→ J. Hurley
from D. Hill
4/3

AUSTRALIAN CANCER SOCIETY

A NATIONAL CANCER PREVENTION POLICY

FOR AUSTRALIA

VOLUME 1

4.2 GOALS AND TARGETS FOR MAMMOGRAPHIC SCREENING FOR BREAST CANCER

The efficacy of mammography in preventing at least 30% of deaths from breast cancer has been established. As recently decided in the UK, the decision to implement a national mammography programme in Australia should be taken by Government, and all aspects of planning for its implementation should begin immediately. We acknowledge that there are already screening programmes in place, some of them being run by State governments and others in private practice. These will continue to develop no matter what happens. The evaluation process of pilot programmes referred to below should not be allowed to hinder their progression. The pressure to have screening programmes will continue to increase during the evaluation. Whatever programmes are developed, they must be accountable to an appropriate body. The ACS acknowledges the work and recommendations of the AHMAC Working Party in this regard.

4.2.1 National Goals

1. To reduce the morbidity and mortality from breast cancer.

2. To establish a national programme for mammographic screening for breast cancer that is accessable and acceptable by all women expected to benefit from it.

4.2.2 National Targets

1. By 1988, the pilot programmes for the development of a national programme of mammographic screening for breast cancer should have commenced.

2. By 1989, all major Government Health agencies, Non-governmental organizations, and major public interest groups concerned with screening for breast cancer should have formed State and national groups to co-ordinate the development and implementation of State mammographic screening programmes.

3. By 1991, a national population-based breast cancer screening programme should be in place.

4. By 1995, 70% of eligible women should have been screened for breast cancer at least once.

5. By 2005, breast cancer mortality should have fallen by 25%.

Director: Graham G. Giles Ph.D
Cancer Epidemiology Centre

15 September, 1987 ref. B111/5.3.

Mr. L.A. Wright,
Executive Director,
Australian Cancer Society,
A & C Building,
500 George Street,
SYDNEY NSW 2001

Dear Mr. Wright,

Thank you for your letter of September 10, regarding the National Breast Study Committee's Mammography Sub-committee. Professor W. Hare will be responsible for the mammography component of the proposed AMEH-ACCV pilot mammographic screening project. He is currently overseas and I have therefore discussed your requests with Professor Lovell.

We suggest that you ask Professor Hare, on his return, if, as he is chairman, he would like to nominate another member of his team to join the sub-committee.

Yours sincerely,

Susan Hurley,
Epidemiologist

SH/db

cc Mr I. Russell

ANTI-CANCER COUNCIL OF VICTORIA, 1 RATHDOWNE STREET, CARLTON SOUTH, AUSTRALIA 3053
☎ (03) 662 3300 Facsimile: (03) 663 3412 Telex: VCCG AA 34158

AUSTRALIAN CANCER SOCIETY INC.
A & C Building, 500 George Street, Sydney. Telephone (02) 267 1944
GPO Box 4708, Sydney, NSW. 2001. Australia. FAX: (02) 261 4123
Telex: AA 71036. Telegraphic address: Austcancer Sydney

Patron: His Excellency the Right Honorable Sir Ninian Stephen, AK, GCMG, GCVO, KBE.

Ask Prof Hall on his return if wine be as chairman, he would like to nominate another member of his team.

B111/5.3

September 10, 1987

Ms Sue Hurley,
Anti-Cancer Council of Victoria,
1 Rathdowne Street,
CARLTON SOUTH, VIC 3053.

Dear Ms Hurley,

The National Breast Study Committee wishes to establish a Mammography Sub-Committee to advise it on technology, reporting and quality control of mammography in breast screening to include

techniques
standardisation of reporting
methods of assessment
data to be collected
comparison between projects
register of abnormal mammograms.

A radiologist is invited to join the sub-committee from each of the mammography projects currently proceeding. Observers will be welcomed from projects at present proposed but not funded.

I should be grateful if you would advise me by 30 September of the name of your representative so that the work of the sub-committee can commence.

With best wishes,

Yours sincerely,

L.A. Wright
Executive Director

cc Mr I. Russell.

AUSTRALIAN CANCER SOCIETY INC.

MINUTES OF THE MEETING OF THE NATIONAL BREAST STUDY COMMITTEE HELD IN THE CONFERENCE ROOM, 3RD FLOOR, 500 GEORGE STREET, SYDNEY ON FRIDAY 23 OCTOBER 1987.

Present:

Mr I. Russell (Chairman)
Dr M. Fett
Mr C. Furnival
Ms J. Hall
Professor W.S. Hare
Professor Langlands
Dr H. Mitchell
Dr R. Reed
Mr S. Renwick
Mr L. Wright (Secretary)

The meeting was opened at 10.10am.

1. Welcome & Apologies:

The Chairman welcomed Dr Fett and Professor Hare as new members of the Committee.

Apologies were received from Dr M. Byrne, Dr S. Redman, Dr I. Ring, Mrs D. Shugg and Professor Tattersall.

