DESCRIPTION OF BREAST AND CERVICAL CANCER SCREENING PROGRAMS

in BRITSH COLUMBIA (CANADA), ENGLAND, SWEDEN, FINLAND AND THE NETHERLANDS

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PURPOSE OF THIS DOCUMENT

The purpose of this document is to provide detailed information about the screening programs examined to those involved in screening programs in Australia, particularly researchers, program staff and policy developers. An important function of this document will be to stimulate new ideas. Potential clients of the screening services may also be interested.

This document also identifies documentation obtained from each screening program (copies of which are held at AIH) and identifies personnel involved in the programs visited, who can be contacted directly. While this report may seem voluminous, information about the programs is doubtless incomplete and this report should therefore not be regarded as authoritative.

The summary of information from each screening program is structured according to the lists below:

Issues explored in relation to cervical screening programmes

1. Aims
2. Status
3. Funding sources and mechanisms
4. Level of funding
5. Patterns of expansion
6. Administrative structure
7. Population covered by individual programmes

Target population

8. Age range
9. Exclusions
10. Numbers

11. Recruitment methods

Screening

12. Location and types of facilities
13. Type of smear taker
14. Qualifications of smear taker
15. Screening interval

Smear reading and reporting -Pathology labs

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Quality assurance of screening programme

26. Administrative structure
27. Performance indicators
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Implementation

29. Phases
30. Timing

31. Workforce provisions
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34. Confidentiality
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PREAMBLE

The Medicheck Churchill Fellowship was provided to enable the author to examine mammography and cervical cancer screening programs in British Columbia (Canada), England, Finland, Sweden and The Netherlands. The Fellowship extended over two months from 6 April 1989 to 31 May 1989.

On following pages the itinerary of the tour is presented. In retrospect, the only changes to the itinerary which would have been desirable would have been to add three or four days to each of Sweden and The Netherlands to enable a more extensive study of the cervical screening programs in those countries.

The principle benefit from this Fellowship is to make available much information about the details of the most successful breast and cervical cancer screening programs to those who are involved in the development and operation of such programs in Australia. In addition, the knowledge and contacts gained by the author are of great assistance in his role of evaluating and developing policy in relation to breast and cervical cancer screening programs in Australia.

It is intended to provide copies of this report to the following groups:

- Churchill Trust
- WA Tyree Foundation
- AHMAC Evaluation Steering Committees
- Cancer Screening Pilot Projects
- Commonwealth and State Health Departments
- Individual researchers
- Minister's Office
- Cancer societies
- Overseas contacts

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DATES (1989) FROM	TO	PEOPLE	PLACE
FINLAND			
Tu 16/5	am	Dr T Kauraniemi	Cancer Soc Policlinic
Tu 16/5	pm	Ms K Louhivuori	Mass Screening Registry Helsinki
W 17/5		Dr T Hakulinen	Finnish Cancer Registry Helsinki
Th 18/5	F 19/5	Prof M Hakama	University of Tampere Tampere
THE NETHERLANDS			
W 24/5		Dr JHCL Hendricks Dr W Holland	St Radbout Hospital Nijmegen
Th 25/5		Dr WA van Veen	Ministry of Welfare, Health and Culture Rijswijk
F 26/5		Prof F de Waard	Preventicon Utrecht

HIGHLIGHTS OF MAMMOGRAPHY PROGRAMS IN BRITISH COLUMBIA, ENGLAND, FINLAND, SWEDEN AND THE NETHERLANDS

This document is not intended to summarise the screening programs examined. The purpose is to present some of the more important or innovative ideas and design features from the individual programs. The document also presents the occasional observation by the author. Detailed information on individual programs is contained in the sections which follow (see Contents).

1. AIMS

The aims of a mammography screening program should be as follows:

- to reduce breast cancer mortality among women offered screening;
- to balance the desired reduction in mortality from breast cancer against minimising:
  - the total cost of breast cancer screening and breast cancer treatment (including financial costs to women)
  - the proportion of women recalled for assessment
  - the number of women subjected to invasive assessment procedures
  - the number of women subjected to open biopsy
  - anxiety among women

Thus the aim of a breast cancer screening program is to maximise the benefit while at the same time minimising the deleterious effects. The achievement of this requires a careful balancing of the enthusiasm of the screening program to detect as many cancers as possible against the deleterious effects to women. This is particularly important in a screening program where women who enter the program are apparently well. Thus, different decision making criteria are required from those which operate in patient care. This must be very well understood by all personnel involved in the operation of a screening program.

The achievement of this balance is most clearly demonstrated in the Dutch program, where the key performance indicators are breast cancers detected and the positive and negative predicative value of referral for follow-up assessment and biopsy. In The Netherlands, great stress is placed on maximising the positive predictive value of all clinical decisions, even at the expense of possibly delaying the

The Netherlands

The Netherland's government has made an in-principle decision to introduce a national screening program. A final decision is expected early in 1990 when additional financial data will be available. A key problem is the integration of all of the components of the screening program.

3. FUNDING SOURCES AND MECHANISMS

In the programs examined, the funding mechanism in operation was closely related to the type of funding mechanism which operates for the usual medical care. In all programs, the initial screen was directly funded by government.

UK

Public fund raising has been very successful and is also a good way of promoting awareness and recruitment.

Sweden

A good argument for including biopsy in the fee for mammographic screen is to ensure that the surgeon is part of the assessment team and to ensure that the radiologist is part of the biopsy team.

4. LEVEL OF FUNDING

UK

Each Regional Health Area (RHA) has flexibility in the screening policy which it adopts, although Department of Health funds are only provided for basic screening.

5. PATTERNS OF EXPANSION

There are two schools of thought on the preferred rate of implementation of a national mammography program. In the first (as in the UK), the mammography program is set up very rapidly (e.g. 3-4 years). The rationale for this approach seems to be that it crystallises political commitment to a national program, which may not eventuate if the program expands very gradually. In a context in which there are pressures for a laissez faire approach to providing screening, this pressure can be mitigated by a commitment to the rapid establishment of a national program. While it is recognised that rapid expansion is likely to produce inferior quality mammography in the first few years, it is said that when the program is in place these problems can be ironed out.

The second method of expansion is for the gradual introduction of screening clinics. This approach is being

The Netherlands

There is great concern about the side effects of screening, particularly false-positives. This is one of the reasons why it has been decided that the screening program should be introduced gradually. It is expected that the full program will be operational in 1993, i.e. a five-year implementation period.

It is planned that the national information system required for quality assurance will be operational by late 1989, i.e. before most of the screening units commence operation.

6. ADMINISTRATIVE STRUCTURE

The population units used for detailed planning of screening programs are similar to the Australian states in British Columbia (the province), the UK (regional health authorities) and The Netherlands (regions). In Sweden and Finland the units are smaller (counties).

Except for British Columbia, all of the programs visited were centrally co-ordinated national programs. The essential components on an organised national program are as follows:

- National mammography screening guidelines

  On specific issues these guidelines should be quite prescriptive and allow no room for modification. This has been achieved rather neatly in England by government only providing funding for screening up to the level specified in the national guidelines (e.g. in relation to age range and screening interval).

  Other aspects of the guidelines should be for guidance only (e.g. the details of the organisation assessment services).

  These guidelines should cover all aspects of the screening program including operations, training, quality control, financing, program revision and review, administrative structure, advisory structure and evaluation.

- A national quality assurance system.

- A national training system.

- A national monitoring and evaluation system.

- A national structure for monitoring, reviewing and modifying the screening program as required.

- Multi-disciplinary co-ordinating group

  - Quality assurance reference centre
  - Radiologist Special Interest Group
  - Surgical Special Interest Group
  - Radiotherapist Special Interest Group
  - Pathologist Special Interest Group
  - Service Managers's Special Interest Group
  - Physicist Special Interest Group
  - Radiographer Special Interest Group
  - Health Education/Publicity Special Interest Group

A recurring theme in discussions was that in order to successfully implement screening programs, there should be specific individuals with responsibility and authority for implementing screening, with minimal other responsibilities.

Most detailed planning for the mammography program is undertaken by the Health Regions and Health Districts in accordance with Forrest guidelines. The Regions and Districts are given a fair degree of flexibility.

Clinicians are to be given substantial roles in management and quality assurance. This is because many of the problems which arise are quasi clinical. The screening program is facilitated by all clinicians being on salaries. This makes it easier for clinicians to take on extra duties and attend meetings.

In each Health Region, there is a need for a high level committee which can command that national standards be adhered to.

One idea for Australia to consider may be establishing a research committee which looks at breast cancer research and attempts to co-ordinate it. In the UK, such a committee has representatives from all of the major cancer research funding agencies. In Australia this might include the NH&MRC, Australian Cancer Society, Victorian Health Promotion Foundation, etc.

It is important that clinical specialty groups be developed which are part of the national mammography screening program network.

The Netherlands

The national screening program comprises four levels:

- national level: national guiding committee and national reference centre

- regional level: 8-10 integral cancer centres/regional joint management boards - responsible for invitations,

The following arguments have been advanced for deferring a decision to screen 40-49 year old women:

- there is a higher proportion of intraduct tumours for which there is no agreed approach to treatment
- cost effectiveness is lower because, even though the younger women live longer, there are many fewer tumours
- effectiveness has not been proven
- technically more difficult.

Inclusion of 40-49 year old women has very major cost implications for a screening program.

The issue of allowing open ended screening above age 65 or 69 has substantial cost implications, especially in the long term.

UK

Among the issues of age limit for screening, screening frequency, one view versus two views and number of readers, the screening of 40-49 year old women is regarded as being of the least scientific importance, although the greatest political importance due to pressure from women in this age group for screening.

9. EXCLUSIONS

UK

Women are screened even if they are symptomatic. Radiographers are trained to inspect women for breast abnormalities.

11. RECRUITMENT METHODS

Individualised recruitment is used in all programs except British Columbia, which will consider using this method if non-individualised recruitment is inadequate. There is an international consensus that by far the most effective method of recruitment is individualised invitation. In only one country (East Germany) has non-individualised recruitment been successful.

BC

It is proposed that a substantial proportion of screening will be conducted in private sector screening facilities. It is proposed, for example, that private radiology practices could do screening sessions in smaller towns. For the duration of the screening sessions, these facilities and the staff would be rented by the screening mammography program from the radiology practice.

UK

Around 60% of the 100 screening programs being established have a mobile unit. Mobile units seem to be very popular and offer a very flexible way of providing screening where it is needed. It was mentioned that mobile units may be cheaper than fixed units although it was not possible to obtain any data.

Fixed units tend to be used in inner cities with high population densities and large towns. The mobile units tend to be caravans rather than self-propelled.

The Netherlands

Recommendations are to keep the average travelling distance for each woman to 8km or less.

13. TYPE OF SCREENING EQUIPMENT

UK

Painful breast compression has been identified as a major problem in more than half of the screening centres.

14. ROLE OF PE AND BSE

In information provided to women, BSE is advocated. No screening clinics conduct routine physical examination.

15. QUALIFICATIONS OF EXAMINERS

In all programs, both fee for service and salaried, radiologists are preferred.

16. NUMBER OF VIEWS

While debate and research on this issue continue, the preferred approach is for there to be two views taken at the initial examination, at which time a decision should be taken as to whether one or two views are required for subsequent examinations. Two views tend to be required

The Dutch have taken a quite different approach. All film processing is done by the radiographer who take the films. This means that the radiographer can check the adequacy of the films while the woman is still in the screening clinic and can take repeat or additional views if required. Several radiographers in the Netherlands remarked that when circumstances dictate that they cannot process their own films, they notice an appreciable reduction in the quality of the films.

Greater attention is given to meticulous quality control of film processing in the Dutch program. This is achieved by a strict program of quality control measurements on the screening system. These data are transmitted electronically on a daily basis to the national reference centre where the performance of every screening clinic is monitored. If problems are detected by the national reference centre, the satellite screening clinic affected is notified immediately. This approach has the advantage that there is continuous external monitoring of the quality of this film taking and processing system.

It is believed that it is cheaper to process films locally than centrally, because it reduced the number of repeat attendances required by women and ensures higher quality films and therefore screening generally.

FILM READING AND REPORTING

19. NUMBER AND QUALIFICATION OF READERS

The most common view is that each film should be read by two radiologists. One commentator expressed the view that possibly one of the readers could be a radiographer and a number of others remarked that both radiographers and non-radiologist doctors could be trained to read mammography films, although this possibility was not being seriously considered by any mammography program. The films tend to be read independently by each reader, with the readers then coming together to reach a consensus recommendation.

UK

A general view is expressed that there should be formal accreditation of clinicians involved in screening mammography in the long term, although looser arrangements should apply while the program is being established.

The number of film readers is an issue requiring research.

The Netherlands

It has been decided that benign lesions found on mammography will not be reported to women or doctors, to reduce unnecessary medical procedures. The national policy is that benign lesions should not be reported.

FOLLOW-UP AND DIAGNOSIS

23. LOCATION AND TYPES OF FACILITIES

There is general agreement that follow-up should be undertaken by a team of clinicians, comprising radiologist, pathologist/cytologist and surgeon. In the UK, Sweden and Finland there are dedicated assessment clinics. This approach seems preferable in ensuring the highest quality assessment services. In the other screening programs, women are referred to usual medical care.

