Cervical cancer screening programmes

MANAGERIAL GUIDELINES

A. B. Miller

World Health Organization
Geneva

CERVICAL CANCER SCREENING PROGRAMMES: MANAGERIAL GUIDELINES

A.B. Miller
Department of Preventive Medicine and Biostatistics
University of Toronto
Toronto
Ontario
Canada

World Health Organization
Geneva
1992

WHO Library Cataloguing in Publication Data

Miller, A. B.
Cervical cancer screening programmes : managerial guidelines / A. B. Miller.

1. Cervix neoplasms – prevention & control 2. Mass screening – organization & administration 3. National health programs I. Title

ISBN 92 4 154447 3 (NLM Classification: WP 480)

Typeset in India
Printed in England
91/9006—Macmillans/Clays—5000

CONTENTS

Preface vii

Chapter 1
Cervical cancer screening programmes as part of national cancer control policies 1

Introduction 1
Assessing the current situation 1
Setting health objectives 2
Evaluating possible strategies 2
Setting priorities using quantitative assessments 3
Conclusion 4

Chapter 2
The natural history of cervical cancer and the implications for screening policy 6

Introduction 6
Classification of cervical cancer 6
Regression of dysplasia 8
Regression of carcinoma *in situ* 9

Chapter 3
Managerial guidelines for implementation and evaluation of cervical screening 15

Background 15
Deciding upon a cervical cancer screening programme 16
Evidence that cervical cancer is a major health problem 16
Characteristics of individuals and populations at risk 17
An appropriate health service infrastructure 17
Technical resources for smear collection and cytological examination 17
Resources for diagnosis and treatment of cases 18
Health service sectors in which screening can be offered 18
Epidemiology 19
Coverage of women at risk 19
Comparison of epidemiology and coverage 20
Use of maternal and child health/family-planning services for initiating screening 20
Use of occupational health services for screening 21
Use of mobile units for screening 22
Costs of screening in different health service sectors 22
Frequency of screening 22
Age to initiate screening 24

Health education about screening 24
Effect of a single smear in a woman's lifetime 25
Economic aspects of screening 26
Monitoring and evaluation of screening 27
Responsibility for cervical cancer screening 28

Chapter 4
Cervical screening in primary health care 30

Setting up a screening service 30
The smear register 30
Training of staff 30
Accommodation and equipment 30
Relationship with the laboratory 31
Relationship with the treating institution 31
The target group for screening 31
Ensuring that the target group is screened 32
Personal invitations 32
Casual attenders 33
Maternal and child health/family-planning clinics 33
Special events 33
Special surveys 34
Recording and reporting 34
Report forms 34
Informing women of their results 34
Management of women with abnormal smears 35
Counselling 35
Repeat cytology 36
Management and treatment of women with cytological abnormalities 36
Follow-up 36

Chapter 5
Information systems for cervical cancer screening 38

Introduction 38
Population-based information systems 38
Information system design 40
Policy issues and use of data 40
Components of information systems 40
Other aspects of information systems 41
Monitoring and evaluation of the programme 41

Chapter 6
Downstaging for cervical cancer 44

Introduction 44
Definition of downstaging 44
The need for downstaging 44

A possible approach to downstaging 45
Women to be examined 45
Personnel needed for the examinations 45
The examination 46
Use of cervical cytology 46
Referral for diagnosis 47
Frequency of examination 47
Evaluation 47
Conclusion 48

References 49

PREFACE

Appropriate management and policies in early detection programmes for cervical cancer are vital to reduce the mortality from the disease. Early detection and screening have been successful in reducing mortality in some developed countries, but not in others, and this is most often due to poor management and implementation of inappropriate policies, screening mainly young women without sufficient coverage of older women. Three-quarters of all women with cervical cancer are in developing countries, yet screening programmes in these countries have had little or no effect on mortality. All too often screening activities are initiated in which only the technical aspects are considered, without due consideration to the need to achieve adequate coverage of women at risk. The guidelines in this book therefore cover programme issues such as the formulation of screening programmes for cervical cancer as part of national cancer control programmes, the natural history of cervical cancer, and the implications for screening policy, service delivery, information systems, and programme evaluation. The book also discusses the concept and role of downstaging in countries that will be unable to provide cytological screening of all adult women at risk in the foreseeable future.

This book should be viewed in conjunction with an earlier WHO publication entitled *Cytological screening in the control of cervical cancer: technical guidelines* (Geneva, WHO, 1988). The two publications, together with the report of a WHO meeting,[a] are intended to assist in the planning, development, management and monitoring of programmes for early detection of cervical cancer. They also contribute to the overall objective of improving the health of women, and thus should be considered alongside other technical and managerial guidelines on maternal health and family planning published by WHO. The present volume provides an outline of the managerial factors to be considered in setting up a cytology screening programme, while the book on technical guidelines focuses on the technical aspects of such programmes, including the taking of smears and their examination, reporting procedures, monitoring and evaluation of the

[a] Control of cancer of the cervix uteri. *Bulletin of the World Health Organization*, **64:** 607–618 (1986).

system, personnel requirements and training, and the equipment and supplies required.

Grateful thanks are due to Professor A.B. Miller, Director of the WHO Collaborating Centre for Evaluation of Screening of Cancer and Chairman of the UICC (International Union Against Cancer) Project on Evaluation of Screening for Cancer, Toronto, Canada, who prepared these guidelines during a period of sabbatical leave taken in the Cancer and Palliative Care Unit, Division of Noncommunicable Diseases and Health Technology, WHO, Geneva, in 1991. WHO also acknowledges the important contributions of Dr J. Chomet, London, England and Dr R. MacLennan, Queensland, Australia, in preparing the initial manuscripts on which this volume is based and the valuable contributions of Dr G. Anderson, Vancouver, British Columbia, Canada; Dr M. Hakama, Tampere, Finland; Dr J. Luande, Dar-Es-Salaam, United Republic of Tanzania; and Dr R. Prado, Santiago, Chile, as well as many WHO staff from headquarters and the regional offices, in reviewing the draft manuscript.

Dr Jan Stjernswärd
Chief, Cancer and Palliative Care Unit
World Health Organization

Chapter 1

CERVICAL CANCER SCREENING PROGRAMMES AS PART OF NATIONAL CANCER CONTROL POLICIES

Introduction

Principles and guidelines to assist health planners in the formulation of national cancer control policies and programmes were discussed at a WHO Meeting in Geneva in October 1983 (WHO, 1984). The report outlines a systematic approach to cancer control, which was subsequently simplified to four basic steps (Stjernswärd et al., 1986):

- assessing the current situation
- establishing health objectives
- evaluating possible strategies
- establishing priorities using quantitative assessments.