2. Minutes of the Previous Meeting:

The minutes of the meeting held on 5 August 1987 were confirmed.

3. Chairman's Report:

The Chairman tabled two documents; an amended version of the report from the Core Data Sub Committee and the Press Release on Mammography by the RACR.

3.1. AHMAC Committee
The Chairman said that AHMAC had set up a Breast and a Cervical Cancer Sub-Committee which had, in turn, created a Working Party on Evaluation. AHMAC would meet in November and prior to that the Working Party would meet to consider a number of recommendations which would be tabled later for discussion.

4. Mammography Sub-Committee:

Professor Hare said that nominations had been received from the projects being funded and Newcastle would be asked to nominate now their funding had been approved. He said a meeting would be called to bring the committee together.

4.1. Mammography Screening Data Trail (MSDT)
Professor Hare tabled a MSDT to which was attached a Mammography Screening Report Form and University of Melbourne Dept of Radiology Mammography Survey.

Professor Hare said that objective reporting required that each centre adopt the essential parts of the forms tabled and described the process of their use.

Mr Russell said that the Mammography Sub-Committee should be convened to discuss the report forms in liaison with the Core Data Sub-Committee (Dr Ring & Dr Fett) and agree upon the recording that would be common to all projects.

There was a broad discussion on the forms tabled particularly as to which parts were appropriate for a screening process for asymptomatic women and which were applicable to screening symptomatic women.

The points agreed were

symptomatic women must be referred for review to avoid legal problems.

cancer probability scales, although not favoured at initial screening should be based on a 5 point index of Tabar

all measurement should be expressed in mms.

Other matters discussed were the number of readings of initial screening, single versus two view mammography.

Mr Renwick also pointed out that the Sydney project would be under way by February 1988 and an agreement on reporting was needed before then.

4.2. Pathology Sub-Committee

Dr Reed said that he was still awaiting the nomination of representatives from Sydney, Newcastle and Melbourne.

Mr Russell suggested that one representative from each State might be sufficient. Dr Reed said that he would prefer to, initially, have a representative from each project to agree to the reporting format to be used. Subsequently State representatives might suffice.

Dr Reed commented that he had sought advice from overseas projects. He would aim to standardise the pathology data collected between States but this would require the sub-committee to remain in being. He said he would try to have a meeting in 1987 and would liaise with the Data Sub-Committee.

5. Recommendations of the AHMAC Working Party on the Evaluation of Breast Cancer Screening Pilot Project:

Mr Russell said that the report and recommendations would be considered by the AHMAC Committee shortly. He tabled the recommendations and supporting segments of the report for discussion.

The meeting briefed the Chairman on each of the recommendations as follows

R1. "That acknowledgement be given to the need to explicitly plan the development of a nation-wide cancer screening program using experience gained from the Breast Cancer Screening Pilot projects as well as other research"

Endorsed

R2. "That breast cancer screening pilot projects which participate in the nationally coordinated evaluation possess a number of mandatory design features as specified in Section 6."

Comments on these features were as under

'review by institutional ethics committee etc'

Mr Renwick said that there could be difficulties where ethics committees had a negative attitude. Others said that as the screening had proven value the projects were not 'experimental' but should be evaluated as a 'service'.

'programs of community awareness etc'

Endorsed

'recruitment strategy to include recall'

Endorsed

'film screen mammography and machine maintenance'

Professor Hare said that there was a need for a better definition of screening equipment and provision for the accreditation of centres.

'regular safety surveillance'

Endorsed

'dedicated film processing and quality control'

Endorsed

'training of film readers'

Endorsed

'screened women informed'

Endorsed

'support and counselling for women with positive results'

Endorsed

'adequate information on screening to be available'

Endorsed

'provision for follow up and follow up care'

Dr Mitchell said that not all women informed of a positive result would agree to 'follow up' action.

This recommendation should be amended by deleting 'obtained' and substituting 'offered'.

'affiliated public sector diagnosis and treatment facility'

Mr Furnival said that this provision, if rigidly imposed would prevent women making a choice for private sector facilities. It was agreed to add the words 'for those who wish public hospital treatment'.

'recruitment strategies'

Their was general agreement that as some of the pilots had no defined target population participation rates could not be calculated for them.

'full documentation of procedures'

Endorsed

'screening staff in contact with the public to be predominantly female'

and

'predominantly female staffing'

Mr Furnival objected to this on the grounds that staff should be selected on the basis of professional competence not sex if the clinics were to establish the standards required.

'pilot project design changes'

Endorsed

Dr Reed noted that one omission was the need for compatibility and standardization of data to allow ready comparison between various projects.

Table of Pilot Project Design Options
Some corrections were advised in respect of the Wesley project.

R3 'compulsory aboriginal component'

Dr Mitchell pointed out that in the Victorian census the numbers describing themselves as 'aboriginal' had doubled in a five year period. This change in

social attitude made a mockery of statistics. The definition of aboriginal was one who chose to describe himself as one. As a racial group aboriginies had lower than average breast cancer incidence and were not logical targets for special attention.