The key variable in the organisation of follow-up and assessment facilities is: at what point in the screening assessment and diagnosis chain the women is referred from the screening program to usual medical care. The three points at which this may occur are: immediately after screening (British Columbia and Netherlands), immediately prior to a definitive surgical procedure (Guildford, UK) and after the first definitive surgical treatment procedure (i.e. breast biopsy $\pm$ mastectomy $\pm$ auxiliary dissection). In order to maximise teamwork and the quality of care given to women in terms of special expertise and facilities, to facilitate data collection for quality control and evaluation it is desirable that as much as possible of the assessment and diagnostic pathway be explicitly included in the screening program. Ideally, this should include the first definitive surgical treatment procedure. Such an approach should be related to the funding mechanism.

UK

There is general agreement that treatment of screen detected lesions should be a clinical super specialty. One possible arrangement is for the screening surgeon to be involved up until biopsy is undertaken and then to refer the patient to the local surgeon with a specific recommended treatment.

UK

There is a national minimal data set for national monitoring. Each RHA is responsible for developing its own QA program. An important goal of the RHA QA program is to identify problems requiring retraining.

Quality assurance reference centres will be established in each Health Region. These will tend to comprise secretarial support (possibly two FTEs) and the part time involvement of specialists in each discipline.

An important component of quality assurance is data collection, and adequate resources must be available for this activity.

The quality assurance manuals and procedures in each clinical specialty area are being developed by groups of clinicians under the auspices of their college or professional association. This activity is being co-ordinated by the national training facilitator located at Oxford.

In October 1989, an evaluation conference will be conducted where screening programs will be asked to present data on their screening performance.

Major priorities must be to promote awareness of breast change specifically, localised non-cyclical unilateral breast pain and to improve diagnostic mammography. This latter issue must not be neglected in establishing a national mammography program.

The Netherlands

On a daily basis, quality assurance data from each satellite screening unit are sent electronically to the national reference centre for assessment and recording. If any deviations are found, the screening clinic is notified immediately with specific advice on the nature of the problem.

One strong argument for a very high quality assurance system is to provide medico-legal protection to clinicians who participate in the screening program.

It was strongly suggested that working in a screening program should be like working in a glass house. This is essential.

2. Indicators of the sensitivity of the screening program. These indicators require data from outside the screening program, particularly knowledge of all breast cancers diagnosed outside the screening program (using data from cancer registries and histopathology laboratories).

The number of interval cancers among women screened negative and as a proportion of the number of cancers expected if there had been no screening.

Independent retrospective review of previous mammograms of all women with breast cancer.

The number of breast cancers among women who did not attend for screening.

3. Indicators of the effectiveness of the screening program in reducing mortality.

Breast cancer mortality. (A detectable reduction in national mortality from breast cancer is unlikely to be observed for 12-15 years.)

National analyses of breast cancer deaths according to screening history.

Annual statistical reports will be prepared for each RHA, each screening office and the whole country.

The Netherlands

One may have to wait over a decade in a large scale screening program before population effects on breast cancer mortality become evident. The program in The Netherlands is being introduced over 1988 to 1993. The maximum effect (a decrease of 500 breast cancers per year) is not expected until 2015, assuming 70% attendance of women aged 50-70 and a positive predictive value of calling a film abnormal of 45%.

Because of the substantial international variations in the risk of death from breast cancer, the gains which might be expected from a mammography program are dependent on the pre-existing breast cancer incidence and mortality rates.

IMPLEMENTATION

27. PHASES

Quality assurance systems should be developed and tested prior to the introduction of screening.

UK

There is a major problem in recruiting high quality laboratory staff and secretarial staff. The quality of these people is a major determinant of the quality of the screening program.

The Netherlands

For radiologists, it is important that they do not only mammography and it is therefore desirable to recruit part-time radiologists. This would also assist the availability of radiologists, as the number willing to work full-time in mammography is likely to be small.

A major problem in The Netherlands was convincing radiologists and pathologists that they needed additional training. Particular aspects which have proven most problematic are:

- becoming oriented towards screening well woman
- understanding performance indicators like positive predictive value
- population health/general public orientation
- everyone can calculate your level of quality, unlike clinical practice.

Both radiographers and clinicians return for a one day refresher/update every year. The Nijmegen National Mammography Reference Centre is responsible for all professional training in The Netherlands. It issues certificates of attendance, which are required for people to be able to screen.

31. RECORD SYSTEM

BC

A Province-wide mammography database is being established. This will record all screens, follow-up and diagnostic data.

The data base will be linked with the Provincial cancer registry.

The online computer system will assist in compiling records where women attend at different screening clinics.

33. COUNSELLING

Little provision appears to have been made for counselling women in the screening programs examined. It would probably be sufficient to train radiographers and nurses involved in assessment in basic counselling and for the staff to have access to an experienced counsellor if a major problem arises.

36. OVERLAP WITH OTHER HEALTH PROGRAMMES

The Netherlands

It was recommended that the cervical and mammography screening programs should use combined organisations at the municipal and regional level.

37. DATA

The Netherlands

Of the interval cancers found in the 12 months following screening, one-third are missed due to perception errors, one-third are decision errors and one-third are undetectable. This is an argument for having multiple readers.

The observation was made that in the UK, Holland and Sweden, breast cancer incidence is identical. However, mortality is greater in the UK than in Holland which is greater than in Sweden. This may be related to the mean diameter of breast cancers at the time of diagnosis: in the UK it is 3.5 cm, in The Netherlands it is 2.5 cm, and in Sweden it is 1.5 cm.

SCREENING MAMMOGRAPHY PROGRAM OF BRITISH COLUMBIA, CANADA

1. AIMS

Initially, several pilot projects are being established to examine:

- methods of recruiting women
- number of women who can be screened per day
- possible locations of additional centres in British Columbia
- efficacy of mobile vans
- observer variability in mammogram intrepretation
- establishment of follow-up procedures
- costs in detail

It has been decided to implement mammography screening before mortality data are available from the Canadian National Breast Screening Study due to concern about the high level of breast cancer mortality.

2. STATUS

The Government of British Columbia has given agreement in principle for there to be a Province wide mammography screening program. The initial plan is for there to be one pilot project with 9 months of data collection followed by 6 months of data analysis. Screening commenced in July 1988.

3. FUNDING SOURCES AND MECHANISMS

Screening is free for women. All follow-up assessment and diagnosis will be charged as for usual medical services. If follow-up is undertaken in the private sector then the provincial health insurance plan will cover the costs.

The Canadian Cancer Society is donating money for 1 mobile van (initially) and volunteer time.

For private sector mammography screening clinics, the provincial government will provide a fee for each mammogram taken. The doctors will bill the British Columbia Breast Screening Program.

The Screening Mammography Program plans to pay all screening clinics a fixed fee for every woman screened, with a certain amount within this fee going to specific individuals. For example, $5 for the film reader, $1 for the clinic director and $1 for education.

The central staff will be funded separately by a block grant.

The cost of screening is volume dependent.

For the pilot project, start-up costs were C$40,795 (using pre-existing mammography clinic). The first nine months of running costs have been C$365,000. This includes amortisation of capital and depreciation.

It was estimated that for the clinic to be cost effective it needed to screen 35-40 women per day. Its current screening rate is 50-55 per day.

The argument was put that it is cheaper to screen and detect cancer early, thereby reducing treatment costs, than it is to not screen. It was estimated that to treat a woman in the last months of her life when she is dying from breast cancer, the cost is C$1,000 per day.

In the National Breast Screening Study it was found that 24 women could be screened per day where mammography and BSE were undertaken at a cost of C$49 per woman. In the pilot project where only mammography is used, 50 women can be screened per day at a cost of C$37 per woman.

In the March or April 1989 edition of Radiology, data from Bird and McLelland of North Carolina show that screening can be done for US$28 per woman, with a US$12 fee for the radiologist. (This may cover only the screen and not the follow-up assessment.)

5. PATTERNS OF EXPANSION

There are plans to have between 25 and 26 fixed screening clinics. The provincial government wants 4 fixed and 1 mobile clinic to be operational by the end of 1989.

It is proposed that the program expand with one clinic opening every couple of months for the next few years.

A second pilot project is currently being established to relieve pressure on the first. This second project will be located in an area which will enable the evaluation of recruitment strategies. The target for recruitment is 70%.

The second pilot project was chosen from among a number of proposals because it will be administered by a hospital, run by radiologists and be located in a shopping centre. Because the pilot will be established from the ground up, it will be possible to ascertain the costs of establishing a clinic very accurately. These data will be used to work out the budgets for future clinics.

To establish the second pilot project, the Breast Screening Program placed advertisements for groups to express interest in establishing screening clinics. Fourteen applications were received. These applicants were then sent comprehensive

orientation material and asked to come to a 5-6 hour meeting at which detailed presentations were made by members of the Breast Screening Program. After this briefing, 10 proposals were submitted and a selection made.

A mobile van is proposed to provide screening in areas of low population density. The Cancer Society of British Columbia is purchasing the van and the provincial government has agreed to pay the running costs.

6. ADMINISTRATIVE STRUCTURE

To establish the Mammography Screening Program of British Columbia, a screening mammography sub-committee was established within the Cancer Control Agency Breast Tumour Group. This sub-committee comprised around 16 members and included representatives of the following groups: radiologists, general practitioners, British Columbia Medical Association Cancer Committee, British Columbia Health Ministry, Cancer Society and the University of British Columbia.

The Mammography Screening Program has been developed separately from the Cancer Control Agency because there was a desire to dissociate the program from "cancer", radiologists would be less antagonistic since they would not see the Cancer Control Agency as trying to corner the market and the program would not be vulnerable to Cancer Control Agency budgetary pressures.

The administrative structure has not been finalised, but the program will be a free standing society.

The central unit responsible for the provincial program will be responsible for: policy, all quality assurance, follow-up of women with abnormal mammograms, evaluation and epidemiology.

Clinics will be responsible for recruitment, collecting registration data, screening and film interpretation.

Each clinic will be headed by a part time radiologist.

Each clinic will have some administrative autonomy.

In small population centres, there will be pre-scheduling and booking of mammograms. When bookings have been made, the centre will be visited by the mobile unit.

8. AGE RANGE

The program is targetted at women aged 40+, as it is believed that there is sufficient evidence available to justify screening women aged 40-49. Women less than 40 require GP referral and consultation with the clinic director.

9. EXCLUSIONS

Women with the following characteristics are precluded from screening:

- Pregnant
- Breast feeding
- Breast implant (compression can rupture implant - may need special views)
- Past history of breast cancer
- Solitary breast lump or nipple discharge

10. NUMBERS

400,000 women aged 40+ in British Columbia. Plan on 50% participation.

Planned screening capacity for fixed units is 13,000 screens per year and for mobile vans 10,000 screens per year.

RECRUITMENT METHODS

It is proposed to recruit women to the screening program using newspaper articles and advertisements, other media and the province-wide resource network of British Columbia Cancer Society volunteers.

It is not proposed that there be a reminder system for women to come back for repeat screens. Women are simply asked to call back in twelve months.

The Medical Services Plan of British Columbia has a comprehensive population list, although there are problems with confidentiality in using this as a call register. The Motor Licence Registry of British Columbia is prepared to make its list available.

If a woman has a negative mammogram, the letter which provides this information to her will also identify future screening requirements. This letter may have a suggested date for the next screen printed on a peel-off, stick-on sticker for the woman to put in her diary.

Screening is by appointment only to keep the costs down. A drop in system would be more expensive.

12. LOCATION AND TYPES OF SCREENING FACILITIES

The first screening clinic in British Columbia has been established on the site of the screening clinic used in the National Breast Screening Study. This centre was in operation from 1983 to 1988.

It is proposed that a substantial proportion of screening will be conducted in private sector screening facilities. It is proposed, for example, that private radiology practices could do screening sessions in smaller towns. For the duration of the screening sessions, these facilities and the staff would be rented by the screening mammography program from the radiology practice.

It was unclear what proportion of the screening clinics would be in the public sector.

13. TYPE OF SCREENING EQUIPMENT

It was recommended that a grid should be used in screening.

It was recommended that mammography machines should be of the high frequency type. (Information on this was obtained from the UK.)

14. ROLE OF PHYSICAL EXAMINATION

The Section of General Practice of the British Columbia Medical Association has adopted the policy that general practitioners should perform annual breast physical examinations and instruct women in breast self-examination.

Physical examination is not currently part of the screening program. Women are advised to have annual PE through usual doctor and to perform BSE. If a high interval cancer rate is observed, consideration will be given to adding PE.

15. QUALIFICATIONS OF EXAMINERS

Not applicable.

16. NUMBER OF VIEWS

Two

17. SCREENING INTERVAL

Annual screening is recommended as the preferred interval. This recommendation will probably yield an interval less than two years (based on cervical experience in BC where a 1 year recommendation has led to an actual average interval of 22 months).

18. LOCATION OF FILM PROCESSING

Film processing will be local, except for mobile clinics.

19. FILM READING AND REPORTING

In British Columbia, the film is read by only one radiologist reader routinely. A sample of films will be reviewed by an external expert radiologist.

All films are set up for the radiologists in advance. The films are batch read at the end of every day of screening.

Currently the previous mammograms of women are not displayed at the time of film reading. However, if there is an abnormality or if the film is equivocal, any previous mammogram is reviewed.

In future, the most recent prior mammogram will always be displayed with the current film. This makes it much easier to perceive abnormalities.

The number of categories that a radiologist has to use in recording the results of film substantially influences the time required to read the film.

