

Duration of Project

It is proposed that the pilot project will operate for two years. Six months will be required for preparation, two years for operation, and then six months for analysis and rundown.

Location proposed

The Amalgamated Melbourne & Essendon Hospitals at the Essendon and District Memorial Hospital. Screening is to be based on the hospital at Essendon because this is regarded by the local community as a centre of health-related community activities rather than as a conventional hospital.

Target Group

Recent research data suggests that women aged 40 years and over are those most likely to benefit from a population-based mammography screening. Therefore, women aged 40-69 years, living in the Essendon, Broadmeadows and Kellor areas will be targeted for this project.

There are 72,527 dwellings in the Essendon-Broadmeadows-Kellor areas with 35,000 women in the target age group (1981 census data). The literature recommends a screening interval of around two years and this means that the initial pilot project will only be a primary screen. The literature also recommends that two views be used for women in the 40-54 age group and one view for women aged 55 years and over. In the studies to date there is an average of 5% of women recalled for a further screening.

Based on the above data, and overseas systems, it will be possible to screen 12 women/hour in the 40-54 age group and 16 women/hour in the 55-69 age group. For those women recalled for a second screen, the rate will be 4 women/hour. With the use of three radiographers, it will be possible to screen every week day and Saturday morning. The times during the day will vary, and will include evening sessions.

If 90% of women between 40-69 from the three areas are screened it is estimated that primary screening will take 76 weeks. Recall screening of 5% of these women will take a further 14 weeks.

ACHIEVING HIGH COMPLIANCE

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The strategies below aim to maximize compliance in the target population. It should be noted that they involve a high commitment of human and financial resources and we wish to note that such a commitment may not be practical or even necessary for a statewide long-term program. We have approached the problem in this way because it is assumed that in a community where there has been no previous mammographic screening offered, nothing less than the utmost effort is likely to produce the desired response rate of 80-90%.

Budget requirements are based on this approach. They include both the budget for staff and materials necessary to produce the 80-90% response rate. It is envisaged that the budget requirements will be higher in the first year and will reduce thereafter.

1. Use of Electoral Register

The most comprehensive list of adult individuals available is the electoral register which we estimate will cover 90-95% of the eligible population of the area selected. Another possibility is the Medicare register, sacrosanct till now, but which would also serve the purposes of this study. It is proposed to use the electoral register (a) as the denominator, which is essential to the estimate of compliance with the screening offer and (b) as the way by which individuals in the target population can be identified and approached for the screening. Since the nature of mammographic screening precludes the "drop in" approach it will be necessary to see women by appointment only. Therefore, letters will be written to women by name at the address given in the electoral register offering appointments at specified times. Early pilot work will be necessary to determine the accuracy of the electoral register. It will also determine the proportion of women who do not accept or fail to keep the appointments offered which will allow an estimate of overbooking necessary to maintain full lists. Women will be asked to accept the appointment or else an alternative they choose in a reply-paid envelope. They will be offered appointments for special sessions at which interpreters in various languages will be present.

Since it will be important to achieve a very clear understanding by women of the nature of the offer and the benefits of mammography, a carefully

pre-tested illustrated pamphlet will accompany the letter of invitation. This will be in all the major languages known to be spoken in the catchment area.

2. Organisation Phases

- a. **Community and Professional Development**
Contact will be made with a number of key community and professional groups who will be subsequently involved with education and recruitment. They include: medical practitioners, local health agencies, municipal council representatives, community leaders, service clubs, unions, employees.
Intensive work with these groups will precede the public launching of the program. In particular, general practitioners are seen to have an important role in promoting and reinforcing mammography among their patients and in playing a part in the subsequent management of patients who have some abnormality detected.

- b. **Initial Public Promotion**
There will be a media campaign designed to create maximum participation of women in the area. This will include local press and electronic media (if appropriate), transit advertising and other outdoor sites where available. The campaign would aim to saturate the target area with posters in locations such as doctors' surgeries, community health centres, shopping centres and other places where women congregate.

- c. **Personal Recruitment**
The personalised letter is the initial approach. The response rate to this will be assessed and then a second letter will be sent to non-responders. If the response to this approach is in the 80-90% range, then no further personal recruitment is necessary.

However, since it is not expected that the direct letter approach will yield a sufficiently high response, additional recruitment drives are proposed and will be undertaken progressively according to the response. The second phase will be an approach to employers and unions to gain access to the women in the work force who would be eligible for mammography. Appointments would be made on the spot by field staff for interested women.

The third approach will be setting up caravans or publicity stands at shopping centres. Appointments would be taken from these areas. Only women in the recruitment zones would be included in these recruitments;

Finally, we will endeavour to involve all GPs as a routine to ask women patients over 50 if they have had a mammogram, and if not, to offer to arrange the appointment as a part of the service provided by the practice. It is envisaged that the greatest response will be to the primary approach, ie, the letter. It is likely that there will be lower proportions recruited by the other methods.

d. **How to Handle Participants** (What happens on the day of mammography)

The key principle guiding the way in which women will be managed during the screening procedure is that the experience will be as pleasant and reassuring as possible. The long term viability of the program will depend on its good reputation among participants and in the community. Therefore-

- i it must be open at times convenient to everybody, including evenings, Saturday mornings, and other times if necessary
- ii there will be minimum waiting time,
- iii staff will be trained to recognise and counsel the over-anxious patient,
- iv quality of the service will be maintained by following up a random sample of participants to evaluate the perceptions of the service provided.

Before leaving the screening centre, participants will be given written information on how results will be notified, future screening and other precautions against breast cancer.

e. **Liaison with the Ministerial Women's Health Policy Working Party**
The Ministerial Women's Health Policy Working Party is currently developing strategies for women's health in Victoria. Liaison will be maintained with this Working Party.

3. Understanding Compliance Behaviour

Research to be conducted by the Centre for Behavioural Research in Cancer (ACCV) will be designed to give a better understanding of the compliance behaviour of the target population.

Designs to be considered include -

- a. experimental designs which vary persuasive approaches and observe compliance rates among the different treatment groups,
- b. prospective designs, in which a sample of the target population is interviewed before the screening program is launched, permitting the identification of factors that discriminate compliers from non-compliers,
- c. retrospective ("case control") designs, in which a sample of compliers is matched with a sample of non-compliers and interviewed in search of discriminating factors.

5. Requirements and Costs

Equipment costs, staff salaries and recruitment costs are as per attached appendices A, B, C and D respectively. Costs associated with cytology of fine needle aspiration and histology from surgical biopsy will be absorbed by the hospital. Costs of the research into compliance will be borne by the ACCV.

6. Project Management Structure

Project Director - Mr. Ian Russell, Head of Surgical Unit No. 1 and the Breast Service - AMEH.

