David Hill
Susan Hurley

REPORT OF THE

WORKING PARTY ON THE EVALUATION OF BREAST CANCER SCREENING PILOT PROJECTS

TO THE

AHMAC SUB-COMMITTEE ON BREAST AND CERVICAL CANCER SCREENING

12 NOVEMBER 1987

[SUPPLEMENTED WITH RELEVANT RECOMMENDATIONS FROM THE AHMAC SUBCOMMITTEE, WHICH WHERE ACCEPTED BY AHMAC]

Australian Health Ministers' Advisory Council

Telephone: (062) 89 7050
Telex: AA62149
Facsimile: (062) 89 8821

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

Ref: _____

27/11/87

Mr L. L'Huillier
Chairman
Australian Health Ministers'
Advisory Council
Health Department of Victoria
555 Collins Street
MELBOURNE VIC 3000

Dear Mr L'Huillier,

On behalf of the AHMAC Subcommittee on Breast and Cervical Cancers I wish to present the reports of the Subcommittee's Working Parties on Breast Cancer and Cervical Cancer Screening. These reports were considered by the Subcommittee at its meeting in Sydney on 16 November 1987. Members were most impressed with the reports of the Working Parties and commend them to AHMAC.

The introduction to each report summarises the points that were addressed. With few exceptions the recommendations of both Working Parties were endorsed by the Subcommittee. Those recommendations which were amended or the subject of a specific comment are detailed in attachment A.

The Subcommittee asked that it be noted that the Cervical Cancer Screening Working Party had invited Malcolm Coppleson, who is an experienced Obstetrician and Gynaecologist with expertise in Colposcopies, to join them but due to the short time frame and other commitments he was unable to attend. Similarly Dr Mary Rickard, an experienced Radiologist with expertise in Mammography was unable to attend the meetings of the Breast Cancer Screening Working Party or to participate in their teleconferences. Despite these shortfalls in membership neither the Working Parties nor the Subcommittee felt that they detracted from the report in any significant way.

The Subcommittee discussed recommendations concerned with on-going action jointly (Breast Cancer Screening Working Party recommendations 14-16, and Cervical Cancer Screening Working Party recommendations 38-41) and agreed that a Steering Committee should be established for each of the two groups (Breast and Cervical). Details of the proposed composition of these Steering Committees is at attachment B. Members also agreed that a National Evaluation Coordination Unit (NECU) be set up within the Australian Institute of Health.

The Subcommittee considered that the major role of the Steering Committees would be to advise governments on possible national screening strategies in consultation with the NECU, States and Colleges, and to report directly to AHMAC.

The Subcommittee asked me to raise with AHMAC the difficulty of identifying a specific point at which screening finished and treatment began. While they were aware of the importance of defining such a point from a charging point of view they were unable to reach agreement.

In considering future developments in respect of Breast and Cervical Cancer Screening the Subcommittee stressed their concern about a number of issues

- the necessity to adopt a staged approach in the funding of projects because cervical cancer screening projects were not as advanced as those for breast screening

- the need for services to be funded quickly for maximum impact which may mean that more money could be required for evaluation of cervical cancer screening at a later stage.

- the importance of the private sector medical network in identifying participants and reasons for non-participation in a national screening program.

- where involved, the private sector would need to meet the basic minimum data set requirements.

- the need for registry systems, with appropriate legislation, if a national screening program is developed.

- the need for the Commonwealth and States to discuss mass screening with the Royal Australasian College of Radiologists, the Royal Australian College of Obstetricians and Gynaecologists, the Royal College of Pathologists of Australasia and the Royal Australian College of General Practitioners. It was recommended that AHMAC negotiate this.

- the under-funding of public laboratories

In conclusion I would like to express my thanks to the members of the Subcommittee and Working Parties, to commend their work to you and recommend that the AHMAC Subcommittee on Breast and Cervical Cancers be disbanded.

Yours sincerely,

Tony Adams
Chairman
AHMAC Subcommittee on Breast
& Cervical Cancers

ATTACHMENT A

BREAST CANCER SCREENING REPORT.

. Recommendation 6 amended to read:

"The Committee recognises that there is limited data about the benefits of screening 40 to 50 year old women and recommends that some pilot projects should address this issue. Projects screening women in the 40 to 50 age group should separately evaluate this group."

. Recommendation 9 reworded as follows:

"For women with abnormal mammograms at least one pilot project should offer, with equal preference, options of referrals:

(a) through the normal medical referral network via the G.P.; and

(b) to diagnostic and treatment services provided by an affiliated facility, with evaluation of the alternatives".

. Recommendation 16 amended by:

Adding the following words to the end of the first paragraph

a. - "provide advice to government on the development of proposals and plans for possible nationwide screening program";

b. Changing the membership of the Committee
- by replacing the pilot project representative on the National Breast Cancer Screening Evaluation Steering Committee with a representative from the Australian Cancer Society Breast Cancer Study Group; and
- the addition of an AHMAC representative

recommended that report be for consideration

. Recommendation 20 was not accepted but it was agreed that the distribution of the reports should be a matter for AHMAC to decide.

. Recommendation 21 was amended to read:

"There is a need to promote criteria for selection of pilot projects to be funded as part of the nationally co-ordinated evaluation, to inform the proposed and anticipated projects of the data requirements and the structure of the national evaluation program so that they can indicate their intention to participate on that basis."

ATTACHMENT B

A National Breast Cancer Screening Evaluation Steering Committee should consist of:

- a representative from the Australian Cancer Society Breast Study Group
- a representative of the Commonwealth Department of Community Services and Health
- an expert in epidemiology and evaluation
- a health services researcher
- a women's health advocate
- a representative of the Royal Australasian College of Radiologists
- the Director of AIH or his/her nominee
- a representative of AHMAC

In selection, attention should be paid to the need for a reasonable level of female representation on the Committee.

A National Cervical Cancer Screening Evaluation Steering Committee should consist of:

- one representative from the Australian Cancer Society Cervical Cancer Study Group
- a representative of the Commonwealth Department of Community Services and Health
- an expert in epidemiology and evaluation
- a women's health advocate
- representatives (2) from appropriate practitioner organisations
- the Director of AIH or his/her nominee
- a representative of AHMAC

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CONTENTS

1. TERMS OF REFERENCE

The Working Party on Evaluation Data from Breast Cancer Screening Pilot Projects met on 1 September 1987 and addressed the following terms of reference:

Design of Pilot Studies

1. To identify the programme design options which should be addressed by the pilot screening projects;

2. To evaluate the extent to which currently identified pilot projects address these design options;

3. To identify whether modifications would be desirable to existing pilot project proposals to address particular design options;

4. To identify whether new pilot projects are required to address particular design options.

Performance Measures

5. To design essential performance measures for pilot projects which are applicable to both the evaluation of pilot projects and the development of performance criteria against which definitive mammography services can be judged.

Data Set

6. To develop a minimum common basic data set from which the essential performance measures will be derived and which can be used for the centralised analysis and reporting of the performance of pilot projects.

2. MEMBERSHIP OF THE WORKING PARTY

This report was prepared over the course of two meetings of the Working Party, which were held at the Australian Institute of Health in Canberra on 1 September 1987 and 29 September 1987. The report was finalized following a tele-conferences held on 27 and 29 October 1987. The Working Party comprised the following members:

Professor Bruce Armstrong (Epidemiology) Chair
NHMRC Research Unit in Epidemiology
and Preventive Medicine
Queen Elizabeth II Medical Centre
NEDLANDS WA 6009

Ms Mary Ambrose (Economist)
Commonwealth Department of Community Services and Health
PO Box 100
WODEN ACT 2606

Ms Stephanie Brown (Health services provider;
Health Issues Centre representing Ms Giles)
3rd floor
148 Lonsdale Street
MELBOURNE VIC 3000 (1st meeting only)

Ms Carla Cranny (Health promotion)
Women's Health Unit
NSW Department of Health
Level 19
McKell Building
Rawson Place
SYDNEY NSW 2000 (1st and 2nd meetings only)

Dr Michael Fett (Epidemiologist) Secretary/convener
Australian Institute of Health
GPO Box 570
CANBERRA ACT 2601

Ms Christine Giles (Health services administrator)
Manager, Women's Health Policy Unit
Health Department of Victoria
GPO Box 3057
MELBOURNE VIC 3001 (2nd meeting and tele-conferences only; represented at 1st meeting by Ms Brown)

Ms Jane Hall (Economist)
Department of Community Medicine
Westmead Hospital
WESTMEAD NSW 2145

Mr Roy Harvey (Economist)
Australian Institute of Health
GPO Box 570
CANBERRA ACT 2601

Dr Paul McCann (Health services administrator)
Commonwealth Department of Community Services and Health
PO Box 100
WODEN ACT 2606

Dr Cathy Mead (Women's health)
Commonwealth Department of Community Services and Health
PO Box 100
WODEN ACT 2606 (1st meeting and tele-conferences only)

Ms Liza Newby (Women and consumers)
Commonwealth Ministerial Advisor in Women's Health
C/- Commonwealth Department of Community Services and Health
PO Box 100
WODEN ACT 2606 (1st meeting and tele-conferences only)

Dr Mary Rickard (Radiologist; Director-designate, Rachel Forster Breast Screening Clinic)
8 Lang Road
CENTENNIAL PARK NSW 2021 (invited, but unable to attend meetings)

Dr Ian Ring (Epidemiologist)
Medical Director
Cancer Epidemiology and Prevention Unit
PO Box 48
BRISBANE QLD 4000 (1st meeting and tele-conferences only)

Mr Ian Russell (Clinician; Australian Cancer Society)
C/- Suite 15
Consulting Rooms
Royal Melbourne Hospital
MELBOURNE VIC 3050 (2nd meeting and tele-conferences only)

Ms Jane Yelland (Health services provider)
Springvale Community Health Service
3 Warwick Avenue
SPRINGVALE VIC 3171 (2nd meeting and tele-conferences only)

Observer

Dr Mark Diesendorf
Australian Institute of Health
GPO Box 570
CANBERRA ACT 2601 (1st meeting and tele-conferences only)

3. RECOMMENDATIONS

Issues for a nation-wide screening programme

R1. Acknowledgement should be given to the need to plan the development of a nation-wide breast cancer screening programme with reference to experience gained in the breast cancer screening pilot projects as well as other research and analysis.

Common features of pilot projects

R2. All breast cancer screening pilot projects which participate in the nationally co-ordinated evaluation should possess the design features specified in Section 6.

Design options

R3. Pilot projects with target populations which include at least 1% aborigines should explicitly measure and maximise their participation rate.

R4. Pilot projects with target populations which include significant proportions of women not fluent in English (10% as a guide) should explicitly measure and maximise their participation rate.

R5. At least one pilot project should attempt to use the Medicare population register for identifying women and to assist in their recruitment.

R6. The AHMAC Sub-committee on Breast and Cervical Cancer Screening should consider whether the lower age limit for women invited for screening in pilot projects should be 40, 45 or 50 years.

R7. At least three of the pilot projects should include physical examination of the breast at some stage in the screening process.

R8. At least one of the pilot projects should conduct research into the most efficacious means of training and using non-radiologists as initial screen readers, including legal, medical, consumer and cost aspects.