These steps are reviewed below in relation to the requirements for the control of cervical cancer.

Assessing the current situation

An initial situation analysis should be conducted, covering five categories of information:

- demographic data;
- cancer data;
- data on other diseases;
- data on health care facilities and personnel;
- policy review.

Cervical cancer is the most common form of cancer in women in most developing countries and the second most common form of cancer in women in the world as a whole (Parkin et al., 1988). It should therefore be accorded high priority in national cancer control programmes worldwide. While primary prevention would be the ultimate objective in the control of any cancer, this is not likely to be possible for cervical cancer in the foreseeable future, hence early detection and, specifically, screening have to be the primary control measures. Even in those developed countries where screening programmes have reduced the incidence and mortality from cervical cancer, continued investment in such programmes is essential to prevent a reappearance of the disease.

It is important to review demographic data in conjunction with available cancer data, as this will indicate the age groups in the female population on which the programme should be concentrated. As is emphasized in other chapters of this book, this will almost invariably be women 35 years of age or above.

Assessment of existing health care facilities and personnel is essential to determine whether it is appropriate to introduce a cervical cytology screening programme. The technical requirements for such a programme are summarized elsewhere (WHO, 1988). This book outlines the requirements for personnel to perform screening, facilities to ensure diagnosis and therapy, and mechanisms to ensure that women avail themselves of these facilities.

Following such considerations, a policy review can be undertaken and a decision taken on whether or not to introduce (or for many developed countries reorganize) a cervical cancer screening programme.

Setting health objectives

With the situation analysis completed, it is possible to establish health objectives and set priorities for the particular country, bearing in mind that the overall objectives of a national cancer control programme are "to reduce morbidity and mortality due to cancer and to improve the quality of life of cancer patients" (WHO, 1984). This means that the objectives of a cervical cancer screening programme will be to reduce morbidity and mortality due to cervical cancer and to improve the quality of life of women who develop the disease.

A country may wish to establish a specific health objective that will provide a quantifiable goal for the programme. In view of the fact that screening programmes in several countries have been able to reduce the incidence and mortality from cervical cancer by 60% (Hakama et al., 1985), such a goal may be appropriate as a long-term objective. This could be approached in stages, an initial objective being to achieve, for example, a 20% reduction in the incidence and mortality from the disease over a period of 10–15 years. It is important to set such a quantifiable objective, as this will provide a yardstick against which the success or failure of the ensuing programme can be assessed.

Evaluating possible strategies

Criteria useful for the evaluation of possible strategies for cancer control programmes in general include:

– criteria applicable to the magnitude of the problem

- criteria applicable to the technological aspects (relating to early detection and treatment)
- criteria applicable to general concerns (of the public, in relation to resources, effects on economic productivity, etc.)
- criteria applicable to political and planning concerns.

For control of cervical cancer, only one proven strategy is currently available, i.e., cytological screening, with appropriate treatment for any abnormalities detected. An alternative but unproven strategy for countries where cytological screening will not be possible in the foreseeable future is visual inspection of the cervix by primary health care workers, with the aim of "downstaging" the disease (see Chapter 6). If this strategy is adopted, every attempt should be made to evaluate its effectiveness in pilot projects before the approach is extended to the rest of the country.

Setting priorities using quantitative assessments

The process of evaluation continues with defining the measures of effectiveness and cost, and for each activity:

- identifying the immediate target;
- estimating the impact in terms of a reduction in incidence or mortality from the disease;
- estimating the resources needed;
- estimating the cost of the activity.

With these estimates it is possible to compare the effectiveness and costs of different approaches to screening for cervical cancer and determine which activities should be given priority. These steps can be undertaken not only for new activities that are being proposed as additions to the existing programme, but also to evaluate activities that are currently in place to see if they should be discontinued. Eddy (1986a) has developed a simple method for comparing the effectiveness and costs of different cancer control activities; the steps involved are based on the report of a WHO meeting (WHO, 1984) and are summarized below:

1. Identify the potential cancer control activities, i.e. cytological screening.
2. Identify the cancer affected by each of these activities, i.e. cervical cancer.
3. Construct a baseline profile for the cancer.
4. Identify the immediate targets of each activity on the cancer site it affects. Estimate the new values for each of the parameters that register an immediate impact of the activity on those targets.
5. Identify the outcomes affected by the activity (e.g. number of patients offered a particular support activity, incidence, mortality). Estimate the value of each type of outcome.

6. Calculate the total points achieved by each programme for each cancer. (Details are provided in Eddy (1986a) on the approach required to do this; it involves estimating the proportion of the population likely to be reached by the activity and the change in mortality resulting from screening.)
7. Calculate the total points attributable to each activity. This is a measure of the effectiveness of the activity.
8. Estimate the financial cost of the activity.
9. Calculate the cost-effectiveness of the activity.

The approach involves estimates and it is likely that different observers will reach different conclusions. However, because the model requires the assumptions made to be specified, varying these assumptions allows the sensitivity of the outcome to the assumptions to be assessed.

Eddy (1986b) has developed the approach further in the form of a computer-based model CAN*TROL for designing strategies for cancer control. The model is based on an analytical framework that enables planners:

- to specify a population and the cancers that affect that population
- to define a group of cancer control activities for the population
- to calculate the effect of the activities on the incidence, prevalence, mortality, and cost of cancers in the population in future years.

The model is available in both mainframe and personal computer versions, and has been used in providing advice to WHO and to some Member States. As in the simpler model described above, the effectiveness of the model is dependent on the validity of the estimates used. For cervical cancer screening, there is a particular problem in that decisions are based on intermediate endpoints, such as changes in stage distribution, and it has yet to be confirmed in practice that the estimates that have to be built into the model result in an achievable reduction in incidence. Nevertheless, the model has been used in evaluating the best approach to cervical cancer screening in Chile (Eddy, 1986c). It was shown that it was far more cost-effective to screen 90% of the female population aged 30–50 years every 10 years than to screen 30% of the female population aged 30–55 years every 3 years (see Chapter 3, Table 7). In practice, the latter strategy was being used; even women under 30 years of age were being screened, many of them apparently annually. This programme was having hardly any impact on incidence and mortality from the disease. By using the available resources more efficiently, they could be redistributed to achieve a substantial benefit at less than half the cost.

Conclusion

Well organized cervical cancer screening programmes can significantly reduce the incidence and mortality from the disease in a country. A

reduction of at least 60% in incidence and mortality from the disease from baseline is possible, the theoretical maximum being of the order of 90%. To be most effective, these programmes must be planned in accordance with the established principles for national cancer control programmes (WHO, 1984). There are far too many examples, in developing as well as developed countries, of available resources being used inappropriately with minimal impact on the incidence and mortality from the disease. Success in this area requires planning, adequate facilities and resources, and coverage of the age groups of women at high risk for the disease.

