing changes in mortality rates is the age-standardised mortality rate. In the recent Australian Federal Government Year 2001 Report on Government Services (2001) the section on Breast Cancer Screening gives data on this parameter. In Australian screening programs there has been only a relatively small reduction in the number of deaths from breast cancer from 1994 to 1998 after the increase from 1987 to 1994 but, taken in association with population growth there is a significant effect on the age standardised mortality rate. That rate has declined from a peak of 27.2 per 100,000 women in 1989 to 23.0 in 1998 and "the decline appears to be strong and consistent from 1994 onwards". In that period screening participation has increased plus the benefits of improved imaging and quality control. In populations of breast cancers which are being diagnosed through mammographic screening programs as many as 50–60% of suspected cancers detected are less than 10mm in diameter or are "in situ" and are diagnosed as a result of a specific abnormality detected at screening. After the second stage of the screening process these may be considered to represent a probable malignancy. The pathway for mammographic screening and assessment and subsequent routine rescreening is shown in Figure 1 (courtesy of the NSW Breast Cancer Institute and the Australian Institute of Health).

Mammographic film reading is done utilising dual reading of all screened films independently by two screening radiologists. The need to have two readers has been shown to be important in early trials of breast screening. As an example of the significance, it was found in the initial Scotland Breast Screening Program that in the first 18 months of the program approximately twenty percent of cancers were detected by only one of the two readers (Kirkpatrick 1991). The particular cases, after being reviewed, revealed that these were very early lesions with subtle presentation. The cost of having two readers is a cost-effective component to yield the desirable level of the marginal cost per year of life saved (MCYLS) discussed in a later section of this paper. The cost per woman screened for Breast-Screen Australia is approximately $100 per woman. (Report on Government Services 2001).

The Mammography Screening Pathway
The Organisational Units Responsible for each Screening Component