Over the years the number of codes used by radiologists to record mammography results has decreased. It was initially five, was then reduced to three and is now two: normal or abnormal.

Radiologists read the films of 40 women per hour. The fee paid is $5 per set.

It is important to use the same film and not to change films to try and overcome technique problems.

The recall rate varies between 7% and 15%. An acceptable recall rate is regarded as being between 9% and 11%. 3% to 4% of women receive a biopsy and 1% are found to have cancer.

20. METHOD OF RESOLVING DIFFERENCES IN FILM REPORTS

Every two months, the five screening radiologists meet as a group and review abnormal films. By then the radiologists also have follow-up information.

Over the last 12 months, an external reviewer has been receiving a 10% random sample of all films, as well as the mammograms for all screen detected cancers and for all interval cancers. If an abnormality is detected by the external reviewer, appropriate clinical action is taken. It is proposed that this review continue.

21. NOTIFICATION OF RESULTS

Both women and nominated doctors are sent all results. Women must nominate a doctor. The doctor is sent result one week ahead of the woman.

23. LOCATION AND TYPES OF FOLLOW-UP FACILITIES

Where a woman is found to have an abnormal mammogram, she will be referred to her general practitioner for further treatment. No follow-up assessment facilities will be provided as part of the screening program.

It was considered politically too difficult to include follow-up assessment in the organised mammography program. The program as currently envisaged will obviously generate a substantial amount of work for private sector radiologists and surgeons, where all follow-up will be on fee for service funded by the Provincial health insurance plan.

25. QUALITY ASSURANCE ADMINISTRATIVE STRUCTURE

A team will be established within the Department of Radiation Physics in the Cancer Control Agency to assess dosimetry and other health physics aspects of mammography.

The subjective quality of the image will be assessed in the central facility by radiologists.

The aim is to reduce the recall rate to less than 8%. (Sickles: 6.5%; Tabar 5%; Hendricks 1%).

There will be centralised review of the anatomical pathology of all breast tumours detected in the screening program.

29. WORK FORCE PROVISIONS

In British Columbia, radiologists currently receive one month of training in mammography during their specialist training.

It is proposed to have formal training and accreditation for radiologists in screening mammography. This will initially comprise a two week course with a period of practical screening in the middle. This screening program will be modelled on the Sickle program, which is designed to be able to be undertaken after normal working hours. The program comprises an initial test (which is repeated at the end of the course), pre-reading of all screening cases and then comparing films where the report disagrees with the report provided by a trained radiologist.

If a radiologist is found to not have the aptitude to undertake screening they are asked to withdraw from the program.

At the central screening clinic it is proposed to have two radiographers and three clerks. The need for clerks may reduce when the computer becomes operational, although an adequate provision of clerks is essential for the proper functioning of a program.

It is expected that one person will be required to chase follow-up data for every two screening clinics.

It was stressed that there should be separate staff for screening mammography and for diagnostic radiology. This is particularly applicable for clinics operating in private radiology practices.

30. COST

The estimated cost of each screen is C$36.71. The screening program will pay C$37.00 per screen to new clinics. Central co-ordination, recruitment and follow-up is estimated to cost C$10.00 per woman screened.

31. RECORD SYSTEM

A Province-wide mammography database is being established. This will record all screens, follow-up and diagnostic data.

Initially the database will use the government computing centre and the government computing network, which extends over the entire Province. All screening centres will have online access to the Province-wide database. This is considered essential.

The data base will be linked with the Provincial cancer registry.

The online computer system will assist in compiling records where women attend at different screening clinics.

The database is currently under development. Facilities are currently available to record screening data. By October 1989 facilities will be available to record follow-up data and to record data from attendances for subsequent mammograms. The computer system will also generate quality control information and statistical information.

Where a woman has a negative mammogram, all printing will be done centrally to reduce costs. Where a woman has a positive mammogram, mailing will be done locally.

Letters will be generated by the computer at the end of each week.

If a woman has a positive mammogram, specific efforts will be made to collect follow-up data.

A complex epidemiological questionnaire is being used to collect information from women presenting for screening. This is being used for research purposes and to see whether it's possible to identify a group to whom mammography can be offered more selectively.

32. LEGAL ISSUES

Concern was expressed about the legal implications of missing lesions. It was felt that if all people are properly trained and there are adequate quality assurance mechanisms, this shouldn't be a problem, i.e. lesions will be missed, but this will be legally defensible.

33. COUNSELLING

In the screening clinics volunteers are available to provide reassurance and to help fill in questionnaires.

In the screening program, great reliance is placed on counselling by general practitioners.

34. INFORMATION FOR WOMEN

As part of the introduction of the screening program, there have been a wide variety of community education activities. A set of pamphlets has also been produced.

INFORMANTS

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Mr Peter Hayles
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Dr Greg Hislop
Epidemiologist
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Ms Beverley Mill
Technologist
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Dr A Helmut Muller
Director
Diagnostic Radiology
Cancer Control Agency of British Columbia

Mrs Eileen Puder
Volunteer with Canadian Cancer Society

Miss Jeannie Schmirler
Chief Technologist
Breast Screening Program of British Columbia

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DOCUMENTS OBTAINED

Organisation chart for the Screening Mammography Program

Mammography Accreditation Procedures - Draft September 1988

Registration form for women attending the Screening Mammography Program

Breast Cancer Treatment Policies from the Cancer Control Agency of British Columbia

Background Information Questionnaire administered to all women attending for mammography

Miscellaneous data collection forms

Miscellaneous pamphlets provided to women

Optimum Mammography Technique

The Annotated Cook Book Approach. Prepared by L Tabar and P B Dean

MAMMOGRAPHY SCREENING IN THE UNITED KINGDOM

1. AIMS

The key step in the breast screening process is the detection of lesions.

Major success factors in screening are the compliance by women (i.e. attendance) and the quality of the screening.

2. STATUS

In 1985 the Forrest Committee was established to advise the UK Government on screening mammography. The Committee reported in 1986. In 1987 the UK Government decided to establish a national screening program through the National Health Service, for completion by 1990.

25 screening offices are to be set up in 1988-89 and 50 are to be set up in 1989-90. Regional Health Authorities are finding the timetable impossible to adhere to. This delay means that the program will not be fully established until 1993/4.

By mid 1989, seventeen screening units had completed one year of screening.

3. FUNDING SOURCES AND MECHANISMS

Until 1992, funding is provided by the UK government specifically for mammography screening. From 1992, funds will be part of the regional health authorities' budgets.

In the United Kingdom, the development of a screening program is facilitated by the fact that all staff are on salaries. This makes it easier for clinicians to take on extra duties and to attend meetings connected with the screening program.

4. LEVEL OF FUNDING

Funding is provided by the Department of Health as follows:

- 19 million pounds per annum on the mammography program, including assessment
- 1.5 million pounds per annum on quality assurance
- 1.0 million pounds per annum on central initiatives
- 0.5 million pounds per annum on training

The 1.5 million pounds for quality assurance results in each region being allocated 100,000 pounds per annum for quality assurance. Each region also received 20,000 pounds per annum for extra treatment costs.

Department of Health funds do not cover any follow on services once tumours are found. Due to the shortage of funds in the National Health Service, once a tumour is found there can be a delay of many weeks before definitive treatment.

The national program has probably been capital under-funded, but the slow start has meant that operating costs have been able to be transferred into capital.

Each Regional Health Area (RHA) has flexibility in the screening policy which it adopts, although Department of Health funds are only provided for basic screening.

The Oxford RHA has decided to have a two year screening interval. They may attempt to save funds by refusing to screen women over 65, although it is considered unlikely that the Department of Health will permit this.

Public fund raising has been very successful and it also raises awareness, which is helpful in recruitment.

5. PATTERNS OF EXPANSION

The Forrest committee was precipitated by the results of the Swedish WE trial. Once the Forrest committee report was submitted, there was a period of 12 months before the government made a decision. Once it had decided, the national training facilitator was given 10 months to set up the national program. The national program was due to commence in April 1987.

While the program is being established, the initial emphasis is on the quality of the screening and compliance, consideration being given to the screening interval at a later date. The latter issue is one of fine tuning.

By mid 1988, every Health Region was to have one screening clinic operating and by mid 1990 every Health District is to have full scale screening. This has meant that the program has been unable to start on a small scale. There has been some delay in the commencement of screening due to problems in the development of standard software.

25 screening offices are to be set up in 1988-89 and 50 are to be set up in 1989-90.

6. ADMINISTRATIVE STRUCTURE

In the United Kingdom, the program is national because of a uniform national approach to:

- policy
- funding
- quality assurance
- education
- monitoring and evaluation.

Following the first report, it was decided that there should be centralised co-ordination focusing on five major initiatives:

1. Developing information systems
2. Training and education
3. Equipment appraisal program
4. Research
5. Quality assurance in
   - acceptability
   - mammography
   - pathology
   - treatment
   - information

It is these five initiatives which form the essence of the national mammography program. Much of the detailed planning of the program is left to Health Regions and Districts, within Forrest guidelines.

The following organisational structure applies at the national level for England and Wales:

- Secretary of State for Health

- Junior Minister for Health

  - Health Education Authority (runs national health education programs)

  - Department of Health for England and Wales (contains the national mammography co-ordinating office: responsible for co-ordination, quality assurance, training, education, general advice, organising meetings of regional co-ordinators)

  - National Advisory Committee on Mammography (Chair, Professor Martin Vessey; experts)

The following organisations report to the Department of Health:

- Cancer Screening Evaluation Unit, Surrey
- UK Cancer Co-ordinating Committee for Research Mammography Sub-committee
- National Training Facilitator
- National Training Centres:
  - Guildford
  - Edinburgh (Scottish program)
  - Nottingham
  - Kings College
  - Manchester
- 14 Regional Health Authorities and Wales
- 90 Family Practitioner Committees

Within each region the structure is as follows:

- regional health authority
- district health authority
  - assessment centres
  - Screening offices
  - Screening units
- Multi-disciplinary co-ordinating group
  - Quality assurance reference centre
  - Radiologist Special Interest Group
  - Surgical Special Interest Group
  - Radiotherapist Special Interest Group
  - Pathologist Special Interest Group
  - Service Managers's Special Interest Group
  - Physicist Special Interest Group
  - Radiographer Special Interest Group
  - Health Education/Publicity Special Interest Group

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   - treatment
   - information

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In the NHS, Regions and Districts have the following responsibilities:

Regions:

- strategic planning
- co-ordination
- resource allocation
- quality assurance

Districts:

- assessment centre
- screening offices
  - screening units
- implementations
- service delivery.

FPCs:

- patient registration for GPs
- administer contracts for GPs, pharmacists, dentists and opticians.

In the future it is likely that the Family Practice Committees will be brought under the responsibility of the Regional Health Authorities.

Health Regions generally have a fair degree of autonomy in deciding how to implement programs.

Under the District Health Authorities, screening is co-ordinated by a screening office.

A very great emphasis is being placed on training for all clinicians participating in the screening program.

Each screening unit, (comprising one assessment centre and one or more screening clinics) would have a program manager (probably a radiologist) with the following people reporting to them: radiographer (with radiographer staff), screening office manager (with clerks reporting to this person) and a community physician for evaluation and quality assurance. The clinicians relate by dotted lines to the program manager.

Several screening programs and screening offices may feed women to individual assessment centres. These assessment centres are managed by the host District.

In Health Regions where each District has an insufficient population to maintain a screening program, the District's form a consortium. The District in which the screening office is located providing managerial support to the office.

The national training facilitator was initially responsible for the training centres. He has now taken on responsibility for organising the quality assurance structure and setting up national groups.

An important component of the national training facilitator's role is finding people and organisations to delegate tasks to.

The national training facilitator is developing a series of work books for training people in how to run the screening system.

The national training co-ordinator believes that program managers and quality assurance managers should tend to be clinicians with their screening program management roles being part time. The rationale for this is that many of the problems that are encountered are quasi clinical.

To set up a national program, everyone must know what's happening. A major role of the national training facilitator is to act as a clearing house for information and to disseminate information.

Clerical support is an essential component of data collection and quality assurance. The clerical support must be of high quality and sufficient salaries to attract such people must be paid. Each screening program has 0.5 FTE clerk to ensure data are collected.

The national mammography co-ordinating office within the Department of Health has proven to be slow and inefficient. This is attributed to the fact that the people in the unit have no direct expertise in screening. Important roles in

this group are statistical control and monitoring intermediate performance of the screening programs.

A recurring theme in discussions was that in order to successfully implement screening programs, there should be specific individuals with responsibility and authority for implementing screening, with minimal other responsibilities.

7. POPULATION COVERED BY INDIVIDUAL PROGRAMS

At 12,000 screens per year, it is estimated that each unit can screen a population of 41,000 women aged 50-64, from a total target population of 500,000 (given UK age-sex structure).

In the United Kingdom, breast cancer incidence is not dissimilar to other countries, but there is a substantially higher breast cancer mortality. This is attributed to late case presentation, possibly because of the absence of readily available diagnostic mammography.

The Mammography Screening Office located in the Camberwell District will serve 6 health districts with a population of 100,000 women aged 50-64 years. These women will be screened by three screening units (one fixed and two mobile) and two assessment centres.

8. AGE RANGE

Breast screening services are to be provided to women aged 59-64. Women aged 65+ may continue to be screened but will not be invited to attend.

The Forrest Report indicates that once women have entered the program, they should continue to have screening available after they turn 65. It is estimated that this will nearly double the cost of screening over the next 10-15 years.