Chapter 2

THE NATURAL HISTORY OF CERVICAL CANCER AND THE IMPLICATIONS FOR SCREENING POLICY

Introduction

In order to understand the recommendations made in this book on screening frequency, as well as on the age group to be screened, it is important to have some knowledge of the natural history of cervical cancer. Although there have been a few studies in which individuals were followed to determine directly the probability of progression or regression of cervical abnormalities detected through screening (e.g. Kinlen & Spriggs, 1978), this has generally been considered unethical and in any case the process of diagnosis may have affected the natural history of the disease. We are therefore dependent on information obtained from the follow-up of women with cytological abnormalities, and studies of the incidence and prevalence of well characterized lesions in defined populations, preferably followed over a long time.

This chapter reviews some of the evidence for regression of precancerous abnormalities of the cervix, and even of carcinoma *in situ* (CIS). Since these lesions, detected by the presence of abnormal cells on a cervical smear, occur most frequently in young women, whereas invasive cervical cancer is very infrequent in such women, screening at too young an age could lead to substantial use of resources in treating lesions with a low probability of progression to invasive cancer.

Classification of cervical cancer

There are two classifications in routine use relating to the presumed precursors of invasive cervical cancer. The first is the descriptive histological classification recommended by the World Health Organization in the series on the International Histological Classification of Tumours. The second and more recent classification (Richart, 1980) uses the generic term of cervical intraepithelial neoplasia (CIN) instead of the two terms "dysplasia" and "carcinoma *in situ*". The two classifications are compared in Table 1.

The CIN classification must be distinguished from the original Papanicolau smear classes of I to V used to classify smears from normal (class I and much of class II) up to presence of cells indicative of malignancy (class V). Although still used by some laboratories, these

Table 1. Histopathological classification of preinvasive lesions of the uterine cervix

Descriptive classification	Cervical Intraepithelial Neoplasia (CIN) classification
Dysplasia, mild	CIN I
Dysplasia, moderate	CIN II
Dysplasia, severe	CIN III
Carcinoma *in situ* (CIS)	CIN III
Microinvasive carcinoma	No CIN equivalent
Invasive carcinoma	No CIN equivalent

classes have been shown not to have strict histological counterparts and are no longer recommended for routine reporting of cervical smears.

The term dysplasia signifies that morphological changes have occurred in the squamous epithelial cells of the cervix, giving them the characteristics of neoplastic cells, but without involvement of the full thickness of the epithelium. When the full thickness of the epithelium is involved, the term carcinoma *in situ* (CIS) is used. Once a small amount of invasion has occurred through the basement membrane of the epithelium, the term microinvasive cancer is used. Invasive cervical cancer is a term used to describe frank histological invasion in a woman with no symptoms of the disease. However, the term cannot be uniformly applied as it requires the availability of both clinical and histological data. Further, a history of presence or absence of symptoms may not be helpful as some women with precancerous lesions may have symptoms similar to those of women with invasive cancer. Obviously some degree of judgement is required by the cytopathologist regarding the extent of the lesions, thus the boundaries between the various degrees of abnormality are not precise. This was the main reason for the introduction of the CIN system; however, as it involves some loss of information by combining severe dysplasia and CIS, it will not be used in this book.

Recently, a further revision of the categories has been proposed, in which mild dysplasia (CIN I) is combined with cytological abnormalities consistent with human papillomavirus (HPV) infection in one category as "low-grade squamous intraepithelial lesions", and moderate dysplasia (CIN II) and severe dysplasia and carcinoma *in situ* (CIN III) are combined in another category as "high-grade squamous intraepithelial lesions", in order to simplify recommendations on management (National Cancer Institute Workshop, 1989). This system is referred to as the Bethesda cytology reporting system.

Regression of dysplasia

In a study conducted in a large laboratory in Toronto, Canada, with a history of uniform classification of cytological abnormalities, it has been possible to assess the propensity for lesions diagnosed as having different degrees of dysplasia to progress (Miller et al., 1991a). The study was largely carried out prior to the widespread acceptance of colposcopy for diagnostic purposes in Canada. Thus, the cases were generally monitored cytologically by repeating smears at intervals of approximately 6 months to one year, unless progression to a more severe cytological abnormality had been demonstrated.

A sample of the records of 176 808 smears examined in the laboratory between 1962 and 1981 was reviewed. All smears from women with a diagnosis of dysplasia or a more severe cytological abnormality were included in the sample, together with a random sample of 3% of all records. The records of 70 236 women were examined, including 20 461 from the random sample and 49 775 selected because of mention of dysplasia on one or more cytology report.

The incidence of dysplasia among women with initially normal smears was quite high, rising to a peak of 55 per 1000 at 20–29 years of age, but falling to a low point of about 26 per 1000 at 50–59 years of age, though it did increase at older ages. However, the incidence of CIS or a more severe cytological abnormality among women who presented with dysplasia was low and relatively uniform up to the age of 50, at under 200 per 100 000, only rising to over 700 per 100 000 at 70 years of age or more. This low rate of progression means that there is only about a 10% chance of dysplasia progressing during a woman's lifetime. Hence the majority of cases of cytological dysplasia do not progress to more severe abnormalities.

The relative risk for a manifestation of CIS or a more severe cytological abnormality in a subsequent smear was greatest for those with severe dysplasia, low for those with mild dysplasia, and intermediate for those with moderate dysplasia (Table 2).

Table 2. Relative risk of carcinoma *in situ* or a more severe cytological abnormality

Diagnosis on original smear	Relative risk (95% CI)
All controls	1.0
Mild dysplasia	4.0 (1.5–11.0)
Moderate dysplasia	14.5 (5.6–37.5)
Severe dysplasia	46.5 (17.8–123)

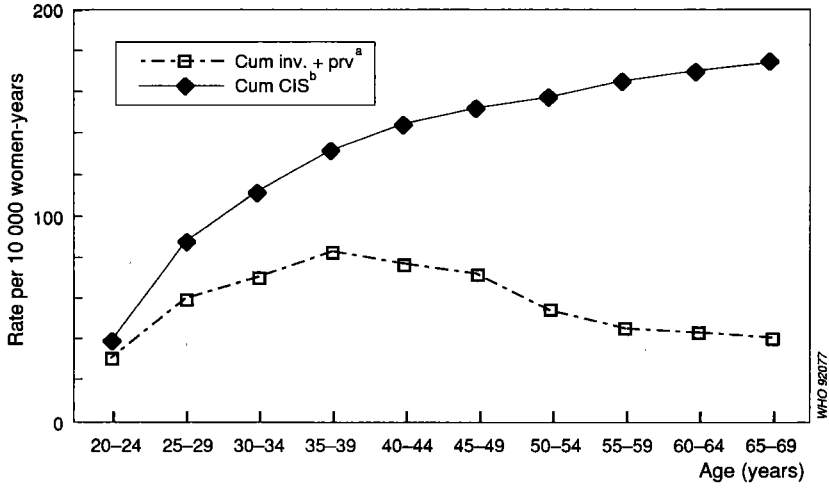
The majority of women with mild dysplasia showed normal cytology at the next smear. Indeed, the majority of women with any type of dysplasia, even those with severe dysplasia, showed no cytological evidence of progression at the next smear; an appreciable proportion of these women showed regression.