Supported by an Advisory Committee, chaired by the Project Director, with members from:-

AMEH

Anti-Cancer Council of Victoria

Health Department, Victoria

Essendon Community

This Committee will be responsible through the Director of Medical Services to the Executive Director - AMEH. (See Appendix F). It will have responsibility for the complete control of the project. It will also report regularly to and be represented on, the proposed Victorian Breast Cancer Screening Advisory Committee.

(1) "What is the age range of women for pilot programs aimed at determining the feasibility of mammographic screening?"

In answering this question it is assumed that the efficacy of the procedure has already been demonstrated for all age ranges that are being considered, and that the pilot study is addressing other issues such as

- the acceptance by women from different age groups
- the number of films and abnormalities which can be handled
- cost/benefit considerations
- organizational feasibility

THE AUSTRALIAN DILEMMA:

We need to be clear on what is the issue we are attempting to resolve. There appears to be 3 possible questions for consideration.

EVIDENCE FROM OVERSEAS STUDIES:

HIP (New York):
 Age at entry 50-64
 30% decrease in mortality in screened women

45-49
 Decrease in mortality shown only for cases diagnosed after reaching 50 years of age

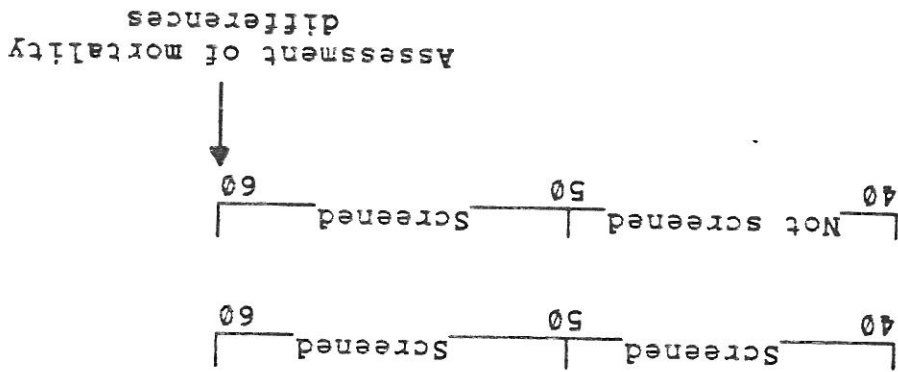
40-44
 No difference in mortality after reaching age 45-49

SWEDEN:
 A reduction in mortality was demonstrated for women aged 50-74 years. Only a small number of deaths were recorded in women aged 40-49 years giving limited statistical power to determine the full effect in the younger women.

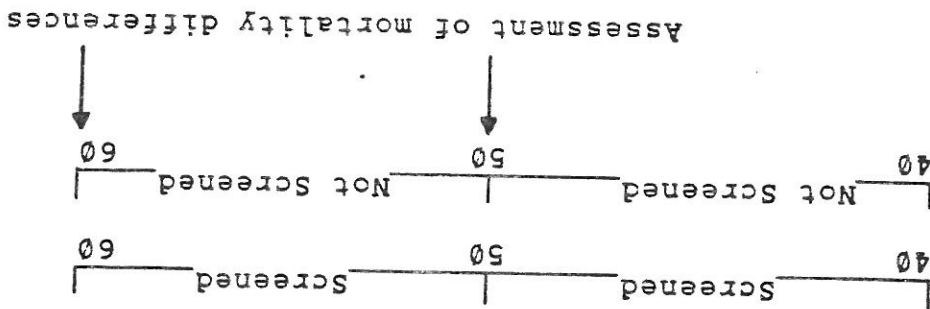
AGES TO START AND STOP SCREENING

ISSUES IN BREAST CANCER SCREENING:
 WHO, WHEN AND HOW OFTEN TO SCREEN

ATTACHMENT 2/1



(b) "Is there a gain in the mortality reduction by beginning to screen women at 40 rather than at 50 years?" This question has not yet been answered. It would be addressed by a study which began the observation of all subjects at age 40. Screening of half of the subjects would begin at age 40 and screening of the other half of subjects would begin at age 50. The evaluation would begin at age 60. Thus:



There are 2 issues to be addressed:
 (a) "Is mammographic screening effective at ages 40-49?" This is answered by comparing the mortality in women who are screened during this age interval with the mortality in women who are not screened in this age interval. Thus there would be 2 parallel groups as in HIP and Sweden:

(2) "What is the age range of women for research programs which are aimed at determining whether mammographic screening is effective for women aged 40-49 years?" Note: If assessment of the efficacy is to be by a reduction in mortality, then very large numbers of subjects will be necessary and a delay of at least 10 years will occur while statistically and clinically valid mortality results accrue. (This type of research would involve repeating the overseas studies.)

(3) "what is the age range of women who should be invited for population screening in Australia?"
An objective decision on this question depends on satisfactory answers to questions (1) and (2) above.

IDEAL FREQUENCY OF SCREENING

EVIDENCE FROM OVERSEAS STUDIES:

HIP: annual mammography taken for 4 years

SWEDEN: women aged 40-49 years screened every 24 months
women aged 50-74 years screened every 33 months

POINTS TO BE CONSIDERED:

1. Ideally the rescreening interval should be less than the lead time of the curable cancers, but there are difficulties in estimating this for breast cancer. Alternative research methods of providing information on which an informed decision could be made include
(a) a randomised control trial of different screening frequencies

(b) a comparison of mortalities between screening programs using different intervals

(c) mathematical modelling with computer simulation of the natural history as shown from screening programs.

2. An experimental study of a screening procedure probably should evaluate screening at the greatest frequency that is likely to be feasible as a service activity.

3. With frequent re-screenings, the proportion of all cases detected as a result of screening will increase, but the average number of cases discovered per examination will decrease.

4. To be 100% effective re-screenings would have to occur at such close intervals as to not be cost efficient. A balance must be drawn. It must be accepted that in practical terms a screening program will not be able to detect 100% of the cancers.

5. If we wish to achieve the same reduction in mortality as has been demonstrated in the overseas studies, then all aspects of our program (including the rescreening interval) must be comparable.

Heather Mitchell
13 April, 1987

Issues in Breast Screening

Mammography - Techniques & Standardisation of Reporting

The RACR Mammography Sub-Committee is active in developing policy in respect to screening. Assuming that screening centres may emerge from both public and private sectors, the Committee is being canvassed currently in respect to the following concept.

"An accredited screening unit would function under the umbrella of a local state cancer authority. An accredited centre would have communication links with the central authority to access data concerning previous examinations. Registration data and findings on screening mammography would be forwarded to the central authority. Would follow-up studies in dubious cases be organised from the central agency? Where would the screening mammograms be held? What would be the situation for a person presenting to another screening centre in the same state for follow-up one or two years later."

The attitude of RACR to some of these matters should be available by mid-year.

Criteria for accreditation of units would include:

- (a) The quality of equipment
- (b) The training and experience of the radiologists and radiographers
- (c) Willingness to co-operate with the central co-ordinating agency.