Apparently women aged 40-49 are flooding into the private sector for mammography.

Due to the uncertainty about the effectiveness of mammography in the 40-49 year age group, a 400,000 pound per annum study is to be conducted into the efficacy of screening in the 40-49 age range.

Of the UK studies which are being established (age 40-49; frequency 1 versus 3 years; one view versus two view), the 40-49 year study is regarded as being scientifically least important because of the rarity of breast cancer in women under 50 and the cost of screening this group. However there is substantial political pressure from women in this age range for screening. Additional concerns about screening in this age group are the high false negative rate and the

increased radiation risk from additional views being required, increased frequency of mammography and increased remaining life span in which radiation induced cancer could develop.

The trial of screening in the 40-49 year age range will test a one year interval. Pilot testing should start in 1990 and if satisfactory a full scale trial will commence in 1992. Intermediate data will be available after two years. Mortality data will be collected and it is expected that results in relation to mortality will be available after 10 years.

The view was put that women aged 40-49 years should not be screened at this time, but the issue should remain open until the results of Swedish and UK studies are available. It is possible to say conclusively that mammography is less effective in women aged 40-49 than in those aged over 50.

In women under 50, mammography is not as sensitive due to dense breast tissue and tumours grow more rapidly, meaning that the interval will need to be shorter than for women over 50.

The inclusion of 40-49 year old women is estimated to increase the total cost of the mammography program two times (if a two year interval is adopted) and three times (if a one year interval is adopted). The suggestion was put that one year versus two year intervals should be tested in the UK study of 40-49 year old women, but this is not possible due to sample size considerations.

9. EXCLUSIONS

It has been decided that when GPs check FPC lists to decide who should be invited for mammography screening the following groups should be excluded: bilateral mastectomy and severe debilitating disease. GPs are strongly advised to quickly check the lists rather than laboriously search their records to ascertain these facts. The screening program is prepared to accept the occasional error.

Past breast cancer patients should be invited for screening of the contralateral breast.

11. RECRUITMENT METHODS

Recruitment is by personalised mailed invitations. There is a variable level of public education. The Family Practitioner Committee is involved in the selection of women with GPs checking the lists. The screening office produces the appointment times and sends out the invitation letters. The screening office then provides information to the Family Practitioner Committee that either the woman attended for

screening or failed to attend. The Family Practitioner Committee holds no clinical data and takes no follow-up action, unlike for cervical cancer.

FPC lists have 10% more names than indicated by the census.

The FPC lists may have incorrect addresses in 30% of cases. At the Kings College screening program in London, only 40% compliance was achieved. 40% of envelopes were returned undelivered.

The major problem with the accuracy of addresses is likely to be repeated in Australia.

A national population register is being compiled for the Poll Tax. This register will not be able to be used for any other purpose, at this stage.

Generally, when a screening program is about to start screening in an area, the GPs are provided with extensive information about mammography screening.

Some general practitioners consider the evidence on the efficacy of mammography equivocal because of the results of the UK trial.

In recruitment using the family practitioner committee list, an area of concern is the recruitment of women who lie outside the boundaries of a screening program. It has been accepted that the resource implications of this variation are likely to be small and will probably balance out in the long run.

Manchester have local community education campaigns prior to sending out the mammography letters.

No one is studying the additional effect of public education above individual recruitment.

Recruitment rates have been found to be very variable, varying from 40% to over 80% in the first round. It must be noted that an important determinant of the variation in these rates is the error rate in the address list.

It has been noted that mammography response rates is substantially higher than cervical cancer screening. This may be because the general practitioner doesn't have to do anything apart from check the list or because mammography screening is novel or less intrusive for women, or because there is greater community concern about breast cancer because it is substantially more common than cervical cancer.

12. LOCATION AND TYPES OF SCREENING FACILITIES

Around 60% of the 100 screening programs being established have a mobile unit. Mobile units seem to be very popular and offer a very flexible way of providing screening where it is needed. It was mentioned that mobile units may be cheaper than fixed units although it was not possible to obtain any data.

Fixed units tend to be used in inner cities with high population densities and large towns. The mobile units tend to be caravans rather than self-propelled.

The Royal Marsden Hospital has set up a fee-for-service (50 pounds) mammography screening van outside the national breast screening service. The following ethical concerns have been raised about this program: among women who cannot afford screening, it creates anxiety which cannot as yet be met by the national screening program; the brochures do not indicate that mammography has not been proven to be effective in women aged less than 50; and the program does not say that a free alternative is available.

The successful mammography programs in Europe all use fixed screening units. No problems have been experienced in getting women to attend. One commentator recommended that wherever possible, fixed units be used.

Fixed units are recommended where the population density is high. The advantages are that one can have onsite processing and there is no need for parking sites for the vans and infrastructure to be available for connection to the vans. Particular disadvantages with mobile units are the time lost when the unit is being moved (half to one week per move) and staff access to the mobile unit.

In remote areas, it may be possible to have a unit in a major centre with an open appointment system, on the grounds that virtually all women will visit a major centre once every year or so and could attend for screening during these visits.

13. TYPE OF SCREENING EQUIPMENT

The Department of Health is criticised for not having organised bulk purchases of mammography machines. Currently each screening program undertakes its own negotiations to purchase this equipment.

14. ROLE OF PE AND BSE

The view is expressed that physical examination and breast self-examination have little to offer above mammography screening. 10% of tumours are radiologically occult even when palpable, although the aim of screening is to detect

very small tumours which are difficult to palpate even if radiologically occult. Therefore, the benefit of PE and BSE remains much in doubt.

16. **NUMBER OF VIEWS**

One mediolateral oblique

The Forrest Report advocates a one view because this was found to be effective in the WE trial. In the Swedish program, two views are now used initially, with the radiologist deciding whether one or two views should be taken at subsequent screens. In 25% of cases two views are required.

In the UK, a multi-centre national randomised trial is being conducted into one view versus two view. There is no consensus as to whether one view or two views is preferable. The study is due to start in late 1989 and results should be available in 3-4 years.

It was suggested that the best regime may be to have two views at the first visit (especially for 40-49 year women) and one view at subsequent visits.

17. **SCREENING INTERVAL**

Three yearly.

Screening interval is regarded as the most urgent issue for study. The national randomised control trial of screening frequency three years versus one year is due to start in 1990 and final results should be available in 1995-6. This study may include a sub-study of number of readers.

The view was expressed that for women over 50 with unlimited resources the interval should be 18-24 months but given resource limitations an interval of less than three years requires justification of benefit versus cost.

Given the importance of quality and compliance over interval initially, it was strongly recommended that the initial screening interval should be 3 years when a screening program is being established, with consideration being given to reducing this interval at a later stage.

Interval cancers are found to be slightly worse than typical cancers. It is unknown if a shorter interval will catch more early cancers.

Screen interval (years)	Estimated percentage of cancers detected by screening excluding 1st screen
1	79%
2	71%
3	63%
4	57%
5	52%

(Based on data from Two Counties study: from Day and Miller p.108)

18. LOCATION OF FILM PROCESSING

For mobile units it is recommended that film processing be done centrally. Radiographers should be extensively trained in taking mammograms and seeing the fruits of their labours before they are sent on mobile units.

At the Camberwell clinic films are processed immediately. This reduces the recall rate. This clinic uses a Kodak mini-loader, which allows daylight processing.

19. FILM READERS

The national mammography program is providing resources for only one reader, although Oxford will have two readers per film.

A general view is expressed that there should be formal accreditation of clinicians involved in screening mammography in the long term, although looser arrangements should apply while the program is being established.

The number of film readers is an issue requiring research.

The general view was put that in establishing a mammography program, where screening policy issues are equivocal (e.g. interval, number of films, number of readers), the cheapest alternative should be pursued until data are available showing that this policy is unsatisfactory.

21. NOTIFICATION OF RESULTS

There is a very strong held view that women should be informed of their results directly. The general practitioner is also informed.

22. FUNDING MECHANISMS

Free to women. Forrest Report recommendations are being funded by DHSS.

23. LOCATION AND TYPES OF FOLLOW-UP FACILITIES

Some RHAs are establishing assessment clinics, while others are ensuring women are referred to surgeons at District General Hospitals.

The establishment of dedicated breast cancer clinics is being strongly advocated.

The view was put that a screening unit should operate as a team including the senior clinicians. The surgeons, radiologist and pathologists should undergo the same training program. Follow-up assessment (second stage screening) should be undertaken according to agreed protocols.

The view was expressed that surgeons not working in the treatment of screen detected breast cancers will tend to be more invasive and less willing to participate in controlled trials.

The general view was expressed that in the long term there should be formal accreditation of clinicians involved in screening mammography, with looser arrangements applying during the setting up stage.

The Colleges of Radiologists and Pathologists have developed specific screening mammography training programs.

There are divergent views on the utility of fine needle aspiration cytology. No data are available on how it influences management in addition to other clinical information. A study is to be designed to examine the contribution of fine needle aspiration cytology.

The view was expressed that co-ordinated grid localisation is as good as or better than stereotactic localisation.

It is recommended that there should be weekly case meetings of the surgeon, radiologist and pathologist.

There is not yet a consensus on the most appropriate treatment for screen detected lesions. British surgeons are organising workshops on the treatment of different types of screen detected lesions.

There is general agreement that treatment of screen detected lesions should be a clinical super specialty. One possible arrangement is for the screening surgeon to be involved up until biopsy is undertaken and then to refer the patient to

the local surgeon with a specific recommended treatment.

Where many surgeons wish to be involved in treating screen detected cancers, it is expected that a number will develop cold feet when they are informed about what's involved in assessment, quality assurance, training etc. It is expected that similar considerations will apply to pathologists and radiologists.

A randomised controlled trial is to be conducted into the treatment of screen detected ductal carcinoma in-situ. This is a "new" disease as it has not presented previously.

25. ADMINISTRATIVE STRUCTURE FOR QUALITY ASSURANCE

The cancer screening evaluation unit is responsible for compiling national statistics on mammography. This unit will also examine the screening histories of all women who develop breast cancer, including breast cancer deaths.

There is a national minimal data set for national monitoring. Each RHA is responsible for developing its own QA program. An important goal of the DHA QA program is to identify problems requiring retraining.

Quality is regarded as the key to a successful screening program.

Quality assurance reference centres will be established in each Health Region. These will tend to comprise secretarial support (possibly two FTEs) and the part time involvement of specialists in each discipline.

In each Regional Health Authority there will be a quality control person with expertise in radiology, pathology, surgery, radiography, health physics and community medicine/evaluation. It will tend to be a part time role.

Some Regional Health Authorities have allocated one full time equivalent anatomical pathologist to co-ordinate breast pathology in each region.

National specialist committees have been established in treatment, surgery, pathology, radiology and research. These committees tend to comprise representatives from each Region.

An important component of quality assurance is data collection, and adequate resources must be available for this activity.

In relation to histopathology, the emphasis in quality assurance will be on consistency of diagnosis rather than on correct diagnosis of a gold standard. The aim is to lift the general standard rather than identify unsatisfactory

pathologists. Such a system will also allow a convergence of opinion on the appropriate diagnosis for ambiguous cases. This program is not designed to test individuals and there is no supposition that any diagnosis is correct. The aim is to improve the standards to a much higher level.

Quality assurance manuals are being produced.

The method for following up interval cancers is yet to be established. Problems with cancer registries are that they tend to only have data on cases two to three years after the case has occurred. Other possible data sources are radiotherapy clinics, pathology laboratories and tamoxifen pharmacy lists. It was suggested that these data may be best collected by an enthusiastic laboratory technician.

26. QUALITY ASSURANCE PERFORMANCE INDICATORS

The Pritchard Report specifies that 5-6 cancers should be found per 1,000 women screened as minimum acceptable performance.

Key performance measures for a breast screening program are:

1. Attendance rates
2. cancers per 1,000 women screened
3. percentage of cancers less than 15mm diameter as proportion of the total cancers detected
4. interval cancer rates in comparison with the expected incidence rate

These performance measures should be adjusted for underlying breast cancer incidence and for stage at which tumours routinely present in the population offered screening.

Within each health region, screening performance will be compared with cancer mortality.

The standard measures for measuring the performance of the screening program fall into three categories (Chamberlain):

1. Immediate performance indicators (for any given population and time period). These indicators use routinely collected screening data.

   Number and proportion of women identified as eligible, invited and responding by age group.

   Number and proportion of women screened within a three year period by age group.

   Number and proportion of women screened within successive intervals from previous screen by age group.

Number and proportion of screened women recalled for diagnostic work-up by type of screen and age group.

Number and proportion of screened women undergoing biopsy by type of screen and age group.

Number and proportion of screened women with screen detected cancer by stage.

For women screened, intervals from screening visits to first assessment clinic visit, to biopsy and to cancer treatment.

2. Indicators of the sensitivity of the screening program. These indicators require data from outside the screening program, particularly knowledge of all breast cancers diagnosed outside the screening program (using data from cancer registries and histopathology laboratories).

The number of interval cancers among women screened negative and as a proportion of the number of cancers expected if there had been no screening.

Independent retrospective review of previous mammograms of all women with breast cancer.

The number of breast cancers among women who did not attend for screening.

3. Indicators of the effectiveness of the screening program in reducing mortality.

Breast cancer mortality. (A detectable reduction in national mortality from breast cancer is unlikely to be observed for 12-15 years.)

