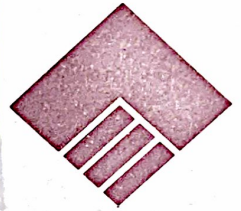




COMMONWEALTH OF AUSTRALIA

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DH
Heather
Cahernell



29 AUG 1991

DEPARTMENT OF
COMMUNITY SERVICES
AND HEALTH

DEPARTMENT OF
HEALTH, HOUSING AND
COMMUNITY SERVICES

Dr Nigel Gray
Director
Anti-Cancer Council of Victoria
1 Rathdowne Street
CARLTON VIC 3053

Dear Dr Gray

I am writing to let you know of developments in cervical cancer screening since we wrote to you early this year on the proposed Commonwealth response to recommendations contained in the report, **Cervical cancer screening in Australia - options for change**, and to thank you for your support and contributions.

I am pleased to be able to advise you that there have been major developments - in particular there has been substantive support for the development of a more organised approach to cervical cancer screening.

In March of this year, all health ministers agreed to cooperate in developing an 'organised approach' to cervical cancer screening. Discussions are proceeding with the States/Territories on appropriate funding arrangements and distribution of responsibilities.

Following extensive consultations, a national screening policy has been adopted. The policy has been endorsed by the Royal Australian College of General Practitioners, Royal Australian College of Obstetricians and Gynaecologists, Royal College of Pathologists of Australasia, Australian Cancer Society, the Australian Health Ministers and the National Health and Medical Research Council, and is supported by many other groups.

The policy is as follows:

Routine screening with Pap smears should be carried out every two years for women who have no symptoms or history suggestive of abnormal cervical pathology. All women who have ever been sexually active should commence having Pap smears between the ages of 18 to 20 years, or one or two years after first sexual intercourse, whichever is later. In some cases it may be appropriate to commence

screening before 18 years of age.

Pap smears may cease at the age of 70 years for women who have had two normal Pap smears within the last five years. Women over 70 years who have never had a Pap smear, or who request a Pap smear should be screened.

The Federal Government will provide \$22.4 million over four years from 1991-92 for the development and implementation of the organised approach to cervical cancer screening. States and Territories will be invited to contribute in order to ensure maximum participation by women.

Funds will be provided for :

- . informing service providers and women about the new policy;
- . improving the reliability of Pap smears and developing guidelines for the management of abnormalities;
- . developing strategies to encourage women to participate in screening at the recommended interval, including reminder/recall services and local educational and promotional activities;
- . developing supplementary screening services appropriate to the needs of special groups;
- . training, monitoring and evaluation.

I enclose a copy of Mr Howe's recent media release on these latest developments.

A communication strategy has been developed in two stages.

The first stage is aimed at service providers to inform them of the national screening policy and to encourage them in using reminder/recall strategies to maximise regular participation in screening at the agreed interval. A letter has been sent to general practitioners and some other service providers, and a booklet for general practitioners is being developed in consultation with the relevant professional bodies.

The second stage of the strategy will be targeted at women to encourage regular participation throughout life in cervical cancer screening in accordance with the agreed screening policy.

Dr Edith Weisberg, Medical Director of the Family Planning Association, NSW, was appointed as Commonwealth

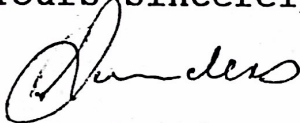
spokesperson on cervical cancer screening in February, 1991.

A committee has been appointed under the chairmanship of Dr Robert Rome, a noted gynaecological oncologist, to review and develop improved quality assurance measures for cervical cytology.

Guidelines for the treatment of cervical abnormalities are being developed by the National Health and Medical Research Council. The Federal Government has funded the Family Planning Association of NSW to analyse data on progression and regression rates of cervical abnormalities which will assist in the development of treatment protocols.

I would like to take this opportunity to thank you for your valuable contribution to the consultative process and look forward to further co-operation as this program develops.

Yours sincerely



Ross Saunders
Acting Assistant Secretary
Health Care Strategies Branch
27 August 1991

BUDGET

1991 - 1992

Brian Howe

Deputy Prime Minister
Minister for Health, Housing and Community Services

BH161/91

20 August 1991

\$22.4 MILLION FOR CERVICAL CANCER SCREENING

The Federal Government will contribute \$22.4 million to improving the effectiveness and reliability of cervical cancer screening in a new four year program which will target at risk women.

Announcing the program today, the Minister for Health, Housing and Community Services, Brian Howe, said that over half of the 1040 cases of cervical cancer diagnosed annually could be prevented by a more effective national screening strategy.

The program will implement the findings of a three year evaluation **Cervical cancer screening in Australia: options for change** which was commissioned by the Australian Health Ministers' Conference and published in October last year.

One of the evaluation's findings was that younger women, who are at relatively less risk of developing cervical cancer, are being screened more frequently than necessary.

In contrast women in higher risk groups, including older women, Aboriginal women, women from a non-English speaking background, and women from isolated rural areas, are infrequently or never screened.

"We need to redirect our efforts to these groups of women if we are to reduce deaths from cervical cancer. This is the aim of the new approach," Mr Howe said.

"The new national screening policy for cervical cancer, which recommends that every woman who has had sexual intercourse and is aged between 18 and 70 is screened every two years, has been endorsed by the National Health and Medical Research Council, Health Ministers, professional bodies and cancer societies.

"The Federal Government will commit \$3.5 million towards implementing the new policy in 1991-92, and a further \$6.6 million for 1992-93, \$6.1 million for 1993-94, and \$6.1 million for 1994-95," he said.

.../2.



"I expect the States and Territories to also make a contribution to ensure maximum participation by women in screening programs."

Mr Howe said the funds would be allocated to:

- informing service providers and women of the new national screening policy;
- improving the reliability of Pap smears;
- developing guidelines for the treatment of abnormalities;
- developing strategies to encourage women to participate in screening at the recommended interval, including reminder/recall services;
- local educational and promotional activities;
- developing supplementary screening services appropriate to the needs of special groups; and
- training, monitoring and evaluation.

He said considerable progress had already been made on implementing the new screening policy.

At the Australian Health Ministers' Conference in March, State and Territory health ministers had endorsed, in principle, an organised approach to cervical cancer screening. The provision of funds in the Federal Budget would now enable further discussions between the Commonwealth and the States and Territories on appropriate funding arrangements and distribution of responsibilities.

"The Federal Government's commitment to improving the effectiveness and reliability of cancer screenings will result in a significant reduction in the number of women developing cervical cancer.

"Women can be reassured that the new screening policy will provide a very high degree of protection against this disease, while at the same time reducing any inconvenience and anxiety that may be associated with Pap smears," Mr Howe said.

Contact: Marilyn Chalkley (06) 277 7680

Anti-Cancer Council of Victoria



9 April 1991

4-0045

Dr. H. Mitchell
Victorian Cytology Service
PO Box 253B
Melbourne Vic 3001

Dear Heather,

I forgot to send you a copy of my response to Mr Candler's request for comment on your National Cervical Cancer Screening Evaluation Report. Hence I'm remedying the defect.

Cheers -

Yours sincerely,

Nigel Gray
Director

Encl. Letter to Mr Candler

Anti-Cancer Council of Victoria



23 January 1991

49-2513

Mr L. Wright
Executive Director
Australian Cancer Society
GPO Box 4708
Sydney NSW 2001

Dear Lawrie,

You asked for comment about the Cervical Cancer Screening Evaluation Report.

I had a letter before Christmas and sent the attached response direct.

Cheers -

Yours sincerely,

Nigel Gray
Director

Att. Ltr to B. Candler

B111/5.2

21 18 January 1991
JAN 1991

Dr. N. Gray ✓
Mrs. E. Henry

CERVICAL CANCER SCREENING

EVALUATION REPORT

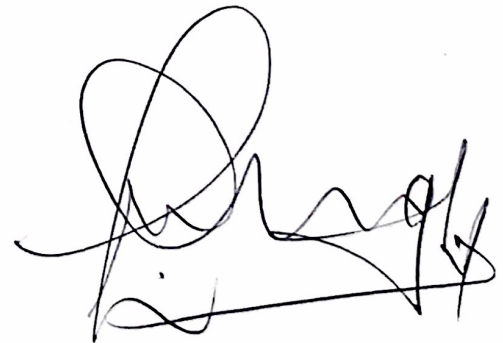
The AHMAC Cervical Cancer Screening Evaluation Steering Committee, chaired by Heather Mitchell, submitted its report late last year. The report was adopted by AHMAC as a guide for future development of services and the report will be further discussed by AHMAC in March.

The Society has been asked to comment and endorse the recommendations in the report by early February. The NCAC does not meet again until 22 March.

The President would appreciate your views, preferably in consultation with some member(s) of your Committee so that an ACS response can be given in the time requested.

Could you let me have these views by the end of January please.

I believe I wrote
to the committee
recently and
you check.

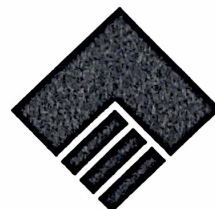


L. A. Wright
Executive Director



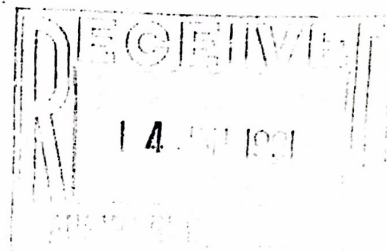
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DEPARTMENT OF
COMMUNITY SERVICES
AND HEALTH

Mr LA Wright
Executive Director
Australian Cancer Society
GPO Box 4708
SYDNEY NSW 2001



Mr Wright

CERVICAL CANCER SCREENING EVALUATION REPORT

I refer to Mr McNeil's letter of 20th December, 1990 which outlined the broad strategy the Commonwealth proposed to adopt for determining a response to the Report. This letter also indicated that further papers on key issues would be distributed shortly, with a view to seeking a national consensus on the proposed response.

Attached, for your further consideration, are the following papers:

- . Cervical Cancer Screening, A National Strategy - an overview of the draft response to the report on Cervical Cancer Screening Evaluation;
- . Draft national cervical cancer screening policy;
- . Strategies to increase the participation of women in cervical cancer screening;
- . Brief for the consultancy to be established to examine quality assurance aspects in cervical cytology;
- . Management of abnormalities; and
- . Organisation and funding of cervical cancer screening services.

As indicated in the letter of 20th December, the Commonwealth is required by the decision of AHMAC to report to Australian Health Ministers in early March 1991.

To meet the timetable set down by AHMAC, it is most desirable that the Commonwealth have your comments on the issues discussed in the papers at the earliest opportunity: Enquiries on this matter should be directed to Mr Dennis Bentley, Director, Cervical Cancer Screening Task Force, telephone no. 062 89 7363.

Yours sincerely



Brian Candler
A/g First Assistant Secretary
Health Care Access Division
10 January, 1991

CERVICAL CANCER SCREENING

A NATIONAL STRATEGY

OVERVIEW

INTRODUCTION

The AHMAC Cervical Cancer Screening Evaluation Report (CCSER) challenges governments, professional groups, and support organisations to provide cervical cytology screening services that are more efficient and cost-effective, drawing on the most recently available epidemiological, behavioural and economic research.

The publication of this report provides an opportunity to maximise the prevention of morbidity and mortality resulting from cervical cancer. The CCSER can be used both as a guide and data resource, to draw together a national cervical cancer screening strategy. This will be based on the most effective programs now operating overseas, but reflecting responses to the report from health departments, professional and consumer groups as to what is achievable, and appropriate, in Australia.

THE CERVICAL CANCER SCREENING EVALUATION REPORT (CCSER)

In 1987, concerns about inequity in distribution and the poor cost-effectiveness of existing cervical cancer screening services prompted health ministers to commission a Commonwealth funded evaluation of existing services, supported by targeted pilot projects.

The report confirmed major concerns about the effectiveness of cervical cancer screening in Australia, when compared with overseas programs. Cervical cancer screening has the potential to prevent over 90% of squamous cervical cancers which would occur without screening. Cervical cancer screening has been practised for over 25 years in Australia, yet only about half of the lives at risk from cervical cancer are currently being saved.

Comparison with overseas models endorsed by the IARC and WHO indicate that significant elements of an organised screening pathway are not yet in place in Australia. Essential elements in an effective program are:

- . an identified target population, via an agreed screening policy and means to identify individual women;
- . measures to guarantee high attendance levels, including adequate and acceptable smear taking services;
- . adequate laboratory facilities for smear reporting and an organised program for quality control;

- . facilities for diagnosis, treatment and follow-up of abnormalities;
- . carefully designed referral and fail-safe linkage systems to ensure management of abnormalities and collecting information about normal screening tests; and
- . evaluation and monitoring systems.

Current cervical cancer screening in Australia is not achieving optimal impact despite substantial expenditure levels. The report advances a number of reasons, including:

- . lack of an agreed screening policy, including a target age group and rescreening interval, and insufficient efforts to increase uptake among the target population;
- . poor access to service providers of choice and other barriers to screening, ranging from negative attitudes to screening and to simply forgetting;
- . absence of fail-safe systems to follow-up women with abnormalities and lack of agreement on appropriate management; and
- . the absence of a national framework to monitor and co-ordinate recruitment, recall, management of abnormalities, and quality assurance.

The opportunity exists for major improvements to be made to current services within existing resources.

Cost-effectiveness of the current arrangements are particularly sensitive to the screening interval and to excessive screening and investigation of abnormalities in the 18-24 year age group, where risk associated with this disease is minimal.

The nature and extent of the criticisms of existing cervical cancer screening services raised in the report create a clear obligation to respond quickly and positively. The Australian Health Ministers' Advisory Council (AHMAC) received the report late in October 1990 as a guide for the future development of cervical cancer screening services in Australia and authorised the Commonwealth to conduct a process of discussion on the recommendations leading to a further report to Health Ministers in March 1991.

DRAFT NATIONAL STRATEGY

In order to crystallise views on key issues, the Commonwealth has produced a series of papers (see attachments) recommending a policy or process to achieve consensus. The principal content of those papers are summarised below:

Screening Policy

A screening policy needs to balance the benefits from screening, such as life years saved and morbidity avoided, against the costs of screening to the individual, such as discomfort and anxiety created, personal time and costs, and financial costs to government, including opportunity costs.

A well-defined and uniformly adopted screening policy is fundamental to developing an effective population based cervical cancer screening program.

The CCSR notes that 90% of invasive squamous cell cervical cancer can be prevented by screening women aged 25-69 years every three years where there are well organised screening arrangements and that the benefits of greater screening frequency are marginal, while costs escalate rapidly. However, recommendations for annual Pap smears continue because of concerns about non existent or ineffective reminder systems, accuracy of screening as currently delivered and possible changes in incidence of the disease and mortality rates among young women.

In recognition of the steps still needed to ensure effective screening programs, the prudent course is initially to endorse the recommendation of the CCSR for a two year screening interval, with a view to extending the interval to three years later when a more effective program is in place and if future experience and data support such a move.

Given the evidence from the available data on the age range for screening, there is a case that screening routinely commence three years after first sexual intercourse and cease at age 70 for women who have previously been screened.

Participation by women

The effectiveness of a population based cervical screening program is closely related to the proportion of women regularly screened, yet there is no organised plan for recruitment and recall of women in the target group.

Formal recruitment and recall plans should be developed, identifying target population groups, including those assessed as being at high risk, and identifying appropriate strategies for recruitment and recall with an indicative timeframe.

The CCESR assumes adoption of targets for cervical cancer screening outlined in Health for All Australians. These are:

- . to increase triennial participation in Pap smear screening to 50% or more of women aged 20-69 years by the year 1990, to 75% or more by the year 1995 and to all but a negligible number by the year 2000;
- . to establish organised population based cervical neoplasia screening programs in each State and Territory by the year 1990.

Appropriate goals should be identified, including participation rates and process targets, and reduction in morbidity and mortality from cervical cancer.

Using the data from the Report on barriers to screening and effectiveness of the different pilot strategies, States and Territories are invited to review their existing programs and develop broad strategies for accomplishing stated goals.

These include:

- . Pap smear screening by General Practitioners;
- . supplementary services provided by alternative smeatakers;
- . community and media based health education programs;
- . reminder and invitation based systems.

The Commonwealth is currently examining options for use of population based registers, such as the Electoral Roll or the Medicare enrolment file, and will provide further advice on their use, including privacy considerations attaching to their use.

Quality assurance in smeataking, smear reading and notification of results

The report raises a number of concerns about the adequacy of quality controls on cervical cytology, including smeataking, smear reading and notification of results. There is insufficient attention paid to these crucial elements of cervical cancer screening, which have such a direct impact on acceptable screening intervals, the confidence women have in the system, costs and ultimately health outcomes.

A consultant will be appointed to examine the need for and identify strategies for establishing appropriate levels of quality assurance in smeataking, testing, reporting and follow-up of abnormalities.