R9. For women with abnormal mammograms, at least one pilot project should offer with equal preference and evaluate the options of referral through the normal medical referral network via the GP and referral to diagnostic and treatment services provided by an affiliated

facility.

Minimum basic data set for evaluating service delivery and client satisfaction

R10. Data specified in Appendix 3 for the minimum basic data set for evaluating service delivery and client satisfaction should be collected and provided to the evaluation co-ordination unit.

R11. Each potential client of a pilot project should be allocated a unique "project number", the Medicare card number should be sought from screened women voluntarily and both of these numbers and the first given name should be used to identify unit record data sent to the evaluation co-ordination unit.

Measuring the costs of pilot projects, diagnosis and treatment

R12. Data on costs and other inputs into the pilot projects as specified in Section 10 should be collected and provided to the national evaluation co-ordination unit.

Organisation of breast cancer screening evaluation

R13. A National Evaluation Co-ordination Unit should be established at the Australian Institute of Health to perform the following functions:

- assist pilot projects with evaluation resources
- participate in the development and installation of project software
- participate in the design of survey instruments
- co-ordinate special surveys
- receive and analyse pilot project evaluation data for purposes of national evaluation
- collect and analyse data on the costs of diagnosis and treatment of breast cancer in screened and unscreened populations
- act as a clearing house for evaluation data and reports
- foster liaison among pilot projects
- assist in the development of proposals and plans for a possible nation-wide screening programme

and the unit should be provided with sufficient resources for these purposes from the "New Initiatives for Women" budget.

The National Evaluation Co-ordination Unit should be managed by a Director of the Unit, who should be administratively responsible to the Director of the AIH.

R14. The National Evaluation Co-ordination Unit should be responsible for co-ordinating the evaluation of both the breast cancer screening pilot projects and cervical cancer screening projects.

R15. Resources from the "New Initiatives for Women" budget should be provided to up to six participating pilot projects for collecting data required both for the nationally co-ordinated evaluation and for local evaluation.

R16. A National Breast Cancer Screening Evaluation Steering Committee should be established. This Committee should be responsible for providing direction and guidance to and assisting in the co-ordination of the evaluation. The Committee should report to the AHMAC and to the Commonwealth Minister for Community Services and Health through his Department. The Committee should liase with the Breast Study Committee of the Australian Cancer Society.

The Director of the Evaluation Unit should report to the Committee, while being administratively responsible to the Director of the AIH.

The Committee should have seven members:

- a representative of the pilot projects participating in the evaluation
- a representative of the Commonwealth Department of Community Services and Health
- an expert in epidemiology and evaluation
- a health services researcher
- a women's health advocate
- a representative of the Royal Australasian College of Radiologists
- the Director of AIH or his/her nominee

In selection, attention should be paid to the need for a reasonable level of female representation on the Committee.

R17. An Annual Forum on Breast Cancer Screening should be held, attended by representatives of pilot projects, the National Evaluation Co-ordination Unit, relevant professional bodies, consumer interests and women's health interests, with the first meeting to be in March or April 1988.

R18. Participating pilot projects and sample survey teams provide client data required for the nationally co-ordinated evaluation to the National Evaluation Co-ordination Unit in the form of identified unit

records.

R19. Recognition should be given to the need for the nationally co-ordinated evaluation of breast cancer screening to include data from at least two years of repeat (incidence) screening from at least two thirds of the participating pilot projects.

R20. This report should be made available to co-ordinators of pilot projects, the Breast Study Committee of the Australian Cancer Society and the Royal Australasian College of Radiologists for comment.

Preliminary estimates of cost of evaluation

R21. Criteria for the selection of pilot projects to be funded as part of the nationally co-ordinated evaluation should be developed and promoted, applications invited from pilot projects and the allocation of resources announced as soon as possible after the AHMAC meeting on 11 December 1987.

4. INTRODUCTION

The Working Party on the evaluation of Breast Cancer Screening Pilot Projects was established by the AHMAC Sub-committee on Breast and Cervical Cancer Screening to make specific recommendations on the evaluation of breast cancer screening pilot projects. This followed the Commonwealth Government's commitment to provide $2.6 million over the next three years as part of the "New Initiatives for Women" package to assess both the feasibility and cost effectiveness of national mammography screening. This commitment was to both assist and respond to State funded pilot projects. In this report the term "breast cancer screening pilot projects" has been used in preference to "mammography pilot projects" because some pilot projects will use other screening methods as well, although it is recognised that all of the pilot projects will include screening mammography.

There are pilot breast cancer screening facilities operating at present or proposed in at least five states (Qld, NSW, Vic, SA and WA) and the possibility exists of nation-wide breast cancer screening services in the foreseeable future. In order to gain maximum value from the breast cancer screening pilot projects in the planning of nation-wide breast cancer screening services, it was proposed that the pilot projects undergo standardised evaluation and that they address design options relevant to nation-wide breast cancer screening services. Consequently, this report addresses the following subjects in turn:

- issues which need to be considered in developing a nationwide breast cancer screening programme
- common features which all pilot projects should possess
- the range of design options which should be addressed by the pilot projects
- an assessment of currently identified pilot projects in relation to these design options
- initiatives that need to be stimulated in existing or new pilot studies
- essential performance measures for the pilot projects
- a minimum common basic data set
- organisational considerations in conducting a nationally co-ordinated evaluation of pilot projects, including disbursement of Commonwealth funds for evaluation

The data from the pilot projects will be used to determine how a nation-wide breast cancer screening programme could be set up.

5. ISSUES FOR A NATION-WIDE SCREENING PROGRAMME

In order to develop a nation-wide breast cancer screening programme, the following issues would need to be considered in detail for each of the possible models of service delivery:

- what are the likely additional resource requirements?
- who delivers the service and how are they trained?
- what are the workforce implications?
- how should the service be distributed geographically?
- who should be screened?
- how should the service be promoted and targeted at all groups to be screened?
- how should those less likely to come forward be recruited?
- how effective is the service likely to be?
- what is its likely cost in relation to effectiveness?
- what are the likely savings (if any) from reduced expenditure on the treatment and care of breast cancer patients and current mammographic screening?
- what are the major determinants of variability in estimates of cost and effectiveness?
- how acceptable would the service be to the client group and specific sub-groups?
- how should the service be funded and what are the respective roles of the public and private sectors?
- what are the possible scenarios and timetables for introducing the model?

Contributions and limitations of pilot projects

In addition to providing breast cancer screening services to the target populations which they serve, the pilot projects will be able to make the following contributions towards the development of a nation-wide breast cancer screening programme:

- provide a range of information against which feasibility of expansion to a nation-wide breast cancer screening programme can be assessed

- provide data on the cost and effectiveness with respect to intermediate targets of various methods for recruiting and screening women (eg: individualised versus mass recruitment, age range, hours of operation, fixed versus mobile clinics, role of clinical examination, training of radiographers and film readers)

- provide practical experience in operating screening clinics, performing and reading mammograms, and diagnosing and treating breast lesions detected by mammographic screening

This input into the planning of a nation-wide screening programme will be required prior to the envisaged completion of the evaluation in 1992. The input will come from interim reporting of the evaluation, as outlined in Section 11.

However, the planning of a nation-wide screening programme will require additional information and analysis beyond that envisaged in the evaluation of the pilot projects. For example, data will be required on:

- human resource availability, requirements and training
- geographic distribution of screening services
- methods of introducing a nation-wide screening programme
- mass media recruitment techniques (eg TV, radio)
- resource requirements.

The pilot projects will also not be able to investigate directly the effectiveness of breast cancer screening on mortality from breast cancer and will not address the important issues of funding mechanisms and the roles of the public and private sectors in providing breast cancer screening services.

RECOMMENDATION 1

Acknowledgement should be given to the need to plan the development of a nation-wide breast cancer screening programme with reference to experience gained in the breast cancer screening pilot projects as well as other research and analysis.

6. COMMON FEATURES OF PILOT PROJECTS

Each pilot project which participates in the evaluation should possess a number of common design features. They are:

- provision for informed consent, both to invasive procedures and to the use of identified data for evaluation and/or research purposes
- review by an institutional ethics committee
- programmes of community awareness and education aimed at enhancing the acceptability of the project and facilitating recruitment
- a recruitment strategy which includes the recall of screened women
- high quality mammography equipment to meet acceptable criteria for performing film screen mammography, including adequate procedures for machine maintenance
- regular surveillance of radiological safety by an external agency, eg Australian Radiation Laboratory
- all films processed by a processing unit dedicated to mammogram processing only, with meticulous quality control
- all radiographers and film readers (including radiologists) with specific training in screening mammography
- screened women informed of both positive and negative results
- availability of adequate support and trained counselling resources for women with positive results
- adequate information on screening and its implications for women to be readily available during recruitment and screening
- provision for follow up of women who have abnormal screening results to ensure that appropriate care is offered
- at least one affiliated public sector diagnosis and treatment facility comprising specialist medical staff who have a special interest in and knowledge of early breast cancer, for those women who choose public hospital care

- a defined target population from which clients are drawn, so that it is possible to measure the proportion of women in the target population who participate

- full documentation of procedures and their change through time, with implementation of changes at identifiable time points to allow the effectiveness of different procedures to be evaluated

- screening clinic staff predominantly female, to enhance the acceptability of the service to consumers

- data to be collected by the pilot projects in a form which permits evaluation and the comparison of pilot projects with each other, and the transmission of these data to the national evaluation co-ordination unit

- a significant period of operation under the original design, before any change in design is introduced

- an identified mechanism for receiving and monitoring complaints

RECOMMENDATION 2

All breast cancer screening pilot projects which participate in the nationally co-ordinated evaluation should possess the design features specified in Section 6.

7. DESIGN OPTIONS

While some common features are considered essential (as outlined above), there is also a need for variety among the pilot projects so that different methods of providing screening can be evaluated and compared. The aspects of pilot projects that were considered, the options that should be covered under these aspects and the options that are covered by the seven funded or proposed pilot projects are displayed in the accompanying Table.