R4 'use of medicare register'

Endorsed

R5 'age limit decision'

The meeting said that if the age limit were lowered to 40 years the initial examination should include a physical examination.

R6 'at least three projects to include physical examination'

The meeting felt strongly that three pilots should not have to undertake physical examination in the initial screening phase and this should be changed to 'at least one'.

R7 'some readers to be medically qualified non-radiologists'

Endorsed - with an emphasis that all readers must be medically qualified.

R8 'investigation into training of non medically qualified readers'

This was thought to be inappropriate for a pilot project and could be looked at once the major decisions on screening were taken.

The meeting was strongly of the opinion the recommendations R7 and R8 should be deleted and be made topics for later separate investigation.

R9 'provision of data to the evaluation coordination centre'

There was discussion on the aims of the evaluation and what results would be obtained. The meeting supported 'cost of cancer detected' but not 'value of life years saved'. Other results could be 'cost per woman attending' 'cost per woman screened' cost per 'abnormal' investigated.

R10 'unique project numbers'

Endorsed

R11 'data on costs to be provided'

Endorsed

R12/ R14 'National Evaluation Coordination Centre to be established'
'a National Breast Cancer Screening Evaluation Screening Committee'

These recommendations generated a long discussion about the division of responsibilities between the AHMAC, AIH and the NBSC. Particular concern was expressed about the size of the 'National Evaluation Coordination Centre (NECC), some of its components and budget, when it could not be raised and staffed with adequately trained people before the pilots were well under way.

The roles of the NBSC as the clinical advisory body and AHMAC as the funding and evaluation body were supported. The possibility of NECC intrusion into the running of pilot projects was raised.

Ms Hall and Dr Mitchell pointed out that the Government were being generous with funds and 3/4 of these funds would be spent in the projects by providing a project officer's salary and costs of surveys, training and evaluation.

The meeting expressed its support for a structure including a funded Project Officer to each pilot project to provide data to the NECC which should report to the AHMAC on data analysis. The NBSC to be the clinical advisers to the AHMAC.

R13 'funding from New Initiatives for Women'

R15 'identification by Project Number'

R16 'need for data from at least five years of repeat screening'

R17 'availability of report'

All endorsed.

6. RACR Press Release

Professor Hare referred to the press release and said that the RACR was aware that there was in existence a large inventory of high quality screening equipment. It was attempting to control this through accreditation to help limit costs and to ascertain equipment capability and staff competence.

Professor Hare said that the RACR was attempting through a survey of equipment and staff training and the accreditation of centres to ensure that a high quality screening service would be available at a predictable cost to Government.

Mr Furnival commended the RACR and said that the RACS would also have to establish its interest in the field. He said that both Colleges had been largely ignored in the setting up of the pilot projects and the controlling machinery contemplated.

The Chairman suggested that the NBSC should meet with both Colleges. Professor Hare agreed in principle but said that his own Mammography Sub-Committee would also be the Mammography Sub-Committee of the RACR.

The Chairman noted that time had expired for interstate delegates and other agenda matters would have to be deferred.

The next meeting will be held in February 1988.

The meeting was closed at 3.00pm.

_____

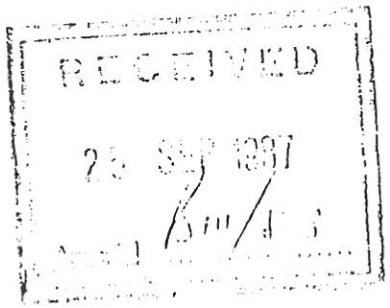
(Chairman)

_____

(Date)

AUSTRALIAN INSTITUTE OF HEALTH

ATTACHMENT 2



Mr Laurie A. Wright
Executive Director
Australian Cancer Society Inc
GPO Box 4708
SYDNEY
NSW 2001

Dear Laurie,

Please find enclosed the report of the Database Sub-committee of the National Breast Study Committee. Please note that this report only relates to service aspects of mammography evaluation and that economic and client acceptability / accessability / satisfaction / knowledge data, which are required for the national evaluation are not included. These areas are being addressed by sub-groups of the AHMAC Mammography Evaluation Working Party.

In addition to the enclosed report, further work will be required to specify the details of service data items in certain areas. For example, mammography coding, cytology and pathology coding. These three items are the subject of other ACS NBSC sub-committees.

If you have any comments on the report would you please give them to either myself or Ian Ring.

Yours sincerely,

Michael Fett

Dr Michael J. Fett
24 September 1987

GPO BOX 570 CANBERRA ACT 2601

WORKING GROUP ON THE EVALUATION OF MAMMOGRAPHY SERVICE DELIVERY

Data Requirements

Draft 22 Sept 1987

This paper identifies the questions to be addressed in the evaluation of mammography pilot projects and the data which need to be collected to answer these questions. The paper only covers the evaluation of service delivery. The issues of cost evaluation and the evaluation of promotion and client satisfaction are to be covered in other papers.