The consultant will work under the directions of a steering group, comprising membership from appropriate professional and consumer groups. A chairman will be appointed by the Commonwealth.

Terms of reference for the consultant will include:

- . review strengths and weaknesses of the current cytology quality assurance program;
- . examine the current laboratory cervical cytology accreditation and inspection program;
- . identify appropriate standards of cervical cytology; and
- . develop a national strategy for achieving compliance with those standards.

Management of abnormalities

The proportion of screened women who are currently investigated for abnormalities far exceeds the proportion who would be expected to develop invasive cancer in the absence of treatment. (At the same time, fail-safe systems to ensure that women with abnormalities are followed-up need to be instituted.)

The recommendations of the report concerning examination of currently available data and institution of a program of discussion by relevant professional societies and colleges have been referred to the Health Care Committee of the NH&MRC for urgent examination.

Organisation and funding

The Commonwealth is seeking views from the States/Territories on the framework and elements of a national cervical cancer screening program, and the appropriate roles for Federal and State governments.

The Commonwealth is also reviewing arrangements for funding of screening services, the costs of which are predominantly currently met through Medicare and Health Program Grants. This includes options for management of available financial resources in accordance with an agreed screening policy to improve the cost-effectiveness of the screening program.

CONSULTATION

Important in the consideration of cervical cancer screening services are the range of professional groups and organisations involved at different stages of the screening pathway, the need for sensitivity to user requirements and the need for effective co-operation and co-ordination.

The consultation strategy adopted by the Commonwealth involves approaching States, professional and consumer groups, using peak organisations such as the NH&MRC and the AHMAC sub-Committee on Women and Health, where appropriate. It is important that all groups likely to be involved share an appreciation of the elements of any effective national screening program.

The broad organisational framework and a national screening policy are key issues on which an early indication of views is sought. Issues of more complexity, such as quality assurance in cervical cytology, need both an environment and timescale conducive to adequate deliberation.

The report to Ministers in March will indicate areas where broad agreement can be achieved and identify remaining unresolved issues, together with appropriate further steps.

ATTACHMENTS

1. Draft national cervical cancer screening policy.
2. Strategies to increase the participation of women in cervical cancer screening.
3. Brief for consultant on quality assurance aspects in cervical cytology.
4. Management of abnormalities.
5. Organisation and funding of cervical screening services.

Commonwealth Department of Community Services and Health
January 1991

ATTACHMENT 1

CERVICAL CANCER SCREENING
A NATIONAL SCREENING POLICY

SUMMARY

A well-defined and uniformly adopted screening policy is fundamental to effective cervical cancer screening in a population. The major components of such a policy are the interval between screening tests, and the age at which screening tests should commence and cease. This paper examines policy options including those outlined in the Cervical Cancer Screening Evaluation Report (CCSESR), and draws some conclusions relevant to an Australian policy.

A screening policy needs to balance the benefits from screening, that is, the life years saved and the morbidity avoided, against the costs of screening, that is, effort and resources required, anxiety created and financial and opportunity costs. Any chosen screening program should be an optimal compromise between the benefits to be gained from, and the costs of all types arising from the screening process.

The recommendation of the CCSESR for a two year screening interval is acceptable, with the possibility of extending this to be reviewed in the light of future data and the introduction of an improved screening program.

Data presented in the CCSESR and other published studies demonstrate that around 90% of invasive squamous cell cervical cancers can be prevented by screening women aged 25 to 69 years at three yearly intervals where there are well organised arrangements for screening. Such a policy, if uniformly adopted by most eligible women, would be more effective in reducing deaths from cervical cancer than is the screening currently being carried out in Australia. This policy could also be more cost-effective than current screening arrangements.

The CCESR strongly emphasised the need for well organised arrangements for cervical cytology screening to ensure that screening is effectively carried out on a population basis. In particular, a high proportion of all eligible women should be screened regularly, and the quality of smear taking, smear reporting, follow-up of women with abnormalities and data collection should be optimal. The CCESR drew attention to significant shortcomings in these areas which led to the recommendation of a two rather than three year screening interval until the shortcomings in recruitment and quality assurance of cervical cytology screening in Australia can be addressed.

There is a clear association between the age at first coitus and a woman's risk of subsequently developing cervical cancer. This suggests that the age of commencement of cervical cancer screening should be related to the time of first coitus, rather

than a screening policy nominating a standard age for all women. Therefore, there is a case for cervical cancer screening to commence three years after the time of first coitus.

REQUIREMENTS OF AN OPTIMAL AUSTRALIAN CERVICAL CANCER SCREENING POLICY

Deaths of women from cervical cancer could be reduced with improved cervical cytology screening practice and organisation. A comprehensive national screening strategy, based on a defined screening policy is necessary to achieve optimal uptake and effective delivery of cervical cancer screening in Australia.

An optimal and acceptable cervical cancer screening policy for Australia should satisfy the following requirements:

- (i) offer a satisfactory level of protection from cervical cancer, within the practical constraints;
- (ii) have an acceptable degree of benefit in relation to costs incurred, i.e. acceptable cost-effectiveness;
- (iii) be understood and adopted by all women at risk, in particular those who are currently under-screened.
- (iv) have an effective communication strategy in regard to both consumers and the professionals who advise them.

Fundamental to a screening policy are -

the interval at which cervical cancer screening is repeated for women who have normal Pap smears;

the target age group for screening.

Currently in Australia authoritative bodies such as the Royal Colleges, cancer councils, NHMRC, and health departments have varying guidelines on the interval at which routine screening should be repeated, and on the age range of women who should be screened. This situation is also seen in other countries (see Appendix 1). This confusion over screening policy is reflected in the lack of uniformity of clinical practice.

This paper examines the rationale and evidence for various screening policies, describes the impact of possible policy options, and draws conclusions about the optimal cervical cancer screening policy for adoption on a national basis. The paper draws on the Cervical Cancer Screening Evaluation Report (CCSESR) of the Australian Health Ministers' Advisory Council (AHMAC)(1) and other relevant material.

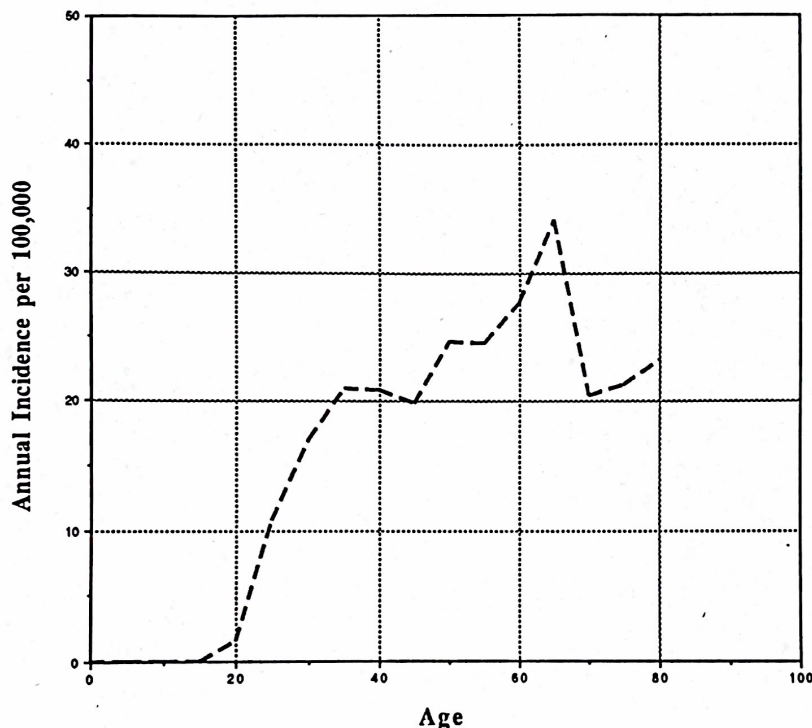
BACKGROUND ON CERVICAL CANCER

Incidence

Cervical cancer is the sixth most common cancer amongst Australian women. In 1982 there were 948 new cases. The lifetime probability of a woman developing the disease is about 1 in 90 (2). This probability would be higher in the absence of cervical cancer screening.

Cervical cancer increases in frequency with age. Only two cases occurred in women under 20 years in 1982-4 (3). The disease is very rare in women aged 20 to 24 years, in whom less than 2% of cases occur (10 in 1982), and in whom the risk of cervical cancer is 1/20th that of women 65-69 years. The incidence rate rises rapidly to a plateau at 35 to 39 years, after which it rises slightly to peak at 65 to 69 years and then declines slowly (2). While the highest incidence rates are in the 65 to 69 year age group, the greatest number of cases occur in the 35 to 39 year age group, as there are more women of this age.

Figure 1: Annual incidence of cervical cancer in 1982 per 100,000 women⁽¹⁾



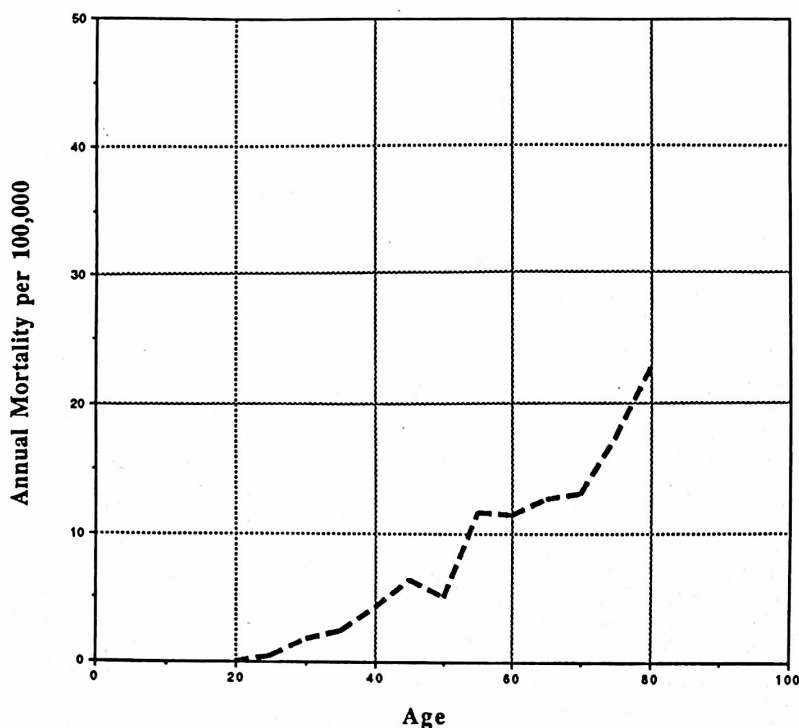
(1) Source: Ref (2)

Mortality

There are around 350 deaths per year from cervical cancer. Deaths from cervical cancer increase steadily from about 25 years into old age. There were no deaths from cervical cancer in women under 25 years of age in 1988. Only around 4% of deaths occur in women 25-29 years (15 in 1988). The majority of deaths, that is, around 70%, occur in women 55 years and over (249 in 1988) (4).

Mortality from cervical cancer has been constantly declining since 1950 when mortality data first became available. This is likely to be due to a decline in incidence of cervical cancer, earlier detection by screening, and improved treatment of early stages of cervical cancer.

Figure 2: Annual mortality from cervical cancer in 1986 per 100,000 women⁽¹⁾



(1)

Based on ABS mortality data for 1988 and ABS population estimates for 30 June 1988

Natural history of cervical cancer

Squamous cell cervical cancer of the cervix is preceded by the precancerous condition of cervical intraepithelial neoplasia (CIN). There are three sequential stages of severity of CIN; CIN 1, CIN 2 and CIN 3. The natural history of CIN can be either progression to more severe stages and invasive cervical cancer in some cases, or spontaneous regression back to lower grades of CIN or normality. It is not possible to predict which cases will regress and which cases will progress, although more severe CIN has a higher probability of progression than lower stages.

Studies have estimated that between 13-60% of CIN 1 and CIN 2 cases progress without treatment (5-12), and between 30-74% of untreated, severe CIN 3 progress to invasive cervical cancer over a period of between one to twenty years (13-16). Estimates of the progression time of CIN vary considerably. It is estimated that CIN may take an average of seven years to reach the most severe stage, ie carcinoma in situ (CIS) (7,17). CIS may then take an average of eight to ten years to become invasive cervical cancer (18). However, rates of progression of cancers are not uniform. Some invasive cancers will take a longer period to develop, and some will take a shorter period. This is reflected in the wide range of estimated progression times.

With present patterns of detection and treatment in Australia, CIN 1-3 is nineteen times more common than invasive cervical cancer on population screening (19). The majority of CIN does not currently progress to invasive cervical cancer as treatment of CIN prevents such progression.

Possible changes in cervical cancer in younger women

In recent years it has been suggested that cervical cancer among young Australian women is becoming more "aggressive", with a shorter precancerous stage, a more advanced stage at diagnosis, and lower survival rates(20). However, data from Victoria, Queensland, New South Wales and South Australia do not support this hypothesis.

Data from the Victorian Cytology Service and the Queensland Radium Institute suggest that technical problems with screening and false negative reports rather than rapid onset cancer is the cause in those cases of cervical cancer found in close time proximity to a negative Pap smear report (21,22).

In Queensland there has been a shift to earlier stage at diagnosis of cervical cancer in women under 40 years and improvement in case survival rates when data from 1982-1988 are compared with data from 1960-1964 (23). In New South Wales during the period 1973-1982 there was no evidence of a trend towards more severe disease in young women. Rather, younger women had an earlier stage of the disease at diagnosis (24). In South Australia, case survival is unchanged for young women diagnosed during 1977-1981 and 1982-1987 and remains better than the survival rate for older women (25)

A task force of the International Union Against Cancer concluded that there was insufficient evidence to support more rapid progression of cervical cancer in younger women, and that potentially the reverse was true (26). In Australia, the available data do not suggest that a more rapidly progressing and lethal type of cancer is becoming common amongst younger women. However, it is essential that adequate data are available to monitor this area of concern. The absence of routine collection of data relating to CIN and CIS cases, and the histopathology of invasive cervical cancer makes this task extremely difficult.

CERVICAL CANCER SCREENING

Cervical intraepithelial neoplasia, a potential precursor to squamous cell cervical cancer, is detectable by screening with Pap smears, and can be treated with the aim of preventing its progression to invasive cervical cancer. Unlike the majority of cancers, squamous cell cervical cancer is preventable in over 90% of cases. The exact proportion prevented depends on the screening interval adopted and age of women screened (27,28).

Effectiveness of cervical cancer screening

Several studies conducted overseas have shown that cervical cytology screening is effective in reducing both the incidence of cervical cancer and mortality from cervical cancer. In those countries which adopted cervical cytology screening in the 1960s, a 30% to 75% reduction in new cases of cervical cancer occurred over

two to three decades (29-32). Similarly, reductions of 20% to 70% in deaths from cervical cancer were observed (33-34).

Other studies have shown that greater incidence and mortality reductions are seen in areas which have a higher participation in screening by eligible women (35-40).

The screening policies adopted overseas are varied. For example, in the Nordic countries screening intervals range from two to three yearly to five yearly. The age group of women eligible for screening varies between 30-49 years and 25-69 years. In those countries which have screening programs available to all eligible women, and which screen 70% or more of these women, deaths from cervical cancer were reduced by 34%-80% in the period from 1963 to 1982 (34). This suggests that screening intervals longer than those generally adopted in Australia, and narrower screening age ranges, will effectively prevent cervical cancer and reduce deaths from the disease.

THE IMPACT OF SCREENING INTERVAL AND AGE FOR SCREENING ON THE EFFECTIVENESS OF CERVICAL CYTOLOGY SCREENING

The potential impact of cervical cancer screening in a population on deaths from cervical cancer depends on the frequency at which screening is performed and the age range of women at which screening is targeted.

Screening interval

To be effective, screening must be repeated at an interval which is less than the duration between the onset of preclinical CIN and its progression to invasive cervical cancer. This interval is estimated to be on average from fifteen to seventeen years, although a wide range from one to thirty years is found (18).

Age range for screening

The benefit of cervical cancer screening in any age group is dependent upon the extent to which cervical cancer is a health risk at that age. Cervical cancer is most commonly found and is an increasing cause of death in women over 35 years. These women are therefore potentially the greatest beneficiaries of screening. It is of concern that screening rates in Australia decline markedly in women over 40 years of age (41).

Although cervical cancer occurs across the whole age span of adult women, frequent screening of considerable numbers of very young women amongst whom only very small numbers of cancers occur produces marginal benefit. The costs associated with screening include not only the direct financial costs of providing screening, but also the financial and other costs incurred by women. Additional costs are created by any unnecessary treatment of abnormalities which would have spontaneously regressed.

An optimal screening policy

A chosen screening policy should strike an optimal balance between finding maximum numbers of cancers and achieving affordable costs. Adoption of a cost-effective and practical approach is essential.