TABLE - PILOT PROJECT DESIGN OPTIONS (at 6 Oct 1987)

DESIGN OPTIONS	ACTUAL OR PROPOSED PUBLICALLY FUNDED PILOT PROJECTS						PRIVATE PROGRAMME
	Syd[1]	Br RWH	W'mead	N'cas	WA	Melb	Br Wes
(Status	funded	open	prop[2]	funded	prop	prop	open)
Recruitment							
Target population							GP ref[3]
Upper SES	+	+	+	+	+	+	most
Lower SES	+	+	+	+	+	+	some
English sp. b'gnd	+	+	+	+	+	+	+
Non-Eng. sp. b'gnd[4]	+	few	+	-	few	+	few
Aborig. b'gnd[5]	+	few	-	-	few	-	-
Metropolitan	+	+	+	+	+		+
Rural	-	UC[6]	-	+	+	-	some
Identification of women							
Elect. records	UC	UC	UC	UC	+	+	-
Medicare records	UC	-	UC	-	-	-	-
Alt. pop. registers	?	?	?	?	-	?	-
Education about mammog. screening							
Local media, posters, etc	+	+	?	+	+	+	+
Networking	+	+	?	+	+	+	+
Health education groups	+	+	+	+	+	+	+
Health infl. educ.	+	+	+	+	+	+	+
Workplace educ.	+	UC	?	+	-	+	-
Targeted educ. outreach	+	+	+	+	+	-	
Recruitment strategy							
Indiv. targeted mail etc	+	UC	UC	+	+	+	-
GP referral	few	+	UC	few	few	+	+
Drop in / self referral	few	+	+	few	few	+	-

	Syd	Br RWH	W'mead	N'cas	WA	Melb	Br Wes
Screening							
Interval			-49:1y[7,8]		-49:1yUC		1y
2 years	−	+	+	+	+	+	+
3 years	+	−	−	−	−	−	−
Age							
Categories 40+[9]	45-70[10]	50-69 45+UC	45-64UC	40-70UC	40-64	50-69	40+
Unit location							
Fixed metropolitan	+	+	UC	+	+	+	+
Mobile metropolitan	+	−	UC	+	UC	−	UC
Comb. fixed/mobile metrop.	+	UC	UC	+	−	−	UC
Mobile rural	−	UC	−	+	+	−	UC
Hours of operation							
Working hours	+	+	+	+	+	+	+
After hours/weekend	+	UC	UC	−	UC	+	UC
Views per breast							
One	+	+	50+:+	±	−	±	±
Two	±	±UC	-50:+	init[11]+	+	init +	init +
Clinical examination							
Present	−	±	?	−	−	13	+
Absent	+	±	?	+	+	+	−
Film processing							
Local[12]	±	−	?	−	−	+	−
Centralized	+	+	?	+	+	−	+
Film reading							
One reader	−	−	−	−	−	−	−
Two readers per film	+	+	+	+	+	+	+
Film reader							
Radiologist	+	+	+	+	+	+	+
Non-radiologist	UC	+	−	−	−	−	+

	Syd	Br RWH	W'mead	N'cas	WA	Melb	Br Wes
Women with abnormal mammogram							
Diagnosis of women with abnormal mammograms							
Affil. facility offered	+	+	+	+	+	+	+
Usual health care provider only	-	-	-	-	-	-	-
Both alternatives offered	-	-	-	-	+	-	-
Cytology diagnosis							
One reader/check reading	UC	1	?	+	+	?	+
Two readers per patient	UC	1*	?	±	-	?	UC
Pathology diagnosis							
One reader/check reading	UC	-	?	+	+	?	+
Two readers per patient	UC	+	?	-	-	?	UC
Treatment provider							
Affil. facility offered	+	?	+	+	+	+	-
Usual health care provider only	-	?	-	-	-	-	+
Both alternatives offered	-	?	-	-	+	-	-

Legend

+	option included in pilot project
-	option not included in pilot project
±	option included in some circumstances and not in others
?	unknown
1	Royal Prince Alfred Area project
2	as yet unfunded proposal
3	general practitioner referral
4	target population comprises at least 5% non-English speaking b'ground
5	target population comprises at least 1% Aboriginal b'ground
6	UC option under consideration
7	1y one year
8	-49 up to age 49 inclusive
9	40+ age 40 and up
10	45-70 between the ages of 45 and 70 inclusive
11	init at each woman's initial screening mammogram
12	films are inspected and at least confirmed as technically satisfactory before the woman leaves the screening clinic
13	on recall

The adequacy of coverage of the design options is now considered in detail. Since three of the pilot projects considered have not yet been funded, the adequacy of coverage by pilot projects which have been funded may need to be reviewed again when decisions on funding have been made. This reconsideration may require new projects or modification to funded pilot projects to ensure that all required design options are covered.

RECRUITMENT

Target population

Taken together, the seven funded or proposed pilot projects considered by the Working Party provide adequate coverage of all of these potential target populations, with the possible exeption of aboriginal women. The Working Party considered it undesirable to recommend the establishment of an additional pilot project directed specifically to aborigines at this stage. Instead, where the target population includes aboriginal women (eg Royal Prince Alfred Area project in inner Sydney, Royal Women's Hospital project in Brisbane, proposal for project in WA), particular attention should be given to measuring and maximising their participation rates. In addition, the AHMAC Sub-committee may wish to consider discussing this issue with aboriginal health organisations.

RECOMMENDATION 3

Pilot projects with target populations which include at least 1% aborigines should explicitly measure and maximise their participation rate.

RECOMMENDATION 4

Pilot projects with target populations which include significant proportions of women not fluent in English (10% as a guide) should explicitly measure and maximise their participation rate.

Identification of women to be screened

The Working Party considered that at least one pilot project should attempt to use the Medicare population register, both for identification of women to be screened and for recruitment. Pilot projects should seek to determine the extent to which the register which they use covers their target population, particularly with respect to minority groups.

RECOMMENDATION 5

At least one pilot project should attempt to use the Medicare population register for identifying women and to assist in their recruitment.

Education about mammography, physical examination of the breast and screening resources

The coverage of these alternatives for education is adequate among the pilot projects reviewed.

Recruitment strategy

The coverage of these alternatives for recruitment is adequate among the pilot projects reviewed. See Appendix 1 for guidelines for the development of recruitment strategies.

SCREENING

Interval

The Working Party considered that women aged 50 years or more should be screened once every two or three years. It was noted that recent evidence suggests that if women 40-49 years of age are screened, they should be screened annually. Among the pilot projects, the present distribution of screening intervals is satisfactory.

Age

The Working Party considered in depth the desirability of screening women in the age range 40 to 49 years. A paper prepared by the Department of Community Services and Health, which argues for a lower limit of 50 years, is attached as Appendix 2. In summary, these arguments are:

1. The evidence for the efficacy of screening women 40 to 49 years of age in reduced breast cancer mortality is not proven, and the pilot projects would be unable to address this question directly.

2. Inviting well women to participate in an unproven screening method, with the potential for false reassurance, unnecessary surgery and anxiety may be ethically unjustifiable, particularly when the question of efficacy is not being addressed directly.

3. It would be preferable to consider screening the technically more difficult pre-menopausal group (roughly, women under age 50) after experience and

skills have been gained through the pilot projects on the over age 50 group.

4. Screening of women aged 40 to 49 years would probably cost between two and four times as much per woman screened as screening women aged 50 plus. This is due to increased screening frequency, more views and a higher number of benign lesions. Given limited resources, this could limit the extent of screening among women over 50, where efficacy in saving lives has been demonstrated, again raising ethical issues.

5. Given finite resources, including 40 to 49 year old women in the pilot projects will reduce the number of screens available to women older than 49 by at least 50%, with a consequent reduction in the informativeness of the pilot projects for this group.

6. Over the next few years, research on mammography in Canada, Britain and continental Europe should clarify this issue.

7. It may prove difficult to alter women's expectations of the service by raising the starting age to 50 once projects have been in operation with a starting age of 40, if new data or resource considerations were to make this desirable.

8. There would be fewer breast cancers induced by mammography per woman screened in women over 50 years than in women under 50 years due to reduced frequency of exposure, fewer exposures, the latency period of cancer induction and because of breast tissue involution at menopause.

The arguments in favour of a lower limit of 40 years of age are:

1. A number of clinicians and researchers hold the view that screening is effective in women aged less than 50 years. While the possibility exists that screening 40 to 49 year old women saves lives, it is desirable to evaluate the screening of this group.

2. The political difficulties in raising the age of commencement of screening could be counterbalanced by such a decision being taken in the context of the announcement of a national breast cancer screening programme.

3. In any public debate on the lower age limit, data derived from pilot projects which had included 40 to 49 year old women would be much more influential than overseas evidence, although numbers of cases will be

very small.

4. While it will not be possible to evaluate the effect of screening on breast cancer mortality directly, the clinical stage distribution of breast cancers found among screened women compared with unscreened women under 50 years of age would provide an indication of the possible effect of screening on mortality.

Working Party members were divided on the question. The attention of the AHMAC Sub-committee is drawn to this issue as one which it may wish to consider. If screening of 40 to 49 year old women does occur, pilot projects should take special care to ensure that cost and effectiveness data can be compiled separately for women less than and greater than 50 at the time of screening.

RECOMMENDATION 6

The AHMAC Sub-committee on Breast and Cervical Cancer Screening should consider whether the lower age limit for women invited for screening in pilot projects should be 40, 45 or 50 years.

Unit location

The coverage of the alternatives for unit location is adequate among the pilot projects reviewed.

Hours of operation

The coverage of the alternatives for hours of operation is adequate among the pilot projects reviewed.

Views per breast

The coverage of the alternatives for number of views per breast is adequate among the pilot projects reviewed. It was noted that adoption of a policy of taking two views per breast would allow evaluation of a policy of taking only one view per breast, provided that one of the two views was the same as that which would be taken in a one-view only programme.

Clinical examination

Only two projects plan to perform clinical examination of the breasts and only one plans to perform them at subsequent as well as initial attendances. The Working Party considered it is desirable that at least one more pilot project include physical examination, with or without instruction in breast

self examination. This addition could take a variety of forms. For example, examinations could be conducted for a limited period only, as a research study; examinations could be confined to women with mammographically dense breasts; examinations could be confined to a lower age group. Of interest is the question of whether clinical examination of the breasts affects client participation or satisfaction.

RECOMMENDATION 7

At least three of the pilot projects should include physical examination of the breast at some stage in the screening process.

Film processing

The coverage of the alternatives for location of film processing is adequate among the pilot projects reviewed.

Film reading

Currently all pilot projects plan to have two independent, initial screen readers. This practice was considered to be desirable. The policy of using only a single reader or selective double-reading could be evaluated in projects using two readers.

Film reader

Pilot projects should have film readers who are medically qualified, and at least one of the readers should be a radiologist. One or two pilot projects should conduct research into the most efficacious means of training medically qualified non-radiologists and non-medically qualified personnel as initial screen readers and of using their skills in a screening programme. Investigations should also be made into the acceptability of these alternatives from legal, medical, consumer and cost viewpoints.

RECOMMENDATION 8

At least one of the pilot projects should conduct research into the most efficacious means of training and using non-radiologists as initial screen readers, including legal, medical, consumer and cost aspects.

WOMEN WITH ABNORMAL BREAST CANCER SCREENING RESULTS

Diagnosis of women with abnormal screening results

All pilot projects will have follow up assessment of women with abnormal or equivocal screening results available in an affiliated diagnosis and treatment facility. The Working Party considers this to be desirable.

All pilot projects recognise that all women have the right to be referred by way of the usual medical referral network. One project proposes to offer, with equal preference, referral by way of the usual medical referral network and referral to an affiliated facility, and to evaluate these alternatives. Since it is important that at least one of the pilot projects evaluates this option, the Working Party considers this to be desirable.

RECOMMENDATION 9

For women with abnormal mammograms, at least one pilot project should offer with equal preference and evaluate the options of referral through the normal medical referral network via the GP and referral to diagnostic and treatment services provided by an affiliated facility.

Cytology diagnosis

The coverage of the alternatives for cytology diagnosis is adequate among the pilot projects reviewed.

Pathology diagnosis

The coverage of the alternatives for histopathology diagnosis is adequate among the pilot projects reviewed.

Treatment provider

All but one of the pilot projects plan to offer an affiliated treatment facility. The Working Party considers this balance to be satisfactory.