These results mean that there is a considerable risk of overtreatment if screening programmes concentrate on younger women, as the incidence of dysplasia becomes high at 20–29 years of age, while the risk of progression to invasive cancer at these ages is very low. To adopt a policy of screening younger women may therefore waste valuable resources on treatment for a condition that will most probably regress.

Regression of carcinoma *in situ*

The idea that CIS itself might regress seems questionable, because the term "carcinoma" would generally be regarded as applying to a progressive lesion. However, the addition of the term "*in situ*" is meant to imply that the lesion has not yet expressed one of the characteristic signs of malignancy, i.e. the ability to invade neighbouring tissue and spread, first locally, and through the lymphatic system, and at a later stage through the bloodstream. Where death occurs, this is usually as a result of complications of local recurrence. In fact, the term "carcinoma" in this context is a misnomer, and it should be kept in mind that CIS is a precursor of invasive cancer, which can be cured if treated appropriately, and which may even regress if left untreated.

The possibility that a number of these lesions might not progress, and that some might actually regress to normal, came from careful study of data derived from screening programmes, largely in North America, and particularly in British Columbia, Canada. The British Columbia laboratory is the only one in a province of over 2 million people, and has been operational since 1949. It moved from an initial phase of providing a diagnostic service to a population-based screening programme in the early 1950s. Study of the records of women screened in this programme showed that a far larger number of cases of CIS were being diagnosed than could be accounted for by the number of cases of invasive cancer that were occurring in the population. Although some of this could be explained by the number of cases of CIS that remained unchanged (measured by the prevalence of CIS in women screened for the first time), there was still a large discrepancy (the "yawning gap") between the cumulative incidence of CIS and the cumulative incidence of invasive cancer together with the prevalence of CIS (Fig. 1). If all cases of CIS progress to invasive cancer or remain unchanged, these two curves should be superimposed. There are only three possible explanations for the "yawning gap": an error in the estimation of incidence or prevalence of CIS, a much higher risk of cervical cancer in younger women than in older women (because



[a] Cum inv. + prv = cumulative incidence of invasive cervical cancer + prevalence of carcinoma *in situ*

[b] Cum CIS = cumulative incidence of carcinoma *in situ*

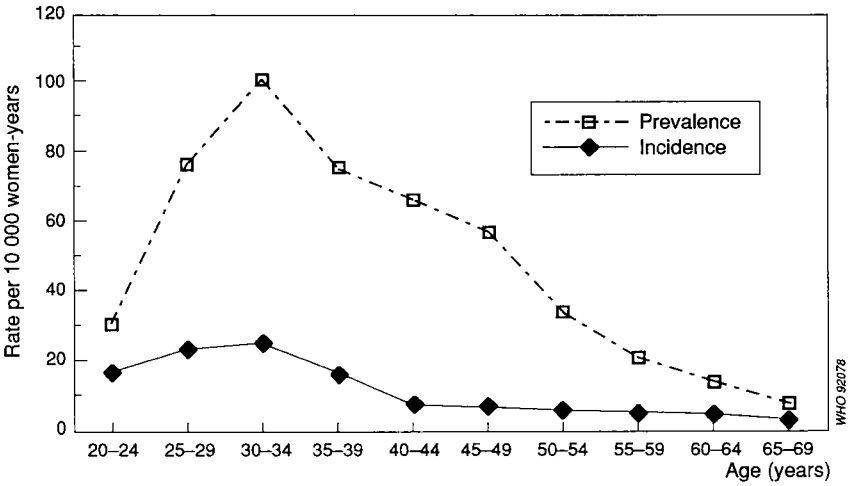
Source: Boyes DA et al. (1982)

Fig. 1. Illustration of the "yawning gap"

the incidence of CIS is largely derived from younger women while the incidence of invasive cancer is largely derived from older women), or regression of CIS. A specially designed investigation, the British Columbia Cohort Study (Boyes et al., 1982), conclusively demonstrated that neither of the first two explanations was correct, and it was concluded that regression must be part of the natural history of CIS.

A second study was recently conducted as an extension of the British Columbia Cohort Study (Miller et al., 1991a). The period of follow-up for the birth cohorts of women (born in 1914–18 and 1929–33) investigated in the British Columbia study was extended from 1969 to 1985. In addition, data were obtained on women born in 1944–48 to determine whether the natural history of cervical cancer was the same in younger women, believed to be at much higher risk of disease than those previously studied. The study focused on the incidence of CIS and of invasive cancer in the three cohorts.

There were over 75 000 women in cohort 1, who were studied from 1951 to 1985, covering the age range 35–69 years. Cohort 2, comprising just over 100 000 women, was studied over the same period, covering the age range 20–54 years. Cohort 3, comprising nearly 140 000 women, was studied from 1961 to 1985 and covered the age range 20–39 years. The data on the prevalence and incidence of CIS in

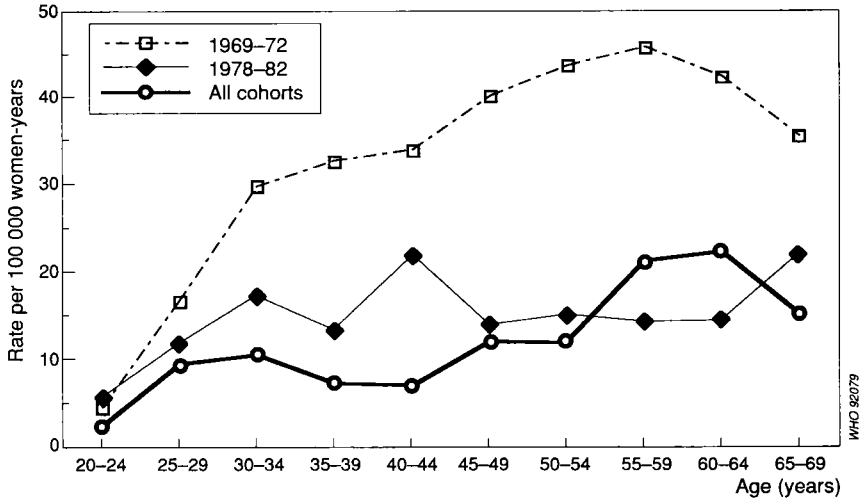


Source: Miller AB et al. (1991a)

Fig. 2. Prevalence and incidence of carcinoma *in situ*

relation to age do not suggest any major difference in the natural history of the disease for the three cohorts; thus the rates were similar at overlapping ages, even though separated by 15 calendar years. The data show that the prevalence and incidence of CIS reach a maximum at about 30–34 years of age, but that new cases continue to occur to an appreciable extent among women in their 60s (Fig. 2, comprising data from all three cohorts).