PROPORTIONS OF CERVICAL CANCER PREVENTED USING DIFFERENT SCREENING POLICIES

In attempting to define an optimal screening policy, it is helpful to examine the differences in the proportions of cervical cancer prevented by commencing screening at different ages and at various intervals.

Such data are available from two studies:

- i) A collaborative study by the International Agency for Research on Cancer (IARC) investigated the risk of cervical cancer amongst women who had had negative smears, as they constitute the population at which screening is directed. Women with an initial positive smear are not included in this study. Screening data on more than one million women contributed to this study. Women, mostly aged 30-64 years, already entered into a screening program were included (27);
- ii) A study by the Kaiser-Permanente Medical Centre in California, which reviewed the screening history and cervical cytology of 85 women diagnosed with cervical cancer. Women 20-69 years with no previously reported abnormality on cervical cytology were included (28).

Screening interval

The percentage reduction in the cumulative rate of cervical cancer estimated by the two studies above, according to different screening intervals is shown in Table 1. The estimates for the two studies are of the same order of magnitude and probably fall within 95% confidence intervals, although they are not exactly the same values.

Screening every three years or less prevents over 90% of cervical cancers. Only a small improvement in prevention is gained by screening every two years rather than every three years. There is minimal improvement from screening annually rather than biennially. Screening every five years still offers a high degree of protection (84%), though somewhat lower than for every three years. Little marginal benefit is gained from a screening interval below three years. With an interval shorter than three years, the number of Pap smears taken over a woman's life increases significantly, as do the associated costs.

TABLE 1: Percentage reduction in the cumulative rate of invasive cervical cancer with different frequencies of screening

Screening interval (years)	IARC study (27): % reduction in cervical cancer(a) 35-64 y	MORELL et al(28): % reduction in cervical cancer 20-65 y
1	93.3	98.8
2	93.3	96.5
3	91.4	89.4
4	-	80.0
5	83.9	-
10	64.2	-

(a) Assuming a screen occurs at age 35 and that a previous screen had been performed

It has been suggested that screening programs should commence with two annual smears to overcome concerns about the accuracy of cervical cytology. However, there are no empirical studies to support this practice, and modelling using the IARC data showed virtually no benefit (42). Commencing routine screening with two annual screens increased average life expectancy by only 0.3 days, while corresponding additional costs were very large. Thus this practice is not useful or appropriate. It would be more appropriate to effectively address concerns about the quality of cytology.

Age at commencement of screening

The risk of cervical cancer is closely related to sexual history. A study of 3280 cloistered nuns suggested cervical cancer is very rare or absent in such women (43). Women who commence sexual intercourse at an early age, or who have multiple sexual partners, or whose partners have multiple sexual partners are more likely to develop cervical cancer. Four case-control studies all found that women with cervical cancer were more likely to have had first coitus under 17 years of age, or to have made multiple marriages, than were women without cancer (44-47).

Analysis of the IARC collaborative study shows that there is minimal change in the probability of developing or dying from cervical cancer, whether three yearly screening is begun at ages 17, 20, 23 or 26 (42)(See Table 2). If screening is begun at age 20 instead of age 17, the probability of developing cervical cancer will be decreased by only an additional 3 in 10,000 compared with a life-time risk without screening of 250 in 10,000 women. The increase in risk from moving the commencement of screening to 23 or 26 years is similarly small. The change in risk is larger in moving from 26 to 29 years (9/10,000), when the incidence of cervical cancer begins to rise markedly. Thus there is only a very small benefit from initiating screening at 17 years compared with 20, 23 or even 26 years. On this basis, it would give effective coverage to delay cervical cancer screening until 25 years of age.

TABLE 2: Estimated outcomes of cervical cancer screening for an average-risk, asymptomatic woman screened every 3 years to age 74

Estimated outcome	No screening	Age at which screening is begun, (years)				
		17	20	23	26	29
Probability of developing invasive cervical cancer per 10,000 women	250	37	40	44	51	60
Probability of dying from cervical cancer per 10,000 women	118	11	13	15	18	22
Increase in life expectancy, (days)	-	98	95	92	87	80
Marginal cost of adding an additional year of life expectancy, (\$) *	-	\$50095	33078	20612	14747	10537

* comparisons are 29 versus no screening, 26 versus 29 and so forth.

Source: reference (42)

The IARC study did not take into account the sexual history of women screened. On the basis of our understanding of the causes and natural history of cervical abnormalities, screening is not appropriate for some years after sexual intercourse commences. Adopting an absolute age for commencement of screening is inappropriate.

The CCSESR recommended that:

"... women should be screened from the age of 18 years or within a year of first sexual intercourse, whichever is later."

This may delay screening of women who became sexually active at an early age beyond a safe limit for the development of precursor stages of cervical cancer. As cervical abnormalities are associated with sexual intercourse, it may be appropriate to make decisions about the commencement of screening only in relation to the time of a woman's first sexual intercourse, rather than setting a minimum age of commencement. As discussed earlier, cervical cancer has a long precursor stage of several years. Bearing in mind the minimal gains generally from commencing screening at an early age, it would appear optimal at present to commence screening about two to three years after first sexual intercourse. Data on this issue should be collected as they become available.

Age at cessation of screening

In Australia the peak incidence of cervical cancer is in the 65-69 year age group, and mortality from cervical cancer continues to rise into old age. It seems appropriate, therefore, to continue screening women up to the age of 70 years and then stop, as recommended by the CCSESR. The evidence suggests that women over 70 years who have been sexually active but have never had a Pap smear should be screened at least once as the benefit of Pap smears for unscreened women over 70 years is substantial, compared with the small benefit for previously screened women over 70 years (42) .

SCREENING POLICIES

The combined effect of varying the screening interval, and the age range for screening has also been estimated by the IARC study (2)(See Table 3). This table also shows the number of smears per woman per lifetime for each policy, as an indicator of the efforts and resources needed to achieve the reductions shown.

Screening women 20-64 years every three years gives only marginally lower prevention rates than yearly screening (93.3% vs 91.2%). Restricting three yearly screening to 25-64 years gives a further minimal reduction (91.7% vs. 89.8%), while raising the age of commencement to 35 produces a 10% drop in prevention rate. A very cautious screening policy of annual smears from age 20 to 34 years thence triennially also produces only a small benefit over three yearly screening of women 20-64 years (91.7% vs 91.2%).

TABLE 3: Effect of different screening policies on prevention of cervical cancer

Screening policy	% reduction in rate of cervical cancer	No. of Pap smears per life time
screening every year, 20-64y	93.3	35
screening every year, 20-34y, then every 3 years, 35-64y	91.7	25
screening every 3 years, 20-64y	91.2	15
screening every 3 years, 25-64y	89.8	13
screening every 3 years, 35-64y	77.6	10
screening every 5 years, 20-64y	83.6	9
screening every 5 years, 25-64y	81.8	8

* assuming incidence rates as found in Western Europe

Source: adapted from reference (27)

Risk factors and screening

The precise causes of cervical cancer are not yet known, although a number of risk factors have been identified. Age is a major determinant of risk. Other associated factors include sexual history, socio-economic status, aboriginality, smoking, previous screening history, and possibly HPV infection. Women who have had their cervix removed during hysterectomy, or have never been sexually active have no significant risk of developing cervical cancer.

Apart from age and the time of first coitus, other risk factors are not useful in setting screening policies. High proportions of cervical cancer cases occur in "low risk" women - the disease is not confined to "high risk" women. Therefore, all women who have been sexually active and have a cervix should be screened regularly, irrespective of the presence or absence of other risk factors.

The main determinant of screening frequency is the natural history of the disease. There is no evidence that cervical cancer behaves differently and develops more rapidly in women with additional risk factors (27).

However, the identification where possible of high risk groups of women who have been found to be comparatively underscreened is useful for targeting recruitment campaigns. The CCSESR identifies these groups as including Aboriginal women, women living in isolated rural areas, women from lower socio-economic groups and women from a non-English speaking background.

Detection of other conditions

It has been suggested that screening asymptomatic women for cervical cancer provides an opportunity for the detection of other asymptomatic conditions, such as ovarian cancer or sexually transmitted diseases. There are no data to support this at present. The frequency of cervical cancer screening should not be chosen on this basis. This does not preclude seeing women more frequently for other conditions as appropriate, such as the monitoring of borderline hypertension.

Cost-effectiveness of different screening policies

The cost per life year gained from current cervical cancer screening practice is around \$44,000. The CCSESR estimates this could be reduced by an organised screening program with triennial screening of women 18-69 years to around \$24,000 per life year saved, or \$31,000 per life year saved with biennial screening. Annual screening in an organised framework at \$53,000 per life year saved would be less cost-effective than current screening (1)(See Table 5).

The additional cost for each life year saved by adopting two yearly rather than three yearly screening would be \$87,000 per life year saved, and for adopting annual rather than two yearly screening would be \$210,000 per life year saved.

Screening women aged 18-24 years two yearly, in addition to women 25-69 years, creates an extra cost per life year saved of over \$767,000 per life year, even when the greater life expectancy for women 18-25 years is taken into account. The additional cost per life year saved from screening women under 20 years is likely to be even higher, as this saves very few lives. In comparison, including women 60-69 years in screening improves cost-effectiveness, due to the high incidence of cervical cancer in this age group.

Clearly, cost-effectiveness declines markedly at decreased screening intervals and larger age ranges. The increased costs from this extra screening are disproportionate to the benefits gained. More intensive screening policies lead to much greater imposition on large numbers of women for whom the benefit is relatively low, higher costs, lower cost-effectiveness, and reduces the health care dollars available for other health interventions.

TABLE 5: Cost and cost-effectiveness of different screening policies with organised screening

	Age range (years)	Screening interval		
		1 yearly	2 yearly	3 yearly
Total cost for 1991-2020(\$million)	18-69 y	\$5,720	\$2,924	\$2,001
	25-69 y	-	2,233	1,527
Average cost per life year saved	18-69 y	\$52,839	\$30,782	\$23,703
	25-69 y	-	23,736	18,371
Marginal cost per life year saved in moving to shorter screening interval*	18-69	\$210,256	\$87,075	\$40,258

Marginal cost per life year saved from:

- (a) including women 18-24 y in screening \$767,770
- (b) including women 25-29 y in screening \$107,111
- (c) including women 65-69 y in screening \$25,814

* ie, 1 yearly = moving from 2 yearly to 1 yearly, etc

Source: adapted from reference (1)

Summary

The IARC and Kaiser-Permanente studies clearly demonstrate that a three year screening interval is very effective, and that commencing screening at age 25 provides a very high degree of protection against cervical cancer. Furthermore cost-effectiveness is optimised by this screening policy. Why then has Australia not adopted such a policy?

PROBLEMS IN ESTABLISHING A UNIFORM SCREENING POLICY IN AUSTRALIA

Cervical cancer screening in Australia has tended increasingly to the practice of annual screening, commencing at the age of first sexual intercourse, no matter at how young an age this occurs. It is noted that this policy was adopted in the absence of any studies on the effect of variations in the screening interval and age range. Cervical cancer screening in Australia has been under close scrutiny over the last three years by the Cervical Cancer Screening Evaluation Steering Committee (CCSESC) of the Australian Health Ministers' Advisory Council (AHMAC). Now is the time for critical appraisal of traditional screening practices and of the options for improvement.

Hesitation in adopting less frequent screening and an older age for commencement of screening appears to stem from four issues:

1. A perception that there has been a large increase in the incidence and mortality of cervical cancer amongst younger women

This has to some degree been accepted as common wisdom. A report from South Australia on cervical cancer incidence from 1977 to 1986 showed an 80% increase in women under 50 years and a 25% decrease in women over 50 years (25). Although incidence rates had risen in women under 50 years, these rates are only marginally above national rates. The increase in incidence in South Australia appeared to be large as initial rates were lower than average compared with other States.

In contrast, in New South Wales, over the ten years from 1973 to 1982 the incidence of invasive cervical cancer decreased by an average of 1.3% per year. Age-specific incidence showed this reduction in all age groups above 35 years. There was no change in incidence in women 15-34 years (24).

Similarly, in Queensland there has not been a statistically significant increase in incidence in younger women when 1960-64 and 1982-86 data are compared (23).

The number of cervical cancer cases and deaths in women under 30 years of age is only a small proportion of the total cases and deaths (10% and 1% respectively). Where only small numbers of cases of disease are observed, as for cervical cancer in women under 30 years, calculated incidence rates are subject to significant random fluctuations and may not represent actual trends. This presents difficulty in interpretation of small data collections at the State/Territory level, where

only a small change in numbers will cause a large change in rates. Larger, national incidence data collections are only available for 1982-1985. Over this short period there has been a 2.8% increase in the age-standardised incidence rate. No consistent increasing trend is observable in women under 30 years(3).

Initial reports on age-specific cervical cancer mortality in Australia from 1950 to 1980 showed an increased incidence in women under 35 years, although overall mortality continued to decline(55). However, a subsequent report covering the period from 1950 to 1984 showed a decline in incidence in women under 35 years(56).

Suggestions of increasing cervical cancer incidence and mortality among younger women are not substantiated when national data are examined. However, it is recognised that only limited national data are currently available which affects the carrying out of long-term epidemiological studies.

2. **Concern that rapid onset cervical cancer, or a more aggressive variant, is becoming more common**

The increasing appearance of a rapidly progressing cervical cancer has been proposed since the early days of cervical cancer screening. There are little convincing data to support this hypothesis. It is likely that some of these cancers may be due to false negative Pap smear reports, rather than to rapid growth rates (18). As discussed earlier, such a concern about cervical cancer in younger women has not been substantiated in Australia. Specialist clinics which see the few cases that do occur treat a highly selected and small group of women not representative of the general screened population. In such clinics, therefore, the overall incidence of these cases appears to be higher than it is.

3. **Difficulty in ensuring women attend for re-screening at the designated interval**

In the absence of reminder or recall mechanisms, a recommendation for a particular screening interval often translates into a much longer, or irregular, screening interval. There is concern that recommending screening every two or three years will result in women attending for screening only every four to six years. Large numbers of Australian women are currently under-screened, highlighting the need for effective strategies for encouraging women to participate in screening at the appropriate frequency. The CCSESR examined this problem and made several recommendations designed to ensure that the majority of Australian women are screened regularly. This is discussed in another paper.

4. **Uncertainty about the accuracy of cervical cytology**

There is some concern that the accuracy of cytology reporting is sub-optimal. Anxiety about false negative reports and under-calling of abnormalities may result in recommendations for more frequent screening. It is known that the cytology laboratory quality assurance practices vary widely between laboratories(1). Therefore, these concerns may to an extent

be justified. However, a number of studies have found that 50% or more of false negative Pap smear reports were due to inadequate smear taking rather than laboratory error(7,49-54). The quality assurance of cervical cytology was also addressed in the CCESR. Several recommendations on quality assurance were made. Commonwealth plans to take this further are outlined in another paper.

PROPOSED AUSTRALIAN CERVICAL CANCER SCREENING POLICY

Based on the epidemiological evidence presented earlier, a routine screening interval of three years can be confidently recommended in the context of optimally organised screening arrangements with high quality screening.

However, it is acknowledged that there are limitations in the present organisation of cervical cancer screening in Australia which place constraints on what is currently achievable in screening. High screening rates, recall and reminder mechanisms, reliable cytology and adequate epidemiological data for monitoring cervical cancer and screening performance are all essential if cervical cancer screening is to be optimally effective. If all these prerequisites were currently in place, a three year screening interval would be optimal. These are essential features of a national cervical cancer screening program. In the interim, while improvements to these areas are being made, it is concluded that it is prudent to adopt a shorter screening interval.

Cervical cancer screening should initially be carried out at two yearly intervals as recommended by the CCESR

In view of the relationship of sexual intercourse to the risk of cervical cancer, it is appropriate to tie the commencement of screening to the age of first coitus rather than to a fixed age. The interval from first coitus to commencement of screening should be shorter than the precursor period of the majority of serious cervical abnormalities.

The available data on the age to commence screening as recommended by the CCESR, suggests that cervical cytology screening should routinely commence three years after first sexual intercourse. Similarly there is a case that screening should cease at age 70 years for women who have been previously screened.

It is recognised that the effectiveness of this screening policy is conditional upon the implementation of effective recruitment, reminder and recall strategies, and on the monitoring of all aspects of cervical cytology screening.

Therefore, the issues of recruitment of women to screening and of quality assurance should be addressed concurrently, and screening policy be reviewed in 1993 when appropriate screening systems are in place as recommended by the CCSR.

Commonwealth Department of Community Services and Health
January, 1991

APPENDIX 1.

EXAMPLES OF RECOMMENDED SCREENING INTERVALS IN AUSTRALIA

National Health and Medical Research Council of Australia

Two smears one year apart, then not more than 3 years between screens.

Commence within three years of sexual activity beginning.

Stop at age 65 years if at least 2 previous smears and no abnormal smears in the preceding 10 years.