National analyses of breast cancer deaths according to screening history.

Annual statistical reports will be prepared for each RHA, each screening office and the whole country.

27. PHASES OF IMPLEMENTATION

Each RHA has been funded to set up one screening unit in 88/89, 2-3 in 89/90 and the remainder (2-6) in 90/91. With one third of women to be invited in each year, all women would have been invited once by 93/94. However, the timetable is slipping, with the main constraint being a lack of radiologists and radiographers. The full program is expected in 93/94.

29. WORKFORCE PROVISIONS

Four training centres for radiographers and radiologists have been set up in England and one in Scotland. The view was expressed that the training period (two weeks for radiographers and four weeks for radiologists) may be too short.

Using one view mammography, each mobile unit is expected to screen 60 women per day.

The demand for radiographers is being met by radiographers being offered part time work and re-entering the workforce.

There is a major problem in recruiting high quality laboratory staff and secretarial staff. The quality of these people is a major determinant of the quality of the screening program.

31. RECORD SYSTEM

There is a national uniform minimum data set. Computerised record systems are operational in Screening Offices. A summary of each woman's screening history is added to the FPC register. This record moves with the woman if she moves within the UK. The SO record system also generates letters, ensures follow-up action is taken, schedules appointments and monitors program performance.

Each screening program is required to produce data according to national standards. These data are being compiled annually for each screening service, for each Health Region and for the national annual report.

Over 95% of the health regions in England and Wales are using a computer system developed by the Oxford Regional Health Authority Information Group. This system runs on a mini computer and is regarded by a number of commentators as being cumbersome and requiring too much data. Difficulties with the Oxford system are that it seeks too much information and the system was adopted for national implementation before it had been fully prototyped and developed. The Department of Health has sponsored this system and only provides computing resources to regions which use this system.

The Oxford Information Group is developing a system for collecting assessment and treatment data.

The view was expressed that the Department of Health should have specified the capabilities and outputs required of a computer system rather than specify that a particular system be adopted.

The computerisation of the NHS central register in 1990 will substantially address the problem of detecting interval cancers among women who move out of the study region.

It is evidently possible to obtain computer systems that journal all data entered every 10 minutes. This means that a maximum of 10 minutes data would be lost if the system crashed. This makes direct data entry a viable proposition.

It is important that forms allow people to tick boxes rather put codes in boxes.

33. COUNSELLING

Information obtained from the breast assessment unit at Kings College Hospital, London

The counsellor attends the session where the cancer diagnosis is confirmed. She is then involved in counselling women from then on. Women are informed of the results of the assessment by a doctor. They then always see the counsellor, where a fuller explanation is provided. The counsellor may visit them at home if required.

A major role of the counsellor is to provide explanations. Denial of cancer is a major problem. Some women believe that mammography caused their cancer, because they felt perfectly well beforehand.

When women attend the assessment centre, the counsellor explains to groups of women what will happen at the assessment centre. The women are told that they will definitely have an answer by the time they leave the clinic.

All women are given the counsellor's phone number and are encouraged to make contact.

Important aims of counselling are to anticipate fears and to tell women what will happen. This greatly aids acceptance.

Women are also seen by a counsellor after surgery. The counsellor fits a temporary prosthesis prior to discharge. A permanent prosthesis is fitted 6 weeks later. Prostheses are very important for psychological well being.

A psychatrist is available for women to be referred to if required. Alternatively Counsellors may seek advice and guidance from the psychiatrist.

All of the counsellors are nurses. This has the advantage that full clinical explanations can be given of the procedures involved and the counsellors can be involved in fitting prostheses.

36. OVERLAP WITH OTHER HEALTH PROGRAMS

Mammography and cervical cancer screening programs use the same FPC system, although mammography program only uses the register for call and re-call.

37. DATA

Preliminary performance data have been obtained from a number of these screening programs.

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HIGHLIGHTS OF CERVICAL PROGRAMS IN BRITISH COLUMBIA, ENGLAND, FINLAND, SWEDEN AND THE NETHERLANDS

This document is not intended to summarise the screening programs examined. The purpose is to present some of the more important or innovative ideas and design features from the individual programs. The document also contains the occasional personal observation by the author. Detailed information on individual programs is contained in the sections which follow (see Contents).

1. AIMS

The aims of a cervical cytology screening program is to reduce mortality from invasive cervical cancer in women by reducing the incidence of invasive cervical cancer and at the same time to minimise the number of investigation and treatment procedures women are subject to, and minimise total program cost.

2. STATUS

BC

A centralised gynaecological cytology screening program began in British Columbia in 1949 with the establishment of a pilot project to determine the efficacy of cervical smears in detecting pre-clinical cancer of the cervix. The pilot project established the value of pap smears, and the Province-wide program proper began in 1951.

UK

Cervical cancer screening has been available in the UK through general practitioners for several decades. Intermittently, efforts to improve population coverage and the quality of smear taking and follow-up services have been made. The current cervical cancer screening programme lacks strong central co-ordination.

Sweden

In Sweden, cervical cytology programs are operated by individual counties. A national program was commenced in the mid 1960s and by 1973 all of Sweden was covered by organised county council cytology programs. Cervical smears are also taken outside of this program.

Finland

Since 1970 there has been full coverage of the national population by an organised mass screening program. Cervical smears are also taken outside of this program.

The Netherlands

Organised population screening for cervical cancer began in 1976. In 1985 the government shifted smear taking from nurses to general practitioners. There is a poor organisational framework for cervical cancer screening.

3. FUNDING SOURCES AND MECHANISMS

In the programs examined, cervical smear services were provided free to women.

BC

The processing and reporting of the smear is paid for by the government grant to the Cancer Control Agency of British Columbia. British Columbia is the only province in Canada where cervical cytology smears are specifically omitted from the pathology fee schedule. This means that there is no private cervical cytology pathology conducted in British Columbia. Similarly, follow-up colposcopy is not on the schedule of fees.

4. LEVEL OF FUNDING

Finland

To minimise costs, nurses take all smears in the organised program and a 5-year screening interval is used.

6. ADMINISTRATIVE STRUCTURE

BC

All cytology is undertaken by one high quality laboratory in the Cancer Control Agency of British Columbia. This was achieved by setting up the public sector laboratory in the late 1940s and early 1950s before wide interest developed in cervical cytology.

A critical success factor in the implementation of this screening program has been gaining the co-operation of the medical profession, particularly general practitioners and gynaecologists. This was done initially by educating gynaecologists who then educated general practitioners.

A centralised gynaecological cytology screening program began in British Columbia in 1949 with the establishment of a pilot project to determine the efficacy of cervical smears in detecting pre-clinical cancer of the cervix. The pilot project established the value of pap smears, and the program proper began in 1951.

UK

In the UK it was widely acknowledged that one of the reasons for the lack of a successful UK screening program has been the lack of central co-ordination and direction.

It is essential that specific individuals be given authority and responsibility for implementing different components of the screening program.

It has been found very helpful to have local co-ordinators (e.g. community nurses) to involve general practitioners in cervical cancer screening.

TARGET POPULATION

8. AGE RANGE

The preferred age range in Sweden, Finland and The Netherlands was from 30 up to between 60 and 70.

9. EXCLUSIONS

UK

Some laboratories are refusing to examine smears where the screening history indicates the woman is being over-screened. In such situations, the lab writes back to the general practitioner saying that there is no clinical indication for an early smear. This policy has the written backing of the local health authority.

11. RECRUITMENT METHODS

There is an international consensus that by far the most effective method of recruitment is individualised invitation. In only one country (East Germany) has non-individualised recruitment been successful.

BC

With no public education programs and no call/re-call register, the program has been able to achieve substantial reductions in cervical cancer mortality and achieve high rates of screening in the population. This was achieved when the program was first set up in the 1950s by a public education program. Since then the

high screening rates have been maintained by undergraduate medical education in the only medical school in the Province inculcating into medical students that women should receive pap smears.

UK

Mammography recruitment has been found to be substantially more successful than cervical recruitment. This is attributed to the following:

- fewer agencies being involved meaning less to go wrong
- novelty of mammography
- less embarrassing
- breast cancer being more common and therefore women are perceived to be a greater risk
- cervical cancer may be associated with promiscuity.

SCREENING

12. LOCATION AND TYPES OF FACILITIES

In Sweden and Finland, almost all smears are taken by nurses. Nurses are widely used for taking smears in the UK. In the Netherlands, in 1985 the taking of smears was transferred from nurses to general practitioners. This is not because of the inadequacy of smears taken by nurses, but the expression of a desire to integrate cervical cancer screening into normal patterns of medical care.

13. TYPE OF SMEAR TAKER

UK

In Manchester a trial has been conducted of "consumer oriented, service initiated" screening services which comprised computerised call and re-call and ensuring that services are acceptable to women. However, this trial has not been successful. Research is currently underway to find out why.

Possible reasons are that there was no specific individual who was given responsibility for conducting the program, where there were specific individuals nominated they had many other tasks to perform, the inadequacy of the database (especially wrong addresses in 20% to 30% of cases), the screening being inconvenient and a small proportion of women not wanting smears.

One of the roles of the general practitioner is to check their lists of women to be invited before the letters are printed. This has not worked because of neglect by some general practitioners. It appears to be very difficult to make general practitioners adhere to a system.

Sweden

90% of smears in the organised screening program are taken by nurses specially trained to take pap smears.

14. QUALIFICATIONS OF SMEAR TAKER

Finland

Smear quality is regarded as the most important quality issue in the cervical program. The Helsinki laboratory has undertaken studies of the influence of different types of spatulas and has found that the Aylesbury spatula achieves much higher rates of endocervical cells (88%) compared with the Ayre spatula (20%).

A study was done in Helsinki of the effect of training smear takers on the quality of smears. In the absence of training, over the span of one year the dysplasia detection rate fell 40% while in the group receiving training the dysplasia detection rate increased 80%.

In Helsinki, nurses receive refresher training in taking pap smears every second year.

15. SCREENING INTERVAL

The minimum screening interval in the organised programs was three years, and a recent cost effectiveness analysis from the Netherlands suggests that the minimum screening interval should be 5 years.

UK

One useful analysis might be to see what screening interval would apply if all currently conducted smears were distributed evenly across the population. The obvious implication is that this could be done at no additional cost.

16. QUALITY ASSURANCE PROTOCOLS

It was suggested that the ongoing review of all of the smear and colposcopy histories of women who died of cervical cancer screening would be a worthwhile activity in identifying program deficiencies.

BC

Several methods are used to achieve high levels of quality in the laboratory:

1. The cytotechnologist places a red dot on the form of any case on which they would like feedback. after this case is reviewed by the other levels of technologists and entered into the patient's file, it is returned to the technologist with feedback.

2. Review of the previous slides of current positive cases and false-negatives (including under-calls). any errors are then re-submitted to the technologist or pathologist involved. all errors involving current cases are also returned to the person involved.

3. All over-calls are returned to the technologist concerned.

   Thus, by monitoring the misses, the under-calls and the over-calls, an accurate picture of the technologist's screening is obtained. records of these are kept for quick reference and this information is then entered into a computer in order to provide each technologist with monthly graphic reports on their work. more comprehensive quality assurance reports are produced at six month and yearly intervals. if problems are detected as a result of these data, the technologist will have their work checked by a senior technologist in order to remedy the situation. if the problem needs further remedying, the technologist will be asked to spend a period of time at the technologist school.

4. Each senior technologist selects a junior technologist each week for close scrutiny of their work.

5. For one week, two to three times per year, all the slides of a particular technologist are re-read by a more senior person. this is the only point at which smears called normal by the most junior technologist are read.

6. Annual evaluation of the work of each technologist.

7. Each technologist attends weekly sessions with the staff pathologist on the training microscope to discuss interesting and unusual cases.

8. The cytology laboratory takes part in an annual national cytology morphology proficiency test using unknown slides. it is the ontario quality control test slide program in which 6 cases are submitted as ordinary cases.

9. The Central component of the quality assurance program is a rigid hierarchial structure in the laboratory, in which abnormal slides are passed to successively more senior staff for review.

10. To maintain high quality slide staining, the same technicians do staining all the time.

11. Gynaecological cytology screening is only undertaken by staff who do nothing else.

12. All of the quality control measures are implemented by one senior technologist. This occupies approximately half an hour per day.

13. Pathologists undertake cytological/histological correlation where a biopsy is taken, and provide feedback to the colposcopist.

14. Where cervical cancer cases occur, previous smears are examined. If there is a sudden worsening of the cervical cytology for a particular woman (e.g. years of class 1 smears and then a class 3 smear), previous smears are reviewed.

15. This quality assurance program has been in operation for a bit over three years now, and the number of errors has been reduced by 50%.

Finland

In the Helsinki laboratory, all pap smears are read twice and 20% are read by a cytolopathologist.

18. **SMEAR READING RATES**

BC

In the opinion of the laboratory director the minimum acceptable smear throughput of a cytology laboratory is 25,000 smears per year. A new laboratory should be permitted 5 years to reach this level. If a laboratory is unable to maintain this level for two consecutive years then its licence to undertake pap smears should be withdrawn.

UK

It is the UK recommendation that a smear reader should read at a rate of 35 slides per day. The public labs tend to read 50 slides per day and the private labs tend to read 80 slides per day.

The view is put that cytology reading is impossible to do as a full time occupation. At the Manchester laboratory, most readers work a 20 hour week. In the four hours per day they read an average of 25 slides.