8. MEASURING THE EFFECTIVENESS OF PILOT PROJECTS

8.1 EACH PILOT PROJECT AS A WHOLE

This section poses questions to be asked in the evaluation of pilot projects as a whole and the performance measures needed to answer these questions. It also identifies desirable performance measures which cannot be derived satisfactorily from pilot projects and must await the development of a population-wide programme.

PILOT PROJECTS

Questions

Q1. How effective are the pilot projects in detecting breast cancer?

Q2. Among the different methods employed in the pilot projects, how does effectiveness vary in altering the stage distribution of cancer at the time of diagnosis as an indicator of possible effects on breast cancer mortality?

Performance measures for national evaluation

PM1. the proportion of all cancers in screened women that are detected by screening

PM2. tumour stage profile at diagnosis among screened women compared with the stage distribution among the target population and among unscreened women.

PM3. the proportion of screened women who prove to have breast cancer detected via screening

PM4. the proportion of screened women who have a biopsy for benign breast disease as a consequence of screening

POPULATION WIDE PROGRAMME

The following evaluation questions and performance measures cannot be addressed satisfactorily by individual pilot projects due to their envisaged target populations having too few women and their time scale being too short. These important questions and measures will have to await the development of large scale screening programmes (at least state-wide).

Questions

Q3. How effective is the screening programme in reducing breast cancer mortality?

Q4. To what extent does breast cancer screening lead to over-diagnosis of breast cancer?

Performance measures

LM1. the incidence and mortality of breast cancer in screened women in the target population

LM2. the incidence and mortality of breast cancer in unscreened women in the target population

LM3. the incidence and mortality of breast cancer in the whole target population

LM4. incidence rates for breast cancer (including interval cases) among screened women during second and subsequent rounds of screening compared with the expected rate from unscreened groups.

8.2 RECRUITMENT STRATEGIES

This section poses questions to be asked in the evaluation of recruitment strategies and the performance measures needed to answer these questions. It also identifies performance measures which pilot projects may wish to use for local evaluation.

Questions

Q5. Among the different methods employed in the pilot projects, how does effectiveness vary in the initial recruitment of women and in the recruitment of women for rescreening?

Q6. Among the different methods employed in the pilot projects, how does effectiveness vary in influencing the level of awareness and knowledge of breast cancer screening among the target population as a whole and among specific sub-groups?

Performance measures for national evaluation

PM5. documented pilot project procedures for client recruitment

PM6. proportion of the whole population of the target geographic area covered by the list of the target population

PM7. proportion of women in the list of the target population who attend the initial screen

PM8. the proportion of women in the list of the target population who attend subsequent screens

PM9. number and proportion of women recruited for their **initial** screen from different subgroups of the target population defined in terms of:
- socioeconomic status
- ethnicity
- geographic location
- age

PM10. number and proportion of women recruited for their **subsequent** screen from different subgroups of the target population defined in terms of:
- socioeconomic status
- ethnicity
- geographic location
- age

Performance measures useful for local evaluation

LM5. awareness of attenders and non-attenders of promotional materials

LM6. media coverage

LM7. telephone enquiries

LM8. other service provider (health care professionals) support in the promotion of the mammographic screening service

LM9. separately identified impact of whole population (media, mass distribution of promotional materials) and individual promotion methods (personalised pamphlets, personal letters)

LM10. number and sources of referrals to the pilot projects

LM11. proportion of women with appointments for initial screening who actually attend

APPENDIX 1

RECOMMENDED GUIDELINES FOR THE DEVELOPMENT OF RECRUITMENT STRATEGIES

The following guidelines are suggested for consideration by pilot projects in the development of promotion and recruitment strategies:

Ingenuity in the promotion recruitment and public education for mammographic screening projects is required. At this stage it is not known which approaches will work to gain maximum acceptability in Australian conditions and for particular target groups.

Projects should be encouraged to explore predictors of participant response by the hours of employment (impact of shift work, part-time/full-time etc).

Preference should be given to developing strategies which would be applicable to large scale ongoing mammographic screening.

All promotional materials and strategies should aim to enhance the acceptability of the project while maintaining high standards of accuracy of information provided, and should reflect the values, cultural norms, languages and practical circumstances of the target population.

All promotional materials and recruitment strategies should be pre-tested on samples of women in relevant target groups prior to distribution or implementation. Pre-testing should assess:

- -acceptability
- -ease of understanding
- -relevance
- -potential offensiveness
- -reactions to controversial and sensitive material.

8.3 SCREENING SERVICES

This section poses questions to be asked in the evaluation of screening services and the performance measures needed to answer these questions. It also identifies performance measures which pilot projects may wish to use for local evaluation.

Questions

Q7. Among the different methods employed in the pilot projects, how does effectiveness vary in screening recruited women?

Q8. Among the different methods employed in the pilot projects, how does effectiveness vary in maintaining quality control of radiography and film processing?

Q9. Among the different methods employed in the pilot projects for maximising client satisfaction, how does client satisfaction vary among women attending for their initial and subsequent screens?

Performance measures for national evaluation

PM11. documented pilot project procedures for screening

PM12. number of women screened over time

PM13. proportion of screening mammograms repeated due to poor technical quality

PM14. the proportion of screened women who are screened:

- negative
- equivocal (then negative or positive)
- positive

at their initial and subsequent screens

PM15. the proportion of screen detected cancers which are detected by mammography, by physical examination of the breast and by both procedures

PM16. sensitivity (cases detected by screening as a proportion of cases detected by screening plus interval cases in 12 months post-screening)

PM17. specificity (non-cases with negative screen as a proportion of all non-cases (i.e. cancer does not develop within 12 months))

PM18. predictive value of positive screen (cases detected by screening as a proportion of all mammograms initiating referral for assessment)

PM19. predictive value of negative screen (non-cases with negative screen as a proportion of all negative screens)

PM20. interobserver agreement on mammography report

PM21. interval between client attending and receiving the result

PM22. client assessment of acceptability and usefulness of the information provided to clients by the service

PM23. client assessment of accessibility of service and convenience of hours of operation

PM24. client assessment of effectiveness of appointment and enquiry systems

PM25. client assessment of waiting times for appointment and at time of service provision

PM26. client assessment of acceptability of type of service

PM27. client assessment of appropriateness of project staff, including perceived technical skills, attitudes, sensitivity and interpersonal/communication skills

PM28. client assessment of acceptability of screening facilities, ie, comfort, physical layout

PM29. client assessment of relevance of sex of service providers

PM30. client assessment of availability of support/referral networks

PM31. client assessment of counselling services

Note: The values obtained for many of these measures are likely to change substantially with repeat screening.

Mandatory performance measure for local evaluation

LM12. proportion of unacceptable radiation exposure tests as determined by an external authority

Suggested performance measures useful for local evaluation

LM13. dosages on staff dosimeters

LM14. reasons for non attendance among women who fail to keep appointment for screening

8.4 FOLLOW-UP AND TREATMENT SERVICES

This section poses questions to be asked in the evaluation of follow-up and treatment services and the performance measures needed to answer these questions. It also identifies performance measures which pilot projects may wish to use for local evaluation.

Questions

Q10. Among the different methods employed in the pilot projects, how does effectiveness vary in assessing and treating women with abnormal breast cancer screening results?

Q11. Among the different methods employed in the pilot projects, how does effectiveness vary in maintaining quality control of client follow-up?

Q12. Among the different methods employed in the pilot projects, how does effectiveness vary in maintaining quality control of cytology and histopathology reporting?

Q13. To what extent does screening lead to biopsies?

Q14. Among the different methods employed in the pilot projects for maximising client satisfaction, how does client satisfaction vary among women attending for assessment of equivocal and abnormal mammograms?

Performance measures for national evaluation

PM32. documented pilot project procedures for follow-up and treatment

PM33. among screened women, the proportion of women with equivocal or abnormal breast cancer screening results who present for assessment, and among these women, the type and frequency of:
- assessment procedures employed
- pathology detected
- treatment administered

PM34. proportion of women referred for assessment who actually present for assessment

PM35. intervals between the client receiving the screening result, being assessed if the result requires assessment, being notified of the result of the assessment and receiving definitive treatment where required.

PM36. the ratio of benign biopsies to cancers diagnosed through screening

PM37. interobserver agreement for cytology results

PM38. interobserver agreement for histopathology results

PM39. client assessment of acceptability and usefulness of the information provided to clients by the service

PM40. client assessment of accessibility of follow-up services and convenience of hours of operation

PM41. client assessment of effectiveness of appointment and enquiry systems

PM42. client assessment of waiting times for appointment and at time of service provision

PM43. client assessment of appropriateness of project staff, including perceived technical skills, attitudes and interpersonal/communication skills

PM44. client assessment of acceptability of assessment facilities, ie, comfort, physical layout

PM45. client assessment of relevance of gender of service providers

PM46. client assessment of availability of support/referral networks

PM47. client assessment of counselling services

Performance measures useful for local evaluation

LM15. reasons for non attendance among women who fail to keep appointment for assessment or treatment

9. MINIMUM BASIC DATA SET FOR EVALUATING SERVICE DELIVERY AND CLIENT SATISFACTION

For the evaluation of service delivery and client satisfaction among the pilot projects, data are required in the following areas (in outline only):

Pilot projects

- description of target population
- project description
- procedures manuals
- recruitment attempts, to be obtained from project records
- screening results, socio-demographic characteristics, knowledge, attitudes and satisfaction of clients, to be obtained from project records and by sample surveys

Follow-up / treatment services

- diagnostic procedures and results, follow-up / treatment procedures and satisfaction data relating to clients referred from pilot projects, to be obtained from records and by sample surveys

Cancer registers / death registers

- diagnostic data relating to all interval cases of breast cancer among screened women and all cases of breast cancer among unscreened members of the target population, to be obtained from records
- cause of death data for all deaths among women in the target population who develop breast cancer, to be obtained from records

Target population

- data on socio-demographic characteristics, knowledge and attitudes from non-attenders in the target population, to be obtained by sample surveys
- data on knowledge and attitudes from booked non-attenders of screening and follow-up / treatment services, to be obtained by sample surveys

These are the data necessary to construct the performance measures for national evaluation listed in Section 8. A full list of data items (some with code lists), including data items which pilot projects may wish to collect for purposes of local evaluation, is presented in Appendix 3 and should be consulted for a full understanding of the data requirements.

RECOMMENDATION 10

Data specified in Appendix 3 for the minimum basic data set for evaluating service delivery and client satisfaction should be collected and provided to the evaluation co-ordination unit.

PROJECT NUMBERS

An issue of significance in relation to the minumum basic data set is the selection of client record identification numbers ("project numbers"), and other data used to identify individual client records. The practicable alternatives are a number unique to the pilot project and the Medicare card number.

A project number which is unique to the project has two advantages over the Medicare card number : Firstly, it is available to the project prior to a recruitment of the client and would therefore be useful for administering recruitment and for evaluating recruitment strategies. Secondly, it is available to the project if a client declines to provide her Medicare number.

The Medicare card number has advantages in greatly facilitating linkage to Health Insurance Commission data bases, for evaluating recruitment strategies using Health Insurance Commission data and for identifying private sector care providers and services. (The Health Insurance Commission uses Medicare card number and first given name for record linkage.)