Royal Australian College of Obstetricians and Gynaecologists

Two smears 1 year apart, then 2 yearly.

If high risk (eg multiple sexual partners or previous abnormality) annual screens for life.

Royal Australian College of General Practitioners

Two annual smears, then not less than 3 yearly.

New South Wales Health Department

Annually.

Queensland Health Department

Annually until age 35 years, then 3 yearly.

Australian Capital Territory Department of Community Services and Health

Annually.

Australian Cancer Society

Annually until age 65 years.

New South Wales Cancer Council

Annually.

Anti-cancer Council of Victoria

Two yearly.

Family Planning Federation of Australia

Victoria - two yearly from 18 years or commencement of sexual intercourse

Tasmania - annually.

Northern Territory - Annually from within 1 year of commencing sexual intercourse to age 60.

EXAMPLES OF RECOMMENDED SCREENING INTERVALS OVERSEAS

United Kingdom

- Department of Health and Social Security
Five yearly from 35-65 years, once between 22-30 years in sexually active women, and early in each pregnancy.
- Royal Colleges of Obstetricians and Gynaecologists, Pathologists, General Practitioners, and Faculty of Community Medicine
Three yearly between 20-64 years.

United States of America

American Cancer Society,
Annually for 2 screens, then at least every 3 years to age 65 years.

The:

National Cancer Institute,
American College of Obstetricians and Gynaecologists
American Medical Association
American Academy of Family Practice
American Nurses Association
American Medical Women's Association

all endorse a policy similar to the following:
Three annual Pap smears from age 18 or commencement of sexual activity. Thereafter screens may be performed less frequently at the physicians discretion.

Canada

The Walton Report to the Canadian Health Department - 2 annual screens, then 3 yearly to age 35 and 5 yearly to age 60.

New Zealand

Two smears one year apart, then repeated at least every 3 years. Commencing with first sexual intercourse and ceasing at age 65 years.

Sweden

Four yearly for ages 30-49 years.

Iceland

Two or 3 yearly for ages 25-70 years.

Denmark

Around 3 yearly, 30-50 years.

Norway

Two to 3 yearly, 25-60 years

Finland

Five yearly, 30-55 years

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ATTACHMENT 2

CERVICAL CANCER SCREENING TASKFORCE

STRATEGIES TO INCREASE THE PARTICIPATION OF WOMEN
IN CERVICAL CANCER SCREENING

INTRODUCTION

The report of the Cervical Cancer Screening Evaluation Steering Committee (CCSESC) identifies deficiencies in the participation of women in cervical cytology screening in Australia and the barriers to full participation in screening by women at risk. The report makes recommendations concerning strategies to optimise the participation rate in screening.

This paper summarises the findings of the CCSESC and outlines a proposed national response to the report's recommendations on the recruitment and recall of women to cervical cytology screening. It also discusses the importance of educational and communication strategies in increasing participation in screening. It is intended that the Commonwealth's proposal will provide a framework for the States and Territories to contribute their plans for initiatives in this area.

The principal information sought from the States/Territories is an outline of State proposals within their jurisdiction on the organisation of recruitment and recall of women, together with an indicative budget.

AREAS FOR IMPLEMENTATION OF STRATEGIES TO INCREASE PARTICIPATION IN
CERVICAL CYTOLOGY SCREENING

The effectiveness of cervical cytology screening programs on a population basis is closely related to the proportion of eligible women being regularly screened. Given the underscreening of some population groups in Australia, strategies to increase participation in cervical cytology screening need to be identified and implemented.

The CCSESR presents extensive information on the pilot projects funded by the evaluation, which trialled a variety of new approaches to the delivery of screening, and recruitment of women to screening. The effectiveness of particular recruitment strategies, service delivery models, and their perceived advantages and disadvantages are discussed in the report.

Strategies to increase participation in cervical cytology screening need to be concentrated in three major areas:

- . the provision of services which are accessible and acceptable to women in the target population
- . the implementation of appropriate educational and promotional campaigns
- . the establishment of a population-based recruitment and reminder system

The provision of services which are acceptable and accessible to women in the target population

The majority of Pap smear tests in Australia are taken by general practitioners. This will almost certainly continue to be the case. Approximately eighty percent of women visit general practitioners at least once a year and therefore general practitioners are well placed to suggest the taking of a Pap smear during routine medical consultations. Research shows that this approach is effective and acceptable to the majority of women and practitioners.

However, the potential of this method of encouraging participation in screening is not being fully realised. Less than two thirds of women at risk from cervical cancer are being screened at sufficiently regular intervals.

The CCESC reported that there is a lack of choice of service providers in some areas of Australia, most notably in isolated rural areas, which is creating a barrier to participation in cervical cancer screening. Experience with pilot projects highlighted the need for providing screening services which are acceptable to women with special needs. For example, special screening clinics staffed by female smear takers, usually specially trained nurses, attracted higher proportions of under-screened and older women. The provision of culturally appropriate services is also essential. A highly personal approach was found to be important in a number of Aboriginal communities. The higher rate of cervical abnormalities and cancer in such groups of women warrants increased efforts to improve their participation in screening.

The Commonwealth is concerned to ensure the continuity of programs currently operating in the States and Territories. State and Territory responses to the issue of the provision of acceptable and accessible services should include recommendations on the future of existing programs.

The provision of appropriate educational and promotional campaigns

Research from overseas indicates that women who have favourable attitudes towards cervical cancer screening, who are accurately informed about screening and who hold beliefs in the benefits of screening, are more likely to attend cervical cancer screening. This was confirmed by pilot project surveys carried out in Australia where a range of promotional and educational programs were demonstrated to have significantly increased participation in screening.

The CCESR recommended that the introduction of an organised approach to cervical cytology screening should be accompanied by appropriate public education to inform women of the need for Pap smears, the availability of services and the appropriate interval and age range for screening.

Educational and promotional campaigns need to include specially designed programs for specific groups of women as well as mass media campaigns. One method of increasing community awareness and knowledge is to use opportunities provided by community and women's groups, clubs or workplaces.

The CCESR recommended that funding be provided for appropriately targeted and designed educational and promotional campaigns. There is a case for a coordinated educational and promotional strategy to define the most appropriate balance of national and more localised campaigns.

The establishment of a population-based recruitment and reminder system

The CCESR considers that the integration of general practice screening with a more systematic invitation approach is required. For example, the report suggests that general practitioners could be encouraged to establish reminder systems designed around the recommended screening interval, with a back-up State/Territory reminder system acting as a safety net by inviting women who have not been screened one year after the interval has expired.

The CCESR identified invitations using population based registers as potentially an important and efficient method of increasing screening coverage and found that there was strong support among women and medical practitioners for the use of personalised letters to invite women to screening. Available databases which provide names, ages and addresses include electoral lists and Medicare records.

The Commonwealth is seeking advice from the Health Insurance Commission and the Privacy Commissioner on the feasibility and privacy aspects of using national reminder systems to support local recruitment and reminder services such as those run by some general practitioners. While reminder services to women already screened are able to obtain the consent of women when they are screened, invitations to women previously unscreened raise unresolved issues. There may also be implications for State/Territory legislation.

The CCESR recommended that funds should be made available for a reminder system for all women who are overdue for their next test and who have not responded to other reminder strategies. A reliable, comprehensive record of women's screening histories is a necessary requirement for such a system. One possible approach as recommended by the CCESR is that this should be one of the functions of cervical cytology registries which should be established by State and Territories.

SUMMARY

Screening services will still largely be provided by general practitioners, but special services need to be designed for groups of currently underscreened women such as isolated rural women, traditional Aboriginal women and women from a non- English speaking background to whom the services currently available are either inaccessible or culturally inappropriate.

Funding is necessary for an effective recruitment and reminder service which ensures optimal participation in cervical cytology screening. The feasibility of the use of population-based registers for recruitment must be addressed. The views of the States and Territories are sought on the likely effectiveness and costs of cervical cytology registries to provide a fail-safe reminder system for women who are overdue for their next Pap smear. Strategies are also necessary for ongoing educational and promotional campaigns which should include a range of programs both nationally and community based.

Commonwealth Department of Community Services and Health
January, 1991

CERVICAL CANCER SCREENING

QUALITY ASSURANCE IN CERVICAL CYTOLOGY

Maintenance of high standards of cervical cytology are the very foundation of an adequate cervical cancer screening program. The level of confidence placed in the service by women being screened and the practitioners advising them are critically affected by those standards. Some women are undergoing an unnecessarily high frequency of Pap tests, partly due to doubts as to the reliability of the tests taken.

The CCESR stresses the dependence of critical steps in the screening pathway on a range of quality assurance measures, including:

- . smear taking, involving regular feedback from cytology laboratories on the quality of smears taken;
- . smear reporting, involving external and internal quality assurance procedures;
- . notification of results; and
- . reporting of abnormalities and services for managing women with abnormalities.

The CCESR that much further investigation of these very complex issues is required, in consultation with the relevant professional groups. In particular, cytology laboratory quality assurance is of central importance.

The diverse range of funding methods currently used to reimburse the variety of cytology services in Australia complicates cost-effectiveness analyses of services provided.

It is also abundantly clear that these investigations cannot be achieved within the current reporting timescale.

The option preferred by the Commonwealth is to commission further research on cervical cytology laboratory quality assurance under the direction of a steering group comprising representatives from appropriate professional bodies, together with recognised experts in the field.

Terms of reference for the further investigations proposed and composition of the steering group are attached.

Commonwealth Department of Community Services and Health
January 1991

**CERVICAL CANCER SCREENING EVALUATION REPORT
CONSULTANCY ON QUALITY ASSURANCE ISSUES**

OBJECTIVE

In response to the findings and recommendations of the Cervical Cancer Screening Evaluation Report, the consultant will examine the need for and identify strategies for establishing appropriate measures for quality assurance in cervical cytology smear reporting, including its relationship to the adequacy of smears taken and the follow-up of abnormalities. The consultant will work under the directions of a steering group and report to that group as directed.

The strategy will include plans for reviewing the effect of existing funding arrangements for cervical cytology services, including provision of recommended quality assurance, training and co-ordination mechanisms.

Operational and outcome targets for cytology laboratories will be identified, together with associated data collection and monitoring systems.

The consultant will be funded by the Commonwealth but acceptable to all members of the consultancy steering group.

The consultant will establish appropriate working arrangements with member organisations, to ensure preservation of confidentiality.

PROPOSED COMPOSITION OF STEERING GROUP

- Chair: - to be nominated by the Commonwealth
- Members:
- Royal College of Pathologists of Australia (RCPA)
 - National Association of Training Authorities (NATA) - Medical Testing Registration Committee
 - National Pathology Accreditation Advisory Council (NPAAC)
 - Australian Society of Cytology (ASC)
 - Royal Australian College of General Practitioners (RACGP)
 - Royal Australian College of Obstetricians and Gynaecologists
 - Family Planning Federation (FPF)
 - Dept. Community Services and Health
 - nominee of the Minister for Community Services and Health

DRAFT TERMS OF REFERENCE

- . In conjunction with the RCPA and NPAAC, review the current cytology quality assurance program and assess its strengths and weaknesses.
- . In conjunction with NATA, examine the current cervical cytology laboratory inspection process. Obtain data on current standards and estimate confidence limits.
- . Identify appropriate and achievable standards of cervical cytology, including minimum levels of specificity and sensitivity.
- . Develop a national strategy for achieving compliance with those standards. The strategy should address:
 - the accreditation system;
 - standards of professional qualifications, training and experience for smearing;
 - criteria for provision of comprehensive, timely and efficient service to practitioners;
 - measures to improve and monitor day to day testing and reporting;
 - provision of data to support regional and national monitoring systems, including research programs, on issues such as participation rates, adequacy and accuracy of tests and incidence of abnormalities;
 - feedback to smear takers and mechanisms to keep them informed of developments in smearing and cervical cytology;
 - reporting standards for abnormalities;
 - co-ordination with general practitioners, recruitment and recall services, registries (where operating) and the individuals; and
 - fail-safe systems to ensure follow-up of abnormal smears.

Commonwealth Department of Community Services and Health
January 1991

CERVICAL CANCER SCREENING
MANAGEMENT OF ABNORMALITIES

The report notes that up to 15% of women screened are found to have abnormalities. Approximately half of these result in treatment of infections or repeat smears. Less than two percent of tests report definite evidence of CIN or invasive cancer.

Nearly 50% of current expenditure on cervical cancer screening is accounted for by investigation of women who receive abnormal Pap smears.

The proportion of women who are currently investigated far exceeds the proportion of women who would develop cervical cancer if no treatment were given. The anxiety engendered in these women is also a significant cost of screening.

Lack of Australian data, the lack of follow-up and monitoring systems to ensure treatment is effective hinder improved management of this aspect of the screening pathway. Nevertheless, it seems that variations in the management recommendations of the laboratories, variation in the guidelines produced by professional societies and those used by individual colposcopists may also be factors in current levels of investigation.

The report recommends examination of currently available data and a program of discussion, research and data dissemination be undertaken by the relevant professional societies and colleges.

This issue has been referred to the Health Care Committee of the NH&MRC, together with a number of issues associated with the screening policy.

An early indication of the views of the Committee has been sought for inclusion in the Commonwealth's initial response to Health Ministers in March 1991.

Commonwealth Department of Community Services and Health
January 1991

CERVICAL CANCER SCREENING

ORGANISATION AND FUNDING OF CERVICAL CANCER SCREENING SERVICES

ORGANISED VERSUS OPPORTUNISTIC APPROACH TO CERVICAL CANCER SCREENING

The Cervical Cancer Screening Evaluation Report notes that the greatest impact on cervical cancer has been achieved in countries or regions which have had organised screening programs. Recommendations of the World Health Organisation and the International Agency for Research on Cancer on cervical cancer screening have identified the requirements for an effective program. Such a program needs attention to all aspects of 'the screening pathway', which comprises:

- . screening of the target population at regular intervals;
- . provision of accessible and acceptable services for taking Pap smears;
- . provision of high-quality services for reporting smears;
- . ensuring follow-up of women with abnormal smears; and
- . a system for the monitoring and evaluation of the whole screening program.

Existing services, characterised in the report as 'opportunistic', are primarily provided through general practitioners, supported to some extent by special services aimed at attracting unscreened, or underscreened women for whom there are a number of recognised barriers to participation.

Options identified in the report for improving services include:

- . restricting delivery of cervical cancer screening services to defined centres, supported by management of abnormalities in specialised assessment centres and block grant funding of services for taking and reporting Pap smears;
- . retaining current arrangements through general practitioners and the current mix of private and public laboratories; or
- . augmenting existing screening services with an organised approach.

The recommendations of the report favour the third option and seek to identify the minimum modifications to the current system essential to an effective and efficient organised program. These elements are discussed individually in the following sections.

In developing a national screening program, it will be necessary to reach a consensus on those elements.

COMMONWEALTH AND STATE ROLES

Discussion of the respective roles of the Commonwealth and States/Territories needs to consider:

- . screening policy development, co-ordination and monitoring; and
- . responsibilities for service delivery.

Development of an appropriate screening policy in the light of current epidemiological, behavioural and economic research, is a matter primarily for health authorities, in consultation with professional and consumer groups, co-ordinated through the National Health And Medical Research Council and the AHMAC sub-Committee on Women and Health. The Commonwealth does not propose to proceed with establishing a National Cervical Cancer Screening Advisory Committee for the present.

Subject to any consequences flowing from the current broader examination of Commonwealth and State/Territory roles in health, no changes are proposed to the existing distribution of responsibilities, pending availability of the findings of the proposed consultancy on quality assurance aspects. In practice, this means enhancement of existing roles, rather than redistribution. Thus, State roles in recruitment and recall systems may be enhanced, as may the Commonwealth role in quality assurance matters.

THE TARGET POPULATION

The draft screening policy recommends a population based approach for women at risk. Within the target population, high priority groups are to be identified according to risk, risk being measured by higher incidence of the disease or levels of screening uptake. The report identifies a number of groups in a high risk category, including Aboriginal and elderly women.

Development of State or Territory plans would include analyses of demographic data to identify numbers and distribution of the target population, with special reference to high risk groups.

Comprehensive screening strategies would be developed in the light of the studies, and would incorporate a notional timescale for achieving set targets.

TARGETS

The report assumes adoption of the targets for cervical cancer screening outlined in Health for All Australians. These are:

- . to increase triennial participation in Pap smear screening to 50 percent or more of women aged 20-69 years by the year 1990, to 75 percent or more by the year 1995 and to all but a negligible number by the year 2000;
- . to establish organised population based cervical neoplasia screening programs in each State and Territory by the year 1990.

Outcome targets would include participation rates, disaggregated for newly recruited women and recalls.

Process targets would focus on significant milestones in setting up elements of the screening pathway.