Mammography Courses:

RACR members have been informed of the following activities:

Formal Courses in 1987

- May 8-9 Breast Imaging Update - Surfer's Paradise
- Sept 2-5 Dr Laszlo Tabar - Melbourne
- Oct 7 RACR Mammography Course - Sydney

Mammography Centres

The RACR aims to designate at least one centre in each state where further experience can be gained. To date the following centres have agreed to co-operate:

- NSW: Sydney Diagnostic Breast Clinic - Dr Joan Croll
- QLD: Wesley Breast Clinic - Dr Cherrill Hirst
- VIC: Alfred Hospital - Dr Nina Sacharias

Much criticism of current mammography concerns the form of report writing. The concept of replacing freehand reporting with a more objective system of cancer probability groupings is to be explored. The criteria on which patients would be placed in particular cancer probability categories is being studied by Doctor J R Frayne of Western Australia.

Standardised Reports

Although film screen mammography is favoured for screening programs, the strength of the method seems better established in the fatty breast of generally older women. For the larger breast with a considerable amount of breast tissue the screen film technique is considered by many as less satisfactory than xeromammography. The article of Skubic and Fatouros (Radiology 1986:161:263-270) is worthy of study. They indicate that the dosage in screen film mammography is particularly dependent on breast thickness and in the large dense breast there is a need for firm compression. When a grid is added, as is often the case for this type of breast, the dosage may exceed that for xeromammography. The question of which in the long run is the better technique for screening mammography will remain clouded until the new xeromammography processing becomes available with supposed significantly lower dose requirements.

Technique

MANAGEMENT OF IDENTIFIED LESIONS -
Discussion by Colin Furnival

The detection of potentially malignant lesions in a Breast Screening Clinic invokes the following logistic support:

- i) Facilities for mammographic localisation and on-site specimen radiography.
- ii) Appropriate surgical techniques.
- iii) Appropriate histopathology service.

The selection of patients for surgical biopsy requires specialist expertise and involves

- i) Clinical judgement.
- ii) Mammographic interpretation.
- iii) Application of appropriate supplementary diagnostic methods e.g., ultrasound and aspiration cytology.

The decision to recommend biopsy must be made with an understanding of

- i) Probability of malignancy (based on predictive values);
- ii) Patient morbidity and anxiety.
- iii) Procedural costs.

The aim of the Screening Clinic is to minimise surgical biopsy, to minimise 'false-positive' results and to eliminate 'false-negative' results.

An overview of results currently obtained is shown in the following tables, which summarise the ratio of benign:malignant histology, among biopsies recommended by BCDDP Centres, DHSS Screening Centres, and the Wesley Hospital Breast Clinic (Brisbane).

BIOPSY RATIOS - SUMMARY

BCDDP	Year 5	4.1:1
Wesley	All Biopsies	2.7:1
Edinburgh	Impalpable	2.78:1
Wesley	Impalpable	3.9:1
Gulldford	Year 5	0.5:1

BIOPSY RATIOS FOR MAMMOGRAPHIC LESIONS

Edinburgh: No. of biopsies = 155
 No. of cancers = 41
 Benign : malignant = 2.78:1

Features of cancers: Calcification 24 (59%)
 Opacity 14
 Both 3

BIOPSY RATIOS FOR BREAST LESIONS

BCDDP
 Year 1 5.5 : 1
 Year 2 6.2 : 1
 Year 3 5.9 : 1
 Year 4 4.8 : 1
 Year 5 4.1 : 1

Talked by I. King

2/4

ATTACHMENT

EVALUATION OF BREAST SCREENING

The aim of the evaluation is not to determine whether screening lowers mortality as that has been established. The aim is to determine how best to establish screening in Australia and the cost of different methods of screening.

The evaluation in effect constitutes an intervention trial and would compare the results of the different approaches being developed in Queensland. At least one private clinic should be included, as well as clinics run by government and community organisations.

The aim of the evaluation would be to determine:

Topic Criteria

- a) Population lists vs combination of G.P. referral and educational programmes as a method of recruitment.
- b) Fixed vs. mobile clinics (Only an issue in metropolitan areas as only mobile clinics likely to be feasible in rural areas.
- c) Need for physical examination (given quality of all aspects of mammography has been maximised).
- d) Quality of mammography.
- e) Number of views required for routine subjects
- f) Rescreening interval.
- g) Staffing.
- h) Operational issues.
- i) Acceptability of service to subjects.
- j) Attitudes to mammography.

- % of population screened.
- Characteristics of attenders/non-attenders.
- Acceptability to public and professions.
- Costs.
- Fixed vs. mobile clinics (Only an issue in metropolitan areas as only mobile clinics likely to be feasible in rural areas.
- Need for physical examination (given quality of all aspects of mammography has been maximised).
- Quality of mammography.
- Detectable cancers missed.
- Inter and intra observer reliability.
- No. of cancers found with *second view*
- Costs including costs of recall where only one view taken.
- Rescreening interval.
- Interval cancers (by age, etc.)
- Costs.
- Depends on issues above.
- Staffing.
- Operational issues.
- % accept invitation for screening.
- % self-referrals.
- Number of repeat films.
- Number referred for assessment.
- Biopsy referral.
- Breast cancers detected.
- Interviews.
- Population survey.
- Market research.
- Attitudes to mammography.

Because cost is such a central issue it will be necessary to employ an economist to ensure a standard costing method for all centres.

Comparative evaluation requires the collection of comparable data from all centres. There is a cost involved in obtaining information which is required not just for the operation of each centre but also to answer the questions above, and this cost should be met by the Commonwealth so that a national policy can be developed.

RESOLUTIONS OF THE MEETING
OF THE NATIONAL BREAST STUDY COMMITTEE
APRIL 24, 1987

1. Overseas studies have established that high quality population-based mammographic screening with expert follow-up treatment can reduce the mortality from breast cancer in the screened population by one third.
2. There is good evidence that screening is beneficial in women over fifty.
3. The committee recommends that pilot programs of breast screening be introduced in Australia in a planned, controlled manner in designated centres.
4. The initial pilot programs should be designed to yield information on incremental costs and incremental benefits.
5. Evaluation of these pilot programs should provide the basis for a national policy on breast cancer screening in Australia and should address issues such as recruitment of women, facilities, staffing and operation of screening centres.
6. A meeting of the directors of the proposed screening programs and appropriate support personnel should be arranged to consider and design documentation and to develop a protocol for evaluation of the screening programs.
7. An updateable list of women in the target population is essential for a mass screening program.



3rd June, 1987.

Dr. Ian Russell, F.R.A.C.S.
C/- Anti-Cancer Council of Victoria,
Keogh House,
1 Rathdowne Street,
CARLTON SOUTH, V. 3053.