However, asking women for their Medicare card number may unintentionally create the impression that the pilot projects are related to Medicare or that a charge may be levied. This could be overcome by informing women that the number is not required for billing, but instead for research purposes, and that while providing the number would be very helpful, it is voluntary.

Given the usefulness of both numbers for evaluating breast cancer screening, it is suggested that, where applicable, every potential client in the target population be allocated a project number and that the Medicare card number also be recorded when supplied by the woman. A pilot project indentifier should be added prior to data transmission to the evaluation co-ordination unit.

RECOMMENDATION 11

Each potential client of a pilot project should be allocated a unique "project number", the Medicare card number should be sought from screened women voluntarily and both of these numbers and the first given name should be used to identify unit record data sent to the evaluation co-ordination unit.

10. MEASURING THE COSTS OF PILOT PROJECTS, DIAGNOSIS AND TREATMENT

Economic costing is aimed at providing the following:

- determining Commonwealth and State funding requirements for a possible extensive breast cancer screening programme
- determining total net cost
- assessing 'value for money', given competing demands from other health interventions for available resources
- identifying the most efficient methods of providing screening mammography

This costing requires data on the cost of each component of the process of breast cancer screening and treatment, and the consequential costs and savings for the health system as a whole.

This section identifies the data to be collected in measuring the costs of screening projects themselves and subsequent costs of diagnosis and treatment. This encompasses the costs of encouraging women to attend for screening, the operation of the screening clinic and the further investigation and treatment of abnormalities whether in the private sector, on a fee for service basis in the public sector or on a no charge to consumer basis. The costs incurred by the women themselves are likely to be quite different between programmes using mobile vans and those operating from a fixed facility. Therefore these costs will also be assessed.

Each pilot project will provide data that will allow calculation of the cost per case detected and disaggregation of this cost into recruitment, screening and re-screening, and where arising directly from screening, diagnosis. Data will also be collected on the costs of diagnosis and treatment for the exclusion and management of breast cancer in both a population offered screening (including both those with abnormalities found by screening and those found outside screening) and a population not offered screening. These data would be collected by a special survey of a sample of screened and unscreened women, recognising that these data will need to be collected longitudinally over an extended period of time.

Within the pilot projects, data should be collected by three methods: continuous or ongoing recording; activity survey of projects; survey of women attending for examination.

Data to be generated by ongoing recording

Cost data are required for five stages of the pilot projects: recruitment; screening; follow-up of abnormal screens; invitation to re-screen; treatment.

Recruitment: all activities associated with advertising, promotion, identifying target individuals and inviting them to attend for screening. Output measure: number of women who attend for screening examinations.

Screening: all activities of screening, including repeat mammograms for technically inadequate films or suspicious findings and the notification of positive and negative results. Output measures: number of women with negative finding plus number of women referred for further investigation.

Follow-up of abnormalities: all further investigation including diagnostic mammography and/or biopsy whether carried out in a public breast clinic or in the private sector, including the notification of women, until a positive or negative diagnosis of cancer on histology results is reached. Output measure: number of women with negative findings plus number of cases of breast cancer times stage at diagnosis.

Invitation to re-screen: all activities associated with maintaining a register of women who have been screened and contacting them for re-screening. Output measure: number of women who attend for re-screening.

In addition to these, there are four other categories of cost which should be separately identified: training; research; evaluation; monitoring and quality assurance.

For each of these nine major activities, the following data should be collected on an ongoing basis:

Staffing

Category x level x time x (salary/wage rates and on-costs)
Category x time x (sessional rates and on-costs)
Category x number of patients x fee
Consultant hours x (rates and on-costs)
Volunteer hours x task

Other medical services

Number of referrals x category x service x fee

Capital

List of equipment and furniture purchased x purchase price x date of purchase x full/part apportionment to activity.

Buildings

Square metres used
Modification costs (with sketch plan)
Number of vans x size x purchase price x purchase date

Consumables

Type of film x quantity x unit price
Type of chemicals x quantity x price
Linen x quantity x price
Disposables x quantity x price
Postage quantity x price
Stationery quantity x price
Telephone usage x price

Operating costs

Estimated consumption of fuel, light, power, water x unit price

Promotion

Advertising, market research

Administration

Travel, meetings, professional activities

Repairs and maintenance

Other

In concept, the analysis of the costs of each pilot project will be able to be presented in a matrix of the nine operating cost categories (recruitment, screening, follow-up, etc.) and the ten expenditure headings (staffing, other medical services, etc.).

Data to be obtained by activity survey

There will be a periodic activity sampling survey of each screening project to assess the reliability of the allocation of costs to the five stages of the screening programme and the four other cost categories; and to provide a basis for the apportionment of two of the other categories of cost generated by pilot activities (ie research and evaluation) to the five stages. Research and evaluation costs must be separated from mammography screening costs.

Data to be obtained by sample survey of women attending for screening

The information required to estimate the costs incurred by individuals attending for screening would be collected by a sample survey of women. This would involve questions about time and costs of travel, parking, child care, time taken from work and whether attendance was combined wih another purpose eg shopping.

Performance measures for national evaluation

PM48. Cost from recruitment to diagnosis per women in target population

PM49. Cost from recruitment to diagnosis per case detected

PM50. Cost of recruitment per women attending for initial and subsequent screens

PM51. Cost of screening per women screened at initial and subsequent screens

PM52. Costs of follow-up and diagnosis per women with equivocal or abnormal screen result at initial and subsequent screens

PM53. Cost of treatment per women with breast cancer detected by screening, diagnosed in the interval between screens, diagnosed in unscreened women in the target population and diagnosed in women not offered screening

PM54. Staff hours (by type) for screening per woman screened at initial and subsequent screens

PM55. Staff hours (by type) for follow-up and diagnosis per woman with equivocal or abnormal screen result at initial and subsequent screens

PM56. Staff hours (by type) for follow-up and diagnosis per screen detected breast cancer at initial and subsequent screens

RECOMMENDATION 12

That data on costs and other inputs into the pilot projects as specified in Section 10 be collected and provided to the national evaluation co-ordination unit.

11. ORGANISATION OF MAMMOGRAPHY EVALUATION

This section of the report covers organisational aspects of the nationally co-ordinated evaluation of mammography pilot projects. This issue is examined in greater detail in Appendix 4.

Project plan

The collection of evaluation data can be divided into three organisationally distinct components. They are:

- The collection of data on recruitment and screening
- The collection of data on diagnosis and treatment of women with abnormal screening results, and register data
- The collection of data by sample surveys, activity surveys and ad hoc research

Establishing mechanisms for collecting data in each of these three areas requires the development of detailed protocols, with timetables and budgets. To develop these protocols, the following process for the entire evaluation project is suggested:

Stage 1 - Establishing Evaluation Co-ordination Unit and preliminary investigations

Activities in Stage 1 are directed towards preparing detailed project plans, with time and cost estimates.

- Establish a National Evaluation Co-ordination Unit
- Conduct an in-depth analysis of an operating pilot project
- Specify in detail the minimum common basic data set
- Develop and test computerised screening clinic data management system after reviewing systems already in operation for this purpose, and install at trial site
- Employ an evaluation project officer in a currently operating pilot project to set up and pilot evaluation data collection
- Contract the detailed design of a suite of sample surveys to be administered in all pilot project target populations.

Stage 2 - Initiate data collection

The activities in Stage 2 are aimed at establishing the data collection infrastructure.

Assist pilot projects in the installation and commissioning of clinic computer facilities.

Assist pilot projects in acquiring resources to collect evaluation data.

Facilitate as necessary the collection of project, diagnostic, treatment and register data.

Facilitate as necessary the conduct of the sample surveys.

Develop and test data analysis programmes using early evaluation data.

Stage 3 - Ongoing data collection and related research

The activities in Stage 3 are aimed at collecting evaluation data and examining broader issues relevant to a possible national screening programme.

Activities as for Stage 2, plus:

Researching issues relevant to establishing a nation-wide breast cancer screening programme

Preparation of ongoing evaluation reports

Stage 4 - Preparation of final reports

It is recognised that researchers affiliated with pilot projects may wish to perform additional studies which may make substantial contributions to breast cancer screening programmes. These studies have not been mentioned in the project plan because they do not require development or co-ordination by the Evaluation Unit. The Evaluation Unit could act as a clearing house for such studies.

Individual pilot projects will be free to analyse and report their own data at any time.

Organisational aspects

The conduct of the evaluation will require the establishment of a National Evaluation Co-ordination Unit and the development of dedicated evaluation resources within each

pilot project.

The National Evaluation Co-ordination Unit could have the following functions:

- Receiving, analysing and reporting pilot project evaluation data for the purposes of national evaluation

- If required, assisting pilot projects with the establishment of resources for conducting the evaluation

- Acting as a clearing house for the pilot projects and for researchers in the area by facilitating the pooling and dissemination of pilot project and research experience

- Fostering a network among project based evaluation staff

- Assisting in the development of plans and proposals for the establishment of a possible nation-wide breast cancer screening programme

In performing these functions, it would be desirable for the Evaluation Unit to draw upon expertise associated with particular pilot projects.

The following functions could be performed by the Evaluation Co-ordination Unit or could be contracted out, possibly to one or several of the pilot projects:

- Designing, commissioning and/or conducting special surveys required for the evaluation

- Participating in, co-ordinating or directing the development of software which could be used to manage a pilot project and also provide data for evaluation.

The Australian Institute of Health would be an appropriate choice for the location of the Evaluation Co-ordination Unit for the following reasons:

- AIH has relationships with the States and Territories as well as with the Commonwealth.

- AIH has developed relevant contacts and experience through its work on the AHMAC Breast Cancer Screening and Cervical Cancer working parties.

- AIH has no direct affiliation with a particular proposal for breast cancer screening services.

- AIH has a mandate to evaluate health services.

- AIH is centrally located.

Locating the Unit at the AIH could present problems in gaining access to Medicare data from the Health Insurance Commission. The Working Party considered that this could be readily overcome by co-operation between the AIH and the Commonwealth Department of Community Services and Health.

Within the National Evaluation Co-ordination Unit, expertise will be required in a number of areas, to perform the following functions:

Project management

Co-ordinate all aspects of the evaluation

Integrate and oversee data from all areas

Epidemiology

For client participation and health related data:

- identify requirements in detail
- co-ordinate the development and installation of data collection mechanisms
- co-ordinate ad hoc surveys (eg data from the cancer registries and from treatment providers)
- interpret and report

Economics

For cost and related resource data:

- identify requirements in detail
- co-ordinate the development and installation of data collection mechanisms
- co-ordinate activity surveys
- co-ordinate ad hoc surveys (eg data from treatment providers)
- interpret and report

Accounting

For cost data:

- identify requirements in detail
- co-ordinate the development and installation of data collection mechanisms
- interpret and report

Behavioural and social sciences

For behavioural and attitudinal data:

- identify requirements in detail

- co-ordinate the development of data collection instruments and sampling frames
- co-ordinate the identification of survey samples and the conduct of surveys
- interpret and report

Co-ordinate the qualitative assessment of the impact on members of the community, of the education component and of breast cancer screening services in general

Statistics

Identify and procure computing resources required for analysis

Analyse and assist in interpretation of data in all areas

Computer systems analysis programming

Design, develop and install pilot project computer facilities

Design and implement mechanisms for data transfer from pilot projects to the Evaluation Co-ordination Unit

Design and implement data handling facilities at the Evaluation Co-ordination Unit

A suggested staffing structure for the Unit is given in Appendix 4. The structure assumes that the Evaluation Co-ordination Unit will also co-ordinate the evaluation of cervical cancer screening projects. The structure and time allocations of staff are very preliminary. They will need to be refined once the evaluation commences and resource requirements are identified in detail. In particular, staffing requirements will need to be blended with those required for co-ordinating the evaluation of cervical cancer screening.