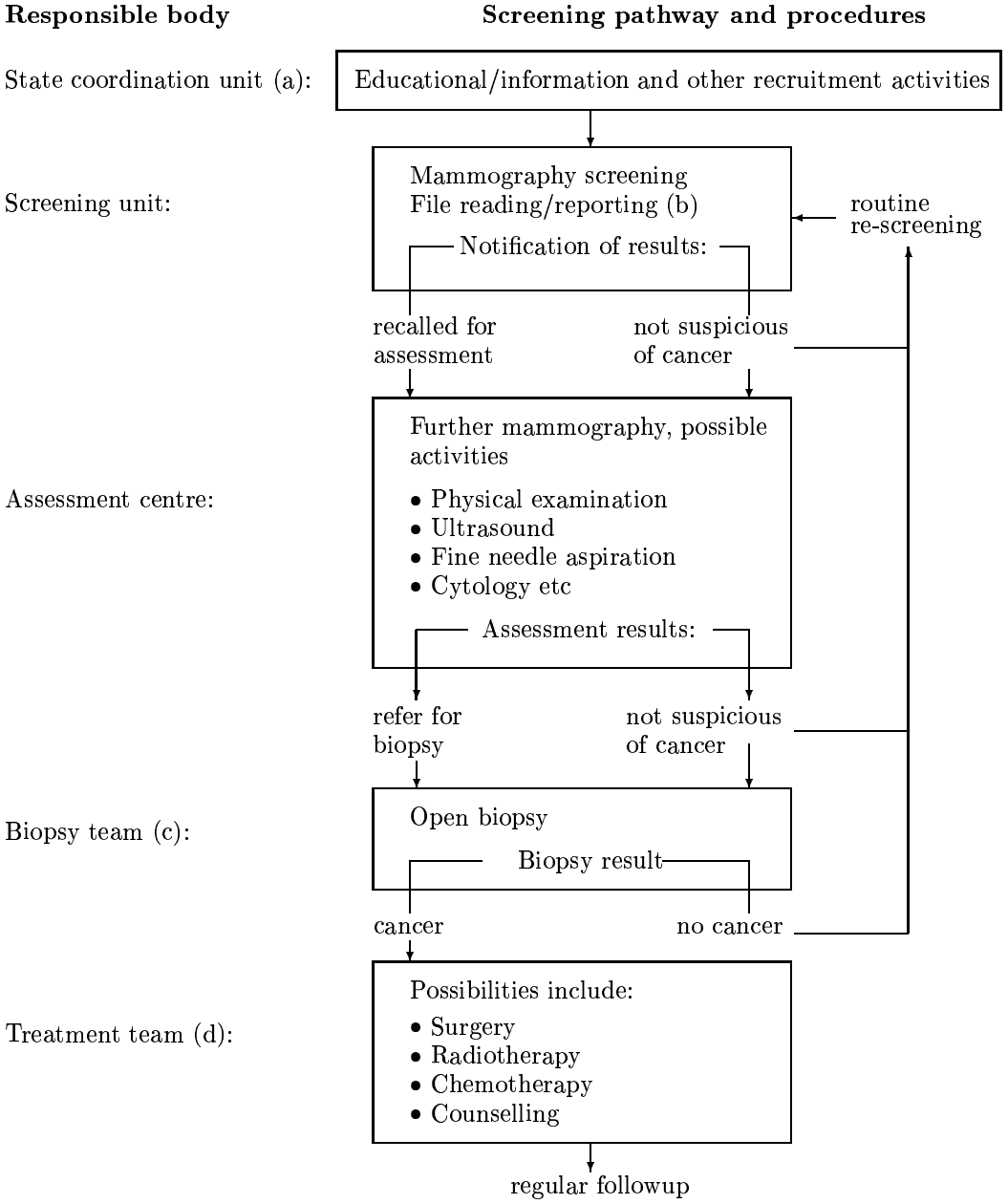

Figure 1: Pathway for mammographic screening and assessment and subsequent routine rescreening. (a) Additional functions of State coordination unit. (b) Film reading/reporting may be carried out by the screening unit or the assessment centre, depending on local requirements. It is vital that the film reader receives routine feedback on the results of the assessment. (c) The biopsy team may be an element of the assessment centre or may be part of the treatment team. (d) The treatment team may be a specialised breast cancer unit or usual medical centre. (Courtesy of NSW Breast Cancer Institute and Australian Institute of Health.)