Dear Ian,

I was sent the Minutes of the National Breast Study Committee Meeting which was held on Friday 24th April. I get the Minutes because of my involvement in the Patient Affairs Committee and also my role as Chairman of the Medical Advisory Committee of the Queensland Cancer Fund. My point in writing relates to statements on page 2 of the Minutes under 3.1.1 - information supplied about the scene in Queensland. I note that the "The Queensland Group" is mentioned. To my knowledge the Steering Committee of the Queensland Breast Screening Program was not asked to supply any information and the information that appears in your Minutes is both wrong and misleading.

Could I make some points to elaborate on that?

1. Firstly, locating the screening clinic in a public hospital, does not present cost problems at least as far as we can see. It does present some difficulties in dissecting out the cost of running the program but our indications are that the service runs rather more cheaply than we could have hoped. The second sentence in that first paragraph is totally wrong. Women with symptoms or signs of breast disease are specifically excluded from the program. A few do sneak in denying that they have breast lumps. Of course women who complain of some breast discomfort are not excluded and this is only reasonable. We are therefore, examining as far as we possibly can, an asymptomatic group of the population.
2. As I mentioned before, I don't know what the Queensland Group is that is mentioned, but certainly the clinic does not consider that mass screening is not viable. We went to an open access clinic initially because of influences other than truly scientific and/or medical. We will be pleased to introduce a population based screening program together with an open access clinic and have written some guidelines for this.
3. The third paragraph is also totally wrong. At present, hospital based equipment is being used but the rules were laid down by the clinic and adhered to. We now have a second machine which is totally dedicated to the clinic's utilisation and throughput will rise very sharply indeed. The clinic is contemplating night

screening but no firm moves are being made at this time. A submission is being presented to the Queensland Health Department shortly for the extension of the service through the Brisbane Metropolitan area and also into other centres in the state.

Obviously since I am not a member of your committee, I cannot ask that the Minutes be corrected but I would hope that the errors of fact would be brought to the attention of your committee. These errors would not have occurred had a member of the clinic staff been appointed to the committee. One would have hoped that in a committee which was considering screening, that a representative of the clinic, preferably the Director, Dr. Christine Baker, would have been asked to provide some information which would have had the advantage of being factual, concise, pertinent and also up to date.

Yours sincerely,

Professor J.F. McCaffrey,
Head, Department of Surgery.

c.c.: Dr. C. Baker,
Royal Women's Hospital.

held in Sydney, Friday June 19th, 1987.

Present

- Dr. Cheryl Hirst - Director Wesley Breast Clinic, Brisbane.
- Dr. Christine Baker - Director Royal Women's Hospital Breast Screening Clinic, Brisbane.

Professor Bruce Armstrong - Chairman Western Australian Steering Committee.

Professor Martin Tattersall - Chairman of New South Wales Steering Committee.

Mr. Ian S. Russell - Director Victorian Screening Project.

Dr. Nigel Gray - Director Anti-Cancer Council of Victoria.

Dr. Jane Hall - Health Economist Westmead Hospital.

Mr. Lawrence Wright - Executive Director Australian Cancer Society.

Dr. Ron Weikle - Melbourne Private Radiologist.

Report of the Royal Womens Hospital Breast Screening Clinic and Data Collection Forms.

Professor Tattersall reported that the Sydney project was designed to screen 36,000 women. Women would be seen in a mobile unit parked in the hospital area and would be seen by appointment only.

X-ray reports will be read by two individuals. One will be a radiologist, the other may be a radiographer. The report will be a simple one indicating the appropriate management of the patient i.e. re-examination or routine re-screening.

The subsequent management of patients with abnormal mammograms will be by the project team.

A radiologist has been appointed as Director plus a research officer funded by the National Health and Medical Research Council.

Professor Armstrong indicated that the Western Australian project had not yet been fully designed. An interesting aspect of this project will be to compare the management of patients with abnormalities by their family doctor and specialist referral compared with management by the screening team.

Dr. Baker reported that the Royal Women's Hospital in Brisbane was at present engaged in random screening of women over 50 plus women who had a previous breast biopsy or had a family history. The clinic has attracted patients by media publicity and patients may come in off the street.

Abnormalities are noted in the x-rays in approximately 6 per 1000 patients half of whom are referred to the general practitioners and half are treated within the hospital system. It is anticipated that this clinic will move to screen a defined population.

- 5/ Agreement should be reached on strategies for management of detected lesions.
- 4/ The nomenclature of the various pathological conditions which will be detected by mammography should be agreed between pathologists associated with the screening project.
- 3/ There is a need to standardize the mammography report. The format of the report of mammography of patients attending a screening clinic should be different from the current reports of radiologists. In essence it is necessary to determine whether there is no suspicion of cancer and the patient should return for screening at the next appropriate time or that there is a suspicion of cancer and further investigations required or that the films are unsatisfactory and should be repeated.
- 2/ Standards for mammography should be established.
- 1/ A minimum core data base should be established for collection by all the pilot projects. Individual projects may collect additional data related to their particular fields of enquiry.

The meeting agreed that :-

team.

Patients with mammographic abnormalities would be recalled to a review clinic and would be managed by a project.

Mr. Russell reported that the aim of the Victoria Project was to address the problems of patient recruitment. The screening would be population based and the population would have a variety of ethnic backgrounds.

His group is currently using the Tabar protocol with a single view. Patients are referred to their general practitioners or to private or public hospitals. He believed that a realistic fee for screening was \$35:00 per patient.

Dr. Meikle, a private radiologist in Melbourne, reported that his group had conducted some market research in Melbourne which indicated that compliance would be low and that only ten per cent of women currently perform regular breast self examination. He believes that training radiographers to perform high quality mammography will be a problem. He had preference for CGR machines. He felt that pneumatic compression of the breast was essential, that a grid should not be used as this increased the dose and above all that there should not only be a dedicated mammography machine but also a dedicated processing machine.

Dr. Hirst reported that the clinic at the Wesley Hospital in Brisbane had grown from a breast treatment clinic. The clinic was run privately. Patients had a mammogram and were examined by a medical officer. Patients were referred to their general practitioner for treatment.

- 6/ Arising from these decisions it was agreed that the National Breast Study Committee should establish a number of working parties to deal with :-
1. Standards for mammography and standardization of mammography reports.
 - ii. Form design and data analysis.
 - iii. Pathology.
 - iv. Strategies for management.
 - v. Economic evaluation.

ROYAL WOMENS HOSPITAL BREAST SCREENING CLINIC - AN INTERVENTIONAL TRIAL.

Recruitment of women for a screening programme may be accomplished in a number of ways. Once the categories of screeners has been decided according to age risk factors or combinations of both, then adequate penetration of the population needs to be achieved if levels of compliance are to be recorded and improved upon.
The R.W.H.B.S.C. at the present time is operating as an open access clinic. We have used

(a) Circularizing General Practitioners.

(b) Media

(c) Targeting womens organizations.

(d) Poster

(e) Cancer Fund

(f) Use of a public relations body.