Questions to be addressed by the evaluation of pilot projects

Among the different methods employed in the pilot projects, how does effectiveness and cost effectiveness vary in:

- initial recruitment of women?
- recruitment of women with previous screening mammogram (ie follow-up)?
- screening recruited women?
- diagnosing and caring for women with abnormal mammograms?
- reducing breast cancer mortality?
- diagnosing breast cancer at a stage when treatment is more effective and less radical?
- maintaining quality control of patient contact and follow-up?
- maintaining quality control of radiography?
- maintaining quality control of film developing?
- maintaining quality control of mammography reporting?
- maintaining quality control of cytology?
- maintaining quality control of pathology?

To what extent does screening mammography lead to over-diagnosis of breast cancer?

What are the human resource requirements for delivering mammography screening and subsequent clinical evaluation?

Subsequent pages of this document identify data items which each pilot project should generate or collect. The items are marked accordingly:

E - required for national evaluation
O - required for pilot project operations, not required for national evaluation

Data required for national evaluation may be provided for the evaluation either as identified or anonymous unit record data or as summary tabulations. This issue requires further consideration.

PILOT PROJECTS

Required documentation for each pilot project

Detailed programme description (through time) E

Target population description: E

- population size
- geographic location
- age composition
- socioeconomic composition
- ethnic composition

Project procedures manuals (through time) for: E

- population list type (inc. coverage of target popln)
- recruitment strategies
- information resources
  - eg pamphlets, telephone spiels, videos
- whether self referral permitted
- appointment systems
- times of operations
- contact and follow-up methods
- rescreening interval(s)
- client flow
- screening methods
  - including mammography machine, film/screen combination
- mammography machine
  - maintenance, calibration, and staff and client exposure assessment programmes
- radiography procedures and quality control procedures
- film developing
  - procedures and quality control procedures
  - maintenance, calibration and chemical replenishment programmes
- film reading
  - procedures, quality control
- staff
  - type, number, role, hours
  - training
- referral mechanisms
- client advice
- counselling mechanisms
- follow-up clinic details
- assessment and treatment resources
  - associated clinic/other
- data collection and processing
- funding
- internal evaluation/performance criteria

For each mammography machine: O

- records of machine maintenance, operations, calibrations and exposure tests
- radiographer staff dosimeter readings

For each film developing machine:

- records of machine maintenance, operations, calibrations, temperature, timings and chemical replenishment

Data to be generated by each pilot project - for all potential clients

For each woman identified as a potential client:

- name: surname, first two given names O
- birthdate E
- postcode of residence E

For each individualised recruitment attempt:

(data as for potential clients plus:)
- type of attempt (coded) E
- date of attempt E
- outcome of attempt (coded) E

For each attendance for screening:

(data as for potential clients plus:)
- client identification number (call project number) O
- date of attendance E
- next of kin O
- client consent: O
  - access to and use of screening and future medical data for research purposes
  - to give report to GP
- breast symptoms in last 12 months O
  - code as: lump
    change in shape of breast
    bloody or clear nipple discharge
    other
    nil
  - do these symptoms influence the passage of this woman through the screening programme? yes/no E
- past surgical treatment for breast disease? yes/no O
  - code as: mastectomy
    prosthesis
    other breast surgery
- radiographer ident. O
- view type E
- view number O
- clinical examiner ident. O
- clinical exam result E
  - code as: bloody or serous discharge, or mass - yes/no
- film reader 1 ident. O
- film reader 1 result (coded) O
- film reader 2 ident. O
- film reader 2 result (coded) O
- final screening result E
  - code as: normal
    abnormal

technically unsatisfactory

- recommendation E
  - code as: repeat screen - technical
    routine rescreening
    early rescreening
    further investigation required; referred
- date of recommendation E
- date client notified of result E
- CLIENT SATISFACTION (possibly sample only) E

Data to be generated by pilot projects - sample of clients only

Socioeconomic status
(method of recording to be determined; possibly use subset of relevant census questions) E

Ethnicity
(as for socioeconomic status) E

Reason for attending (sample only) E
- "How did you find out about the clinic?" eg letter, publicity, GP, group, follow-up, call back

Breast cancer risk profile - OPTIONAL

REGISTERS

ı to be obtained from cancer registers/death registers

each case of breast cancer among the target population
:h screened and unscreened), including interval cases:

:a as for potential clients plus:)
mode of detection E
- code as:screening
other
date of diagnosis E
diagnosis: E
- Snomed
- ICD 0
- TNM
- stage
- size
- location
where attended for definitive treatment E
- code as:follow-up clinic
private
other public
follow-up declined
unknown
- NAME AND ADDRESS OF PROVIDER(S) E
diagnostic and treatment procedures (coded; Medicare item
numbers?) E
dates of procedures E
residual disability (coded) E
cause of death - ICD 9 (if applicable) E
date of death (if applicable) E

ival times for breast cancer according to tumour
et , stage and pathological diagnosis E

lation crude and age specific incidence rates and
ality rates for breast cancer among women E

to be obtained from death registers

each death among screened women:

a as for potential clients plus:)
cause of death - ICD 9 E
date of death E

DIAGNOSIS / TREATMENT SERVICES

Data to be obtained from diagnosis/treatment services

For each woman referred for diagnosis:

(data as for potential clients plus:)

- where attended — E
  - code as: follow-up clinic
    private
    other public
    follow-up declined
    unknown
  - NAME AND ADDRESS OF PROVIDER(S) — E
- diagnostic and treatment procedures (coded; Medicare item numbers?) — E
- dates of procedures — E
- if mammogram:
  - view type and number — O
  - film reader 1 ident. — O
  - film reader 1 result (coded) — O
  - film reader 2 ident. — O
  - film reader 2 result (coded) — O
  - final result — E
- if cytology:
  - reader 1 ident. — O
  - reader 1 result (coded) — O
  - reader 2 ident. (if applicable) — O
  - reader 2 result (coded) (if applicable) — O
  - final result — E
- if ultrasound:
  - result — E
- if histology:
  - reader 1 ident. — O
  - reader 1 result (coded) — O
  - reader 2 ident. (if applicable) — O
  - reader 2 result (coded) — O
  - final result — E
- diagnosis — E
  - ICD 9
  - if malignant:
    - Snomed
    - ICD 0
    - TNM
    - stage
    - size
    - location
- CLIENT SATISFACTION — E

Data to be obtained from target population by sample survey

Socioeconomic status
(see above)

Ethnicity
(see above) E

Reason for non-attendance at screening programme E

- coded as:
  - other mammography (eg private sector) E
  - migration away
  - death (date?)
  - ineligible (eg bilat. mastectomy)
  - refusal (reason?)
  - unable (reason?)
  - other (reason?)

Report on National Breast Study Committee Meeting,
held at the Australian Cancer Society, Sydney on August 5th, 1987

Present: Mr. I. Russell (Chairman)
Dr. M.J. Byrne
Mr. C. Furnival
Ms. J. Hall
Professor A. Langlands
Dr. H. Mitchell
Ms. S. Redman
Dr. R. Reed
Mr. S. Renwick
Dr. I. Ring
Mrs. D. Shugg
Professor M. Tattersall
Mr. L. Wright (Secretary)
Ms. S. Hurley
Dr. M. Fett
Dr. T. Adams

I attended the above meeting at the invitation of Mr Russell. The following matters relevant to Victorian plans for mammographic screening were discussed.

1. Dr Tony Adams (NSW Department of Health) said that the Australian Health Ministers' Advisory Council (AHMAC) had established a sub-committee to advise it on a national strategy for the early detection of breast cancer. The sub-committee is to report its findings to the AHMAC meeting in April 1988. AHMAC hope to establish evaluation criteria for screening programmes and a policy for state/commonwealth funding on the basis of the sub-commttee's report.

2. Current status of projects

<u>New South Wales</u>

(i) Rachel Forster Hospital Breast Clinical project

- has state funding and will start screening in November or thereabouts
- a radiologist (Mary Ricard) has been appointed as Project Director
- features include
    - single view mammography
    - mobile screening facility
    - independent interpretation of mammograms by a radiologist and a radiographer
    - automatic 2 view mammography and clinical assessment for women with symptoms or breast lumps
    - collection of risk factor information for a sample of women only.

(ii) Westmead Hospital

- proposals being drawn up
- plan to incorporate an evaluation of oestrogen receptor assays from the fine needle aspirates

(iii) Newcastle project

- proposals being developed by John Forbes et al
- a mobile screening facility will be used.

Professor Tattersall said that at least one progect in addition to the Rachel Forster project will be funded by the NSW state government.

Victoria

Mr. Russell mentioned (briefly) that the AMEH project had been assured of state government funding.

Queensland

There are two 'screening' services operating

- Wesley Hospital - screens women referred by their GPs

- Women's Hospital - is about to start screening women who present spontaneously.

It was unclear whether these two projects would be applying for further funding.

Western Australia

- proposals being developed
- screening facility will be mobile
- will compare different outcomes when women are referred to the health care system for assessment rather than being assessed through the screening programme.

3. I gained the impression from discussions and a background paper tabled at the meeting (prepared by the Commonwealth Department of health for AHMAC) that the Commonwealth would not fund mammographic screening projects. The Commonwealth would like the states to fund the pilot projects, but will provide funds for evaluation (via salaries for a project officer and a part-time epidemiologist for each project).

4. There was a lot of discussion about the relative merits of population-based screening and "opportunistic" screening (where women drop in rather than being invited to attend) and how these two approaches can be evaluated and compared.