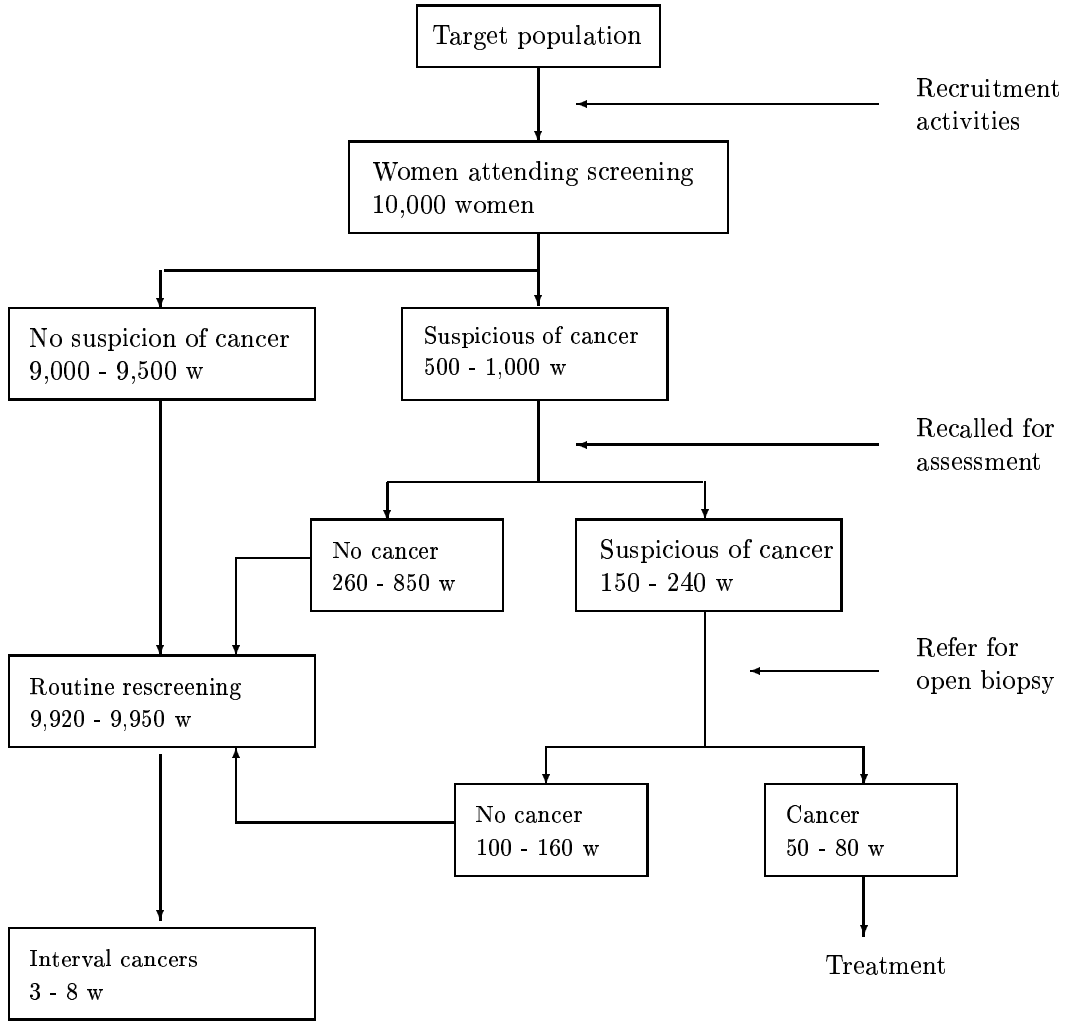

Figure 2: Initial screening - estimated number of women reaching various stages of screening for every 10,000 women screened. (Courtesy of NSW Breast Cancer Institute and Australian Institute of Health.)

PROGRESSION OF THE INITIAL INDICATION OF A BREAST MALIGNANCY

The basic cause of breast cancer is still not known but the progression is understood in terms of molecular biology. The progression may be slow or rapid and the latter situation gives rise to the problem of "interval cancers" where a tumour may develop rapidly shortly after awomen is screened as "clear" but develop to a fatal state with metastases prior to the next scheduled screening. An up to date study on this matter has recently been published (Rickard and Taylor 1998) and shows that there was no significant difference between the proportional incidence rates for the 50 to 69 year age group (for Central and East Sydney Screening) and those of major successful overseas screening trials.

The 12 month interval cancer incidence per 10,000 screens was 4.17 for the 40–49 year age group (95% confidence interval) and 4.64 for the 50–69 year age group.

TREATMENT

Surgery is the mainstay of breast cancer treatment. Fortunately a number of randomised clinical trials have shown that conservative surgical procedures result in equivalent mortality and survival rates to radical surgery (Fisher et al. 1989). Reports from some Australian sources indicate that breast conservation is possible in approximately 45% of cases (Malycha 1993).

Adjuvant therapy, particularly systemic cytotoxins or hormonal drugs such as tamoxifen, has proved effective in reducing mortality. Although the initial gains were small (Hurley 1991), more recent data is much more encouraging for reduction in mortality as summarised by McDonald and Qazi (1998).

MAMMOGRAPHY

Mammographic screening is recognised as the "gold standard" for screening for breast cancer. It uses "soft" X-rays and relies heavily on experienced radiologists' interpretations of both "direct" and "indirect" signs. However, mammogram interpretation is both time-consuming and difficult, requiring the expertise of trained radiologists. An excellent description of mammographic evaluation is given in the review paper by Sickles (1986).

Ultrasound has been shown to often augment mammography in situations such as dense breasts and cyst/solid differentiation.

Other imaging methods: ultrasound, static thermography, trans-illumination, and MRI have not demonstrated sufficient effectiveness to substitute for mammography in screening. Mammography has very good spatial resolution needed for sensitivity but is not as good in depth resolution. MRI is not very good at spatial resolution but can resolve well "layer by layer" in depth for chemical changes. It does require expert interpretation and is very costly.