These intermediate targets are indicators en route to the ultimate objective of cervical cancer screening; the reduction in premature deaths from cervical cancer to 10 percent or less of the potential lives lost in the absence of screening.

ADMINISTRATION/CO-ORDINATION

State/Territory units play a key role in planning, co-ordination and administration of regional and local cervical cancer screening programs and support services. Their functions may vary between jurisdictions, depending on the roles allocated to non-government organisations such as the Family Planning Association and the presence of cervical cytology registries.

The views of States/Territories are sought on the most appropriate administration and co-ordination structures for their jurisdictions.

ROLE OF CERVICAL CYTOLOGY AND CANCER REGISTRIES

Features of an organised approach to cervical cancer screening that are more or less essential to increasing participation rates are:

- . reminder services for women who do not otherwise attend rescreening;
- . fail-safe systems to ensure follow-up of women with significantly abnormal smears;
- . compilation of individual womens' cervical screening histories;
- . monitoring of screening rates and cervical cancer.

The CCSR notes that cervical cytology registries, which record the results of Pap smears, would fulfil all these functions. The report recommends the establishment of cervical cytology registries, together with funding for cancer registries, to monitor cervical cytology and cancer cases.

The Commonwealth notes that alternative arrangements may operate in some States. Registries may raise issues of privacy, although this was not found to be an issue by the two pilot projects which operated registries. The Commonwealth seeks States' and Territories' views on preferred methods for providing these functions.

There are also questions about inter-state mobility and reliability of addresses which will have to be examined if effective reminder systems are to be designed using registers.

COMMUNICATIONS PROGRAM, INCLUDING MEDIA

The communications program, or strategy, would include national and local elements. At the national level, a spokesperson will be appointed to assist in promoting the screening policy to professional and consumer groups. Professional advice on marketing the policy may also be sought.

States should examine their needs for educational and promotion campaigns as an integral element of the strategy.

SPECIAL PROGRAMS AND PROJECTS FOR HIGH RISK GROUPS

In accordance with the recommendations of the report, States would be expected to continue to be responsible for recruitment and recall services, including special services for high risk groups.

Attachment 2 seeks to draw together strategies to increase participation that were found to be effective in the evaluation. States/Territories should identify their plans in the light of regional requirements.

WORKFORCE EDUCATION AND TRAINING

The Report refers briefly to professional education about cervical cancer screening, and includes some estimates of increased cervical cytology workload generated by a national screening program.

The undergraduate and ongoing education needs of medical and nurse practitioners, both in relation to smear taking and screening

practices, need to be examined in depth, together with training of cytotechnologists. The Commonwealth could initiate appropriate studies.

DATA COLLECTION AND MONITORING

Screening services are by their nature costly and are particularly dependent on routine collection and analysis of data to ensure they are efficient, effective and well targeted. They are an indispensable element in epidemiological and clinical research on this disease.

Monitoring should encompass:

- . Participation rates of the target population and sub-populations;
- . adequacy of the tests being taken;
- . level of abnormality found on tests;
- . accuracy of the test reports;
- . long-term outcomes of treatment for screen-detected abnormalities;
- . impact on cervical cancer morbidity and mortality;
- and
- . the cost of the screening program.

TRANSITIONAL PLANS

The Commonwealth is concerned to ensure continuity of programs currently operating in States/Territories. State responses should include plans for continuation of projects or other arrangements for them to be superseded or replaced, as appropriate.

COSTS

The Commonwealth is seeking an indication of estimated extra costs for elements of an organised approach to cervical screening. This should include capital and operating costs, as applicable, for example;

- . administration/co-ordination;
- . cervical cytology registries;
- . subsidy for cancer registries;
- . communications program, including media;
- . special programs and projects;
- . workforce education and training;
- . data collection and monitoring.

FUNDING

Under current funding arrangements for cervical cancer screening, the Commonwealth meets most of the expenditure by governments, estimated in the report at \$125 million per annum. States meet some costs for screening support services and treatment in public hospitals. Women attending screening services also contribute substantial amounts.

There is a wide range of funding mechanisms currently in use both for smear taking, cervical cytology and follow-up treatment and management of abnormalities. Funding for the other parts of the screening pathway is limited.

The report examines a number of possible funding mechanisms aimed at providing appropriate incentives to improve standards of service and reducing the apparent anomalies arising from multiple funding sources. The future source, extent and nature of the funding of the other elements of the screening pathway is a matter which requires attention.

Further investigation of possible funding issues is being undertaken in conjunction with program development.

EVALUATION

The Commonwealth would probably wish to follow normal practice and seek an independent evaluation of the program.

States and Territories would be consulted in developing terms of reference and methodologies for the evaluation. The evaluation would need to scrutinise all steps of the screening pathway and be able to rely largely on data collected routinely as part of the monitoring of the program.

It is important that arrangements for the evaluation be put in place early in the life of the new program, with a view to reporting after three years of operation, say 1994/95.

Commonwealth Department of Community Services and Health
January 1991

Anti-Cancer Council of Victoria



17 January 1991

49-2498

Mr B. Candler
Acting First Assistant Secretary
Health Care Access Division
Department of Community Services & Health
GPO Box 9848
Canberra ACT 2601

Dear Mr Candler,

I received your letter of 10 January about the Cervical Cancer Screening Evaluation Report. I've read the report.

You invite comments. In general I agree with the tenor of your overview and therefore have little to add. Points which attracted my attention, however, included:

1. Page 2 - The absence of a national framework to monitor and coordinate recruitment. It's always hard to argue with such a national framework. However, I'm fairly happy with the idea of a state based framework as the populations at risk are much more manageable and the service care delivery tends to be mediated through the State. This does not mean that I disagree with the idea of the Commonwealth establishing an overview from time to time - obviously this would be a good thing.
2. Page 3 - I agree with the comment that benefits of more frequent screening are marginal and that we should continue to try and target the never or rarely screened. These remain the Anti-Cancer Council's prime target in Victoria.

You will be aware of the fact that the Victorian Pap Smear Registry has been a relatively trouble-free operation and that we are all in favour of this approach to rescreening.

3. Page 4 - I note the Commonwealth is examining options for the use of population-based registers and is discussing the privacy considerations. I think this is a very important political hot potato. I don't see any way in which mammographic screening can be introduced in Australia without such a list, as we do not have an established list of already screened women who can be reminded. However, it is possible to approach well over 90% of the population at risk for cervical cancer by the establishment of a Victorian style Pap register. Hence, privacy is a lesser problem for this particular program.

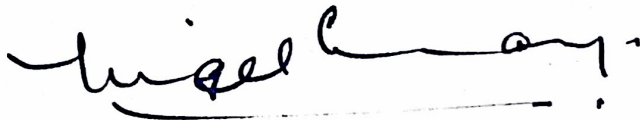
Nevertheless I think privacy is a major issue for public health at this point in time and would encourage you to work on it.

4. Page 5 - In regard to the the terms of reference for the consultant to review quality control - this is something the Royal Colleges have always done very well. I'm not sure that you could not consider delegating the matter to the College of Pathologists. They would feel considerably less threatened by such a process, and have always done these things fairly well historically.

These are personal comments - I haven't had time to pass them through a committee.

Best wishes.

Yours sincerely,

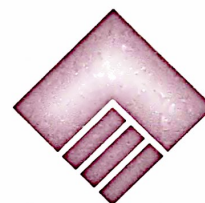
A handwritten signature in black ink, appearing to read "Nigel Gray". The signature is written in a cursive style with a long horizontal stroke at the end.

Nigel Gray
Director



COMMONWEALTH OF AUSTRALIA

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DEPARTMENT OF
COMMUNITY SERVICES
AND HEALTH

Dr Nigel Gray
Director
Anti-Cancer Council of Victoria
1 Rathdowne Street
CARLTON VIC 3053

14 JAN 1991

Dr Gray

CERVICAL CANCER SCREENING EVALUATION REPORT

I refer to Mr McNeil's letter of 20th December, 1990 which outlined the broad strategy the Commonwealth proposed to adopt for determining a response to the Report. This letter also indicated that further papers on key issues would be distributed shortly, with a view to seeking a national consensus on the proposed response.


Attached, for your further consideration, are the following papers:

- . Cervical Cancer Screening, A National Strategy - an overview of the draft response to the report on Cervical Cancer Screening Evaluation;
- . Draft national cervical cancer screening policy;
- . Strategies to increase the participation of women in cervical cancer screening;
- . Brief for the consultancy to be established to examine quality assurance aspects in cervical cytology;
- . Management of abnormalities; and
- . Organisation and funding of cervical cancer screening services.

As indicated in the letter of 20th December, the Commonwealth is required by the decision of AHMAC to report to Australian Health Ministers in early March 1991.

To meet the timetable set down by AHMAC, it is most desirable that the Commonwealth have your comments on the issues discussed in the papers at the earliest opportunity: Enquiries on this matter should be directed to Mr Dennis Bentley, Director, Cervical Cancer Screening Task Force, telephone no. 062 89 7363.

Yours sincerely


Brian Candler
A/g First Assistant Secretary
Health Care Access Division
10 January, 1991

CERVICAL CANCER SCREENING

A NATIONAL STRATEGY

OVERVIEW

INTRODUCTION

✓ The AHMAC Cervical Cancer Screening Evaluation Report (CCSER) challenges governments, professional groups, and support organisations to provide cervical cytology screening services that are more efficient and cost-effective, drawing on the most recently available epidemiological, behavioural and economic research.

✓ The publication of this report provides an opportunity to maximise the prevention of morbidity and mortality resulting from cervical cancer. The CCSER can be used both as a guide and data resource, to draw together a national cervical cancer screening strategy. This will be based on the most effective programs now operating overseas, but reflecting responses to the report from health departments, professional and consumer groups as to what is achievable, and appropriate, in Australia.

THE CERVICAL CANCER SCREENING EVALUATION REPORT (CCSER)

✓ In 1987, concerns about inequity in distribution and the poor cost-effectiveness of existing cervical cancer screening services prompted health ministers to commission a Commonwealth funded evaluation of existing services, supported by targeted pilot projects.

✓ The report confirmed major concerns about the effectiveness of cervical cancer screening in Australia, when compared with overseas programs. Cervical cancer screening has the potential to prevent over 90% of squamous cervical cancers which would occur without screening. Cervical cancer screening has been practised for over 25 years in Australia, yet only about half of the lives at risk from cervical cancer are currently being saved.

✓ Comparison with overseas models endorsed by the IARC and WHO indicate that significant elements of an organised screening pathway are not yet in place in Australia. Essential elements in an effective program are:

- WVOK . an identified target population, via an agreed screening policy and means to identify individual women;
- WVOK . measures to guarantee high attendance levels, including adequate and acceptable smear taking services;
- OK . adequate laboratory facilities for smear reporting and an organised program for quality control;

- OK. facilities for diagnosis, treatment and follow-up of abnormalities;
- OK. carefully designed referral and fail-safe linkage systems to ensure management of abnormalities and collecting information about normal screening tests; and
- OK. evaluation and monitoring systems.

!!
Current cervical cancer screening in Australia is not achieving optimal impact despite substantial expenditure levels. The report advances a number of reasons, including:

- lack of an agreed screening policy, including a target age group and rescreening interval, and insufficient efforts to increase uptake among the target population;
- poor access to service providers of choice and other barriers to screening, ranging from negative attitudes to screening and to simply forgetting;
- absence of fail-safe systems to follow-up women with abnormalities and lack of agreement on appropriate management; and

the absence of a national framework to monitor and co-ordinate recruitment, recall, management of abnormalities, and quality assurance. X

The opportunity exists for major improvements to be made to current services within existing resources.

Cost-effectiveness of the current arrangements are particularly sensitive to the screening interval and to excessive screening and investigation of abnormalities in the 18-24 year age group, where risk associated with this disease is minimal.

The nature and extent of the criticisms of existing cervical cancer screening services raised in the report create a clear obligation to respond quickly and positively. The Australian Health Ministers' Advisory Council (AHMAC) received the report late in October 1990 as a guide for the future development of cervical cancer screening services in Australia and authorised the Commonwealth to conduct a process of discussion on the recommendations leading to a further report to Health Ministers in March 1991.

DRAFT NATIONAL STRATEGY

In order to crystallise views on key issues, the Commonwealth has produced a series of papers (see attachments) recommending a policy or process to achieve consensus. The principal content of those papers are summarised below:

Screening Policy

A screening policy needs to balance the benefits from screening, such as life years saved and morbidity avoided, against the costs of screening to the individual, such as discomfort and anxiety created, personal time and costs, and financial costs to government, including opportunity costs.

A well-defined and uniformly adopted screening policy is fundamental to developing an effective population based cervical cancer screening program.

The CCESR notes that 90% of invasive squamous cell cervical cancer can be prevented by screening women aged 25-69 years every three years where there are well organised screening arrangements and that the benefits of greater screening frequency are marginal, while costs escalate rapidly. However, recommendations for annual Pap smears continue because of concerns about non existent or ineffective reminder systems, accuracy of screening as currently delivered and possible changes in incidence of the disease and mortality rates among young women.

In recognition of the steps still needed to ensure effective screening programs, the prudent course is initially to endorse the recommendation of the CCESR for a two year screening interval, with a view to extending the interval to three years later when a more effective program is in place and if future experience and data support such a move.

Given the evidence from the available data on the age range for screening, there is a case that screening routinely commence three years after first sexual intercourse and cease at age 70 for women who have previously been screened.

Participation by women

The effectiveness of a population based cervical screening program is closely related to the proportion of women regularly screened, yet there is no organised plan for recruitment and recall of women in the target group.

Formal recruitment and recall plans should be developed, identifying target population groups, including those assessed as being at high risk, and identifying appropriate strategies for recruitment and recall with an indicative timeframe.

Yes

1.

The CCESR assumes adoption of targets for cervical cancer screening outlined in Health for All Australians. These are:

- . to increase triennial participation in Pap smear screening to 50% or more of women aged 20-69 years by the year 1990, to 75% or more by the year 1995 and to all but a negligible number by the year 2000;
- OK* . to establish organised population based cervical neoplasia screening programs in each State and Territory by the year 1990.

Appropriate goals should be identified, including participation rates and process targets, and reduction in morbidity and mortality from cervical cancer.

Using the data from the Report on barriers to screening and effectiveness of the different pilot strategies, States and Territories are invited to review their existing programs and develop broad strategies for accomplishing stated goals.

These include:

- . Pap smear screening by General Practitioners;
- . supplementary services provided by alternative smertakers;
- . community and media based health education programs;
- . reminder and invitation based systems.

The Commonwealth is currently examining options for use of population based registers, such as the Electoral Roll or the Medicare enrolment file, and will provide further advice on their use, including privacy considerations attaching to their use.

Quality assurance in smertaking, smear reading and notification of results

The report raises a number of concerns about the adequacy of quality controls on cervical cytology, including smertaking, smear reading and notification of results. There is insufficient attention paid to these crucial elements of cervical cancer screening, which have such a direct impact on acceptable screening intervals, the confidence women have in the system, costs and ultimately health outcomes.

A consultant will be appointed to examine the need for and identify strategies for establishing appropriate levels of quality assurance in smertaking, testing, reporting and follow-up of abnormalities.

*discuss
with Secretary*

*OK - W
Sanderson*

The consultant will work under the directions of a steering group, comprising membership from appropriate professional and consumer groups. A chairman will be appointed by the Commonwealth.

Terms of reference for the consultant will include:

- . review strengths and weaknesses of the current cytology quality assurance program;
- . examine the current laboratory cervical cytology accreditation and inspection program;
- . identify appropriate standards of cervical cytology; and
- . develop a national strategy for achieving compliance with those standards.

Management of abnormalities

The proportion of screened women who are currently investigated for abnormalities far exceeds the proportion who would be expected to develop invasive cancer in the absence of treatment. (At the same time, fail-safe systems to ensure that women with abnormalities are followed-up need to be instituted.)

The recommendations of the report concerning examination of currently available data and institution of a program of discussion by relevant professional societies and colleges have been referred to the Health Care Committee of the NH&MRC for urgent examination.

Organisation and funding

The Commonwealth is seeking views from the States/Territories on the framework and elements of a national cervical cancer screening program, and the appropriate roles for Federal and State governments.

The Commonwealth is also reviewing arrangements for funding of screening services, the costs of which are predominantly currently met through Medicare and Health Program Grants. This includes options for management of available financial resources in accordance with an agreed screening policy to improve the cost-effectiveness of the screening program.

CONSULTATION

Important in the consideration of cervical cancer screening services are the range of professional groups and organisations involved at different stages of the screening pathway, the need for sensitivity to user requirements and the need for effective co-operation and co-ordination.

OK

We will use this!

OK-

SS

The consultation strategy adopted by the Commonwealth involves approaching States, professional and consumer groups, using peak organisations such as the NH&MRC and the AHMAC sub-Committee on Women and Health, where appropriate. It is important that all groups likely to be involved share an appreciation of the elements of any effective national screening program.