Fig. 3 (derived by combining data from all three cohorts) shows the estimated incidence of invasive cancer in women who had at any time (including in the past) been screened for cervical cancer. The incidence of invasive cancer was less at comparable ages for cohort 2 than cohort 1, possibly reflecting the fact that a greater proportion of the women in cohort 2 had had several negative screening tests; however, the incidence in cohort 3 was similar to that in cohort 2. The figure also shows the incidence of invasive cancer in the general population during 1969–72 and 1978–82 (including unscreened as well as screened women). The difference between the curves reflects the benefit of the screening programme in reducing the incidence of the disease. The cumulative incidence of invasive cancer over the age range 20–69 years was 1.63% for 1969–72, 0.76% for 1978–82 and 0.55% for the screened women in the three cohorts. Thus the incidence of invasive cervical cancer among the women who were screened was less than one-third of the incidence in the general population in 1969–72. This probably underestimates the effect of screening, as the screening programme was already having some effect in 1969–72. Fig. 3 also shows that the incidence of invasive cervical cancer in the women who were screened was high above 55 years of age; this was probably accounted



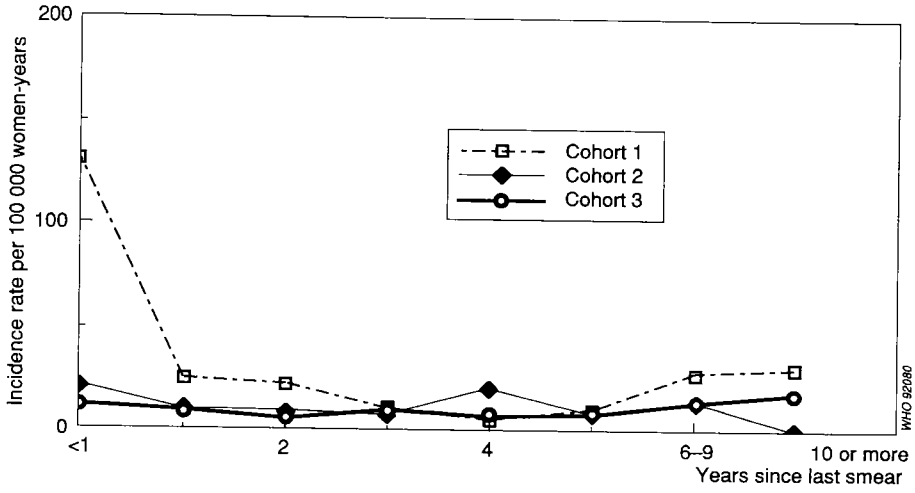
Source: Miller AB et al. (1991a)

Fig. 3. Incidence of invasive cervical cancer, in British Columbia, Canada, in the general population (1969–72 and 1978–82) and in women who have been screened (all cohorts combined)

for by the women who had failed to attend for follow-up after initially being screened and who returned to the screening programme because of symptoms of disease. It has been well documented in both British Columbia and Ontario, Canada, that the majority of women who develop invasive cervical cancer have either not been screened at all, or have not been screened for 5 years or more (Anderson et al., 1988; Carmichael et al., 1984). That this may indeed be so is indicated by evidence of low rates of invasive cancer in women who had had one negative smear, which persisted for at least 5 years, with even lower rates if there had been two negative smears. The rates were almost as low for older as for younger women with two negative smears (Fig. 4). Further, in each cohort the rates were even lower for women who had had four or more negative smears (Fig. 5).

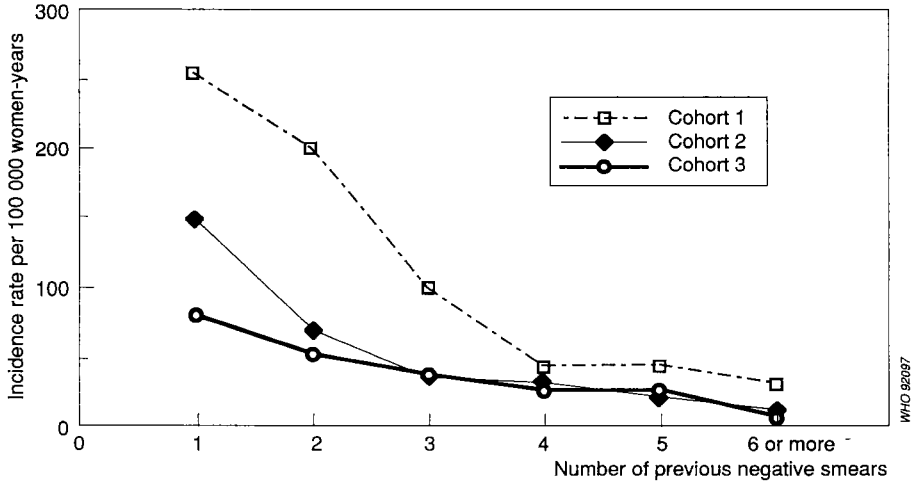
Thus the findings from this study are compatible with those previously reported (Hakama et al., 1985). They show that younger as well as older women who have had two or more negative smears have low rates of invasive cancer, thus confirming the validity of the conclusions drawn by the IARC Working Group on Cervical Cancer Screening (1986). There is no evidence from these data to suggest that re-screening should be more frequent for younger women than older.