MAMMOGRAPHY AS AN ACCEPTED SCREENING TEST

Specificity of Screening in the early Detection of Breast Cancer - "False Negatives" and "False Positives"

The two main concepts of diagnostic tests which are well accepted are "sensitivity" and "specificity". Those concepts are:

1. A measure of sensitivity is the probability of correct diagnosis of "positive" cases.
2. A measure of specificity is the probability of correct diagnosis of "negative" cases.

The practice of mammography has good sensitivity but is not as good in specificity. One of the main disadvantages of any screening program is lack of specificity of the screening test because a test that is not specific to the disease in question will give false positive results. A false positive result can cause the patient needless anxiety, inconvenience in having to undergo further diagnostic tests, and possible morbidity if these tests are invasive; it also results in considerable expenditure of personal and health service resources. New computer aided diagnostic methods are improving specificity as well as sensitivity (Nguyen et al. 1998).

Other epidemiological parameters derived from the basic results of mammography (see Table 1) and Rose & Barker's book (Rose and Barker 1986) on introductory epidemiology are "prevalence" and "positive predictive value", PPV.

	Reference Test (disease)		
	Positive	Negative	Totals
Survey Test			
Positive	True positives correctly identified = (a)	False negatives = (b)	Total test positives = (a+b)
Negative	False negatives = (c)	True negatives correctly identified = (d)	Total test negatives = (c+d)
Totals	Total true positives = (a+c)	Total true negatives = (b+d)	Grand Total = (a+b+c+d)

Table 1: Basic results of mammography from and Rose & Barker (1986).

From this table the following definitions are derived.

Sensitivity: A sensitive test detects a high proportion of the true cases, and this quality is measured here by a/(a + c).

Specificity: A specific test has few false positives, and this quality is measured by $d/(b+d)$.

Systematic error: For epidemiological rates it is particularly important for the test to give the right total count of cases. This is measured by the ratio of the total numbers positive to the survey and the reference tests, or $(a+b)/(a+c)$.

Positive predictive value: This is the proportion of test positives that are truly positive. Systematic error and predictive value must depend on the relative frequency of true positives and true negatives in the particular study group (ie on prevalence of abnormality).

In addition to its sensitivity and specificity, the performance of a test is measured by the predictive value of a positive or negative result. For a positive result this is given by $a/(a+b)$, which represents the likelihood of a person with a positive test having the disease. When a disease has a low prevalence the proportion of true negatives $(b+d)$ in the population in relation to true positives $(a+c)$ is greater than when prevalence is high; and the proportion of false positives (b) will be greater in relation to (a). The predictive value of a positive result must therefore fall (or rise) as prevalence declines (or increases). This point is of practical importance, because new diagnostic tests are usually first tested in hospitals or clinics, where prevalence is high. Despite satisfactory levels of sensitivity and specificity these tests may be disappointing when applied to the general population, because the yield of false positives is too great. Table 2, from Rose and Barker's book (1986), shows results from a breast cancer screening program, using palpation and mammography, where the sensitivity was 67% and the specificity 98%, yet the predictive value of a positive screening test was only 20%.

	Breast Cancer		
Screening	Present	Absent	Total
Positive	127	497	624
Negative	63	19 313	19 376
Total	190	19 810	20 000

Table 2: Results from a breast cancer screening program from Rose and Barker (1986). Sensitivity = 67% (127/190); specificity = 98% (19 313/19 810); predictive value = 20% (127/624).

Assessing a screening test requires not only a comparison with a reference test but also measurement of the test's repeatability, which shows the extent to which a single screening measurement may be taken as a sufficient guide to action. In breast screening readers are used for each mammogram and any differences in assessment referred in consultation with a third specialist.