The broad organisational framework and a national screening policy are key issues on which an early indication of views is sought. Issues of more complexity, such as quality assurance in cervical cytology, need both an environment and timescale conducive to adequate deliberation.

The report to Ministers in March will indicate areas where broad agreement can be achieved and identify remaining unresolved issues, together with appropriate further steps.

ATTACHMENTS

1. Draft national cervical cancer screening policy.
2. Strategies to increase the participation of women in cervical cancer screening.
3. Brief for consultant on quality assurance aspects in cervical cytology.
4. Management of abnormalities.
5. Organisation and funding of cervical screening services.

Commonwealth Department of Community Services and Health
January 1991

ATTACHMENT 1

CERVICAL CANCER SCREENING

A NATIONAL SCREENING POLICY

SUMMARY

A well-defined and uniformly adopted screening policy is fundamental to effective cervical cancer screening in a population. The major components of such a policy are the interval between screening tests, and the age at which screening tests should commence and cease. This paper examines policy options including those outlined in the Cervical Cancer Screening Evaluation Report (CCSESR), and draws some conclusions relevant to an Australian policy.

A screening policy needs to balance the benefits from screening, that is, the life years saved and the morbidity avoided, against the costs of screening, that is, effort and resources required, anxiety created and financial and opportunity costs. Any chosen screening program should be an optimal compromise between the benefits to be gained from, and the costs of all types arising from the screening process.

The recommendation of the CCSESR for a two year screening interval is acceptable, with the possibility of extending this to be reviewed in the light of future data and the introduction of an improved screening program.

Data presented in the CCSESR and other published studies demonstrate that around 90% of invasive squamous cell cervical cancers can be prevented by screening women aged 25 to 69 years at three yearly intervals where there are well organised arrangements for screening. Such a policy, if uniformly adopted by most eligible women, would be more effective in reducing deaths from cervical cancer than is the screening currently being carried out in Australia. This policy could also be more cost-effective than current screening arrangements.

The CCESR strongly emphasised the need for well organised arrangements for cervical cytology screening to ensure that screening is effectively carried out on a population basis. In particular, a high proportion of all eligible women should be screened regularly, and the quality of smear taking, smear reporting, follow-up of women with abnormalities and data collection should be optimal. The CCESR drew attention to significant shortcomings in these areas which led to the recommendation of a two rather than three year screening interval until the shortcomings in recruitment and quality assurance of cervical cytology screening in Australia can be addressed.

There is a clear association between the age at first coitus and a woman's risk of subsequently developing cervical cancer. This suggests that the age of commencement of cervical cancer screening should be related to the time of first coitus, rather

than a screening policy nominating a standard age for all women. Therefore, there is a case for cervical cancer screening to commence three years after the time of first coitus.

REQUIREMENTS OF AN OPTIMAL AUSTRALIAN CERVICAL CANCER SCREENING POLICY

Deaths of women from cervical cancer could be reduced with improved cervical cytology screening practice and organisation. A comprehensive national screening strategy, based on a defined screening policy is necessary to achieve optimal uptake and effective delivery of cervical cancer screening in Australia.

An optimal and acceptable cervical cancer screening policy for Australia should satisfy the following requirements:

- (i) offer a satisfactory level of protection from cervical cancer, within the practical constraints;
- (ii) have an acceptable degree of benefit in relation to costs incurred, i.e. acceptable cost-effectiveness;
- (iii) be understood and adopted by all women at risk, in particular those who are currently under-screened.
- (iv) have an effective communication strategy in regard to both consumers and the professionals who advise them.

Fundamental to a screening policy are -

the interval at which cervical cancer screening is repeated for women who have normal Pap smears;

the target age group for screening.

Currently in Australia authoritative bodies such as the Royal Colleges, cancer councils, NHMRC, and health departments have varying guidelines on the interval at which routine screening should be repeated, and on the age range of women who should be screened. This situation is also seen in other countries (see Appendix 1). This confusion over screening policy is reflected in the lack of uniformity of clinical practice.

This paper examines the rationale and evidence for various screening policies, describes the impact of possible policy options, and draws conclusions about the optimal cervical cancer screening policy for adoption on a national basis. The paper draws on the Cervical Cancer Screening Evaluation Report (CCSESR) of the Australian Health Ministers' Advisory Council (AHMAC)(1) and other relevant material.

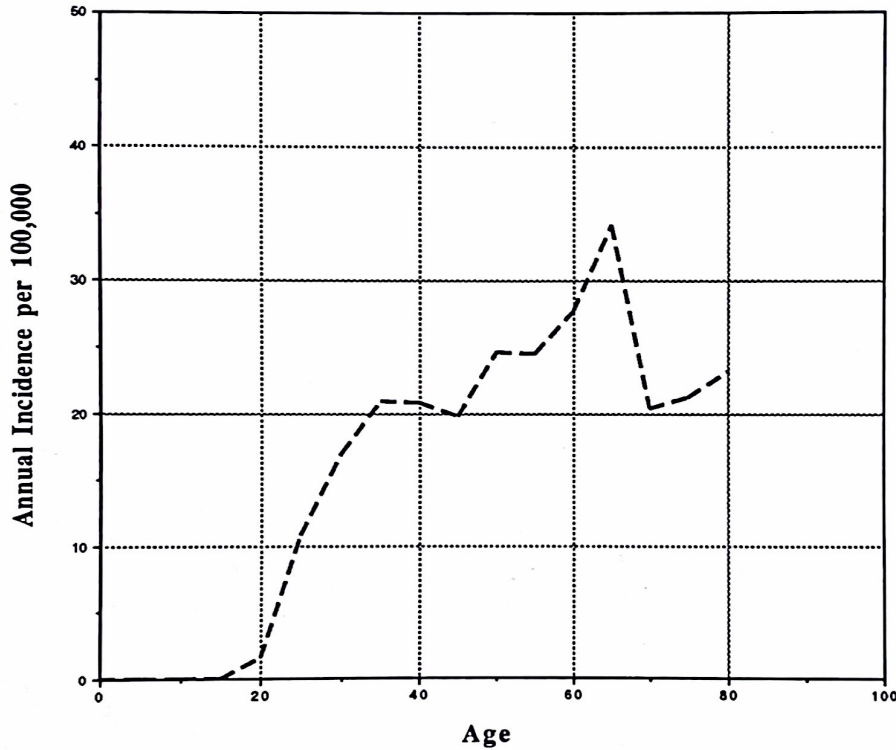
BACKGROUND ON CERVICAL CANCER

Incidence

Cervical cancer is the sixth most common cancer amongst Australian women. In 1982 there were 948 new cases. The lifetime probability of a woman developing the disease is about 1 in 90 (2). This probability would be higher in the absence of cervical cancer screening.

Cervical cancer increases in frequency with age. Only two cases occurred in women under 20 years in 1982-4 (3). The disease is very rare in women aged 20 to 24 years, in whom less than 2% of cases occur (10 in 1982), and in whom the risk of cervical cancer is 1/20th that of women 65-69 years. The incidence rate rises rapidly to a plateau at 35 to 39 years, after which it rises slightly to peak at 65 to 69 years and then declines slowly (2). While the highest incidence rates are in the 65 to 69 year age group, the greatest number of cases occur in the 35 to 39 year age group, as there are more women of this age.

Figure 1: Annual incidence of cervical cancer in 1982 per 100,000 women⁽¹⁾



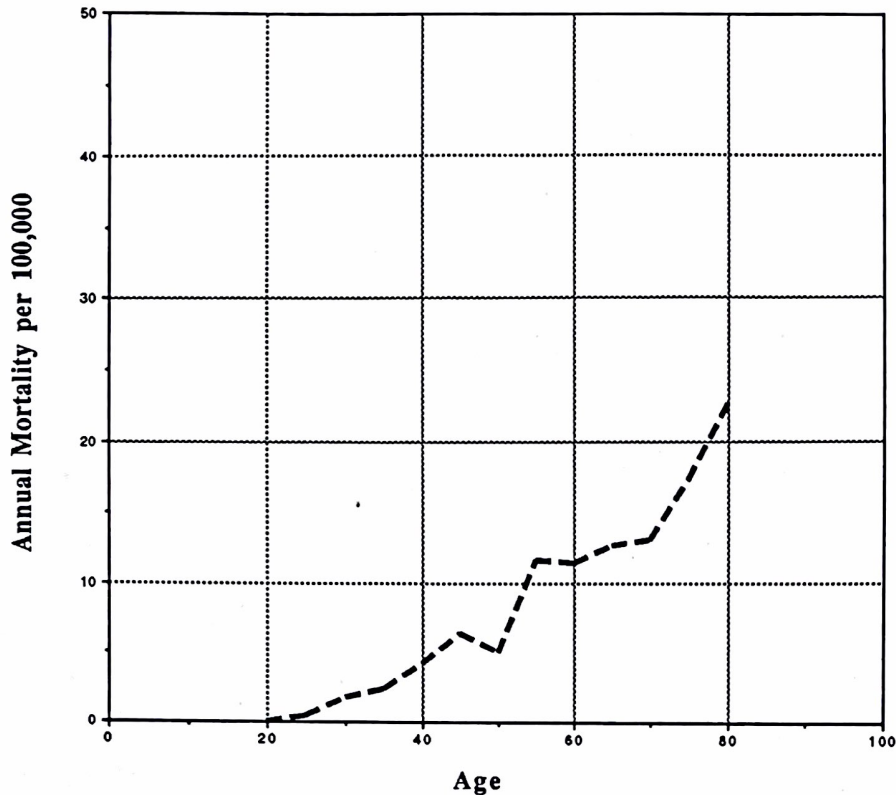
(1) Source: Ref (2)

Mortality

There are around 350 deaths per year from cervical cancer. Deaths from cervical cancer increase steadily from about 25 years into old age. There were no deaths from cervical cancer in women under 25 years of age in 1988. Only around 4% of deaths occur in women 25-29 years (15 in 1988). The majority of deaths, that is, around 70%, occur in women 55 years and over (249 in 1988) (4).

Mortality from cervical cancer has been constantly declining since 1950 when mortality data first became available. This is likely to be due to a decline in incidence of cervical cancer, earlier detection by screening, and improved treatment of early stages of cervical cancer.

Figure 2: Annual mortality from cervical cancer in 1986 per 100,000 women⁽¹⁾



(1)

Based on ABS mortality data for 1988 and ABS population estimates for 30 June 1988

Natural history of cervical cancer

Squamous cell cervical cancer of the cervix is preceded by the precancerous condition of cervical intraepithelial neoplasia (CIN). There are three sequential stages of severity of CIN; CIN 1, CIN 2 and CIN 3. The natural history of CIN can be either progression to more severe stages and invasive cervical cancer in some cases, or spontaneous regression back to lower grades of CIN or normality. It is not possible to predict which cases will regress and which cases will progress, although more severe CIN has a higher probability of progression than lower stages.

Studies have estimated that between 13-60% of CIN 1 and CIN 2 cases progress without treatment (5-12), and between 30-74% of untreated, severe CIN 3 progress to invasive cervical cancer over a period of between one to twenty years (13-16). Estimates of the progression time of CIN vary considerably. It is estimated that CIN may take an average of seven years to reach the most severe stage, ie carcinoma in situ (CIS) (7,17). CIS may then take an average of eight to ten years to become invasive cervical cancer (18). However, rates of progression of cancers are not uniform. Some invasive cancers will take a longer period to develop, and some will take a shorter period. This is reflected in the wide range of estimated progression times.

With present patterns of detection and treatment in Australia, CIN 1-3 is nineteen times more common than invasive cervical cancer on population screening (19). The majority of CIN does not currently progress to invasive cervical cancer as treatment of CIN prevents such progression.

Possible changes in cervical cancer in younger women

In recent years it has been suggested that cervical cancer among young Australian women is becoming more "aggressive", with a shorter precancerous stage, a more advanced stage at diagnosis, and lower survival rates (20). However, data from Victoria, Queensland, New South Wales and South Australia do not support this hypothesis.

Data from the Victorian Cytology Service and the Queensland Radium Institute suggest that technical problems with screening and false negative reports rather than rapid onset cancer is the cause in those cases of cervical cancer found in close time proximity to a negative Pap smear report (21,22).

In Queensland there has been a shift to earlier stage at diagnosis of cervical cancer in women under 40 years and improvement in case survival rates when data from 1982-1988 are compared with data from 1960-1964 (23). In New South Wales during the period 1973-1982 there was no evidence of a trend towards more severe disease in young women. Rather, younger women had an earlier stage of the disease at diagnosis (24). In South Australia, case survival is unchanged for young women diagnosed during 1977-1981 and 1982-1987 and remains better than the survival rate for older women (25)

A task force of the International Union Against Cancer concluded that there was insufficient evidence to support more rapid progression of cervical cancer in younger women, and that potentially the reverse was true (26). In Australia, the available data do not suggest that a more rapidly progressing and lethal type of cancer is becoming common amongst younger women. However, it is essential that adequate data are available to monitor this area of concern. The absence of routine collection of data relating to CIN and CIS cases, and the histopathology of invasive cervical cancer makes this task extremely difficult.

CERVICAL CANCER SCREENING

Cervical intraepithelial neoplasia, a potential precursor to squamous cell cervical cancer, is detectable by screening with Pap smears, and can be treated with the aim of preventing its progression to invasive cervical cancer. Unlike the majority of cancers, squamous cell cervical cancer is preventable in over 90% of cases. The exact proportion prevented depends on the screening interval adopted and age of women screened (27,28).

Effectiveness of cervical cancer screening

Several studies conducted overseas have shown that cervical cytology screening is effective in reducing both the incidence of cervical cancer and mortality from cervical cancer. In those countries which adopted cervical cytology screening in the 1960s, a 30% to 75% reduction in new cases of cervical cancer occurred over

two to three decades (29-32). Similarly, reductions of 20% to 70% in deaths from cervical cancer were observed (33-34).

Other studies have shown that greater incidence and mortality reductions are seen in areas which have a higher participation in screening by eligible women (35-40).

The screening policies adopted overseas are varied. For example, in the Nordic countries screening intervals range from two to three yearly to five yearly. The age group of women eligible for screening varies between 30-49 years and 25-69 years. In those countries which have screening programs available to all eligible women, and which screen 70% or more of these women, deaths from cervical cancer were reduced by 34%-80% in the period from 1963 to 1982 (34). This suggests that screening intervals longer than those generally adopted in Australia, and narrower screening age ranges, will effectively prevent cervical cancer and reduce deaths from the disease.

THE IMPACT OF SCREENING INTERVAL AND AGE FOR SCREENING ON THE EFFECTIVENESS OF CERVICAL CYTOLOGY SCREENING

The potential impact of cervical cancer screening in a population on deaths from cervical cancer depends on the frequency at which screening is performed and the age range of women at which screening is targeted.

Screening interval

To be effective, screening must be repeated at an interval which is less than the duration between the onset of preclinical CIN and its progression to invasive cervical cancer. This interval is estimated to be on average from fifteen to seventeen years, although a wide range from one to thirty years is found (18).

Age range for screening

The benefit of cervical cancer screening in any age group is dependent upon the extent to which cervical cancer is a health risk at that age. Cervical cancer is most commonly found and is an increasing cause of death in women over 35 years. These women are therefore potentially the greatest beneficiaries of screening. It is of concern that screening rates in Australia decline markedly in women over 40 years of age (41).

Although cervical cancer occurs across the whole age span of adult women, frequent screening of considerable numbers of very young women amongst whom only very small numbers of cancers occur produces marginal benefit. The costs associated with screening include not only the direct financial costs of providing screening, but also the financial and other costs incurred by women. Additional costs are created by any unnecessary treatment of abnormalities which would have spontaneously regressed.

An optimal screening policy

A chosen screening policy should strike an optimal balance between finding maximum numbers of cancers and achieving affordable costs. Adoption of a cost-effective and practical approach is essential.

PROPORTIONS OF CERVICAL CANCER PREVENTED USING DIFFERENT SCREENING POLICIES

In attempting to define an optimal screening policy, it is helpful to examine the differences in the proportions of cervical cancer prevented by commencing screening at different ages and at various intervals.

Such data are available from two studies:

- i) A collaborative study by the International Agency for Research on Cancer (IARC) investigated the risk of cervical cancer amongst women who had had negative smears, as they constitute the population at which screening is directed. Women with an initial positive smear are not included in this study. Screening data on more than one million women contributed to this study. Women, mostly aged 30-64 years, already entered into a screening program were included (27);
- ii) A study by the Kaiser-Permanente Medical Centre in California, which reviewed the screening history and cervical cytology of 85 women diagnosed with cervical cancer. Women 20-69 years with no previously reported abnormality on cervical cytology were included (28).

Screening interval

The percentage reduction in the cumulative rate of cervical cancer estimated by the two studies above, according to different screening intervals is shown in Table 1. The estimates for the two studies are of the same order of magnitude and probably fall within 95% confidence intervals, although they are not exactly the same values.