Initial estimates of the annual cost of the evaluation co-ordination unit are $199,000, assuming that the unit is located at the AIH and that the unit is also responsible for co-ordinating the evaluation of cervical cancer screening services. This estimate is based on the assumption that central evaluation resources are shared with the central evaluation component of the cervical cancer screening projects, as outlined in the Report of the AHMAC Working Party on Cervical Cancer Screening. (See Section 12 of this report.)

RECOMMENDATION 13

A National Evaluation Co-ordination Unit should be established at the Australian Institute of Health to perform the following functions:

- **assist pilot projects with evaluation resources**
- **participate in the development and installation of project software**
- **participate in the design of survey instruments**
- **co-ordinate special surveys**
- **receive and analyse pilot project evaluation data for purposes of national evaluation**
- **collect and analyse data on the costs of diagnosis and treatment of breast cancer in screened and unscreened populations**
- **act as a clearing house for evaluation data and reports**
- **foster liaison among pilot projects**
- **assist in the development of proposals and plans for a possible nation-wide screening programme**

and that the unit be provided with sufficient resources for these purposes from the "New Initiatives for Women" budget.

The National Evaluation Co-ordination Unit should be managed by a Director of the Unit, who should be administratively responsible to the Director of the AIH.

Co-locating the evaluation of breast cancer and cervical cancer screening services would provide the following advantages:

Breast and cervical cancer screening have many features in common, especially in the problematic areas of recruitment, community education and the interrelations between screening and the health care system at large. In the process of developing and testing solutions for either cancer, valuable experience and knowledge will be gained which can be applied to the other cancer. This is likely to result in considerable time and cost savings

Within the Evaluation Unit, staff time can be shared by the breast and cervical cancer evaluations. This is also likely to result in significant cost savings.

RECOMMENDATION 14

The National Evaluation Co-ordination Unit should be responsible for co-ordinating the evaluation of both the breast cancer screening pilot projects and cervical cancer screening projects.

Within each pilot project, major functions can be divided according to whether they are service functions (which would be required even without evaluation) or evaluation functions. Generally, service functions would be the responsibility of the pilot projects and the state funding bodies, while evaluation functions would be the responsibility of the evaluation team within each pilot project. One important area of overlap is data management and data transmission. Here it is probably desirable for computerised data management systems in the pilot projects to be eligible for funding as part of the evaluation, as such systems would greatly facilitate data collection and transmission.

RECOMMENDATION 15

Resources from the "New Initiatives for Women" budget should be provided to up to six participating pilot projects for collecting data required both for the nationally co-ordinated evaluation and for local evaluation.

Controlling and co-ordinating mechanisms

To successfully implement the evaluation while taking account of groups with legitimate interests and ensuring that the results of the evaluation of the pilot projects make a useful contribution to the future development of breast cancer screening in Australia, it is essential that appropriate organisational structures be developed. The approach preferred by the Working Party is for the establishment of an evaluation steering committee and for there to be an annual forum on breast cancer screening.

The evaluation steering committee could be called the National Breast Cancer Screening Evaluation Steering Committee.

RECOMMENDATION 16

A National Breast Cancer Screening Evaluation Steering Committee should be established. This Committee should be responsible for providing direction and guidance to and assisting in the co-ordination of the evaluation. The Committee should report to the AHMAC and to the Commonwealth Minister for Community Services and Health through his Department. The Committee should liase with the Breast Study Committee of the Australian Cancer Society.

The Director of the Evaluation Unit should report to the Committee, while being administratively responsible to the Director of the AIH.

The Committee should have seven members:

- **a representative of the pilot projects participating in the evaluation**
- **a representative of the Commonwealth Department of Community Services and Health**
- **a expert in epidemiology and evaluation**
- **a health services researcher**
- **a women's health advocate**
- **a representative of the Royal Australasian College of Radiologists**
- **the Director of AIH or his/her nominee**

In selection, attention should be paid to the need for a reasonable level of female representation on the Committee.

Assuming the Steering Committee meets four times a year, the preliminary estimate of the cost of the Committee is $10,000 per annum.

The annual forum on breast cancer screening would have the following roles:

- provide a forum for the exchange of information on breast cancer screening
- assist in the coordination of breast cancer screening activities by developing networks
- provide advice and suggestions to pilot projects and the nationally co-ordinated evaluation

It is envisaged that pilot projects, the Evaluation Unit, relevant professional bodies, consumer interests and health interests would be invited to participate. The first forum could be usefully held in March or April of 1988. It is envisaged that participants' costs would be met by their own organisation or institution, except in special circumstances.

RECOMMENDATION 17

An Annual Forum on Breast Cancer Screening should be held, attended by representatives of pilot projects, the National Evaluation Co-ordination Unit, relevant professional bodies, consumer interests and women's health interests, with the first meeting to be in March or April 1988.

There will also be a need for periodic meetings between pilot project staff and staff of the National Evaluation Co-ordination Unit.

Data collection

Pilot project procedures will be documented by pilot projects and affiliated staff.

Data from routine screening operations will be recorded by pilot projects and affiliated staff as a concomitant of routine operations.

Data from breast cancer diagnosis and treatment services provided by assessment clinics affiliated with screening projects will be obtained routinely by project affiliated staff.

Data from breast cancer diagnosis and treatment services which are provided outside the pilot projects and their affiliated clinics will by collected on a case by case basis by research staff affiliated with a pilot project.

Data from cancer registers and death registers will be collected periodically by research staff affiliated with a pilot project.

Data from special surveys will be collected by survey teams which will need to work closely with the pilot projects, if not actually under their direction.

Data transmission to the Evaluation Co-ordination Unit

It is envisaged that project descriptions and procedures manuals will be altered from time to time as experience accumulates. These manuals will be sent to the Evaluation Unit as they become available.

An issue of potential sensitivity is the form in which data on individuals should be provided to the Evaluation Unit. As outlined in Section 9, it is recommended that data on

individuals be sent to the Evaluation Unit in the form of unit records with client or subject number, Medicare number and first given name. Full name is not sought. (The Health Insurance Commission matches records using Medicare card number and first given name.) The merits of this approach are that: it enables the Evaluation Unit to compile longitudinal screening and outcome records for individuals; it permits flexiblility of analysis at the Evaluation Unit; and there is a much lower risk of breach of confidentiality than for fully named data. The only significant limitation of this approach is that a name-number link would need to be provided at a future date if future linkage with National Death Index (NDI), National Cancer Statistics Clearing House (NCSCH) and possibly Medicare data is desired (unless the Medicare card number and first given name are provided).

It is emphasised that the provision of unit record data is in **no way** intended to limit the use which the pilot projects and affiliated staff may make of the data which the projects generate. It is envisaged that the volume of data which they will generate just for the purposes of the national evaluation will provide substantial opportunities for analysis beyond those required for the national evaluation.

Service, diagnosis and treatment primary data will be sent to the Evaluation Unit at frequent, regular intervals (eg quarterly) to facilitate the preparation of timely reports.

Primary data generated by special surveys which are part of the national evaluation will be sent at intervals during data collection, or, for brief surveys, upon completion of data collection.

Generally, surveys initiated by state based investigators would be made available to the Evaluation Unit as reports, although primary data may be sought for surveys which address questions directly relevant to national evaluation.

RECOMMENDATION 18

Participating pilot projects and sample survey teams provide client data required for the nationally co-ordinated evaluation to the National Evaluation Co-ordination Unit in the form of identified unit records.

Timing

Funds for the national evaluation of mammography pilot projects have been budgetted for 1987/88 and promised for 1988/89 and 1989/90. As of late 1987, only two potential pilot projects are operational, both in Brisbane. One of these is a wholly private sector operation. The Sydney and Melbourne pilot projects are planned to commence operations

in early 1988. There are currently no planned commencement times for the Western Australian or South Australian pilot projects, the funding of which has not been confirmed. Since it would take at least six months from time of funding for a project to commence operations, the most optimistic scenario is for the WA and SA projects to start in mid-1988. This timing has significant implications for the evaluation:

> Firstly, the start-up times of the WA and SA projects are the most significant determinants of the duration of screening operations which can be included in the evaluation, if more than three or four projects are to be evaluated. This is because short periods of operation would provide cost and performance data which are likely to be significantly worse than those applying to a steady state programme. This arises from start-up / bedding-in costs and the inevitable learning curves which will be experienced by all staff of screening projects, assessment centres and treatment providers. As a result, these data will be of limited use for long term planning.
>
> Secondly, with a re-screening interval of around two years, only the Royal Women's Hospital in Brisbane will be able to provide substantial data on re-screening for inclusion in the final report if the evaluation is to end in mid-1990. It is important to include a substantial period of re-screening in the evaluation because it is essential to know whether women will return for re-screening (and the determinants of re-screening rates) and because the screen prevalence of breast cancer in the first screen is likely to be higher than for subsequent screens (once the "back log" is cleared). Again, absence of data from re-screening will lead to unreliable resource estimates for a steady state screening programme.
>
> Thirdly, data on costs of treatment will only become available gradually over the period following diagnosis, as treatment may continue over a woman's remaining lifespan. Preferrably these costs would be gathered and reported for the first two years post diagnosis and up until first recurrence, and ideally collected until the woman' death.

Thus, while useful preliminary reports will be available within 18 months of commencement and at regular intervals thereafter, it is essential that at this early stage recognition be given to the fact that the majority of screening projects should complete two screening cycles as part of the evaluation. (However, recent advice suggests that the steady state was reached in the Edinburgh project only in the third screening cycle.) Assuming a mid-1988

start-up, a two year re-screening interval and six months to prepare the final report, most of the components of the evaluation should conclude at the end of 1992 at the earliest, recognising that only initial treatment data will be available at that time. Even so, it is acknowledged that there will be requirements from the funding authorities for regular reporting and provision of interim results for public policy purposes.

RECOMMENDATION 19

Recognition should be given to the need for the nationally co-ordinated evaluation of breast cancer screening to include data from at least two years of repeat (incidence) screening from at least two thirds of the participating pilot projects.

RECOMMENDATION 20

This report should be made available to co-ordinators of pilot projects, the Breast Study Committee of the Australian Cancer Society and the Royal Australasian College of Radiologists for comment.

12. PRELIMINARY ESTIMATES OF THE COST OF EVALUATION

This section presents estimates of the approximate costs of the central component of the national evaluation. These estimates of cost are preliminary only. A suggested project plan for deriving more accurate cost estimates is presented in Appendix 4.