MORTALITY VERSUS SURVIVAL RATE

In screening for cancer, the principle question is whether the identification of individuals at an earlier stage in the natural history of their disease and consequent treatment reduce mortality. It is a commonly held belief that this is necessarily the case for cancers where the survival rate varies substantially with the stage at diagnosis. However, the argument here is fallacious and can be confounding according to H. Cuckle (1990), who comments as follows:

"The first and most obvious bias is called the 'lead time' bias. Suppose that a cancer was diagnosed incidentally whilst investigating some completely unrelated problem, and the patient refused treatment. The time from diagnosis to death would necessarily be longer than had the cancer been diagnosed clinically when the patient would have presented with symptoms, yet the date of death would have been unchanged. Thus, the extra time the cancer was observed (the 'lead time') increased the survival time but did not change the outcome. The second bias is called the 'length' bias. This arises because of the variability in rate or progression of the disease, for a given site of cancer, so that for example some cancers are aggressive and will lead to death just a few years after initiation whereas other cancers of the same site are indolent and may take decades. Since the latter spend more time in the preclinical stages there are more opportunities for incidental diagnosis. It follows that in a group of cancers diagnosed early there will be a disproportionate number of indolent cases with good survival.

These biases mean that to evaluate screening for cancer the mortality rate and not the survival rate should be used, comparing it in those who are screened and similar individuals who are not."

RANDOMISED TRIALS

The randomised trial of screening is by far the most reliable source of data since it is unbiased. The cumulative breast cancer mortality rate in those allocated to the screening arm is in expectation the same as that in the control arm. Any differences that emerge will be either due to chance or to the effect of screening. The extent to which change may either cloud a true effect or lead to an apparent effect that does not exist is influenced by:

1. size of trial;
2. magnitude of the true effect;
3. compliance in the screening arm of the program;
4. screening in the control arm ('contamination') of the program;
5. duration of follow-up, and
6. method of randomisation.

As with any epidemiological study the ability to show an effect is dependent on the size of the trial and the magnitude of the true effect. The more deaths from breast cancer that accumulate the smaller the influence of chance which will be particularly important if the true effect is small. The effective size of a screening trial may be only a fraction of its actual size if compliance is low and contamination is high (Cuckle 1990, Table 1). The ability to demonstrate an effect is dependent on the duration of follow-up because the deaths prevented by screening are likely to have occurred many years after it was done. Those who die of breast cancer in the first years after screening will be predominantly women with advanced disease at the time of screening who will have derived little benefit from it. Thus the cumulative numbers of death in the two arms of the trial are likely to be small and similar in the first, say, 5 years and only begin to differ after that time.

OTHER CONFOUNDING MATTERS

Breast carcinomas are classified histologically into ductal or lobular types. Each type is further divided into in-situ and invasive categories. Ductal carcinomas in-situ (DCIS) can remain

harmless for years but stellate and fast growing tumours can lead to mortality in a relatively short time if not detected (which is difficult in many cases for small tumours in a complex background of the mammographic image). This is made a more difficult task when radiologists commonly read screening mammograms at 70 to 80 an hour - often after a day's work on other matters. In the Australian screening system two views are taken (oblique and cranio caudal) but in the UK system only one view is taken and this can be a source of confounding in some cases. The increased cost of having a second reader viewing of the mammograms is considered highly desirable as explained previously.

Some non-neoplastic conditions can present clinically with a breast mass and simulate neoplasms clinically and in mammograms. Some of these are quite common lesions such as duct ectasia and fat necrosis.

TARGET GROUP FOR MAMMOGRAPHY

Meta-analysis of a number of screening studies done in the 1980's suggested that mammography has a worthwhile role in reducing breast cancer mortality particularly for women over the age of 50 (Australian Cancer Society 1993). A further meta-analysis of studies done 1966–1993 published in 1995 (Kerikowske et al. 1995) gave support to this decision. The most women who are at risk from developing breast cancer are post-menopausal women aged 50–65. In 1990 the Commonwealth Government of Australia phased in a National Program of Breast Screening biennually for women over 50 years of age and particularly those 50–69. The breast tissue of younger women is more dense than that of older women making mammography less accurate. Ultrasonography is a preferred modality for women under 30.