I believe that the most relevant parameters for economic evaluation of screening programmes are the cost per life year saved or cost per quality adjusted life year saved (QALY). As none of the Australian projects will be randomised, no data on the reduction in breast cancer mortality achieved by screening will be collected. Effectiveness data for Australian studies will

therefore have to be extrapolated from randomised controlled trials (RCT) conducted overseas (primarily, the Swedish two counties trial). The results of RCTs cannot be extrapolated to opportunistic screening - so such projects cannot be evaluated in terms of cost per life year saved. Alternative parameters, such as cost per cancer detected, could be used to compare population based and opportunistic screening projects, but I think that such comparisons are misleading and unfair to population-based programmes.

I made these points at the meeting and there was considerable discussion. Professor Langlands, Dr. Byrne and Dr. Mitchell were in favour of population-based screening, but Dr Ring and Mr Furnival (from Queensland) were in favour of opportunistic screening. Ms Hall and Dr Fett thought that comparisons between population-based and opportunistic projects on the basis of parameters such as cost per cancer detected were reasonable, and there was further heated discussion.

4. The following sub-committees of the National Breast Study Committee were established,

- Radiology Sub-committee (convener, Prof. Hare)
- Pathology Sub-committee (convener, Dr Reed)
- Data Sub-committee (convener, Dr Ring)

5. Other matters

i. a relatively cheap piece of stereotactic equipment for fine needle aspiration biopsy of non-palpable lesions has become available in the UK. Stereotactic equipment is currently not available in Australia.

ii. the presence of a cytopathologist during radiologically localised fine needle aspiration is required.

iii. the question of liaison with GPs was discussed.

- Professor Tattersall said that the Rachel Forster project intended to provide screenees' GPs with a mammography report, when the woman nominated a GP

- ideally, women would remain within the projects for assessment and treatment, but it was recognised that some women would seek management outside the projects

- the importance of maintaining good rapport and cooperation between pilot projects and GPs was stressed. GPs might think that screening projects encroached on their role as primary health care providers.

iv. the importance of including some sort of counselling in pilot projects was mentioned. Recording and evaluating the type of counselling provided was also seen as important

v. patient education videos may be shown in the Rachel Forster mobile van

vi. Dr Reed said that diagnosis of tumours < 5mm was a difficult problem. He suggested that the Pathology sub-committee would produce recommendations

vii. the possibility of a register of abnormal mammograms was discussed and referred to the Mammography sub-committee

viii. it was generally agreed that standardisation of projects with respect to data collection was important. In practice I think this is unlikely to occur, particularly as the Rachel Forster and Queensland Groups have started screening

ix. concerns about the financial, logistic and staffing implications of a national mammographic screening programme were discussed briefly.

Susan Hurley
August 6, 1987
67-nbsc-01

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held at the Australian Cancer Society, Sydney on August 5th, 1987

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Susan Hurley
August 6, 1987
67-nbsc-01

tabled 5/8/87

NATIONAL BREAST STUDY COMMITTEE

DRAFT PROTOCOL FOR MANAGEMENT OF LESIONS DETECTED BY BREAST SCREENING

INTRODUCTION

The following paragraphs are concerned particularly with impalpable abnormalities detected by mammography; the management of palpable tumours which are first detected in a screening examination is the same as for those tumours with a clinical presentation. However, in the case of such palpable tumours, the need for pre-operative diagnosis based on clinical judgement, mammography, aspiration cytology and in some cases 'tru-cut' biopsy is emphasised: frozen section histology may be used to confirm a diagnosis but it is recommended that the routine use of frozen section to establish a diagnosis immediately before definitive surgical treatment, should be avoided.

Appropriate surgical techniques for the treatment of established cancers are discussed below.

DIAGNOSIS OF EARLY LESIONS

In a Breast Screening Service, the Radiologist is the captain of the diagnostic team. Although many established primary cancers have specific diagnostic features on mammographic examination, the features of early breast cancer are less specific, usually comprising a small, localised density with or without microcalcification. Microcalcification itself is not a diagnostic feature and although certain patterns can be clearly recognised as benign or malignant, there is a substantial 'grey area' where the pattern is typical of neither benign or malignant microcalcification. Attempts to characterise all patterns of microcalcification as 'typically benign' or 'typically malignant' have been unsuccessful.

Thus the provisional diagnosis and the decision to biopsy a suspicious lesion is determined by the opinion of an experienced Radiologist. When such a suspicious lesion is identified, there are two options.

OPTION 1 - localisation biopsy with specimen radiography

This technique, which is now the standard method of management in Australia involves some method of mammographic localisation of the lesion by the Radiologist, immediately before surgical biopsy. The localisation procedure is carried out with local anaesthetic; surgical biopsy is more easily done with a general anaesthetic.

In the localisation procedure, either a guidewire is inserted so that its tip lies close to the lesion, or a mixture of radio-opaque contrast with a visible dye (such as Methylene Blue) is injected close to the lesion. There are several types of guidewire (e.g. Kopan's needle); the injectable dye technique has the disadvantage that dispersal of the visible dye may make the biopsy imprecise. Where a guidewire is used, the appropriate cosmetic incision should be made: The guidewire should not be followed from its point of entry in the skin (which is frequently in the upper part of the breast).