In the British Columbia Cohort Study, estimates were made of the proportion of cases of CIS that regressed (Boyes et al., 1982). These were minimal estimates, since such estimates would not include the



Source: Miller AB et al. (1991a)

Fig. 4. Incidence of invasive cervical cancer after two negative smears



Source: Miller AB et al. (1991a)

Fig. 5. Incidence of invasive cervical cancer with number of previous negative smears

cases of CIS that occurred and regressed in the time between examinations. A similar exercise was performed in the update of the study (Miller et al., 1991a), with estimates of regression being made over the age range during which each cohort was followed: for cohort 1, 61% of cases of CIS were estimated to have regressed over the age range 40–64 years; for cohort 2, 70% over the age range 25–54 years; and for cohort 3, 77% over the age range 15–39 years. The implication is

that the natural history of carcinoma *in situ* involves a dynamic process, with regression most likely to occur at younger ages, but still occurring at a significant rate at older ages. The effect on screening policies is to emphasize the importance of screening at older ages, at a sufficient frequency to ensure that the majority of cases of invasive cervical cancer are detected, but infrequently enough to avoid too much nonprogressive disease being detected and therefore having to be treated. It must be kept in mind that these studies have all indicated that CIS can usually be detected for several years before it progresses to invasive cancer, if it is going to do so; this latent period has been estimated to be about 10 years. In addition, empirical studies (IARC Working Group on Cervical Cancer Screening, 1986; Yu et al., 1982) and clinical experience (Hakama et al., 1991) show that screening every 5 years leads to a substantial reduction in the expected incidence of cervical cancer, providing the laboratory services are efficient, achieving adequate sensitivity in examining the smears, and the diagnostic and treatment services are adequate to ensure that those with abnormal smears are appropriately managed.

Chapter 3

MANAGERIAL GUIDELINES FOR IMPLEMENTATION AND EVALUATION OF CERVICAL SCREENING

This chapter is concerned with the basis for managerial decisions on the implementation of screening for cervical cancer, i.e. with policy decisions on whether to implement screening or not, and decisions on the sector of the health service in which screening should be organized and on who should be responsible for managing the screening programme in a region. It also deals with the surveillance and evaluation of screening, especially within different sectors of a health service. Thus the chapter considers the problems associated with screening from a programme management viewpoint.

Where to begin screening within a population will depend on a comparison of information on who is developing cervical cancer with information on the extent of coverage by different sectors of the health service, together with a consideration of the costs and feasibility of implementation of screening in both the short term and the long term.

Background

The specific etiology of cervical cancer is unknown; however, the disease is strongly associated with early age at first intercourse and multiple sexual partners (both of the woman and of her male partner), supporting a sexually transmitted infectious agent as the principal cause. Other factors that may have a causal role include parity, cigarette smoking and use of oral contraceptives. These risk factors also tend to be associated with the preinvasive stages of cervical cancer, including carcinoma *in situ* and moderate and severe dysplasia.

There is substantial laboratory evidence to suggest that human papillomavirus (HPV) infections of the cervix may be a cause of cervical cancer (WHO, 1987); however, the epidemiological evidence suggests that only a small proportion of women infected with the virus develop the disease. Thus, there are no grounds for utilizing tests for HPV in screening for cervical cancer.

This knowledge on risk factors for cervical cancer does not provide a practical strategy for prevention of the disease, other than general recommendations to use barrier contraceptives, a recommendation compatible with efforts to prevent the spread of human immunodeficiency

virus (HIV) and sexually transmitted diseases. Technically, the use of exfoliative cytology to detect precursor lesions and preinvasive cervical cancer is highly effective (WHO, 1986), and can prevent morbidity and mortality from the disease. To be effective at the general population level, however, careful organization of screening programmes is required, together with monitoring and surveillance (Hakama et al., 1985). Although there are very few populations, especially in developing countries, where cervical cancer is not an important public health problem, the decision to implement a screening programme will depend on several factors, including competing health and other priorities, and the availability of facilities and resources.

Deciding upon a cervical cancer screening programme

As discussed in Chapter 1, the decision to implement screening for cervical cancer should be based on:

- evidence that cervical cancer is a major health problem;
- characteristics of individuals and populations at risk;
- an appropriate health service infrastructure;
- technical resources for smear collection and cytological examination;
- resources for diagnosis and treatment of cases.

Evidence that cervical cancer is a major health problem

Data on the occurrence of the disease are a prerequisite for planning any cancer control programme. Ideally, these data should be the national cancer incidence and mortality rates. However, incidence data can only be obtained from population-based cancer registries; these are seldom available on a national basis, but in some countries registries may be operational in some areas. Mortality data are more often available, though the efficiency with which death certificates are completed will influence the extent to which they can be regarded as reliable. For cervical cancer, there is a particular problem as the cause of death may be described as cancer of the uterus, without specifying whether the site was the cervix or the body of the uterus. In general, it is appropriate to include all deaths from uterine cancer in mortality data on cervical cancer.

In many developing countries, cancer incidence data are not available, and mortality data are unreliable. Under such circumstances data from hospitals or pathology laboratories can be used, with the relative frequency of the different forms of cancer indicating their relative importance. It is usually possible to analyse such data by age and sex; data may also be available on a historical basis. Analysing the data by age will indicate in which age group the majority of cases are occurring, and this will identify the priority age groups on which to con-

centrate screening. In most countries the incidence of invasive cervical cancer is very low in women under 25 years of age, increases at about 35–40 years of age, and reaches a maximum in women in their 50s and 60s. Such data should of course be interpreted in relation to the age structure of the population.

Characteristics of individuals and populations at risk

The epidemiological indicators of risk (such as multiple sexual partners) are of little value in selecting women for screening. As indicated above, the most important risk factor for determining the priority group for screening is age. In addition, there is an inverse relationship between socioeconomic status and risk of cervical cancer in all countries, which means that the women at lowest risk of the disease are often the ones who request and adhere to screening. In contrast, the women at greatest risk of the disease, i.e. those from low socioeconomic classes, will often have so many other problems (in addition to health) that neither they nor their physicians will recognize the high priority with which they should be screened, once they reach 35 or 40 years of age. When screening programmes are being organized, these social characteristics of the disease should be recognized, to ensure that action is taken to target those at greatest risk of the disease.

An appropriate health service infrastructure

For screening to be introduced into a region, a basic health service infrastructure should exist at both the primary health care level and the district hospital level (see below). At the primary level, ideally a mechanism should exist to identify women in the target age group in the population (see Chapter 4); however, these women can be identified and screened in the absence of such a mechanism. Although preferable, it is not essential for a special service to be established for cervical cancer screening. In many countries, the only feasible approach to implementing screening is through existing health services.

Technical resources for smear collection and cytological examination

Before a screening programme is started, the resources must be in place for taking the smears (see Chapter 4) and a cytology laboratory must be accessible to examine and report on the smears (WHO, 1988). To ensure that the laboratory services are both efficient and cost-effective, they should be centralized, each laboratory being supervised by a full-time cytopathologist, with an organized system of quality assurance and continuous education of cytotechnologists.