Evaluation co-ordination unit salaries per annum (based at AIH; see Appendix 4 for details)	$139,000
Evaluation co-ordination unit running costs per annum	$50,000
Steering Committee (4 meetings) per annum	$10,000
	$199,000

From $1 million per annum this leaves $801;000 available for national evaluation activities within the pilot projects. If six projects participate there would be, on average, $133,000 per project. This corresponds closely with an estimated cost per pilot project of $126,000 (see Appendix 4) for a project officer, training of radiologists and radiographers, data collection and evaluation running costs.

The development of computer software could cost around $10,000 and each pilot project could require computer hardware and software to be installed at an approximate cost of $10,000. With six pilot projects participating, the cost of computer facilities amounts to $70,000 once only.

Preliminary estimate of once only cost of providing computing facilities:	**$70,000**

The contribution of these resources to each pilot project will greatly assist each project in performing its routine functions of records management, and contribute to local evaluation, where possible, as well as funding the project's participation in the national evaluation.

Selection of pilot projects for national funding

The minimum level of funding required by each pilot project to effectively participate in the nationally co-ordinated evaluation is estimated to be approximately $100,000. Given the total level of resources available, this has implications for the number of projects whose participation in the evaluation can be funded. An absence of funding is not intended to preclude participation in the evaluation by other projects, provided they are prepared to self-fund additional

staff which may be required and provide data in the major areas of the minimum data set to the National Evaluation Co-ordination Unit.

RECOMMENDATION 21

There is an urgent need to develop and promote criteria for the selection of pilot projects to be funded as part of the nationally co-ordinated evaluation, to invite applications from pilot projects and to announce the allocation of resources as soon as possible after the AHMAC meeting on 11 December 1987.

APPENDIX 2

CASE FOR LIMITING SCREENING IN PILOT PROJECTS TO THOSE AGED 50 YEARS AND ABOVE

This paper is provided for information.

PAPER FOR 2ND MEETING OF AHMAC WORKING PARTY ON MAMMOGRAPHY SCREENING

AGE RANGE OF TARGET POPULATIONS FOR MAMMOGRAPHY PILOT PROJECTS

The upper age limit for invitation to screening of 69 is not presently in contention due to likely reduced acceptability and reduced benefits in terms of lower life expectancy. It may be practical to lower this to 64.

The key question is whether to screen women between 40 and 49 years.

The Commonwealth objectives in providing funds to pilot projects to evaluate mammography screening are:

(1) to assess if population screening can be successfully implemented in Australia; and

(2) to assess cost implications, including cost effectiveness.

To screen women outside the age range in which the effectiveness has been proven would adversely affect the satisfactory resolution of these two objectives, and similarly compromise the future extension of mammographic screening in Australia. The reasons for this view are outlined below.

(1) *Effectiveness*

No study has demonstrated that screening women under 50 reduces the mortality from breast cancer.

An analysis of the HIP data by Habbema in 1985 is used to support screening in 40-49 year olds. This analysis demonstrated an "apparent homogenous mortality reduction across five year age groups" (40-64) and concluded that the issue could not be resolved with the results of the HIP study, because of the small numbers involved .

Support for and against screening 40-49 year olds can be obtained from a variety of groups worldwide. Arguably the best considered and most objective view is that of the European Group for Breast Cancer Screening (which includes Habbema) ie;

> "It is now (1987) clear that mammographic screening is of benefit in reducing mortality in the over 50 age group whereas the advantages of screening for younger women remain to be proven".

The allocation of fixed resources has an ethical dimension to the extent that every woman screened under 50 would mean 2-3 less women over 50 screened.

(6) *Political*

Even at the pilot stage decisions on age range, if wide, tend to pre-empt future policy and resource allocation decisions.

To start with a 40+ target group and later reduce this would be less attractive and more difficult than expanding on a 50-64 target group with a technically efficient service.

The latter would also be consistent with the Federal Health Ministers commitment and the case argued by the Minister and Department in the Budget context.

Conclusion

There are two broad possibilities.

The first is to target women variously in the 40-74 year age range in the pilot projects and at the end of the process try to come back to the most appropriate age range depending on demonstrated effectiveness and resource availability.

The second is to target women 50-64, and demonstrate that high quality screening can be effective, well organised and conducted efficiently. In the three years pilot projects will operate, overseas research will have elucidated questions of age range. The cost effectiveness question will not have been compromised by inconclusive research in Australia and there will be a sound basis for expanding the pilot projects in terms of the number of women screened, and the age range of women screened, if this is still an issue.

To give screening the opportunity to reduce mortality in the under 50s would require annual two view mammography compared with the proven 40% mortality reduction in the over 50s of single view mammography with an interval of almost three years.

(2) *Quality*

High quality mammography, including interpretation and further investigation of abnormals is necessary to achieve satisfactory results. Such quality is usually proceeded by training and substantial experience. The development of these currently limited skills should be a function of the pilot projects, as is the development of organisational infrastructures.

It would be preferable to screen the more difficult pre menopausal women after the skills had been developed.

(3) *Cost*

While there is room for debate about the effectiveness of screening under 50s there can be little argument concerning the relative cost effectiveness. Factors such as annual screening, two views, higher rates of abnormal screens, re-examination and biopsies etc, and the overall lower incidence would all contribute to substantially increasing the costs with no guarantee of improving the benefits.

The only factor improving the cost effectiveness in the 40-49 age group would be an increased number of life years saved (presuming some effectiveness). However, discounting of benefits over time results in this theoretical improvement being substantially reduced.

When considering a national program the inclusion of women 40-49 would increase by approximately 4-5 times the ongoing investment required by State and Federal Governments.

(4) *Research*

One justification for mammography screening in the under 50s is in a research project to evaluate its effectiveness. However, in the anticipated life of the pilots it would be virtually impossible to arrive at a conclusion. Also in this period it is expected that research in Canada, Britain and Europe would provide answers to this question.

(5) *Ethics*

Some would see substantial problems in promoting an invasive service to well women where the benefits are not proven. Even though the service would be free to the consumer their costs may include false reassurance, unnecessary surgery and anxiety.

APPENDIX 3

MINIMUM BASIC DATA SET FOR EVALUATING SERVICE DELIVERY AND CLIENT SATISFACTION

This Appendix identifies data items which each pilot project should generate or collect for the comparative evaluation of service delivery and client satisfaction among the pilot projects. The items are marked accordingly:

E - These items are required for national evaluation.
O - It is suggested that pilot projects collect these data for their own use. These items are not required for the national evaluation

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 radiation exposure assessment
- 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 radiation exposure tests
- radiographer staff dosimeter readings

For each film developing machine: O

- 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 where individually targetted recruitment is to be used:

- name: surname, first two given names — O
- first given name — E
- birthdate — E
- postcode of residence — E
- client identification number (call 'project number') — E

For each individualised recruitment attempt:

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

For each attendance for screening:

(data as for potential client plus:) — E
- first given name — E
- Medicare card number (if provided) — E
- date of attendance — E
- method of recruitment — E
  - response to invitation
  - referred by GP
  - referred by other health care worker
  - self referred
- 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? O
  - code as: mastectomy
    prosthesis
    other breast surgery
    nil
- radiographer ident. — O
- view type — O
- 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) E
- film reader 2 ident. O
- film reader 2 result (coded) E
- final screening result E
  - code film reader and final result as:

	Result	Recommendation
A.	film technically unsatisf.	repeat screening mammography
B.	normal	rescreen at predetermined interval
C.	equivocal	refer for full mammography: (result: normal/abnormal)
D.	abnormal	refer for clinical evaluation with a view to biopsy

- date of recommendation E
- date client notified of result and recommendation E

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

Project number for each response	E
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 - "How did you find out about the clinic?" eg letter, publicity, GP, group, follow-up, call back	E
Exposure to promotional materials	E
Knowledge of and attitudes to breast cancer screening	E
Assessment of accessability and convenience	E
Presence of other service provider support	E
Satisfaction with the service provided	E

- acceptability and usefulness of the information provided to clients by the service
- accessibility and conveniences of hours of operation
- effectiveness of appointment and enquiry systems
- waiting times for appointment and at time of service provision
- acceptability of mobile, fixed or combination services
- appropriateness of project staff, including perceived technical skills, attitudes and interpersonal/communication skills
- acceptability of screening facilities, ie, comfort, physical layout
- relevance of gender of service providers
- availability of support/referral networks

Breast cancer risk profile	O

FOLLOW-UP / TREATMENT SERVICES

Data to be obtained from follow-up/treatment services

For each woman referred for follow-up or treatment:

- project number — E
- where attended (multiple, in sequence) — E
  - code as: follow-up clinic
    private
    other public
    follow-up declined
    unknown
- name and address of care provider(s) — E
  (These data are required to obtain service and cost data only; they are not required at the National Evaluation Co-ordination Unit.)
- definitive follow-up/treatment procedures (coded) — E
- date of commencement of definitive follow-up/treatment — E
- if mammogram:
  - view type and number — O
  - film reader 1 ident. — O
  - film reader 1 result (coded) — E
  - film reader 2 ident. — O
  - film reader 2 result (coded) — E
  - final result — E
- if cytology:
  - reader 1 ident. — O
  - reader 1 result (coded) — E
  - reader 2 ident. (if applicable) — O
  - reader 2 result (coded) (if applicable) — E
  - final result — E
- if ultrasound:
  - result — E
- if histopathology:
  - reader 1 ident. — O
  - reader 1 result (coded) — E
  - reader 2 ident. (if applicable) — O
  - reader 2 result (coded) — E
  - final result — E
- diagnosis — E
  - ICD 9
  - if malignant:
    - Snomed
    - ICD 0
    - TNM
    - stage
    - size
    - location
- satisfaction with the service provided — E
  - acceptability and usefulness of the information provided to clients by the service

- accessibility and conveniences of hours of operation
- effectiveness of appointment and enquiry systems
- waiting times for appointment and at time of service provision
- appropriateness of project staff, including perceived technical skills, attitudes and interpersonal/communication skills
- acceptability of assessment facilities, ie, comfort, physical layout
- relevance of gender of service providers
- availability of support/referral networks

REGISTERS

Data to be obtained from cancer registers

For each interval case of breast cancer and cases occurring in unscreened members of the target population:

- project number (where applicable)	E
- birthdate	E
- postcode of residence	E
- date of diagnosis	E
- diagnosis:	E
- Snomed	
- ICD 0	
- stage (where available)	
- name and address of care provider(s) (These data are required to obtain service and cost data only; they are not required at the National Evaluation Co-ordination Unit.)	E
- cause of death - ICD 9 (if applicable)	E
- date of death (if applicable)	E

Survival times for breast cancer according to tumour diameter, stage and pathological diagnosis (where available) E

Population crude and age specific incidence rates and mortality rates for breast cancer among women (where available) E

Data to be obtained from death registers

For each death among cases of breast cancer in the target population:

- project number	E
- cause of death - ICD 9	E
- date of death	E

TARGET POPULATION AND MEDIA

Data to be obtained from non-attenders in the target population by sample survey

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

Ethnicity E
(as for socioeconomic status)

Reason for non-attendance at screening programme E

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

Exposure to promotional materials E

Knowledge of and attitudes to breast cancer screening E

Assessment of accessibility and convenience E

Presence of other service provider support E

Data to be obtained from booked non-attenders of screening service by sample survey

Reason for non-attendance E

Assessment of accessibility and convenience E

Presence of other service provider support E

Data to be obtained from booked non-attenders of follow-up an

Reason for non-attendance E

Assessment of accessibility and convenience E

Presence of other service provider support E

Data to be obtained by environmental monitoring, either ongoing or by sample survey

Media coverage	0
Telephone enquires	0

APPENDIX 4

MAMMOGRAPHY EVALUATION PROJECT PLAN IN MORE DETAIL BASED ON A.I.H AS THE EVALUATION CO-ORDINATION UNIT

This appendix presents detailed cost estimates for a suggested staffing structure of the Evaluation Co-ordination Unit. It also presents a preliminary project plan for initiating the evaluation and for developing detailed cost estimates for the remainder of the evaluation. The proposal has not been agreed to in detail by the Working Party. It is presented for purposes of discussion and to indicate the likely magnitude of the resources required. These estimates are based on consideration of the minimum resources required to ensure that the evaluation is of high quality and of greatest possible utility in long term planning. It is possible that the resource requirements have been underestimated. Detailed planning will be necessary once funding for the Evaluation Coordination Unit becomes available. An overview of the data collection methods for the evaluation as a whole, along with issues which affect resource planning, are presented in Attachment 1.