In the UK, a one month turnaround time between receiving a pap smear and sending the report is considered satisfactory.

20. **NOTIFICATION OF RESULTS**

In Sweden, women and doctors are only informed if the result is positive. In all other programs women are informed of both positive and negative results.

FOLLOW-UP AND DIAGNOSIS

22. **LOCATION AND TYPES OF FOLLOW-UP FACILITIES**

In the organised programs in British Columbia, UK and Sweden, women attend specific follow-up clinics in public hospitals. These clinics are staffed by gynaecologists (and some GPs) who have had special training in the colposcopic evaluation of women with abnormal smears.

Both in the UK and British Columbia, colposcopy is regarded as being a super specialty within gynaecology and is only performed in non fee-for-service colposcopy clinics. All gynaecologists doing colposcopy provide data. In Australia, one approach to this might be to develop colposcopy clinics in public hospitals where colposcopists could be trained. This could be combined

a group of colposcopists and epidemiologists developing standard protocols for the management of smear detected lesions. In the long term, the clinical outcomes of the colposcopy clinics could be compared with the outcome of women colposcoped at other venues.

Fail-safe mechanisms are essential to ensure that women with abnormal smears receive adequate treatment.

BC

There is a very high degree of acceptance by general practitioners and gynaecologists of the cervical cytology laboratory's recommendations for management of abnormal smears.

Colposcopy following cervical cytology is undertaken in 22 colposcopy clinics around the Province. Each operates a variable number of sessions per week ranging from 1 to 3.

Of the 200 gynaecologists in the province of british columbia, only 32 specifically trained gynaecologists undertake colposcopy. Colposcopy is funded on a sessional basis. The gynaecologists agree among themselves who is to be trained in colposcopy. This nominated person then receives formal training in colposcopy, with refresher sessions. This system was achieved with the support of very senior gynaecologists. A very small amount of colposcopy is undertaken by other gynaecologists. However, this is not paid for by the Province. There is no scheduled fee for colposcopic diagnosis.

Quebec will now only fund colposcopy which is performed in a hospital clinic.

The view was expressed that if all gynaecologists undertook a small amount of colposcopy, expertise would not emerge. This would result in early invasive cancer being missed and the under-treatment of invasive cancers.

UK

For each District Health Authority, one to two gynaecologists are responsible for colposcopy. Most colposcopy is done in gynaecology departments in hospitals. Some GPs have been specially trained in colposcopy and undertake colposcopy in these clinics. Colposcopy by general practitioners in their surgery has been strongly discouraged.

Generally, the laboratories assume the responsibility for following up women with abnormal smears.

In Oxford, three deaths from cervical cancer resulted because positive results were sent to general practitioners who did not ensure that the women received treatment. Because of cases like this, the Department of Health has insisted that the laboratories develop fail-safe mechanisms.

UK colposcopists are starting to query the need to perform colposcopy on minor lesions (see UK intercollegiate working party report P.12).

23. FUNDING MECHANISMS

In British Columbia, UK and Sweden follow-up and diagnosis are funded as part of the screening program and are free to women.

24. COUNSELLING

No specific provisions for counselling were observed.

QUALITY ASSURANCE OF SCREENING PROGRAMME

26. ADMINISTRATIVE STRUCTURE

In relation to quality control there is a need for both external quality control (e.g. proficiency testing and slide programs) and mandatory internal quality control procedures.

BC

The quality control methods employed in the laboratory are directly applicable to other laboratories and have resulted in a demonstrable improvement in the quality of pap smears in the three years since the quality control program was introduced.

UK

There is a national move towards proficiency testing with circulation of sets of slides. However, there is no commitment of funds to enable laboratories to overcome deficiencies and no procedures have been developed to address the situation in which slide readers do not pass the proficiency test.

A major shortcoming of the new UK proficiency testing system is that no mechanism has been developed for handling slide readers who fail the proficiency testing after initial re-training and re-testing.

The proficiency testing scheme tests very low standards of reading. Its aim is to identify poor readers, not to educate. The slides are limited to unambiguous cases and apply the notion of the gold standard. In mammography in the UK quite a different system is being adopted, whereby difficult and ambiguous cases are circulated among pathologists in order to develop a consensus on the diagnosis. One difficulty in cytology slide circulation schemes is that it is very difficult to get multiple slides, since they are not made from a single block.

The suggestion was put forward of a Standing Committee which conducts confidential enquiries into the reasons behind all deaths from cervical cancer.

31. WORKFORCE PROVISIONS

UK

The adequate provision of workforce is regarded as one of the principal determinants of the quality of a screening program. This applies in all areas, including secretarial and technical support staff.

33. RECORD SYSTEM

BC

There is a cervical cytology database within the cytology laboratory which functions as a Province-wide cytology registry.

UK

There is mandatory provision of data from District Health Authorities (pathology laboratories and FPCs) to Regional Health Authorities and to the Department of Health.

To move towards uniformity of path lab recommendations, one condition for being able to participate in a registry might be for a laboratory to have to use prescribed recommendations when reporting abnormalities. Another possibility is for consortiums of laboratories to develop joint recommendations.

LEGAL ISSUES

35. INFORMED CONSENT

UK

Informed consent is not obtained for colposcopy.

37. OVERLAP WITH OTHER HEALTH PROGRAMMES

In none of the screening programs examined was cervical cancer screening combined with mammography screening. In the Netherlands it was recommended that cervical and cervical screening programs should have a common administrative structure.

38. DATA

BC

1.7% of women screened are referred to colposcopy.

BRITISH COLUMBIA CERVICAL CYTOLOGY PROGRAM

1. AIMS

To provide cervical cytology screening to eligible women in the Canadian Province of British Columbia.

2. STATUS

A centralised gynaecological cytology screening program began in British Columbia in 1949 with the establishment of a pilot project to determine the efficacy of cervical smears in detecting pre-clinical cancer of the cervix. The pilot project established the value of pap smears, and the Province-wide program proper began in 1951.

3. FUNDING SOURCES AND MECHANISMS

For more than 30 years, the laboratory service has been funded by the Government of British Columbia on an at-cost basis. The laboratory is funded as one component of its host organisation, i.e. the Cancer Control Agency of British Columbia.

4. LEVEL OF FUNDING

The gynaecological cytology laboratory costs C$3.5m per annum.

5. PATTERNS OF EXPANSION

There has been a yearly increase of approximately 1.5% in the number of smears examined, roughly equal to the yearly increase in the number of women in the Province.

6. ADMINISTRATIVE STRUCTURE

The gynaecological cytology laboratory of the Cancer Control Agency of British Columbia (CCABC) is the only provider of gynaecological cytology laboratory services in British Columbia.

When the laboratory was being established, co-operation between the British Colombia Medical Association and the British Colombia branch of the Canadian Cancer Society was crucial, along with the enthusiastic support of a group of gynaecologists.

The British Columbia Cervical Cytology Program, comprising the cytology laboratory, a network of colposcopy clinics and the gynaecological oncology service, are part of the Cancer Control Agency of British Columbia. The CCABC is mostly a cancer hospital, and is government funded as such. The

Cervical Cytology Program comprises between 8% and 10% of the budget of the CCABC. The annual budget of the CCABC is C$50m.

The Cervical Cytology Program processes around 600,000 smears per year, 3,000 colposcopies per year and 100 cone biopsies per year. As well as being responsible for cytology, the service is also responsible for the anatomical pathology of cervical cancer cases. Copies of the organisational structure of the Division of Cytology, the aims of the CCABC and the most recent annual report of the CCABC have been obtained.

8. AGE RANGE

It is recommended that screening be provided for all sexually active women, with screening ceasing for women over 60 who have had at least two prior adequate negative smears. However, the upper age limit is left to the discretion of personal physicians. The laboratory will screen all slides presented.

10. NUMBERS

From a total population in British Columbia of 3.5 million, 600,000 smears were read in 1988 and 500,000 women were screened.

2,500 smears are preocessed by the Program's labs each day.

11. RECRUITMENT METHODS

For the first decade of the program, there was a lot of public and professional education about pap smears. Since 1965, no public education has been provided. Undergraduate and professional education at the University of British Columbia Medical School is the main method of maintaining recruitment rates. Recalling women for smears after the prescribed interval is up to the local doctor. Smear services are also provided in prisons, native reservations and family planning clinics.

If a smear is abnormal, the laboratory ensures follow-up action is taken. This is initially done through the smear taker. If unsuccessful, the woman is approached directly.

No. of women screened in British Columbia (1985) by age TII (1.)

Age group (years)	Female population	No. (%) screened	% age of each age group screened
15-19	103,000	25,571 (6)	25
20-34	380,800	224,970 (49)	59
35-59	415,800	168,186 (36)	40
60 and over	266,600	44,179 (9)	16
TOTAL	1,166,200	462,906 (100)	40

Since 1970 approximately 85% of women have been screened at least once.

12. LOCATION AND TYPES OF FACILITIES FOR TAKING SMEARS

Over 90% of smears are taken by general practitioners. There are 3,000 GPs in British Columbia. Nurses take smears from special groups e.g. native reservations. It has been observed that the smears taken by nurses are of higher quality than those taken by GPs.

14. QUALITY ASSURANCE OF SMEAR TAKING

If no endocervical cells are present on a smear, the doctor is notified. The laboratory's policy is that if that woman's smears for the preceding two or three years have been negative, then a repeat smear is not required. If there is a history of abnormal smears, then the lab requests that the smear be repeated as soon as possible.

15. SCREENING INTERVAL

Annual pap smears are recommended up to age 35. After this age, the frequency may be reduced to every second or third years, providing no significant degree of dysplasia or carcinoma in-situ has been detected. 451 of women are screened yearly. The average re-screening interval is 20 months.

16. LABORATORY QUALITY ASSURANCE PROTOCOLS

The aim is to achieve a uniform high quality of cytology reading.

Now that quality control standards and systems are in place, it would be possible to decentralise the British Columbia laboratory system.

Several methods are used to achieve high levels of quality in the laboratory:

1. The cytotechnologist places a red dot on the form of any case on which they would like feedback. after this case is reviewed by the other levels of technologists and entered into the patient's file, it is returned to the technologist with feedback.

2. Review of the previous slides of current positive cases and false-negatives (including under-calls). any errors are then re-submitted to the technologist or pathologist involved. all errors involving current cases are also returned to the person involved.

3. All over-calls are returned to the technologist concerned.

   Thus, by monitoring the misses, the under-calls and the over-calls, an accurate picture of the technologist's screening is obtained. Records of these are kept for quick reference and this information is then entered into a computer in order to provide each technologist with monthly graphic reports on their work. More comprehensive quality assurance reports are produced at six month and yearly intervals. if problems are detected as a result of these data, the technologist will have their work checked by a senior technologist in order to remedy the situation. if the problem needs further remedying, the technologist will be asked to spend a period of time at the technologist school.

4. Each senior technologist selects a junior technologist each week for close scrutiny of their work.

5. For one week, two to three times per year, all the slides of a particular technologist are re-read by a more senior person. this is the only point at which smears called normal by the most junior technologist are read.

6. Annual evaluation of the work of each technologist.

7. Each technologist attends weekly sessions with the staff pathologist on the training microscope to discuss interesting and unusual cases.

8. The cytology laboratory takes part in an annual national cytology morphology proficiency test using unknown slides. it is the ontario quality control test slide program in which 6 cases are submitted as ordinary cases.

9. The central component of the quality assurance program is a rigid hierarchial structure in the laboratory, in which abnormal slides are passed to successively more senior staff for review.

10. To maintain high quality slide staining, the same technicians do staining all the time.

11. Gynaecological cytology screening is only undertaken by staff who do nothing else.

12. All of the quality control measures are implemented by one senior technologist. This occupies approximately half an hour per day.

13. Pathologists undertake cytological/histological correlation where a biopsy is taken, and provide feedback to the colposcopist.

14. Where cervical cancer cases occur, previous smears are examined. If there is a sudden worsening of the cervical cytology for a particular woman (e.g. years of class 1 smears and then a class 3 smear), previous smears are reviewed.

15. This quality assurance program has been in operation for a bit over three years now, and the number of errors has been reduced by 50%.

17. NUMBER AND QUALIFICATION OF READERS

The laboratory has 42 technologists.

The laboratory has its own training school. To enter the school a person must have completed the first year of science at university. The school has the capacity to train 4-6 people per year and training takes 20 months. This is followed by an examination. If this examination is passed, the person becomes a grade 1 technologist for 5 years. Then they are given 3 months training followed by an examination. If this is passed they become a grade 2 technologist. There are 4 further grades of technologist. Promotion to these levels is on merit with an additional 3 months of training.

Class 1 readers are allowed to sign out normal slides. Class 2 readers are allowed to sign out mild atypia. Class 3 to 6 readers are allowed to sign out moderate atypia. Anything which is more severe must be reviewed by a pathologist. A slide with a severe abnormality will be reviewed by a class 1 or 2 reader, a class 3 reader, a class 4, 5 or 6 reader and by a cytopathologist. i.e. there are 4 levels of reading for the most severe abnormalities. It can take three days for an abnormal smear to go through this sequence.

18. SMEAR READING RATE

Grade 1 and 2 technologists read 90 smears per day. More senior staff read fewer. The cytopathologist reads 50 abnormal smears per day. Approximately 4% of smears are referred to a cytopathologist. The average smear reading rate is 65 per day. It routinely takes the laboratory 3 weeks to process a smear. If the doctor requests a smear to be processed urgently, the results will be phoned back to the referring doctor by the next day.