Resources for diagnosis and treatment of cases

The success of cervical screening is dependent on appropriate treatment being available for women with abnormal cytology. If suitable accessible facilities for such treatment do not exist in the area (e.g. a department of gynaecology in the district hospital) screening will be of no value. Part of the difficulty with this requirement is that when screening is first introduced in an area, cases with advanced (but until then undiagnosed) cervical cancer will be found. Such cases will give rise to two difficulties: first, a cervical smear will often be negative even in the presence of clinically obvious cancer, because only necrotic tissue is collected, which does not provide cells that can be interpreted by the cytologist. Therefore the practitioner or allied health worker must be able to recognize such disease, and refer the patient for diagnosis and therapy whatever the findings on the smear, or preferably without waiting for the smear results (or even taking a smear). Secondly, patients with advanced cancer of the cervix will require much more sophisticated treatment services than those with early or preinvasive disease (the disease sought in a continuing screening programme). A region may be unable to afford sophisticated therapy for patients with advanced disease (where the outcome is likely to be poor anyway), but may be able to provide the simpler surgery capable of curing early disease. It will be important to recognize the implications of this, as otherwise the programme may encounter public resistance or become discredited because it may seem that screening has no effect on the outcome of the disease.

However, it is important to recognize that extensive facilities are not required for the diagnosis and management of early cervical cancer or precancerous lesions. In particular, colposcopy services are not essential, even though, if available, they will facilitate the diagnosis and management of precancerous lesions. The successful early programmes in British Columbia, Canada, and Finland were introduced without the availability of colposcopy, and had their major impact prior to the introduction of such facilities. Indeed, there is good evidence that the introduction of colposcopy substantially increased costs (Miller et al., 1991a). The basic requirements for diagnosis and management of precancerous lesions are described elsewhere (WHO, 1988). Briefly, tissue diagnosis is achieved by a directed punch biopsy, with a cone biopsy often sufficing for treatment of severe dysplasia or carcinoma *in situ*. Such procedures should be well within the competence of a district department of gynaecology.

Health service sectors in which screening can be offered

If it has been decided to initiate a cervical cancer screening programme, a decision will have to be taken on whether to incorporate

screening into existing services such as maternal and child health and family planning, or into other services with an older clientele.

This decision will be based on a consideration of the epidemiology of the disease, the group targeted for screening, the coverage of women at risk by different health service sectors and the relative costs. The goal for planners of screening programmes is to obtain high coverage of the women at risk of cervical cancer by appropriate health service sectors or alternative screening programmes, and to keep the costs to a minimum. Ideally, services should be selected that include the women at highest risk, have the resources to take smears, and can recall women who have been screened.

Epidemiology

The groups targeted for screening should be women at risk of cervical cancer as defined by known risk factors, including age and low socioeconomic status. Screening should be aimed at the age groups in which cervical cancer is common, starting 1–2 years before the incidence of invasive cervical cancer reaches appreciable levels. The implication of this is that, when programmes are introduced, careful consideration should be given to starting screening no earlier than 35 years of age. This will largely eliminate the problem of dysplasia in younger women, as evidence shows that the vast majority of these lesions regress spontaneously (see Chapter 2). In developing countries this is particularly important, because resources are likely to be very limited and the age structure of the populations means that costs are much less if tests are concentrated on older women.

Coverage of women at risk

In developed countries, information on the coverage of women at risk by different sectors of the health services is potentially available from health service records. The concept of what is required is simple, and attempts to answer the question—"What proportion, by age group, of women in the population are seen by specified health service sectors?" Although precise information can be difficult to obtain due to the many different sources of data and the difficulties of data retrieval, only estimates are required, and informed guesses by experts will usually be adequate. These should be based on the ages of women using different services such as maternal and child health, family planning, primary health care, private physicians, and public hospitals and health centres, together with estimates of the proportion of the population using these services.

Some developing countries will also have access to such data and informed management decisions can be taken on which health service

sectors should undertake cervical cancer screening. In many developing countries, however, the options may be limited. Other than the maternal and child health and family-planning services (discussed in more detail below), there may be only the network of primary health care workers, often already strained, especially in rural and overpopulated urban areas. A decision to base screening on these workers will depend on the extent to which they can undertake additional tasks.

Comparison of epidemiology and coverage

Review of the coverage of the population by different health services may show that the women at highest risk of cervical cancer are not being adequately contacted by an appropriate service. This is likely to be the case for women older than 35 or 40 years of age in most countries. Under such circumstances, in order to achieve sufficient coverage of the population, the programme manager will need to explore alternative means of increasing contact, using personal invitations based on existing population registers (see Chapter 4). Unfortunately, in many countries, such registers do not exist, though in most rural areas there may be a mechanism through village elders to systematically identify those in the target group. Collaboration with such sources by primary health care workers may help to facilitate high coverage of the population at risk. In addition, every opportunity should be taken through primary health care in the community to ensure smears are taken as appropriate when older women make contact with services for other health reasons. If the existing primary health care workers are already overburdened, however, and their number cannot be increased, it may be necessary to recruit a mobile team of specially trained community health workers who can visit the different areas in turn, combining the collection of smears from women in the target age group with other public health activities. Such workers may already exist, but it may be necessary to increase their number and reduce their areas of operation to enable them to add cervical cancer screening to their responsibilities.

Use of maternal and child health/family-planning services for initiating screening

In many countries, maternal and child health/family-planning (MCH/FP) services have been used for initiating cervical cancer screening programmes. In Canada, for example, many programmes reached a high proportion of young sexually active women in the population by targeting women who were being prescribed oral contraceptives for a cervical smear. The arguments often made in support of the use of MCH/FP services for cervical screening include:

- there is a high coverage of young women who are sexually active;
- a baseline is created for further screening after 35 years of age when the risk of cervical cancer is greater;
- there are educational benefits; women can become accustomed to the procedure and can be taught its importance.

Unfortunately, as indicated from the comparison of epidemiology and coverage, the target group that should be recruited into cervical screening is largely not covered by MCH/FP services; money spent now on screening women using these services will not have an important impact on cervical cancer for 10–20 years. No country can afford such a waste of resources. Further, it is by no means clear that women whose screening experience is related to childbearing will regard attending for cervical smears as an appropriate activity when they are no longer having children. Thus, the only group attending MCH/FP services who should be targeted for a cervical smear are the older women, i.e. those over the age of 35 or 40, according to whichever year has been selected for initiation of screening.

The main value of MCH/FP services in cervical cancer screening programmes is thus not to screen the young mothers, but to ensure through the young mothers that their mothers and aunts are screened. With the extended families in many developing countries MCH/FP services could be used, therefore, largely to reach the women who no longer require their services. However, this would imply that there is another health service sector, consisting largely of primary health care workers, to which these older women could be referred.