With regard to population based screening, we shall be entering into this in the very near future. The catchment population considered for population screening is that area north of the Brisbane river, approximately 500,000. The population to be screened at the R.W.H.B.S.C. would consist of those women who usually attend a public hospital. In addition discussions are in hand with The Wesley Hospital to screen those women in this catchment area who elect to go privately for a screening examination.

There is still some analyzing of the percentage of women who go public or private but both sectors would be involved in this population screening. This mix of both facets of medicine most accurately represents the true framework in which screening for breast cancer in Australia will be performed.

The population of women 50 and over in this catchment area is 61,500 and with the inclusion of women with a family history and previous surgery to their breasts as well as self referrals the total number is 80,000. Approximately half those women would attend the public hospital so we are looking at screening 40,000 women, the actual yearly number is still to be determined depending on the rescreening interval of 2 or 3 years.
We are currently examining the possibility of co-ordinating the activities of public hospitals in other parts of the state with regard to breast screening.

From this population screening, in addition to normal risk factors information would be available on

1. Characteristics of attenders/non attenders.
2. Distance a woman has to travel for a screening. This information would be necessary for planning placements of mobile units, the next step in screening.
3. Ethnic groups could be assessed as regards compliance.
4. Acceptability to public and professions.
5. Costs.

Australia has no ready made age sex register as the English have compiled for their G.P.'s. This situation could be overcome with the use of electoral rolls or Medicare records. The clinic will access the electoral roll, thereby comparing attendance with the electoral roll.

Methods of recruitment.

1. Personalized invitation.

2. Non personalized invitation.

3. Letter drops.

4. Education.

5. G.P. involvement.

6. Increasing community awareness.

All G.P.'s in the immediate vicinity should be encouraged to participate.

1. By supporting the screening programme.

2. It would be preferable if the woman was examined prior to her coming to the clinic so any obvious lumps could receive priority attention. Also this would negate the clinical examination at the clinic.

3. Each G.P. would in return receive notification of the result of the screening.

Equipment.

Mammography machine. The choice of the versatility of this piece of equipment depends on whether it is to be used for pre operative intensive investigations as well as screening or only screening. All mammography machines should be dedicated units.

A dual focal spot mammography machine, with a high output mA is necessary when magnification views are needed to reduce motion blurring. In addition provision for localization procedures should be included in this piece of equipment.

Screening units engaged solely in screening require only a single focal spot, preferably not more than 0.3mm. A good power supply is necessary and the machine should be able to withstand jolting if a mobile unit is used.

Automatic compression may prove less time consuming and a cassettes rather than vacuumbags could be used to allow a greater throughput of patients.

Processors.

A dedicated processor is advisable for screening units. Strict monitoring of temperature, developing time and replenishing rates is necessary if quality mammography is to be attained. It is advisable if mobile units are planned that processing from these units be undertaken at the central screening unit.

Multiviewer

A multiviewer film reading device should allow for rapid reading of films.

Computer

Computerised recording would serve three main areas.

1. Patient identification and tracking.

2. Data analysis with regard to risk factors, results and efficacy.

3. Cost analysis

It is important that there be co-operation and standardization of data collection between screening clinics.

Staffing.

With regard to staffing certain areas should be looked at carefully,

1. comprehensive training especially radiographers and radiologists.

2. adequate levels of staff.

Depending on whether a clinical examination is included in the initial screen or not, the use of nurse examiners specifically trained in clinical examinations can be cost saving instead of using doctors. Alternatively, radiographers could perform the clinical examination.

Radiographer.

From our experience a radiographer is able to do obliques on 20 patients in 5 hours, approximately, one patient every 8.5mins if the radiographer is processing the films as well. Possibly 40 patients a day with one radiographer doing only obliques is an adequate staffing level. 60 patients, obliques only with two radiographers, or a dark room attendant. A reduction of 10% for two view mammography.

The Forrest Report suggests two radiographers take 40 single obliques in three and a half hours whereas one radiographer takes 30 single obliques in three and a half hours.

Radiologist.

Films should be placed ready for viewing on the multiviewer to save valuable radiologists time. This could be done by a clerical person or a dark room attendant. We are using 12hrs/week radiologist time to read 300 films. Forrest Report suggests 110 films / hr but that is with a multiviewer. Another alternative to radiologist screening the films, is to use trained medical personnel as screeners, or trained radiographers. This is working well in the U.K. and the Netherlands.

If a clinical examination is included in the initial screen then a medical personnel is needed to assess both the results of the clinical examination and the mammogram, to decide if a woman has to return for further assessment. If only a mammographic examination is performed then the services of a manager with computer skills, organizational abilities and a sound knowledge of medical economics could be used instead of a doctor.

Statistician

Analysis of the data is another area that is necessary so as to plan for the future. One is available. An economist is costing the clinic.

Data entry personnel, receptionist, and other clerical support are all vitally necessary to the smooth operation of a screening clinic.

... areas to be considered here.

1. The initial screen.

2. Investigation of abnormalities.

Every effort should be made to ensure that the actual screening examination is as pleasant as possible to the consumer to encourage compliance with repeat screening invitations. The majority of the consumers (90%) are normal. This fact is of prime importance when designing a screening program. It is thought necessary at the R.W.H.B.S.C. that all women receive notification of their results as soon as possible.

If further investigations namely, additional mammograms, ultrasound a further clinical exam or a fine needle aspiration biopsy is necessary then these further investigations should be expedited.

Documentation of data.

Data should be concise and accurate as many thousands of sets of information will be collected. The forms from the R.W.H.B.S.C. are included.

ROYAL WOMEN'S HOSPITAL BREAST SCREENING CLINIC - AN INTERVENTIONAL TRIAL.

Recruitment of women for a screening programme may be accomplished in a number of ways. Once the categories of

ROYAL WOMEN'S HOSPITAL
BREAST SCREENING CLINIC

QUESTIONNAIRE

Surname: _____
 Given Names: _____
 U.R. Number: _____
 Sex: _____
 D.O.B.: _____
 (Affix Patient ID. Label)

It would be helpful if you could fill in this questionnaire.

1. If you are still having periods, when was the first day of the last one? D M M Y

2. Could you be pregnant? No=1 Yes=2

3. At what age did your periods start? _____

4. If you have had any children how old were you when your first child was born? _____

5. How many children have you had? _____

6. If you have ever taken the oral contraceptive pill, total length in years? _____

7. If you are no longer having periods, how old were you when they stopped? _____

8. If you have ever taken hormone tablets for change of life symptoms, how long in years? _____

9. If you examine your breasts how many times a year do you do this? _____

10. List any members of your family with breast cancer? _____

RELATION _____ AGE CANCER DETECTED _____ ONE OR BOTH BREASTS _____

11. Does your doctor examine your breasts regularly each year? No=1 Yes=2

12. How did you find out about the clinic?
 (1) Radio or TV (2) Newspaper or Magazine
 (3) Doctor (4) Friend (5) Relative
 (6) Through work (7) Ladies Bowlers (8) Other

Referring Doctor: _____
 Address: _____

D M M Y

DATE OF VISIT

TYPE OF VISIT

Baseline = 1
 Routine FU 2 to 5

CONSENT

I give permission to The Royal Women's Hospital Breast Screening Clinic to perform mammography & clinical examination of my breasts and to exchange any information with my personal physician. All information will be treated in strictest confidence & if any results are used for research, my identity will be protected.