19. REPORTING CODES

The codes used are shown on the forms provided.

The screen reader has access to the smear history. This results in much more informed recommendations. These recommendations tend to be followed by general practitioners. Smears are reported in one of five categories:

Class 1:	Negative
Class 2:	Benign atypias and mild to moderate dysplasia;
Class 3:	Carcinoma in-situ or severe dysplasia. Coplposcopy recommended.
Class 4:	Carcinoma in-situ or invasive carcinoma.
Unsatisfactory:	A smear has too few cells for interpretation, or is obscured by inflammatory cells or blood.

20. NOTIFICATION OF RESULTS

Smear results are always reported to the smear taker and not to the woman from whom the smear was taken.

21. FUNDING MECHANISMS FOR SMEAR TAKING

General practitioners receive a fee for service which is funded by the government sponsored provincial health insurance plan. No payment is made by women.

The processing and reporting of the smear is paid for by the government grant to the Cancer Control Agency of British Columbia. British Columbia is the only province in Canada where cervical cytology smears are specifically omitted from the pathology fee schedule. This means that there is no private cervical cytology pathology conducted in British Columbia.

22. LOCATION AND TYPES OF FOLLOW-UP FACILITIES

Colposcopy following cervical cytology is undertaken in 22 colposcopy clinics around the Province. Each operates a variable number of sessions per week ranging from 1 to 3.

Of the 200 gynaecologists in the province of british columbia, only 32 specifically trained gynaecologists undertake colposcopy. Colposcopy is funded on a sessional basis. The gynaecologists agree among themselves who is to be trained in colposcopy. This nominated person then receives formal training in colposcopy, with refresher sessions. This system was achieved with the support of very senior gynaecologists. A very small amount of colposcopy is undertaken by other gynaecologists. However, this is not paid for by the Province. There is no scheduled fee for colposcopic diagnosis.

The gynaecologists and GPs tend to follow closely the recommended treatment issued by the cytology laboratory.

Where a repeat smear is requested by the laboratory, only one follow-up reminder is sent to chase the second smear.

Where investigation is recommended, intensive follow-up occurs. After 4 months a follow-up letter is sent and after another 6 months phone calls are made.

Severe dysplasia or carcinoma in situ are deemed to require a long-term follow-up. The computer automatically generates an annual reminder letter to the physician for these women.

All colposcopists complete a standard form which records the clinical impression, the results of the colposcopic biopsy and then the synthesis of all available information in a colposcopic evaluation and recommendation. The data collection form has been designed to minimise clerical time. (Note the multiple copies.)

The principle goal of colposcopy is to reduce the frequency of diagnostic cone biopsies.

The view was expressed that if all gynaecologists undertook a small amount of colposcopy, expertise would not emerge. This would result in early invasive cancer being missed and the under-treatment of invasive cancers.

In relation to colposcopy, the Cancer Control Agency provides training at no charge, a quality control system, ongoing education courses and sessional payment for colposcopy.

Following colposcopic evaluation, the woman is referred to her own doctor for treatment.

The specific indications for colposcopy have been developed in a policy of the Cancer Control Agency. A copy has been obtained.

The gynaecologists collaborate with the pathologists in arriving at the final colposcopic evaluation and recommendation.

For women who develop invasive cervical cancer, both previous smears and previous colposcopic evaluations are reviewed.

Systematic statistical quality control is undertaken of colposcopy, with annual feed back to colposcopists on their performance.

23. FUNDING MECHANISMS FOR FOLLOW-UP EVALUATION

With agreement of the professional association of gynaecologists, there is no scheduled fee for colposcopic evaluation of women with abnormal smears. Colposcopy is paid sessionally. The rationale is that colposcopy is a diagnostic service. Following colposcopic evaluation women are referred back to their usual physician.

24. QUALITY ASSURANCE PERFORMANCE INDICATORS

The type of indicators used can be seen from the laboratory quality assurance manual which has been obtained. Colposcopy quality is assessed by comparing the colposcopic impression with previous cytology results, colposcopic impression with biopsy results, colposcopic evaluation with colposcopic impression, colposcopic evaluation with biopsy, and cytology with biopsy. These data are compiled for each colposcopist. Each colposcopist is given their results plus the average result for all colposcopists.

31. WORKFORCE PROVISIONS

The cytology laboratory has its own training school. It trains 4 to 6 technologists at any one time in a 20 months training course.

Basic colposcopy training is a 1 month course comprising 3 clinics per week, 3 afternoons doing cytological pathological correlation with the same patients, correlation sessions arriving at the colposcopic recommendations, a reading course, a formal 2-day colposcopy course, and attending

clinics for new gynaecological cancer patients twice a week. This 1 month training course is split in two with one month in the community in the middle.

The gynaecologists are free to come back at any time for refreshers. There are annual day-long meetings to review issues. All colposcopists must be Fellows of the Royal College of Obstetricians and Gynaecologists of Canada.

32. COSTS

In 1987 it cost C$6.30 to process each smear, including all laboratory services and quality control. More comprehensive cost data have been obtained.

33. RECORDS SYSTEM

Three records systems record data for the cervical cytology program:

- laboratory quality control system on a micro. A copy of this software has been obtained
- Provincial cancer registry
- Provincial cytology registry data base.

In 1976, discrepancies were noticed in the number of cervical cancer cases identified by the cancer registry and the number identified by the cytology database. This arose because local pathologists were calling cases cancer which the CCA downgraded to carcinoma in-situ. However the cancer registry was not able to downgrade. Since then the database and registry have agreed to use the best data and all cases are reviewed by a small group of pathologists.

The cytology database was card-based until 1976. It has undergone three major computer upgrades since then. The current system has been in operation since 1983.

The database receives all pap smear requests and reports, all colposcopy reports and all anatomical pathology reports.

Codes have been designed to minimise storage requirements and to maximise ease of access. It can take between 30 seconds and 2 minutes to retrieve a woman's screening history. A major problem is patient identification, as there is no external identification number. Doctors will record a previously generated laboratory number on forms in only 75% of smears. A major problem is record linkage with duplicate records.

The database currently contains records for 11 million women. It is so large that it is very difficult to do analyses.

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The database currently contains records for 11 million women. It is so large that it is very difficult to do analyses.

Slide retention

Positive smears are kept forever. If a woman ever has positive cytology then all of her slides will be retained forever. Negative smears are retained for 8 years.

34. CONFIDENTIALITY

Privacy legislation is in force which gives patients access to their own records.

35. INFORMED CONSENT

Formal informed consent is required for colposcopy and treatment.

36. LEGISLATIVE REQUIREMENTS

Cancer is a notifiable disease, therefore notification is compulsory. Colposcopists are not obliged to provide data to the cytology database, but there is a lot of professional peer pressure to submit data.

37. OVERLAP WITH OTHER HEALTH PROGRAMS

There is no overlap between the cervical cytology program and the mammography program.

38. DATA

Between 1965 and 1970, 85% of women in the Province had been screened at least once. This figure has been maintained. Each year 10% of pap smears are for new women.

It seems to be very difficult to get beyond 85% of women having had at least one smear.

High screening rates are observed in women of child-bearing and menopausal age, as women are presenting to doctors in these age ranges. Some very long smear intervals are observed for women who don't attend doctors between these two periods.

Results and investigations in 1985 (1.) p977

1.7% of screenees are referred for colposcopy

No. of women screened and no. of cases of squamous carcinoma in situ of the cervix in British Columbia T1 (1.)

	No. of women	% of referrals for colposcopy
New patients referred for colposcopy	8,188	
Dx severe dysplasia or carcinoma in situ	3,000	37%
Dx persistent, mild or moderate dysplasia (CIN I-II)	5,188	63%

Rates of carcinoma in situ in British Columbia x age - see T III (1.)

Year	Population over age 20 (000's)	No. of women screened	No. of cases detected	Rates per 100 000 women screened
1955	422.9	11,707	52	12.3
1960	486.4	59,844	221	45.4
1965	543.2	161,556	504	92.8
1970	664.4	297,407	761	114.5
1975	805.5	355,917	1,239	153.8
1980	926.2	433,329	1,545	166.8
1985	1,063.1	465,676	1,420	133.6

Incidence of invasive SCC of the cervix and refined mortality TIV

	Population over age 20 (000's)	Total No. of cases	Incidence per 100 000	No. of deaths	Rate per 100 000
1955(?)	422.9	120	28.4	*	*
1958	473.0	112	23.7	54	11.4
1960	486.4	96	19.7	48	9.9
1965	543.2	80	14.7	42	7.7
1970	664.4	82	12.3	46	6.9
1975	805.5	70	8.7	42	5.2
1980	912.9	63	6.9	24	2.6
1985	1,063.9	68	6.4	33	3.1

* Refined mortality was not calculated until 1958.

- 78% drop in incidence of clinically invasive squamous Ca of the cervix and 72% drop in mortality between 1955 and 1985 (if rates for 1980-85 are averaged) (1.) p.977.

- The proportion of microinvasive and early invasive Ca has fallen from about 10% of the yearly total in 1955 to 2% in 1985. (1.) p.977.

- Of invasive cervical cancer cases 1975-1985,
  69% were over 50 years
  75% had no previous pap smear

39. BIBLIOGRAPHY

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DOCUMENTS OBTAINED

Annual Report 1987-1988
Cancer Control Agency of British Columbia

Cytology Office Manual 1986
Cancer Control Agency of British Columbia

The British Columbia Cancer Registry
(Comprehensive descriptive paper)

Data Collection Package

Occupational and Environmental Health Research Unit
Statistics Canada 1988

Organisational structure of Division of Cytology

Formal documentation of the purposes of the Cancer Control Agency of British Columbia

Gynaecological Cytology Screening Laboratory (an overview of all of the functions of the laboratory)

Three pamphlets from the CCABC entitled:
- Colposcopy
- Laser therapy for gynaecology patients
- Cryotherapy for gynaecology patients

An extract from the Cancer Treatment Manual of the Cancer Control Agency of British Columbia covering carcinoma of the cervix

Costing of cervical cytology at the Cancer Control Agency

Software for the Cytology Laboratory Quality Control Program of the Cancer Control Agency (on 5 1/4" floppy disk)

Follow-up notes for entry clerks

Form requesting follow-up information for the Cancer Registry

Forms requesting follow-up information for the Cytology Database

Form for collecting colposcopy data

Data on CIS rates per 1,000 females screened in British Columbia by age group between 1972 and 1988

Data on the female population and number of women screening in British Columbia during 1985 by age group

Data on the distribution of smear interval in British Columbia

MAMMOGRAPHY SCREENING IN THE NETHERLANDS

1. AIMS

To provide all eligible women with high quality mammography screening. To ensure that mammography screening is continuously evaluated.

2. STATUS

The Netherland's government has made an in-principle decision to introduce a national screening program. A final decision is expected early in 1990 when additional financial data will be available. A key problem is the integration of all of the components of the screening program.

3. FUNDING SOURCES AND MECHANISMS

A special allocation of government funds will be made available for the mammography program. In The Netherlands, great emphasis is being placed on minimising costs while maximising effectiveness.

4. LEVEL OF FUNDING

Funding is only being made available to provide screening. All follow-up assessment and diagnosis will be financed as part of usual medical care.

5. PATTERNS OF EXPANSION

There is great concern about the side effects of screening, particularly false-positives. This is one of the reasons why it has been decided that the screening program should be introduced gradually. It is expected that the full program will be operational in 1993, i.e. a five-year implementation period.

Throughout the country, each region is asked to prepare a local plan for implementation and then each region is requested to establish first, one, and then additional centres. This means that screening is introduced simultaneously in all regions throughout the country.

It is planned that the national information system required for quality assurance will be operational by late 1989, i.e. before most of the screening units commence operation.

6. ADMINISTRATIVE STRUCTURE

The national screening program comprises four levels:

- national level: national guiding committee and national reference centre
- regional level: 8-10 integral cancer centres/regional joint management boards - responsible for invitations, regional co-ordination of central units, planning and financial administration.
- regional/local level: central screening unit (20-25): (film reading and local administration)
- local level: screening unit (50-60): film processing and taking; 2-3 for each central unit.

No commercial screening is to be permitted.

All aspects of mammography screening are centrally controlled.

The central screening units do not undertake any screening or assessment. They are responsible for administration, film reading, notification of results and data collection only.

To plan the mammography screening program, each of the 8 integral cancer centres have been requested to prepare a plan for each region for review by the national steering committee.

In The Netherlands the following committees have been involved in the development and implementation of mammography:

- National Health Council Committee: advised on the desirability of mammography
- National Advisory Council for Public Health: reported on organisational aspects
- Erasmus University: cost effectiveness analysis
- Health Insurance Executive Board: program financing
- National Organisation for Quality Assurance in Hospitals: in conjunction with medical colleges and national cancer council, developed quality assurance guidelines.

There are currently two committees in operation:

. National Steering Committee: overall direction

. Steering Committee on Breast Cancer Information: developing information system.

7. POPULATION COVERED

The technical capacity of a 1-mammography machine screening unit is 15,000 screens per year. Realised capacity is expected to be 12,000 screens/year.

The Netherlands has a population of 15 million, which is very similar to Australia (16 million). This means that the Dutch have a very similar scale of operation to that which would be required for a national program in Australia.

8. AGE RANGE

The current policy on age range is that screening should be offered to women aged 50-70. The decision whether to screen women aged 40-49 has been deferred for 10 years.