Screening every three years or less prevents over 90% of cervical cancers. Only a small improvement in prevention is gained by screening every two years rather than every three years. There is minimal improvement from screening annually rather than biennially. Screening every five years still offers a high degree of protection (84%), though somewhat lower than for every three years. Little marginal benefit is gained from a screening interval below three years. With an interval shorter than three years, the number of Pap smears taken over a woman's life increases significantly, as do the associated costs.

TABLE 1: Percentage reduction in the cumulative rate of invasive cervical cancer with different frequencies of screening

Screening interval (years)	IARC study (27): % reduction in cervical cancer(a) 35-64 y	MORELL et al(28): % reduction in cervical cancer 20-65 y
1	93.3	98.8
2	93.3	96.5
3	91.4	89.4
4	-	80.0
5	83.9	-
10	64.2	-

(a) Assuming a screen occurs at age 35 and that a previous screen had been performed

It has been suggested that screening programs should commence with two annual smears to overcome concerns about the accuracy of cervical cytology. However, there are no empirical studies to support this practice, and modelling using the IARC data showed virtually no benefit (42). Commencing routine screening with two annual screens increased average life expectancy by only 0.3 days, while corresponding additional costs were very large. Thus this practice is not useful or appropriate. It would be more appropriate to effectively address concerns about the quality of cytology.

Age at commencement of screening

The risk of cervical cancer is closely related to sexual history. A study of 3280 cloistered nuns suggested cervical cancer is very rare or absent in such women (43). Women who commence sexual intercourse at an early age, or who have multiple sexual partners, or whose partners have multiple sexual partners are more likely to develop cervical cancer. Four case-control studies all found that women with cervical cancer were more likely to have had first coitus under 17 years of age, or to have made multiple marriages, than were women without cancer (44-47).

Analysis of the IARC collaborative study shows that there is minimal change in the probability of developing or dying from cervical cancer, whether three yearly screening is begun at ages 17, 20, 23 or 26 (42)(See Table 2). If screening is begun at age 20 instead of age 17, the probability of developing cervical cancer will be decreased by only an additional 3 in 10,000 compared with a life-time risk without screening of 250 in 10,000 women. The increase in risk from moving the commencement of screening to 23 or 26 years is similarly small. The change in risk is larger in moving from 26 to 29 years (9/10,000), when the incidence of cervical cancer begins to rise markedly. Thus there is only a very small benefit from initiating screening at 17 years compared with 20, 23 or even 26 years. On this basis, it would give effective coverage to delay cervical cancer screening until 25 years of age.

TABLE 2: Estimated outcomes of cervical cancer screening for an average-risk, asymptomatic woman screened every 3 years to age 74

Estimated outcome	No screening	Age at which screening is begun, (years)				
		17	20	23	26	29
Probability of developing invasive cervical cancer per 10,000 women	250	37	40	44	51	60
Probability of dying from cervical cancer per 10,000 women	118	11	13	15	18	22
Increase in life expectancy, (days)	-	98	95	92	87	80
Marginal cost of adding an additional year of life expectancy, (\$) *	-	\$50095	33078	20612	14747	10537

* comparisons are 29 versus no screening, 26 versus 29 and so forth.

Source: reference (42)

The IARC study did not take into account the sexual history of women screened. On the basis of our understanding of the causes and natural history of cervical abnormalities, screening is not appropriate for some years after sexual intercourse commences. Adopting an absolute age for commencement of screening is inappropriate.

The CCSESR recommended that:

"... women should be screened from the age of 18 years or within a year of first sexual intercourse, whichever is later."

This may delay screening of women who became sexually active at an early age beyond a safe limit for the development of precursor stages of cervical cancer. As cervical abnormalities are associated with sexual intercourse, it may be appropriate to make decisions about the commencement of screening only in relation to the time of a woman's first sexual intercourse, rather than setting a minimum age of commencement. As discussed earlier, cervical cancer has a long precursor stage of several years. Bearing in mind the minimal gains generally from commencing screening at an early age, it would appear optimal at present to commence screening about two to three years after first sexual intercourse. Data on this issue should be collected as they become available.

Age at cessation of screening

In Australia the peak incidence of cervical cancer is in the 65-69 year age group, and mortality from cervical cancer continues to rise into old age. It seems appropriate, therefore, to continue screening women up to the age of 70 years and then stop, as recommended by the CCSESR. The evidence suggests that women over 70 year

who have been sexually active but have never had a Pap smear should be screened at least once as the benefit of Pap smears for unscreened women over 70 years is substantial, compared with the small benefit for previously screened women over 70 years (42) .

SCREENING POLICIES

The combined effect of varying the screening interval, and the age range for screening has also been estimated by the IARC study (2)(See Table 3). This table also shows the number of smears per woman per lifetime for each policy, as an indicator of the efforts and resources needed to achieve the reductions shown.

Screening women 20-64 years every three years gives only marginally lower prevention rates than yearly screening (93.3% vs 91.2%). Restricting three yearly screening to 25-64 years gives a further minimal reduction (91.7% vs. 89.8%), while raising the age of commencement to 35 produces a 10% drop in prevention rate. A very cautious screening policy of annual smears from age 20 to 34 years thence triennially also produces only a small benefit over three yearly screening of women 20-64 years (91.7% vs 91.2%).

TABLE 3: Effect of different screening policies on prevention of cervical cancer

Screening policy	% reduction in rate of cervical cancer	No. of Pap smears per life time
screening every year, 20-64y	93.3	35
screening every year, 20-34y, then every 3 years, 35-64y	91.7	25
screening every 3 years, 20-64y	91.2	15
screening every 3 years, 25-64y	89.8	13
screening every 3 years, 35-64y	77.6	10
screening every 5 years, 20-64y	83.6	9
screening every 5 years, 25-64y	81.8	8

* assuming incidence rates as found in Western Europe

Source: adapted from reference (27)

The age-specific incidence rates of cervical cancer and the natural history of the disease in Australia are similar to that of the western countries on which the IARC study is based. Although some differences to the proportion of cancers prevented in the IARC study may be found, it is unlikely that they would differ greatly in magnitude or trend. In the absence of adequate Australian cervical cytology data collections, the IARC study provides the best estimates of the effectiveness of cervical cancer screening policies currently available.

From these data, three yearly screening of Australian women aged 20-69 years would prevent 702 (or 83%) of the 845 cases of squamous cervical carcinoma which are occurring annually with current screening practices. Two yearly screening would prevent an additional 26 (or 3%) cancers each year, and annual screening a further 16 (or 2%) cancers each year. Increasing the age range to 18-69 years would only result in 0-1 extra cancers being found per year. Decreasing the age range to 25-69 years would lead to only 8-10 more cancers occurring per annum, and no change in mortality. (1)(See Table 4).

TABLE 4:

Number and percent of currently occurring cervical cancers per annum preventable by different screening policies in Australia*

 Number of cancers currently occurring per annum = 845

Screening policy	Number of current cancers preventable	Percent of current cancers preventable
3 yearly screening: age 20-69y	702	83%
18-69y	703	83%
2 yearly screening: age 20-67y	728	86%
18-69y	729	86%
1 yearly screening: age 20-69y	744	88%
18-69y	745	88%

* Assuming cancer incidence rates in the absence of screening of a western country

Source: adapted from reference (1)

It is important to note that the overall effectiveness of population cervical cytology screening will not benefit women who do not participate in screening. The importance of recruitment of women to cervical cytology screening is further discussed in another paper.

Risk factors and screening

The precise causes of cervical cancer are not yet known, although a number of risk factors have been identified. Age is a major determinant of risk. Other associated factors include sexual history, socio-economic status, aboriginality, smoking, previous screening history, and possibly HPV infection. Women who have had their cervix removed during hysterectomy, or have never been sexually active have no significant risk of developing cervical cancer.

Apart from age and the time of first coitus, other risk factors are not useful in setting screening policies. High proportions of cervical cancer cases occur in "low risk" women - the disease is not confined to "high risk" women. Therefore, all women who have been sexually active and have a cervix should be screened regularly, irrespective of the presence or absence of other risk factors.

The main determinant of screening frequency is the natural history of the disease. There is no evidence that cervical cancer behaves differently and develops more rapidly in women with additional risk factors (27).

However, the identification where possible of high risk groups of women who have been found to be comparatively underscreened is useful for targeting recruitment campaigns. The CCSESR identifies these groups as including Aboriginal women, women living in isolated rural areas, women from lower socio-economic groups and women from a non-English speaking background.

Detection of other conditions

It has been suggested that screening asymptomatic women for cervical cancer provides an opportunity for the detection of other asymptomatic conditions, such as ovarian cancer or sexually transmitted diseases. There are no data to support this at present. The frequency of cervical cancer screening should not be chosen on this basis. This does not preclude seeing women more frequently for other conditions as appropriate, such as the monitoring of borderline hypertension.

Cost-effectiveness of different screening policies

The cost per life year gained from current cervical cancer screening practice is around \$44,000. The CCSESR estimates this could be reduced by an organised screening program with triennial screening of women 18-69 years to around \$24,000 per life year saved, or \$31,000 per life year saved with biennial screening. Annual screening in an organised framework at \$53,000 per life year saved would be less cost-effective than current screening (1)(See Table 5).

The additional cost for each life year saved by adopting two yearly rather than three yearly screening would be \$87,000 per life year saved, and for adopting annual rather than two yearly screening would be \$210,000 per life year saved.

Screening women aged 18-24 years two yearly, in addition to women 25-69 years, creates an extra cost per life year saved of over \$767,000 per life year, even when the greater life expectancy for women 18-25 years is taken into account. The additional cost per life year saved from screening women under 20 years is likely to be even higher, as this saves very few lives. In comparison, including women 60-69 years in screening improves cost-effectiveness, due to the high incidence of cervical cancer in this age group.

Clearly, cost-effectiveness declines markedly at decreased screening intervals and larger age ranges. The increased costs from this extra screening are disproportionate to the benefits gained. More intensive screening policies lead to much greater imposition on large numbers of women for whom the benefit is relatively low, higher costs, lower cost-effectiveness, and reduces the health care dollars available for other health interventions.

TABLE 5: Cost and cost-effectiveness of different screening policies with organised screening

	Age range (years)	Screening interval		
		1 yearly	2 yearly	3 yearly
Total cost for 1991-2020 (\$million)	18-69 y	\$5,720	\$2,924	\$2,001
	25-69 y	-	2,233	1,527
Average cost per life year saved	18-69 y	\$52,839	\$30,782	\$23,703
	25-69 y	-	23,736	18,371
Marginal cost per life year saved in moving to shorter screening interval*	18-69	\$210,256	\$87,075	\$40,258
		-	-	-

Marginal cost per life year saved from:

(a) including women 18-24 y in screening	\$767,770
(b) including women 25-29 y in screening	\$107,111
(c) including women 65-69 y in screening	\$25,814

* ie, 1 yearly = moving from 2 yearly to 1 yearly, etc

Source: adapted from reference (1)

Summary

The IARC and Kaiser-Permanente studies clearly demonstrate that a three year screening interval is very effective, and that commencing screening at age 25 provides a very high degree of protection against cervical cancer. Furthermore cost-effectiveness is optimised by this screening policy. Why then has Australia not adopted such a policy?

PROBLEMS IN ESTABLISHING A UNIFORM SCREENING POLICY IN AUSTRALIA

Cervical cancer screening in Australia has tended increasingly to the practice of annual screening, commencing at the age of first sexual intercourse, no matter at how young an age this occurs. It is noted that this policy was adopted in the absence of any studies on the effect of variations in the screening interval and age range. Cervical cancer screening in Australia has been under close scrutiny over the last three years by the Cervical Cancer Screening Evaluation Steering Committee (CCSESC) of the Australian Health Ministers' Advisory Council (AHMAC). Now is the time for critical appraisal of traditional screening practices and of the options for improvement.

Hesitation in adopting less frequent screening and an older age for commencement of screening appears to stem from four issues:

1. A perception that there has been a large increase in the incidence and mortality of cervical cancer amongst younger women

This has to some degree been accepted as common wisdom. A report from South Australia on cervical cancer incidence from 1977 to 1986 showed an 80% increase in women under 50 years and a 25% decrease in women over 50 years (25). Although incidence rates had risen in women under 50 years, these rates are only marginally above national rates. The increase in incidence in South Australia appeared to be large as initial rates were lower than average compared with other States.

In contrast, in New South Wales, over the ten years from 1973 to 1982 the incidence of invasive cervical cancer decreased by an average of 1.3% per year. Age-specific incidence showed this reduction in all age groups above 35 years. There was no change in incidence in women 15-34 years (24).

Similarly, in Queensland there has not been a statistically significant increase in incidence in younger women when 1960-64 and 1982-86 data are compared (23).

The number of cervical cancer cases and deaths in women under 30 years of age is only a small proportion of the total cases and deaths (10% and 1% respectively). Where only small numbers of cases of disease are observed, as for cervical cancer in women under 30 years, calculated incidence rates are subject to significant random fluctuations and may not represent actual trends. This presents difficulty in interpretation of small data collections at the State/Territory level, where

only a small change in numbers will cause a large change in rates. Larger, national incidence data collections are only available for 1982-1985. Over this short period there has been a 2.8% increase in the age-standardised incidence rate. No consistent increasing trend is observable in women under 30 years(3).

Initial reports on age-specific cervical cancer mortality in Australia from 1950 to 1980 showed an increased incidence in women under 35 years, although overall mortality continued to decline(55). However, a subsequent report covering the period from 1950 to 1984 showed a decline in incidence in women under 35 years(56).

Suggestions of increasing cervical cancer incidence and mortality among younger women are not substantiated when national data are examined. However, it is recognised that only limited national data are currently available which affects the carrying out of long-term epidemiological studies.

2. Concern that rapid onset cervical cancer, or a more aggressive variant, is becoming more common

The increasing appearance of a rapidly progressing cervical cancer has been proposed since the early days of cervical cancer screening. There are little convincing data to support this hypothesis. It is likely that some of these cancers may be due to false negative Pap smear reports, rather than to rapid growth rates (18). As discussed earlier, such a concern about cervical cancer in younger women has not been substantiated in Australia. Specialist clinics which see the few cases that do occur treat a highly selected and small group of women not representative of the general screened population. In such clinics, therefore, the overall incidence of these cases appears to be higher than it is.

3. Difficulty in ensuring women attend for re-screening at the designated interval

In the absence of reminder or recall mechanisms, a recommendation for a particular screening interval often translates into a much longer, or irregular, screening interval. There is concern that recommending screening every two or three years will result in women attending for screening only every four to six years. Large numbers of Australian women are currently under-screened, highlighting the need for effective strategies for encouraging women to participate in screening at the appropriate frequency. The CCSESR examined this problem and made several recommendations designed to ensure that the majority of Australian women are screened regularly. This is discussed in another paper.

4. Uncertainty about the accuracy of cervical cytology

There is some concern that the accuracy of cytology reporting is sub-optimal. Anxiety about false negative reports and under-calling of abnormalities may result in recommendations for more frequent screening. It is known that the cytology laboratory quality assurance practices vary widely between laboratories(1). Therefore, these concerns may to an extent

be justified. However, a number of studies have found that 50% or more of false negative Pap smear reports were due to inadequate smear taking rather than laboratory error(7,49-54). The quality assurance of cervical cytology was also addressed in the CCSESR. Several recommendations on quality assurance were made. Commonwealth plans to take this further are outlined in another paper.

PROPOSED AUSTRALIAN CERVICAL CANCER SCREENING POLICY

Based on the epidemiological evidence presented earlier, a routine screening interval of three years can be confidently recommended in the context of optimally organised screening arrangements with high quality screening.

However, it is acknowledged that there are limitations in the present organisation of cervical cancer screening in Australia which place constraints on what is currently achievable in screening. High screening rates, recall and reminder mechanisms, reliable cytology and adequate epidemiological data for monitoring cervical cancer and screening performance are all essential if cervical cancer screening is to be optimally effective. If all these prerequisites were currently in place, a three year screening interval would be optimal. These are essential features of a national cervical cancer screening program. In the interim, while improvements to these areas are being made, it is concluded that it is prudent to adopt a shorter screening interval.

Cervical cancer screening should initially be carried out at two yearly intervals as recommended by the CCESR

In view of the relationship of sexual intercourse to the risk of cervical cancer, it is appropriate to tie the commencement of screening to the age of first coitus rather than to a fixed age. The interval from first coitus to commencement of screening should be shorter than the precursor period of the majority of serious cervical abnormalities.

The available data on the age to commence screening as recommended by the CCSESR, suggests that cervical cytology screening should routinely commence three years after first sexual intercourse. Similarly there is a case that screening should cease at age 70 years for women who have been previously screened.

It is recognised that the effectiveness of this screening policy is conditional upon the implementation of effective recruitment, reminder and recall strategies, and on the monitoring of all aspects of cervical cytology screening.