Signature: _____

LAST MAMMOGRAM

1. None
2. 1 year or more
3. 6 - 12 months ago
4. Less than 6 months

ROYAL WOMEN'S HOSPITAL
 BREAST SCREENING CLINIC
 FORM NO. 6: CYTOLOGY AND
 HISTOPATHOLOGY

1. Date

DD MM YY

2. Visit

baseline 1
 follow-up 2
 " 3
 " 4
 " 5

Surname: _____
 Given Names: _____
 U.R. Number: _____
 Sex: _____
 D.O.B.: _____
 (Affix Patient ID. Label)

3. Investigation Right Left

cytology 1 histology 2

4. Are both breasts involved?

Yes 1
 No 2

5. This form:

right breast 1
 left breast 2

CYTOLOGY:

6. Cytology result:

dominant lesion: 1 2 3 4 5
 2nd lesion: 1 2 3 4 5
 cytology code: 1 2 3 4 5
 topography: 1 2 3 4 5

HISTOLOGY:

7. Benign calcification present?

Yes 1
 No 2

8. Malignant calcification present?

Yes 1
 No 2

10. Multifocal malignancy?

Yes 1
 No 2

11. Histology result:

dominant lesion: 1 2 3 4 5
 2nd lesion: 1 2 3 4 5
 histology code: 1 2 3 4 5
 topography: 1 2 3 4 5

AXILLARY NODES:

12. Number of nodes biopsied?

nodes: 1 2 3 4 5

13. Number of positive nodes found?

nodes: 1 2 3 4 5

14. Position of nodes labelled?

yes 1
 no (Go to Q. 15) 2

15. Highest positive node?

apical 1
 central 2
 pectoral 3

15. Highest node examined?

apical 1
 central 2
 pectoral 3

22. Number of significant masses present
 none (Go to Q. 30) 11
 one 12
 two 13
 three or more 14
 Right Left

23. Shape of dominant mass:
 round or oval 11
 lobulated 12
 irregular 13
 Right Left

24. Edges of dominant mass:
 sharp 11
 indistinct 12
 spiculated 13
 partially obscured 14
 Right Left

25. Halo present:
 none 11
 fully 12
 partially 13
 Right Left

26. Dominant radiographic mass corresponding to dominant clinical mass?
 Yes 11
 No 12
 Right Left

27. Dominant mass shown in all projections?
 yes 11
 no 12
 Right Left

17. Calcification:
 none (Go to Q. 22) 11
 vascular (Go to Q. 26) 12
 non-vascular, not in mass - scattered 13
 (Go to Q. 22) - clustered 14
 - clustered 14
 - scattered 15
 & clustered 15
 Right Left

18. Number of calcifications in cluster:
 < 5 11
 5 - 10 12
 > 10 13
 Right Left

19. Density of calcification in cluster:
 faint 11
 moderate 12
 dense 13
 heterogeneous 14
 Right Left

20. Shape of calcifications in clusters:
 punctate, round 11
 linear, branching 12
 casting 13
 ring-shaped 14
 heterogeneous 15
 (Go to Q. 22)
 Right Left

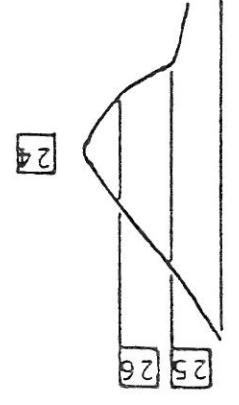
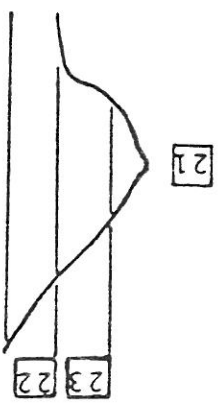
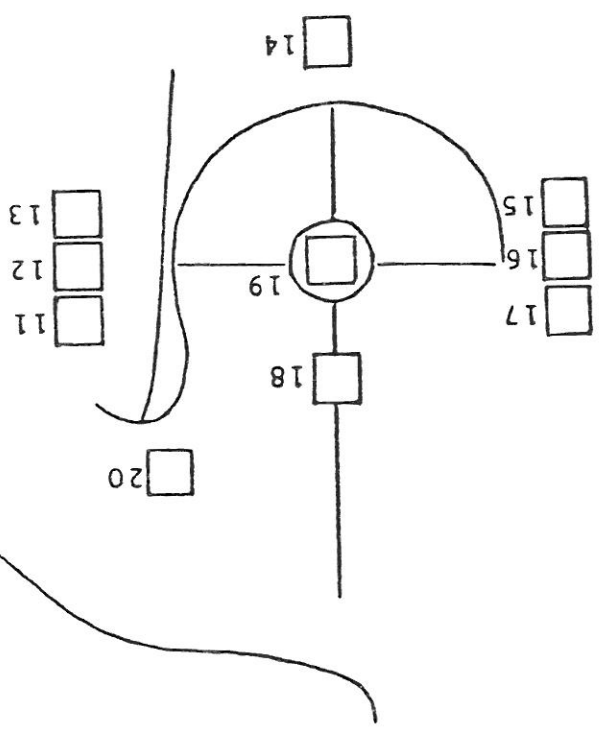
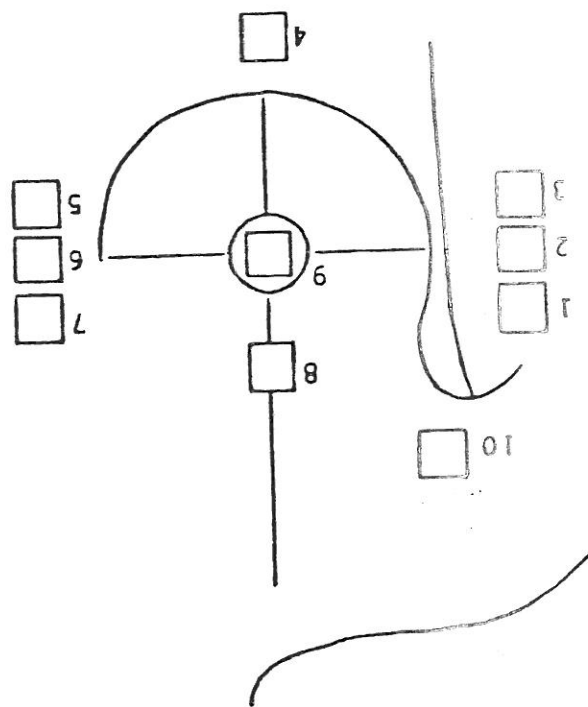
21. Non-vascular within a mass:
 benign 11
 malignant 12
 indeterminate 13
 Right Left

Hammography (cont'd)

Surname: _____
 Given Names: _____
 U. R. Number: _____
 D. O. B.: _____

28. Dominant mass size and location.

Right Left



Right breast Left breast
 Site code of mass

Right Left
 A.P.
 Vertical
 Transverse

28. Size of dominant mass in mm:

RECEIVED
14 MAY 1987
Ans. P. Jm/S

Could you please let me know if your organisation will be able to participate in the work of this subcommittee and, if so, the name of your representative. As soon as all nominations have been received, the AHMAC secretariat will make the necessary arrangements for the meeting and advise members accordingly.