This project plan is based on the assumption that the National Evaluation Co-ordination Unit will be established at the Australian Institute of Health and that the Unit will also co-ordinate the evaluation of cervical cancer screening (as indicated in the Report of the AHMAC Working Party on Cervical Cancer Screening).

A variety of tasks could be contracted out. For example, the development of clinic software and the detailed design of data collection instruments. If these tasks were contracted out, the cost of the Evaluation Unit would be little changed, since most of the required effort will be in co-ordinating data collection and in preparing reports.

Stage 1 - Establishing Evaluation Co-ordination Unit: preliminary investigations

Activities in Stage 1 are directed towards preparing detailed project plans, with time and cost estimates.

<u>Task A</u>

Establish a National Evaluation Co-ordination Unit, initially comprising:

Epidemiologist (1)	(On AIH staff)
Economist (1)	$38,000 + 20%
Behavioural or social scientist (1)	$35,000 + 20%
Computer systems analyst/programmer(1,2)	$35,000 + 20%
Accountant (1)	$38,000 + 20%
Statistician (1)	$40,000 + 20%

Clerical administrative class 4	$24,000 + 20%
Cl. admin. 2/3 / WPO	$21,000 + 20%
	$231,000

Notes

(1) Assuming that the Unit would also coordinate the evaluation of cervical cancer screening and that staff time is apportioned equally between breast and cervical cancer.

(2) Initially high level, then lower level.

Commence: As soon as desired
Duration: Approximately 4 months to recruit staff.
Ongoing cost: $138,600 p.a. assuming staff spend one half of their time on the project (excluding salary and oncosts for AIH staff epidemiologist). If located at AIH, overheads and computing time will be met by AIH.

Task B

Conduct an in-depth analysis of an operating pilot project to ascertain:

- methods, costs and timing for developing a computerised screening clinic data management system
- costs and timing for installing a computerised system
- labour and other resource requirements for maintaining and operating such a system
- labour and other resource requirements for preparing and transmitting evaluation data

This analysis would preferrably be conducted at one or both of the screening clinics which are currently operational in Brisbane.

Commence:	As soon as systems analyst recruited	
Duration:	Approximately 3 months	
Cost:	3 trips Canberra - Brisbane @ $420 =	$1260
	TA for 15 days @ $90/d =	$1350
	(Salaries in Evaluation Unit above)	
		$2610

Task C

Develop and test computerised screening clinic data management system and install at trial site

Commence:	As soon as Task B completed	
Duration:	Approximately 3 months	
Cost:	2 trips Canberra - Brisbane @ $420 =	$840
	TA for 10 days @ $90/d =	$900

(Salaries in Evaluation Unit above) $1740

Hardware / software packages - Cost unknown, costing data will come from Task B

Task D

Employ an evaluation project officer in the Royal Women's Hospital screening clinic in Brisbane to perform the following roles:

- collect diagnosis and treatment data for women with abnormal mammograms
- provide project with assistance in aspects of operations which are relevant to evaluation

This exercise would provide the following data:

- the level of staffing required in each pilot project to collect data required for the evaluation
- an early indication of the likely level of success which will be achieved in obtaining diagnosis and treatment data
- identify potential problem areas in conducting the clinical component of the evaluation

Commence: As soon as desired
Duration: 4 months
Cost/project: $33,000 pa + 20% = $13,200

It is suggested that, on average, each pilot project will require the following level of resources for national evaluation:

Project officer + 20% on costs	$39,000
Sample surveys and other data collection	$60,000
Training of radiologists and radiographers	$20,000
Running costs of evaluation	$10,000
	$129,000

Individual pilot projects are likely to vary from these estimates, because some elements of the evaluation may be confined to some of the pilot projects only (eg collecting cost data on diagnosis and treatment).

Task E

In consultation/collaboration with state based researchers planning to run research projects as part of pilot projects (eg Sydney, Melbourne), design in detail a suite of sample surveys to be administered in all pilot project target populations. The survey designs would include estimates of duration and cost.

Designing the instruments could be contracted to one of the pilot projects, although their administration would be coordinated centrally.

Commence:	As soon as behavioural scientist recruited	
Duration:	Approximately 3 months	
Cost:	3 trips Canberra - Sydney @ $190 =	$570
	3 trips Canberra - Melbourne @ $268 =	$804
	TA for 12 days @ $90/d =	$1080
	(Salaries in Evaluation Unit above)	
		$2454
	Possibly consultant @ $60/hr	

Stage 2 - Initiate data collection

The activities in Stage 2 are aimed at establishing the data collection infrastructure.

Task A

Assist pilot projects in the installation and commissioning of clinic software systems.

Assist pilot projects in aquiring resources to collect evaluation data.

Co-ordinate the collection of project, diagnostic, treatment and register data,

Commence:	Approximately 2 months prior to each pilot project's planned commencement date
Duration:	2 months
Cost:	Determine using data from Stage 1

Task B

Conduct, co-ordinate or commission the administration of the sample surveys.

Commence:	Upon completion of design of sample surveys
Duration:	Determine using data from Stage 1
Cost:	Determine using data from Stage 1

Task C

Develop and test data analysis programmes using early evaluation data.

Commence:	When system analyst's time permits
Duration:	Unknown
Cost:	Probably Evaluation Coordination Unit salaries only

Stage 3 - Ongoing data collection and related research

The activities in Stage 3 are aimed at collecting evaluation data and examining broader issues relevant to a nation-wide screening programme.

Activities as for Stage 2 plus:

Task A

Researching issues relevant to establishing a nation-wide breast cancer screening programme

This would commence with the preparation of a research programme which includes timetable and cost data.

Commence:	As Evaluation Co-ordination Unit staff time permits
Duration:	Unknown
Cost:	Unknown; largely Evaluation Co-ordination Unit salaries

Task B

Preparation of ongoing evaluation reports

Commence:	As Evaluation Co-ordination Unit staff time permits
Duration:	Unknown
Cost:	Unknown; largely Evaluation Co-ordination Unit salaries

Stage 4 - Preparation of final reports

Stage 4 is aimed at bringing the evaluation to a conclusion.

Commence:	During latter phases of data collection
Duration:	Unknown
Cost:	Unknown; largely Evaluation Co-ordination Unit salaries and printing

Depending on the level of expansion of breast cancer screening, consideration may need to be given in Stage 4 to an ongoing role for the Evaluation Co-ordination Unit in advising on the development of breast cancer screening services, performing quality control and monitoring acceptability and resource utilization. This could be performed at a reduced level of resourcing for the Unit.

APPENDIX 4 ATTACHMENT 1

DATA COLLECTION WITHIN MAMMOGRAPHY PILOT PROJECTS – METHODS AND ISSUES

Area of data	Methodology	Issues which affect resource planning	Other issues
Documentation of project and procedures	Drafting	Level of detail Number of participating pilot projects	Format Prepared by project staff and possibly by evaluation staff
Collection of routine screening data	Recording data during clinic operations Data entry (Possibly processing and analysis)	Form design, printing, completion Software design and installation in relation to: – system capability (eg holding and processing of target population records; volume of processing) – projects which use software and local modifications Computer hardware requirements (as for software) Initial recording of data on forms or computer Which pilot projects avail themselves of common software Data transmission for pilot projects which use their own systems Number of participating pilot projects Client throughput by projects	Data to be collected by pilot project staff
Collection of diagnosis and treatment data of screened women (inc. costs)	Questionaires: – mail – telephone – face to face (Possibly processing and analysis) Collection of cost data?	Proportion of clients giving consent Size of case load Possibility of payment of respondents Response rate from each type of contact Questionaire design Data collection costs Number of participating pilot projects Client throughput by projects Proportion of women with abnormal mammograms who are managed outside project affiliated assessment clinics	Source of cost data? Data to be collected by evaluation staff
Collection of diagnosis and treatment data of women not screened (inc. costs)	Questionaires: – mail – telephone – face to face (Possibly processing and analysis)	Sample size Possibility of payment of respondents Response rate from each type of contact Questionaire design Data collection costs Number of participating pilot projects	Should this survey be confined to target populations, be conducted outside them or both? Source of cost data? Who will collect these data? eg: evaluation staff – project/centra?; special team eg commercial firm

Area of data	Methodology	Issues which affect resource planning	Other issues
Activity survey for cost alloc.	Sample survey	Sample size Design of instruments Data collection costs Number of participating pilot projects	Who will collect these data? eg evaluation staff - project/centre? special team eg commercial firm
Cancer register data	Periodic request for abstraction from computerised files (Possibly data entry)	Method of providing data Frequency of providing data Number of cases Method of record linkage Number of participating pilot projects Client throughput by projects	Data to be collected by evaluation staff
Death register data	Periodic request for record linkage	Method of providing data Frequency of providing data Number of deaths Method of record linkage Number of participating pilot projects Client throughput by projects	Data to be collected by evaluation staff
Survey of target population for SES, ethnicity	Sample survey or analysis of census data	Use census data or conduct sample survey If sample survey: Sample size Mode of administration Design of instruments Data collection costs Number of participating pilot projects	Who will collect these data? eg evaluation staff - project/centre? special team eg commercial firm
Survey of target population for acceptability	Sample survey	Sample size Design of instruments Data collection costs Number of participating pilot projects	Who will collect these data? eg evaluation staff - project/centre? special team eg commercial firm
Survey of screen non-attenders for SES, ethnicity, reason for non-attendance	Sample survey	Sample size Design of instruments Data collection costs Number of participating pilot projects	Uncertain applicability of this survey to projects where recruitment is not individualised Who will collect these data? eg evaluation staff - project/centre? special team eg commercial firm

Area of data	Methodology	Issues which affect resource planning	Other issues
Survey of attenders for SES, ethnicity, acceptablity	Sample survey (pref. exit interview)	Sample size Design of instruments Data collection costs Number of participating pilot projects	Uncertain applicability of this survey to projects where recruitment is not individualised Data to be collected by pilot project and/or evaluation staff
Survey of assessment/ treatment non-attenders	Sample survey	Sample size Design of instruments Data collection costs Number of participating pilot projects	Who will collect these data? eg evaluation staff - project/centre? special team eg commercial firm