With the aid of one of the foregoing techniques, the Surgeon will then excise a block of tissue (usually 2-3cm. diameter), which contains the putative lesion. Frozen section histology must not be used because of the difficulty of diagnosis in such early lesions. Instead, the specimen is immediately X-rayed, to ensure that the abnormality has been included in the biopsy. It is recommended that the wound should not be closed until the Surgeon has seen the films: In cases of doubt, further excision of adjacent tissue and further specimen radiography may be necessary. Localisation biopsy should not be attempted without accessible specimen radiography.

When excision has been confirmed by specimen radiography, the tissue is submitted for rapid paraffin section histology.

(In a well-organised Screening Service this report should be available in less than 24 hours.)

Although wound closure without drainage is preferrable, the prevention of a wound haematoma is more important than the doubtful risk of dissemination of malignant cells along a drain track.

OPTION 2 - localised aspiration cytology

Whereas fine needle aspiration is a straightforward procedure in the case of a palpable mass, the use of aspiration cytology for an impalpable lesion presents considerable difficulty. This is a technique for the Radiologist, not the Surgeon.

Although a similar method to that which is used for localisation and insertion of a guidewire may prove successful, there is no certainty that the needle will remain in the precise position during aspiration. It is therefore recommended that some form of stereotactic device (e.g. the CGR Stereotix) should be used.

adaptor - frame/software.

~50,000 used in Sweden eval in UK

With this device, the patient is prepared as for localisation but using the stereotactic attachment, preliminary films are taken to give a 3-dimensional localisation of the lesion. A needle-guide is then moved into position, using a computerised control system which obtains information from the preliminary films. When the needle guide is correctly positioned, a fine needle aspiration is performed.

This option is not currently used in Australia and thorough clinical assessment will be necessary before it can be accepted as an alternative to localisation biopsy.

BIOPSY RATIO

In all Breast Screening facilities records must be kept to show the final diagnosis of impalpable lesions which are submitted to biopsy. The diagnostic efficiency of the Screening Service

can be measured by the ratio of benign to malignant lesions proven by localisation biopsy. This ratio should approximate to 1:1 as experience in breast screening increases. In some centres, particularly in Scandinavia, much lower biopsy ratios (e.g.0.2:1) have been reported but this can only be achieved by dependence upon localised aspiration cytology (see option 2) as a selection procedure. This will be an objective for the future.

Reports from the United States of biopsy ratios as high as 5:1 reflect special considerations in that country. Such results are quite unacceptable in a Breast Screening Service.

2-3 cancers / 1 benign lesion Tabar - 1:1 ratio

MANAGEMENT OF CONFIRMED MALIGNANCIES

ignore U.S.

One of the aims of Breast Screening is to minimise the surgical treatment required for detected disease. Nevertheless, modified radical mastectomy remains an effective method for the treatment of primary breast cancer and is an appropriate technique for the treatment of the larger, clinically palpable malignancies, also for extensive or intraduct (in situ) carcinoma and for multifocal disease.

However, for the treatment of smaller palpable or impalpable lesions, conservative surgery with radiation therapy is the treatment of choice. Such procedures are initiated by the Surgeon in consultation with the Radiotherapist. The surgical options are either a complete local excision (which may have been adequately done at the time of biopsy), combined with full axillary dissection, or quadrantectomy combined with full axillary dissection. The technique of axillary sampling is less reliable for the detection of axillary metastases and full axillary clearance avoids the need to irradiate the axilla. (Where surgical clearance has been done, the axilla should not be irradiated.)

Although the disease control obtained by local surgery, axillary clearance and post-operative radiation treatment is identical to that obtained by radical mastectomy, it is equally clear that conservative surgery without radiation therapy gives an unacceptably high rate of local recurrence.

A further cause of high local recurrence rates appears to be the attempted treatment of lesions which are too large or too extensive to manage by conservative techniques. Such disease is better treated by modified radical mastectomy.

GENERAL CONSIDERATIONS

Some degree of anxiety is usually associated with attendance at a Breast Screening Clinic. Anxiety is minimised when operating personnel are considerate and reassuring and when rapid reporting of results is ensured. Such considerations must be carried through to the management of detected lesions and reassurance, early reporting of results and the provision of sufficient time for detailed discussion of treatment options are important priorities for the Surgeon, the Radiotherapist and the patient.

C.M. FURNIVAL 31.7.87

Report on National Breast Study Committee Meeting,
held at the Australian Cancer Society, Sydney on August 5th, 1987

Present: Mr. I. Russell (Chairman)
Dr. M.J. Byrne
Mr. C. Furnival
Ms. J. Hall
Professor A. Langlands
Dr. H. Mitchell
Ms. S. Redman
Dr. R. Reed
Mr. S. Renwick
Dr. I. Ring
Mrs. D. Shugg
Professor M. Tattersall
Mr. L. Wright (Secretary)
Ms. S. Hurley
Dr. M. Fett
Dr. T. Adams

I attended the above meeting at the invitation of Mr Russell. The following matters relevant to Victorian plans for mammographic screening were discussed.