The subcommittee is to report on its findings in time for consideration by Health Ministers at their next Conference currently scheduled for early March 1988. Consequently, I would like to convene the first meeting of the Mammography Screening Subcommittee by no later than the end of June. Meetings will probably be held in Sydney unless there is a definite need for the subcommittee to meet elsewhere.

I have agreed to chair the subcommittee and, in addition to three other representatives of AHMAC, the Council has requested that your organisation be invited to participate in the work of the group. Nominations have been also requested from the Australian Institute of Health and the National Health Technology Advisory Panel.

At their recent Conference in Fremantle, Health Ministers agreed that a Commonwealth/State co-ordinating group should be established under the auspices of the Australian Health Ministers' Advisory Council (AHMAC) to provide a mechanism for the development of a national strategy for the early detection of breast cancer. This subcommittee has been asked to undertake an evaluation of mammographic screening and other programs for the early detection of breast cancer, to examine and resolve a range of issues surrounding mammographic screening and report on the co-ordination of funding arrangements.

Dear Mr Steel

Mr K.W. Steel
President
Australian Cancer Society Inc
Box 4708 GPO
SYDNEY 2001

Telephone: (062) 89 7050
Telex: A462149
Facsimile: (062) 82 1262

Ref: _____

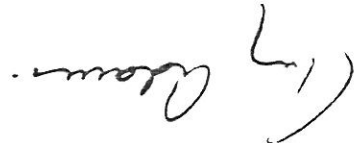
Secretariat
Commonwealth Department of Health
PO Box 100, WODEN ACT 2606

Australian Health Ministers' Advisory Council

ATTACHMENT 3

Should you wish to discuss the work of the subcommittee further I may be contacted on (02) 2176188.

Yours sincerely



Dr Tony Adams
Chief Health Officer
NSW Department of Health
May 1987



THE UNIVERSITY OF NEWCASTLE
 New South Wales 2308
 Australia.
 FACULTY OF MEDICINE

TELEEX 4428194 NEWUN
 TELEPHONE 680401
 EXT

SR:TA

1st June, 1987

Ian Russell
 Chairman, National Breast Study Committee
 Anti-Cancer Council of Victoria
 1 Rathdowne Street
 CARLTON SOUTH VIC 3053

Dear Ian,

Thank you for your letter of 13th May.

The establishment of a register of patients with abnormal mammograms seems like an excellent idea. It would be interesting to use the register to explore why the woman was screened (e.g. was it patient or doctor determined, was there pain or tenderness, was it routine?), since this may give valuable information about the factors which determine the operation of screening procedures currently, and therefore provide some clues for establishing an effective community wide screening programme. It would also be interesting to evaluate morbidity resulting from current screening and follow-up practices by asking the woman about her satisfaction with the process and her response to any delay between initial screen, being informed of an abnormality and having the abnormality dealt with. I would think that patients would be positive about such a register provided that it was made clear that the aims were to improve service, that only a limited number of defined people had access to their names and that they could refuse to be part of any research that used the register.

I agree with your comments about the management of patients with abnormal mammograms and the NSABP Study. I would be particularly interested in knowing whether they are collecting quality of life information. It increasingly appears the quality of life data can make a critical contribution in understanding the effectiveness of management strategies in cancer patients.

I am looking forward to the next meeting.

Yours sincerely,

Sally

Dr. S. Redman,
 Lecturer in Behavioural Science
 in Relation to Medicine

LUDWIG INSTITUTE FOR CANCER RESEARCH

SYDNEY CANCER THERAPY BRANCH

Tel: (02) 660.7362 Telex: 25984

University of Sydney
Sydney N.S.W. 2006
Tel: (02) 692.3675/6
(02) 660.1701
(02) 660.1333

Royal Prince Alfred Hospital
Sydney N.S.W. 2050
Tel: (02) 516.8952/3

27th May, 1987.

Mr. Ian Russell,
Australian Cancer Society Inc.,
National Breast Study Committee,
Anti-Cancer Council of Victoria,
1, Rathdowne Street,
CARLTON SOUTH, VIC. 3053

Dear Ian,

Thank you for your letter of May 13th. I will let you know who has been appointed as manager of the Mammographic Screening Project. Advertisements for this position close in the next few days, and hopefully we will be able to appoint some person shortly after that. In terms of its organisation, I have been appointed Chairman of the Steering Committee which reports to the Minister of Health.

In regard to the possibility of establishing a national register of mammographic abnormalities, I feel that this is an important goal, and the matter will be discussed by our Steering Committee in the next few days. It will also be important, I think, to define at which stage mammographic abnormalities might be registered. Our own view is that mammographic screening should be reported in an extremely simple way (probably by ticking a box), the questions will be whether the film is technically adequate, whether it is normal or whether follow-up mammography with more view is required. We plan to have two individuals reading the films. Individuals who are called back from the primary mammographic screen will have more detailed mammography at Rachel Forster Hospital, and presumably some of those will go onto biopsy. At which stage individuals with abnormalities should be registered is obviously a matter of some importance which should be discussed between the various mammographic screening projects.

In regard to the management of patients with in situ cancers, we would be pleased to receive a copy of the NSABP protocol for discussion by our own clinical group.

In regard to impalpable cancers, I am not sure whether there are specific proposals that you wish to bring forward at this stage. My own view is that a randomised study of breast conservation might be the most appropriate theme, but clearly whether or not radiation is required, as well as other questions could also be considered.

.../2.

MHNT:HN

M.H.N. TATTERSALL, FRACP,
DIRECTOR,
Professor of Cancer Medicine,
University of Sydney.



Yours sincerely,

I will let you know the outcome of our Mammographic Steering Committee meeting when these matters are discussed in the near future.

Mr. Ian Russell,
re: National Breast Study Committee.
27th May, 1987.

35

cont/d....