Therefore, the issues of recruitment of women to screening and of quality assurance should be addressed concurrently, and screening policy be reviewed in 1993 when appropriate screening systems are in place as recommended by the CCSR.

Commonwealth Department of Community Services and Health
January, 1991

APPENDIX 1.

EXAMPLES OF RECOMMENDED SCREENING INTERVALS IN AUSTRALIA

National Health and Medical Research Council of Australia

Two smears one year apart, then not more than 3 years between screens.

Commence within three years of sexual activity beginning.

Stop at age 65 years if at least 2 previous smears and no abnormal smears in the preceding 10 years.

Royal Australian College of Obstetricians and Gynaecologists

Two smears 1 year apart, then 2 yearly.

If high risk (eg multiple sexual partners or previous abnormality) annual screens for life.

Royal Australian College of General Practitioners

Two annual smears, then not less than 3 yearly.

New South Wales Health Department

Annually.

Queensland Health Department

Annually until age 35 years, then 3 yearly.

Australian Capital Territory Department of Community Services and Health

Annually.

Australian Cancer Society

Annually until age 65 years.

New South Wales Cancer Council

Annually.

Anti-cancer Council of Victoria

Two yearly.

Family Planning Federation of Australia

Victoria - two yearly from 18 years or commencement of sexual intercourse

Tasmania - annually.

Northern Territory - Annually from within 1 year of commencing sexual intercourse to age 60.

EXAMPLES OF RECOMMENDED SCREENING INTERVALS OVERSEAS

United Kingdom

- Department of Health and Social Security
Five yearly from 35-65 years, once between 22-30 years in sexually active women, and early in each pregnancy.
- Royal Colleges of Obstetricians and Gynaecologists, Pathologists, General Practitioners, and Faculty of Community Medicine
Three yearly between 20-64 years.

United States of America

American Cancer Society,
Annually for 2 screens, then at least every 3 years to age 65 years.

The:

National Cancer Institute,
American College of Obstetricians and Gynaecologists
American Medical Association
American Academy of Family Practice
American Nurses Association
American Medical Women's Association

all endorse a policy similar to the following:
Three annual Pap smears from age 18 or commencement of sexual activity. Thereafter screens may be performed less frequently at the physicians discretion.

Canada

The Walton Report to the Canadian Health Department - 2 annual screens, then 3 yearly to age 35 and 5 yearly to age 60.

New Zealand

Two smears one year apart, then repeated at least every 3 years. Commencing with first sexual intercourse and ceasing at age 65 years.

Sweden

Four yearly for ages 30-49 years.

Iceland

Two or 3 yearly for ages 25-70 years.

Denmark

Around 3 yearly, 30-50 years.

Norway

Two to 3 yearly, 25-60 years

Finland

Five yearly, 30-55 years

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CERVICAL CANCER SCREENING TASKFORCE**STRATEGIES TO INCREASE THE PARTICIPATION OF WOMEN
IN CERVICAL CANCER SCREENING****INTRODUCTION**

The report of the Cervical Cancer Screening Evaluation Steering Committee (CCSESC) identifies deficiencies in the participation of women in cervical cytology screening in Australia and the barriers to full participation in screening by women at risk. The report makes recommendations concerning strategies to optimise the participation rate in screening.

This paper summarises the findings of the CCSESC and outlines a proposed national reponse to the report's recommendations on the recruitment and recall of women to cervical cytology screening. It also discusses the importance of educational and communication strategies in increasing participation in screening. It is intended that the Commonwealth's proposal will provide a framework for the States and Territories to contribute their plans for initiatives in this area.

The principal information sought from the States/Territories is an outline of State proposals within their jurisdiction on the organisation of recruitment and recall of women, together with an indicative budget.

AREAS FOR IMPLEMENTATION OF STRATEGIES TO INCREASE PARTICIPATION IN CERVICAL CYTOLOGY SCREENING

The effectiveness of cervical cytology screening programs on a population basis is closely related to the proportion of eligible women being regularly screened. Given the underscreening of some population groups in Australia, strategies to increase participation in cervical cytology screening need to be identified and implemented.

The CCSESR presents extensive information on the pilot projects funded by the evaluation, which trialled a variety of new approaches to the delivery of screening, and recruitment of women to screening. The effectiveness of particular recruitment strategies, service delivery models, and their perceived advantages and disadvantages are discussed in the report.

Strategies to increase participation in cervical cytology screening need to be concentrated in three major areas:

- . the provision of services which are accessible and acceptable to women in the target population
- . the implementation of appropriate educational and promotional campaigns
- . the establishment of a population-based recruitment and reminder system

The provision of services which are acceptable and accessible to women in the target population

The majority of Pap smear tests in Australia are taken by general practitioners. This will almost certainly continue to be the case. Approximately eighty percent of women visit general practitioners at least once a year and therefore general practitioners are well placed to suggest the taking of a Pap smear during routine medical consultations. Research shows that this approach is effective and acceptable to the majority of women and practitioners.

However, the potential of this method of encouraging participation in screening is not being fully realised. Less than two thirds of women at risk from cervical cancer are being screened at sufficiently regular intervals.

The CCESC reported that there is a lack of choice of service providers in some areas of Australia, most notably in isolated rural areas, which is creating a barrier to participation in cervical cancer screening. Experience with pilot projects highlighted the need for providing screening services which are acceptable to women with special needs. For example, special screening clinics staffed by female smear takers, usually specially trained nurses, attracted higher proportions of under-screened and older women. The provision of culturally appropriate services is also essential. A highly personal approach was found to be important in a number of Aboriginal communities. The higher rate of cervical abnormalities and cancer in such groups of women warrants increased efforts to improve their participation in screening.

The Commonwealth is concerned to ensure the continuity of programs currently operating in the States and Territories. State and Territory responses to the issue of the provision of acceptable and accessible services should include recommendations on the future of existing programs.

The provision of appropriate educational and promotional campaigns

Research from overseas indicates that women who have favourable attitudes towards cervical cancer screening, who are accurately informed about screening and who hold beliefs in the benefits of screening, are more likely to attend cervical cancer screening. This was confirmed by pilot project surveys carried out in Australia where a range of promotional and educational programs were demonstrated to have significantly increased participation in screening.

The CCESR recommended that the introduction of an organised approach to cervical cytology screening should be accompanied by appropriate public education to inform women of the need for Pap smears, the availability of services and the appropriate interval and age range for screening.

Educational and promotional campaigns need to include specially designed programs for specific groups of women as well as mass media campaigns. One method of increasing community awareness and knowledge is to use opportunities provided by community and women's groups, clubs or workplaces.

The CCESR recommended that funding be provided for appropriately targeted and designed educational and promotional campaigns. There is a case for a coordinated educational and promotional strategy to define the most appropriate balance of national and more localised campaigns.

The establishment of a population-based recruitment and reminder system

The CCESR considers that the integration of general practice screening with a more systematic invitation approach is required. For example, the report suggests that general practitioners could be encouraged to establish reminder systems designed around the recommended screening interval, with a back-up State/Territory reminder system acting as a safety net by inviting women who have not been screened one year after the interval has expired.

The CCESR identified invitations using population based registers as potentially an important and efficient method of increasing screening coverage and found that there was strong support among women and medical practitioners for the use of personalised letters to invite women to screening. Available databases which provide names, ages and addresses include electoral lists and Medicare records.

The Commonwealth is seeking advice from the Health Insurance Commission and the Privacy Commissioner on the feasibility and privacy aspects of using national reminder systems to support local recruitment and reminder services such as those run by some general practitioners. While reminder services to women already screened are able to obtain the consent of women when they are screened, invitations to women previously unscreened raise unresolved issues. There may also be implications for State/Territory legislation.

The CCESR recommended that funds should be made available for a reminder system for all women who are overdue for their next test and who have not responded to other reminder strategies. A reliable, comprehensive record of women's screening histories is a necessary requirement for such a system. One possible approach as recommended by the CCESR is that this should be one of the functions of cervical cytology registries which should be established by State and Territories.

SUMMARY

Screening services will still largely be provided by general practitioners, but special services need to be designed for groups of currently underscreened women such as isolated rural women, traditional Aboriginal women and women from a non- English speaking background to whom the services currently available are either inaccessible or culturally inappropriate.

Funding is necessary for an effective recruitment and reminder service which ensures optimal participation in cervical cytology screening. The feasibility of the use of population-based registers for recruitment must be addressed. The views of the States and Territories are sought on the likely effectiveness and costs of cervical cytology registries to provide a fail-safe reminder system for women who are overdue for their next Pap smear. Strategies are also necessary for ongoing educational and promotional campaigns which should include a range of programs both nationally and community based.

Commonwealth Department of Community Services and Health
January, 1991

CERVICAL CANCER SCREENING

QUALITY ASSURANCE IN CERVICAL CYTOLOGY

Maintenance of high standards of cervical cytology are the very foundation of an adequate cervical cancer screening program. The level of confidence placed in the service by women being screened and the practitioners advising them are critically affected by those standards. Some women are undergoing an unnecessarily high frequency of Pap tests, partly due to doubts as to the reliability of the tests taken.

The CCESR stresses the dependence of critical steps in the screening pathway on a range of quality assurance measures, including:

- . smear taking, involving regular feedback from cytology laboratories on the quality of smears taken;
- . smear reporting, involving external and internal quality assurance procedures;
- . notification of results; and
- . reporting of abnormalities and services for managing women with abnormalities.

The CCESR that much further investigation of these very complex issues is required, in consultation with the relevant professional groups. In particular, cytology laboratory quality assurance is of central importance.

The diverse range of funding methods currently used to reimburse the variety of cytology services in Australia complicates cost-effectiveness analyses of services provided.

It is also abundantly clear that these investigations cannot be achieved within the current reporting timescale.

The option preferred by the Commonwealth is to commission further research on cervical cytology laboratory quality assurance under the direction of a steering group comprising representatives from appropriate professional bodies, together with recognised experts in the field.

Terms of reference for the further investigations proposed and composition of the steering group are attached.

Commonwealth Department of Community Services and Health
January 1991

**CERVICAL CANCER SCREENING EVALUATION REPORT
CONSULTANCY ON QUALITY ASSURANCE ISSUES**

OBJECTIVE

In response to the findings and recommendations of the Cervical Cancer Screening Evaluation Report, the consultant will examine the need for and identify strategies for establishing appropriate measures for quality assurance in cervical cytology smear reporting, including its relationship to the adequacy of smears taken and the follow-up of abnormalities. The consultant will work under the directions of a steering group and report to that group as directed.

The strategy will include plans for reviewing the effect of existing funding arrangements for cervical cytology services, including provision of recommended quality assurance, training and co-ordination mechanisms.

Operational and outcome targets for cytology laboratories will be identified, together with associated data collection and monitoring systems.

The consultant will be funded by the Commonwealth but acceptable to all members of the consultancy steering group.

The consultant will establish appropriate working arrangements with member organisations, to ensure preservation of confidentiality.

PROPOSED COMPOSITION OF STEERING GROUP

- Chair: - to be nominated by the Commonwealth
- Members:
- Royal College of Pathologists of Australia (RCPA)
 - National Association of Training Authorities (NATA) - Medical Testing Registration Committee
 - National Pathology Accreditation Advisory Council (NPAAC)
 - Australian Society of Cytology (ASC)
 - Royal Australian College of General Practitioners (RACGP)
 - Royal Australian College of Obstetricians and Gynaecologists
 - Family Planning Federation (FPF)
 - Dept. Community Services and Health
 - nominee of the Minister for Community Services and Health

DRAFT TERMS OF REFERENCE

- . In conjunction with the RCPA and NPAAC, review the current cytology quality assurance program and assess its strengths and weaknesses.
- . In conjunction with NATA, examine the current cervical cytology laboratory inspection process. Obtain data on current standards and estimate confidence limits.
- . Identify appropriate and achievable standards of cervical cytology, including minimum levels of specificity and sensitivity.
- . Develop a national strategy for achieving compliance with those standards. The strategy should address:
 - the accreditation system;
 - standards of professional qualifications, training and experience for smearing;
 - criteria for provision of comprehensive, timely and efficient service to practitioners;
 - measures to improve and monitor day to day testing and reporting;
 - provision of data to support regional and national monitoring systems, including research programs, on issues such as participation rates, adequacy and accuracy of tests and incidence of abnormalities;
 - feedback to smearers and mechanisms to keep them informed of developments in smearing and cervical cytology;
 - reporting standards for abnormalities;
 - co-ordination with general practitioners, recruitment and recall services, registries (where operating) and the individuals; and
 - fail-safe systems to ensure follow-up of abnormal smears.

Commonwealth Department of Community Services and Health
January 1991

CERVICAL CANCER SCREENING
MANAGEMENT OF ABNORMALITIES

The report notes that up to 15% of women screened are found to have abnormalities. Approximately half of these result in treatment of infections or repeat smears. Less than two percent of tests report definite evidence of CIN or invasive cancer.

Nearly 50% of current expenditure on cervical cancer screening is accounted for by investigation of women who receive abnormal Pap smears.

The proportion of women who are currently investigated far exceeds the proportion of women who would develop cervical cancer if no treatment were given. The anxiety engendered in these women is also a significant cost of screening.

Lack of Australian data, the lack of follow-up and monitoring systems to ensure treatment is effective hinder improved management of this aspect of the screening pathway. Nevertheless, it seems that variations in the management recommendations of the laboratories, variation in the guidelines produced by professional societies and those used by individual colposcopists may also be factors in current levels of investigation.

The report recommends examination of currently available data and a program of discussion, research and data dissemination be undertaken by the relevant professional societies and colleges.

This issue has been referred to the Health Care Committee of the NH&MRC, together with a number of issues associated with the screening policy.

An early indication of the views of the Committee has been sought for inclusion in the Commonwealth's initial response to Health Ministers in March 1991.

Commonwealth Department of Community Services and Health
January 1991

CERVICAL CANCER SCREENING

ORGANISATION AND FUNDING OF CERVICAL CANCER SCREENING SERVICES

ORGANISED VERSUS OPPORTUNISTIC APPROACH TO CERVICAL CANCER SCREENING

The Cervical Cancer Screening Evaluation Report notes that the greatest impact on cervical cancer has been achieved in countries or regions which have had organised screening programs. Recommendations of the World Health Organisation and the International Agency for Research on Cancer on cervical cancer screening have identified the requirements for an effective program. Such a program needs attention to all aspects of 'the screening pathway', which comprises:

- . screening of the target population at regular intervals;
- . provision of accessible and acceptable services for taking Pap smears;
- . provision of high-quality services for reporting smears;
- . ensuring follow-up of women with abnormal smears; and
- . a system for the monitoring and evaluation of the whole screening program.

Existing services, characterised in the report as 'opportunistic', are primarily provided through general practitioners, supported to some extent by special services aimed at attracting unscreened, or underscreened women for whom there are a number of recognised barriers to participation.

Options identified in the report for improving services include:

- . restricting delivery of cervical cancer screening services to defined centres, supported by management of abnormalities in specialised assessment centres and block grant funding of services for taking and reporting Pap smears;
- . retaining current arrangements through general practitioners and the current mix of private and public laboratories; or
- . augmenting existing screening services with an organised approach.

The recommendations of the report favour the third option and seek to identify the minimum modifications to the current system essential to an effective and efficient organised program. These elements are discussed individually in the following sections.

In developing a national screening program, it will be necessary to reach a consensus on those elements.

COMMONWEALTH AND STATE ROLES

Discussion of the respective roles of the Commonwealth and States/Territories needs to consider:

- . screening policy development, co-ordination and monitoring; and
- . responsibilities for service delivery.

Development of an appropriate screening policy in the light of current epidemiological, behavioural and economic research, is a matter primarily for health authorities, in consultation with professional and consumer groups, co-ordinated through the National Health And Medical Research Council and the AHMAC sub-Committee on Women and Health. The Commonwealth does not propose to proceed with establishing a National Cervical Cancer Screening Advisory Committee for the present.

Subject to any consequences flowing from the current broader examination of Commonwealth and State/Territory roles in health, no changes are proposed to the existing distribution of responsibilities, pending availability of the findings of the proposed consultancy on quality assurance aspects. In practice, this means enhancement of existing roles, rather than redistribution. Thus, State roles in recruitment and recall systems may be enhanced, as may the Commonwealth role in quality assurance matters.

THE TARGET POPULATION

The draft screening policy recommends a population based approach for women at risk. Within the target population, high priority groups are to be identified according to risk, risk being measured by higher incidence of the disease or levels of screening uptake. The report identifies a number of groups in a high risk category, including Aboriginal and elderly women.

Development of State or Territory plans would include analyses of demographic data to identify numbers and distribution of the target population, with special reference to high risk groups.

Comprehensive screening strategies would be developed in the light of the studies, and would incorporate a notional timescale for achieving set targets.