1. Dr Tony Adams (NSW Department of Health) said that the Australian Health Ministers' Advisory Council (AHMAC) had established a sub-committee to advise it on a national strategy for the early detection of breast cancer. The sub-committee is to report its findings to the AHMAC meeting in April 1988. AHMAC hope to establish evaluation criteria for screening programmes and a policy for state/commonwealth funding on the basis of the sub-commttee's report.

2. Current status of projects

<u>New South Wales</u>

(i) Rachel Forster Hospital Breast Clinical project

- has state funding and will start screening in November or thereabouts
- a radiologist (Mary Ricard) has been appointed as Project Director
- features include
  - single view mammography
  - mobile screening facility
  - independent interpretation of mammograms by a radiologist and a radiographer
  - automatic 2 view mammography and clinical assessment for women with symptoms or breast lumps
  - collection of risk factor information for a sample of women only.

(ii) Westmead Hospital

- proposals being drawn up
- plan to incorporate an evaluation of oestrogen receptor assays from the fine needle aspirates

(iii) Newcastle project

- proposals being developed by John Forbes et al
- a mobile screening facility will be used.

Professor Tattersall said that at least one progect in addition to the Rachel Forster project will be funded by the NSW state government.

Victoria

Mr. Russell mentioned (briefly) that the AMEH project had been assured of state government funding.

Queensland

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Evaluation of mammographic screening programmes

The following are suggested criteria for evaluating mammographic screening programmes

1. **General evaluation**

- Attendance rates, by age, country of origin and place of residence relative to screening centre.
- Referral rates for complete mammography, clinical assessment, fine needle aspiration and biopsy.
- Sensitivity* , specificity† and predictive value positive‡ of screening mammography, complete mammography, and other investigations. Preferably, a standard definition for false negatives will be adopted. In most previous studies, breast cancers detected in the 12 months following screening have been defined as false negatives, but in the West London study false negatives were measured after 6 months.
- Quality control data on mammography and histopathology. This should allow measurement of interobserver agreement in interpretation of tests, as was done in the Canadian National Breast Screening study for mammography interpretation.
- Staging of cancers detected.
- Treatment

2. **Economic evaluation**

The additional data required will depend on the type of economic evaluation planned. Collection of the following should be considered.

- Maximum screening rates achieved and achievable with screening centre staff.
- Screening costs, including:
  - capital outlay, operating costs, overheads. Preferably, methods for measuring and allocating these costs will be standardised.

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* Sensitivity = TP/(TP + FN)

† Specificity = TN/(TN + FP)

‡ Predictive value positive = TP/(TP + FP); where TP = true positives, FP = false positives, TN = true negatives, and FN = false negatives.

  - costs of clinical assessment, investigations and biopsy for false positives. These costs may vary depending on whether the patient is investigated in a public hospital or privately. Costs and frequencies for both types of referral should be obtained.
  - costs incurred by patients attending screening.
  - recruitment and advertising costs.

- Treatment costs, including:
  - costs of treating additional cases detected.
  - costs of treating cases earlier and cost of longer follow up.
  - savings due to earlier stage at treatment.

- Utility values, including
  - value to women of reassurance that they do not have breast cancer
  - disadvantages of investigations for false positives
  - improvement in quality of life through early treatment.

- Measures of effectiveness

  The effectiveness of mammographic screening programmes is best described in terms of reduction in breast cancer mortality. As no randomized controlled trial of screening appears to be planned in Australia, effectiveness measures will have to be obtained from overseas studies.

Susan Hurley,

Cancer Epidemiology Centre,

Anti-Cancer Council of Victoria,

August 5 1987

Appendix : data management and computing tasks for AMEH mammographic screening project.

1. The following will need to be generated:
   - Personal invitations to attend for screening. Women's names and addresses to be obtained from the electoral roll.
   - Repeat invitations to women who fail to attend.
   - Letters advising women of results at each stage of screening programme (screening mammography, complete mammography, clinical assessment(s), diagnostic tests). At each stage the result will be either "normal", in which case advice regarding the recommended time for the next screening will be given, or "abnormal", in which case an appointment for the next stage will be given.
   - "Sticky" labels for attaching to screenees' records and mammography films.
   - Daily lists of women invited to attend.
   - Possibly, a computerised booking system, for mammography and clinical assessment.
   - Possibly, "canned" reports of mammograms (for the woman's general practitioner).

2. Data entry facilities will be needed for the following:
   - Demographic and risk factor information obtained at the first attendance.
   - Procedures performed and action taken during each of up to 5 visits
   - Mammography reports
   - Histopathology reports
   - Treatment of women diagnosed as having breast cancer and staging of their cancers.