MAMMOGRAPHY EQUIPMENT AND RESOURCES FOR SCREENING

Mammographic screening facilities utilise soft X-ray equipment which takes oblique and cranio caudal views plus ultrasound equipment. Breast clinics are equipped with these facilities. Mobile vans with X-ray breast screening equipment are also used to cover population areas where clinics are not established. The mammograms are taken back to a major centre for processing and examination and diagnosis of suspect cases. Treatment for malignant cases after confirmation from core biopsy is usually surgical and requires only a brief bed stay for simple surgical cases. More advanced cases can require mastectomy with a longer hospital stay and chemotherapy.

COST EFFECTIVENESS CONSIDERATIONS

The differences between cost minimisation, cost-effectiveness, cost-utility and cost-benefit analysis are explained by Elliott and Harris (1997) including pitfalls in their usage. In cost-effectiveness analysis the outcome of the intervention and the comparator must be measured in the same unit such as number of lives saved.

Cost effectiveness can be expressed (Lindfors and Rosenquist 1995) as the "marginal cost per year of life saved" (MCYLS):

MCYLS $= (C_s - C_o)/(Y_s - Y_o)$ where, over the period concerned:

C_s = total cost for observation

Y_s = years of life accumulated in the screened group

Y_o = years of life accumulated in the observed group

Using this definition Lindfors and Rosenquist (1995) have calculated (in their Table 6) the marginal cost per year of life saved for a number of different screening strategies for age groups and screening frequency. The MCYLS range from $US16 000 to $US31 900.

Their most effective recommendation in 1995 was:

Age group:	50–79
Strategy:	biennial
MCYLS:	$US16 000

This strategy compares well with the Australian policy (50–69 biennially)

THE CONTINUED BASIS FOR SCREENING TESTS

Although no optimum strategy has yet been found or proven screening should be done on a continuing basis in order to detect the occurrence of breast cancer at an early enough stage to help subsequent efforts to save lives. In Australia the National Screening Program recommends testing for the target group every 2 years. The US study by Lindors and Rosenquist (1995) has suggested that for improved cost-effectiveness of breast screening women 50–79 years should be every 2 years and women 40–49 annually.

CONCLUSION

The randomised trial process is the most reliable method of assessment of efficacy of screening programs and is without bias. Many countries recommend regular screening for women of certain age groups and others in high risk groups such as those with familiar history of breast cancer. Recently the results presented from screening programs have indicated that they are effective in reducing the mortality rate (Anderson, 1998). However controversy still exists. Criticisms by Gotsche and Olsen (2000) stated that their meta-analysis of results of eight earlier trials showed that the six of those reporting favourable results had statistical randomisation faults. However the Gotsche and Olsen report is being challenged and they are also accused of omitting more recent favourable results from the two of the eight papers which reported unfavourable results. An outline of the controversy is given by Rubin (2000). Specific information continues in The Lancet correspondence pages (see Gotsche and Olsen reference entry herein).

The mortality rate from breast cancer has decreased significantly from 1995 due, in part, to the increasing utilisation of mammography (Bassett et al. 1997) and improvements in technology, film quality, double reading of mammograms, better quality control and management (Cardenosa et al. 2000). There is also the separate factor of contributions from improved treatments so the respective contributions to mortality reduction is difficult to quantify. A good summary of the practicalities and problems, including human aspects, associated with screening programs as well as the benefits has been given by Hirst and Kearsley (1991) with particular relevance to Australia's first population based mammography screening project as well as four international screening studies at that time. They clearly pointed out that "mammographic screening is not simply a technical exercise". Quality control, strategic organisation and experienced staff are necessary for success and is now evidenced in reports such as the year 2001 Report on Government Services, section on Breast Cancer. Also since 1994 in the USA the Mammography Standards Act required Federal accreditation of all mammography facilities.

The evidence available to date suggests that, provided there are optimal conditions of quality control and staff expertise, mammography has the potential to reduce mortality from breast cancer. Screening is often multidisciplinary and a successful effective program may mean cutting across normal professional and organisational boundaries.

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