I believe that an essential first step is to get radiologists to agree on the classification of the abnormalities and preferably this should be done on a numerical scale. This is getting well without my personal field of expertise but I believe that Joan Croil would broadly agree with the recommendations which were published by Young, et al. in the Archives of Surgery, July 1986 which gave five classes of a mammogram report. I believe that a major shortcut to reducing the costs of mammography would be simply to ask radiologists reading films to allocate the mammogram to a class rather than to embark on a tortuous and convoluted descriptive report. The other major consideration from this type of reporting is that it would allow a comparison between centres. It has generally been assumed in all of the discussions that I have listened to that, while expertise in Australia may be somewhat less than that in Sweden or Britain, it would be fairly uniform. This has not proved to be the case in the Canadian experience which was reported by Cornelia Baines in Radiology in August of last year. She showed that the positive predictive value, i.e. the probability that cancer was present (as measured by the referral by the radiologists of that patient to a diagnostic clinic) varied between 2.7 and 16.5, i.e. between 1 in 25 abnormalities being malignant to 1 in 6 abnormalities being malignant. Unless we have consistent reporting, the spectrum of cost is going to be enormous with no way of deciphering how the different costs emerge.

A register of mammographic abnormalities. The main problem that I can see in this area is the fact that one is now registering abnormalities which will not turn out to be cancer. I do not see too much of a problem regarding the registration of patients who go on to have cancer demonstrated, but in terms of the quality of mammography, the non-malignant abnormalities will prove to be the area in which greatest controversy exists.

I will comment on the matters which you raised one by one.

Thank you for the facsimile of the amended letter which I received on the 13th.

Dear Ian,

Mr. Ian Russell,
 Australian Cancer Council Inc.,
 1 Rathdowne Street,
 CARLTON SOUTH VIC. 3053

19th May 1987

Department of Radiation Oncology
 Professor A.O. Langlands BSc DMRT (Ed) FRCP (Lond) FRACP FRCS (Ed)
 Director

Westmead Hospital
 Westmead NSW 2145
 Australia
 Telephone 633 6489
 Telex Number 120298
 Telegraphic Code Address WESHOS
 Facsimile 633 4984

PROFESSOR A. O. LANGLANDS
Director, Radiation Oncology

Alan

Yours sincerely,

With kind regards.

Obviously, however, these are the views of a non-surgeon and they are largely academic.

The last problem is the management of the impalpable invasive tumour. Again, from first principles I would fear the adoption of a less aggressive approach to these tumours than exists for the management of palpable invasive carcinoma. I do not really conceive of palpability being a major factor in decision-making.

The management of intraduct carcinoma is not one with which I have any great familiarity and my views are very much those of the armchair specialist. It would be my view, however, that it is difficult to justify the routine dissection of the axilla if one accepts the worldwide figure of 2% axillary involvement in patients with apparently localised intraduct tumours in the breast. Secondly, I would find a considerable difficulty in conceiving of protocols which required dissection of the axilla and irradiation of the breast without worrying about overtreatment. The last consideration, which I think merits discussion, is whether by this approach we are effectively excluding competent plastic surgeons who might manage these patients more appropriately by subcutaneous mastectomy. There must be patients in whom the risk of bilateral disease is high and patients in whom other risk factors such as familiar incidence would merit this approach as opposed to the definitive excision of the tumour. In summary, therefore, I have several fundamental reservations about the NSABP Project.

Queensland Department of Health

Cancer Epidemiology and Prevention Unit

State Health Building

47-108 Charlotte Street

GPO Box 45

Brisbane 4001

Telephone 221 0515
Telex (CA 12531)

27 May 1987

Mr I. Russell,

Chairman,

Australian Cancer Society Inc.,
Anti-Cancer Council of Victoria,

1 Rathdowne Street,

CARLTON SOUTH, VIC. 3053

Dear Mr Russell,

Thank you for your letter.

On the issue of a register of mammographic abnormalities, I think this could certainly be handled by Cancer Registries and I think this would not pose any practical difficulties. Another way of handling this would be for each screening centre to operate its own local registry. This would have the advantage of ensuring that important direct link with quality assessment and also it might be better and simpler from the point of view of ensuring that the abnormalities are followed-up.

I think the idea of a randomised study on the management of in-situ cancer is certainly worth exploring. The issue of sample-size is important and it would be worthwhile perhaps to raise this with an biostatistician once it has been decided how big a difference between the groups is to be detected.

Could you please forward further mail to the above address in Brisbane.

Yours sincerely,

(Ian Ring)
Medical Director

P.S. I would suggest that at least two outside experts attend the meeting of the Directors of the Mammography Clinics. One of these should be a Health Economist and the other should be able to advise the group on evaluation.

You will be interested to hear that at the last meeting of the Breast Clinic of the Royal Women's Hospital it was decided that the Clinic would now operate to serve the needs of the community.



Mr. Prof.
Mr. Prof.
Inquiries:
Telephone:



DR. COLIN M. FURNIVAL
MB, ChB, FRCS, FRACS
Telephone: (07) 832 5614

Alhol Place,
303 Wickham Terrace,
Brisbane, Qld. 4000.

16 June 1987

Mr I. Russell, FRACS,

Chairman,
National Breast Study Committee,
Anti-Cancer Council of Victoria,
1 Rathdowne Street,
CARLTON SOUTH 3053

Dear Ian,

NATIONAL BREAST STUDY COMMITTEE

Thank you for your letter of 13th May and I must apologise for the long delay in my reply.

With reference to the question of a Register of Mammographic Abnormalities, I cannot see any reliable way of establishing this so that it would include all relevant cases. I think that compliance with any request for registration of such cases would be a problem not only in relation to confidentiality (which I think could be overcome) but more importantly in terms of the day to day running of a radiological practice where the interest in entering cases into such a register may be minimal. It seems to me that the best way to establish such a register would be to depend exclusively on dedicated diagnostic/screening centres but of course this would be selective and, it might be argued, could introduce bias into any results.

The use of the Cancer Registry would restrict the registration of mammographic abnormalities to proven cancers and I am not sure that this would be the purpose of the registry as proposed by Professor Hare.

In relation to your second question, the management of patients with abnormalities detected by screening, I think this is a worthwhile and feasible proposition. This could effectively be done by the existing diagnostic/screening units. We have had our own follow-up of such cases at the Wesley Hospital since 1982, and would be glad to enter this and subsequent data into a National Study. We have however been aware of the difficulty of attempting to impose any treatment protocol upon the surgeons involved, but if it was agreed to adopt a standard protocol it would certainly be easy to offer this to the surgeon in each case.

There are really two questions which require an answer: First the results of treatment, by any means, of impalpable cancers and second, the results of treatment options which might be addressed in a randomised trial. I would strongly support the investigation of both of these questions. In view of the small numbers, I would agree that we should look at the possibility of contributing to NASBP but before making a final

COLIN FURNIVAL



With kind regards,
Yours sincerely,

I would welcome another meeting of the Committee, but could it be after the 19th July, since I will be away until that time? I know that we are all busy people, but I had a sense that the last meeting was under some pressure to finish on time and I wonder if we might aim for a slightly longer session next time?

decision about this, I think our data from Queensland could give a five year total of the number of appropriate cases as an indication of our potential accrual within Australia. The foregoing comments really apply to both intraduct and invasive, impalpable breast cancers.