The national policy is for screening to be made available for women aged 50-70 because of the results of the cost-effectiveness analysis and because no report demonstrates unequivocally the effectiveness of screening women aged 40-50.

9. EXCLUSIONS

Women with breast symptoms are discouraged from attending for screening and are advised to see their doctor.

11. RECRUITMENT METHODS

Mass media and individualised recruitment are used. Individualised recruitment uses municipal population registers. The participation rate for women aged 50-70 is 63% in Nijmegen.

Programs of public and professional education are being prepared by The Netherlands Cancer Foundation.

12. LOCATION AND TYPES OF SCREENING FACILITIES

Facilities are dedicated screening units. Three different types are envisaged - fixed, mobile and semi-mobile. The type of unit chosen for an area will depend on the population density and geographic distribution. Recommendations are to keep the average travelling distance for each woman to 8km or less.

13. TYPE OF SCREENING EQUIPMENT

Evidently screening mammography machines more than 2 years old may have limitations in their automatic exposure controls which result in different film densities for different breast thicknesses.

A daylight developing system has been tested and has been found to be too slow. It is considered to be not worth the money.

Film screen mammography is used universally throughout The Netherlands. The Utrecht program used xeromammography until 1985, when it changed to film screen mammography.

16. NUMBER OF VIEWS

The current national policy is that women aged 50-54 should have two views. Women aged 55-70 should have one view initially, with an additional view being left to the radiographer's discretion.

The Dutch government is about to be advised that this policy should be changed to be two views for the first round and then the radiologist to decide whether one or two views are required at subsequent rounds. The radiographer would still be left with the discretion of doing an additional view if required.

17. SCREENING INTERVAL

The national policy on screening interval is that women aged 50-64 should be screened every two years and women aged 65-70 should be screened every three years.

18. LOCATION OF FILM PROCESSING

All film processing is done locally by the radiographer who has taken the film. Local processing works because of very stringent quality control procedures (see below).

Several radiographers stated that they observe their quality slipping when they don't monitor their own films. They believe that it is essential that they process their own films to maintain highest quality.

It is believed that it is cheaper to process films locally than centrally, because it reduced the number of repeat attendances required by women and ensures higher quality films and therefore screening generally.

19. NUMBER AND QUALIFICATION OF FILM READERS

All film readers are radiologists and there are two readers per film. They read the films independently and reach a consensus assessment where there are any differences.

Previous films are always presented when available.

Even though films are read by radiologists, radiographers should be trained to read the films so that if they spot something they can make a note. This will increase the sensitivity of the film reading.

The films of one woman can be read per minute.

Very low recall rates (less than 1%) are achieved by simply calling only one film in every 100. The radiologists are prepared to wait another two years if a lesion looks mildly suspicious. This approach maximises the cost effectiveness of the screening program.

In Utrecht, radiographers have been trained to over-call films, with a single radiologist making the final decision on the films. This procedure has been used as a stop gap due to a shortage of radiologists.

21. NOTIFICATION OF RESULTS

Both the woman and her GP are informed of screening results.

It has been decided that benign lesions found on mammography will not be reported to women or doctors, to reduce unnecessary medical procedures. The national policy is that benign lesions should not be reported.

23. LOCATION AND TYPES OF FOLLOW-UP AND DIAGNOSIS FACILITIES

The national policy is that if a woman's mammogram is suspicious or shows cancer, both the woman and the general practitioner are informed and the woman is referred to the general practitioner who refers her to a surgeon.

The surgeon then has the principal role in the management of the woman and co-ordinates all subsequent procedures. This is undertaken in the normal medical care system.

In The Netherlands, all follow-up assessment and subsequent treatment must comply with government approved protocols. If procedures do not comply with the protocols, the clinician responsible must report why the protocol was not followed. Otherwise, he/she is liable to be sued by the government and by the patient.

There is a desire to confine the evaluation of impalpable lesions to specialist centres.

It is not permitted to call women back for early re-screening (e.g. at 6 months). It is felt that if this was possible the number of biopsies could be reduced further.

25. ADMINISTRATIVE STRUCTURE OF QUALITY ASSURANCE

On a daily basis, quality assurance data from each satellite screening unit is sent electronically to the national reference centre for assessment and recording. If any deviations are found, the screening clinic is notified immediately with specific advice on the nature of the problem.

The Nijmegen Reference Centre has developed a special phantom for screening mammography.

The National Reference Centre has also developed protocols for the routine checking of mammography and processing equipment. These protocols are continually under development and updating.

This approach is used to ensure high, uniform quality of all film machinery and film processing.

In other areas of quality assurance, programs are currently under development.

26. QUALITY ASSURANCE PERFORMANCE INDICATORS

For first round screening, the positive predictive value of referral for assessment and biopsy should be 30% and for the second round it should be 70%.

One may have to wait over a decade in a large scale screening program before population effects on breast cancer mortality become evident. The program in The Netherlands is being introduced over 1988 to 1993. The maximum effect (a decrease of 500 breast cancers per year) is not expected until 2015, assuming 70% attendance of women aged 50-70 and a positive predictive value of calling a film abnormal of 45%.

The expected cancer detection rate is 6 cancers per 1,000 women in the first round and 3 cancers per 1,000 women in the second round.

27. PHASES AND TIMING OF IMPLEMENTATION

National organising body was set up at commencement of the program in 1988. Regional boards will be phased in over 4 years. The number of central units operating under each regional board will be gradually increased over 7 years.

Each central unit will initially set up 1 screening unit per year. The full complement of screening units will be gradually increased over 7 years. Thus the screening network will be complete by 1995. (Further increases in the screening network facilities beyond 1995 are to provide services for the increasing target population size.)

A "working-in" period of 1 year will be required for each screening unit, during which screening will operate at half capacity.

A major constraint in implementation is the time required for radiographer training.

Both the National Organisation and the Regional Boards will have their full complement of personnel from the start, so that they can be deployed in extending the screening network in the region concerned.

29. WORKFORCE PROVISIONS

There is a great shortage of trained cytologists in The Netherlands.

Training courses for radiographers and clinicians involved in mammography are currently being established and will be available only at the Nijmegen National Reference Centre.

For radiologists, it is important that they do not only mammography and it is therefore desirable to recruit part-time radiologists. This would also assist the availability of radiologists, as the number willing to work full-time in mammography is likely to be small.

A major problem in The Netherlands was convincing radiologists and pathologists that they needed additional training. Particular aspects which have proven most problematic are:

- becoming oriented towards screening well woman
- understanding performance indicators like positive predictive value
- population health/general public orientation
- everyone can calculate your level of quality, unlike clinical practice.

With local film processing, 50-80 woman can be screened per day using one machine and 3-4 radiographers. Screening must not be rushed or mistakes will be made.

In the National Mammography Reference Centre radiographer training comprises 1 week of theory and 6 weeks of practical.

The radiologist training program involves 1-2 days of theory and then 3 weeks of practice.

The training of pathologists involves 1-2 days of theory (shared with the radiographers) and then 3-4 days experience. There is no organised training for surgeons yet.

Both radiographers and clinicians return for a one day refresher/update every year. The Nijmegen National Mammography Reference Centre is responsible for all professional training in Holland. It issues certificates of attendance, which are required for people to be able to screen.

Most radiographers work part time in screening.

30. COST

Estimated cost/life-year gained DG 9,700 ($A5,800).

It was observed that the cost of the Dutch program (with the two year interval) are the same per capita as the cost of the UK program (three year interval), due to many fewer referrals. Even so, the Dutch program has the same cancer detection rate and the cancers detected are smaller. There are many fewer false positives. In The Netherlands a clinical mammogram costs DG150 ($A90). A screening mammogram costs DG75 ($A45). This includes invitation and evaluation.

It is expected that The Netherlands program will cost DG45 million per annum when the program is fully operational (A$27 million per year).

The final report on the cost effectiveness analysis being undertaken by Erasmus University will be available at the end of 1989.

31. RECORD SYSTEM

Standard software is being developed which will be made available to all screening clinics. The data set will be very simple e.g. individual identification, address, marital status, birth date, screening result (suspicious for malignancy/not), recommendation.

The cancer registry is an integral component of any cancer screening program.

It is planned that the new information system will be operational by late 1989 i.e. before most of the screening projects commence operations.

32. LEGAL ISSUES

Consideration is being given to the issue of privacy in relation to monitoring data arising from the screening program, and also whether cancer registry data on interval cancers can be made available to the screening program.

The Dutch government is preparing an Act on medical screening which will cover issues such as:

- ensuring high quality of all aspects of a screening program;
- preventing commercial initiatives;
- ensuring an appropriate balance between risks and benefits.

Commercial initiatives are not permitted due to concerns about their low quality, the use of poorly trained staff and the fact that they speculate on the fear of cancer to recruit women.

36. OVERLAP WITH OTHER HEALTH PROGRAMS

It was recommended that the cervical and mammography screening programs should use combined organisations at the municipal and regional level.

37. DATA

In the first round of screening in the city of Arnhem, 1.8% of women were referred for assessment and 0.6% were found to have cancer. In the seventh round of screening in the Nijmegen, 0.4% were referred and 0.3% were found to have cancer.

In Utrecht, a reduction in breast cancer mortality has been observed in the population. No such reduction has been observed in Nijmegen.

In women aged 40-49, with a two year screening interval, 50% of the cancers are found at screening and 50% are interval cancers. In women aged 50+ with a two year screening interval, 70% of cancers are found at screening and 30% are found in the interval.

Under age 50, 30% of cancers are ductal in situ. Between ages 50-64, 15% and age 65+, less than 10%. The breast cancer mortality rate of women not screened in Nijmegen is very similar to the rate in women in a control population, suggesting that selection bias of low risk women for screening in Nijmegen has been a minor factor in producing the relative reduction in breast cancer mortality observed.

Of the interval cancers found in the 12 months following screening, one-third are missed due to perception errors, one-third are decision errors and one-third are undetectable. This is an argument for having multiple readers.

In a few months, Nijmegen follow-up data to 1988 should be available.

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Summary of the report by the Health Council on the introduction of the mammographic screening program in The Netherlands, June 1987.

Intensive care quality assurance: the centralised approach for mammography screening. In English, describes the radiology quality control program.

Implementation of a national breast cancer screening program in The Netherlands. W A Van Veen (a good overview of the national mammography program).

Two letters from Dr Muir Grey outlining collaboration between the UK and The Netherlands mammography program.

Flow diagram of assessment protocol.

Guidelines for quality assurance in a national screening program for carcinoma of the breast. National organisation for quality assurance in hospitals, November 1988.

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PLANNING THE MAMMOGRAPHY PROGRAM IN THE NORTH WESTERN HEALTH REGION OF ENGLAND

This paper provides an outline of how a mammography screening program might be introduced in an Australian State.

North Western Regional Health Authority:
4 million total population
300,000 women aged 60-64

According to the Forrest Report the North Western Regional Health Authority is entitled to 7.5 Forrest screening units. This entitlement is used to determine the level of funding. The plan was for there to be one unit introduced in the first year, 4 introduced in the second year and 2.5 introduced in the third year.

In 1987, circulars arrived from the Department of Health and Social Security directing that a mammography screening program be established. The RHA then circulated a questionnaire to ascertain the level of current mammography and the interest in establishing initial screening centres. Three districts were found to have a commitment to breast cancer screening. While the DHSS specified that one screening centre should be specified initially, the Region decided to establish 3 due to the expressed interest.

A regional steering group on breast screening services was established with representation from all relevant disciplines. Generally, community representation is deficient because of poor mechanisms for identifying suitable representatives, not because of any lack of desire to seek community input.

A full time regional co-ordinator was then appointed. At the end of the first year, three screening units had been established. It was left to the districts to decide whether to have fixed or mobile units.

Plans were developed to expand the screening program from three to seven units. It was decided that there should be five specialist assessment teams in the Region, with four of these teams providing first and second stage screening and one providing first stage screening in three clinics and second stage screening in one clinic.

After the plans for expansion had been developed, a regional seminar for 100 people was held in which each health district sent in 5 or 6 people representing community physicians and health professionals. The conference process was intended to assist people to develop their screening plans. The population was divided into groupings of 50,000 women eligible to be screened, as this was the population for each screening unit as

specified in the Forrest Report. Services were to be planned locally according to the Forrest Report and then the details were to be discussed with the District and the Health Regions. The planning processes for there to be Regional plans and then district plans with Regional input to ensure that Forrest and regional guidelines are observed.

Where groups of Health Districts couldn't agree on where facilities should be located, agreement was developed to have mobile assessment teams which would operate out of multiple assessment facilities located throughout the Region. These assessment facilities could be used for screening at other times.

Public fund raising has been very successful and also raises awareness of the screening program.

The national screening program was probably capital under-funded but the slow start means that operating costs have been able to be transferred into capital.

Quality assurance is to be achieved by developing sub-groups in the following areas: mammography, pathology, treatment, information, recruitment (including information to women and GP information and knowledge) and consumer satisfaction.

A regional quality assurance manager/ co-ordinator is to be appointed. The general preference is for a senior regional medical officer to undertake this role. It is expected that this regional person's time involvement will be quite small. Their main function will be as a backstop if problems arise.

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An overview of screening for breast cancer including a summary of the Forrest Report.

Breast Cancer Screening: An overview of the current situation and future requirements.

Funding for breast screening services

Allocations from regional reserves 1989-90