Use of occupational health services for screening

In some countries (e.g. China) occupational health services have been used extensively for cervical screening, with evidence of success in ensuring compliance and in reducing the incidence of the disease. If the occupational health services in a country are an integrated part of health care, such an approach will contribute to the control of cervical cancer among women with access to the services; however, the coverage is unlikely to be complete, particularly for rural populations, and there is a risk that women will be lost from screening when they leave the occupation. Further, many occupational health services serve a mainly young age group. Thus, the women being targeted may be too young (as with maternal and child care services) and indeed may leave the occupation just as they are reaching the age of maximum incidence of cervical cancer and be lost from screening. As far as possible, therefore, occupational health services should be used to supplement the main programme, but not substitute for it. This will be facilitated if an appropriate information system can be developed for the programme, as described in Chapter 5.

Use of mobile units for screening

Mobile units or teams have been used in many circumstances for cervical screening. If used in the context of an organized programme, i.e. with the target population defined and personal invitations to individual women based on appropriate record systems, mobile units can increase the coverage of scattered (rural) populations in the target age group. Their use in the context of "health fairs" is not recommended, however, as almost invariably the target population cannot be properly defined, which means that the wrong age group is screened and women cannot be traced subsequently to ensure that those found to have cytological abnormalities attend for further diagnosis and treatment. Resources expended on mobile units under these circumstances can almost always be better spent in a more formally organized programme directed to women in the target age group.

Costs of screening in different health service sectors

The costs of screening can be considered in two main categories: the costs of contacting women in the target group, and the incremental costs of providing cytology and diagnostic and treatment services. Only the costs of contact will vary significantly between the different options for screening. Costs may appear lower if an existing service is used, but this will only be true in cost-effectiveness terms if this service has direct contact with the target group. For example, although it may appear to be attractive to use MCH/FP services, because large numbers of women are under observation, if the women screened are too young, the costs will have been largely wasted and the cost-effectiveness of the programme will be low. Thus it may be more cost-effective to expand an existing service to cope with larger numbers of women in the target age group, even though this approach may initially appear more costly.

Frequency of screening

The results of an international collaborative investigation have shown that women with a negative cervical smear have low rates of invasive cancer for 5 years, with the rates remaining below those in the general population for 10 or more years (IARC Working Group on Cervical Cancer Screening, 1986). The rates are even lower in women who have had two negative smears. This means that it is quite unnecessary to screen women annually, and that it may be almost as effective to screen women every 5 years. Unfortunately, in many countries there are some programmes where women are screened every 6–12 months. Resources are being overused on a small proportion of the population, with very little benefit; much more effect would be achieved with high

coverage of the population and limited numbers of smears in the women's lifetime.

Table 3 (WHO, 1986) illustrates the effect of different screening intervals on the estimated risk of invasive cervical cancer in women aged 35–64 years, based on data from screening programmes in Europe and North America. The women all had a negative cervical smear at 35 years of age. The table shows that the reduction in incidence from screening every 2 years is as great as from annual screening, and that the reduction in incidence from screening every 3 years is almost as great; even screening every 5 years offers substantial benefits.

These estimates assume total coverage of the population. Although this is the ideal to be aimed for, it is rarely achieved; Table 4 illustrates the effects of screening different proportions of the population at different frequencies.

It is clear that it is more cost-effective to recruit a high proportion of the population and screen them infrequently, than recruit a low proportion and screen them often. Table 4 is based on the assumption

Table 3. Reduction in the cumulative incidence of invasive cervical cancer over the age range 35–64 years, with different frequencies of screening[a]

Frequency of screening	Percentage reduction in cumulative incidence	No. of tests
1 year	93	30
2 years	93	15
3 years	91	10
5 years	84	6
10 years	64	3

[a] From WHO, 1986.

Table 4. Reduction in the cumulative incidence of invasive cervical cancer over the age range 35–64 years, with different proportions of the population screened and different frequencies of screening

Frequency of screening	Proportion screened	Percentage reduction in cumulative incidence	No. of tests[a]
1 year	20%	19	6
2 years	30%	28	4.5
3 years	40%	37	4
5 years	50%	42	3
10 years	80%	51	2.4

[a] Per woman in the total population.

that all women have similar degrees of risk. However, it has been shown that the women at low risk of cervical cancer in a population are more likely to be screened than those at high risk. Table 4 therefore overemphasizes the degree of benefit that would be achieved by screening a small proportion of the target population too often.

Age to initiate screening

The age at which screening is initiated is also highly relevant to the optimal use of the resources available. Table 5 illustrates the effect of initiating screening at different ages on the estimated risk of invasive cancer, based on data from Cali, Colombia (a country with a high incidence of cervical cancer). The estimates assume total coverage of the population.

Table 5 demonstrates that the reduction in incidence from starting screening at 20 years of age is as great as from starting at 25 years of age, and the reduction in incidence from starting at 35 years of age is almost as great. Table 5 also shows the effect of screening every 2 years over the age range 20–39 years, as could happen in a programme based entirely on MCH/FP services. It is clear that the reduction in incidence is substantially less than from starting screening at 35 years of age, while the resources required are greater.

Health education about screening

There are three mechanisms available for informing women about screening and persuading them to attend: public education campaigns to encourage women to request screening, professional education to ensure that primary health care workers include their patients in screening programmes, and an organized programme combining these two elements with a mechanism to ensure that women are invited to be screened. The first two elements have been shown to be insufficiently effective in programmes in developed countries such as Canada and the United Kingdom. Furthermore, it is not clear whether they have been targeted to those most in need of information. Hence, special efforts are required to bring many at-risk women into screening programmes.

However, it is unlikely that all women in the target population will respond to simple invitations to attend for screening, especially if they are out of touch with the health care system, or if their previous experience with the system has not been positive. In addition, most women at high risk of the disease have other health, social or economic problems which they may perceive as being of greater priority than their need for a cervical smear. Accordingly, a coordinated programme of health promotion is needed to ensure that women in the

Table 5. Reduction in the cumulative incidence of invasive cervical cancer for different ages at initiation of screening

Age screening initiated	Frequency of screening	Percentage reduction in cumulative incidence	No. of tests
20 years	5 years	84	9
25 years	5 years	84	8
35 years	5 years	77	6
20 years (until 39 years)	2 years	52	10

target group understand the reasons for screening, what the procedure involves, the meaning of the results and the purpose and effectiveness of any recommended treatment. Operational research to determine the best ways to recruit women into the programme may also be required. The approaches to health promotion should be client-centred, and appropriate to the local cultural setting. In designing these approaches, key parties for participation are women, health care providers, community leaders and those involved in other relevant sectors such as education.

Information on cervical cancer and the role of the male in prevention as well as in encouraging his partner to participate in screening should be communicated sufficiently early in life to have an effect (i.e. at the onset of sexual maturity), and be available to all adults.

Effect of a single smear in a woman's lifetime

Even low-level activities, appropriately directed, can be quite valuable. An appropriately timed smear, once in a woman's lifetime, could reduce the incidence of invasive cervical cancer. In order to be most effective, however, the single smear should be timed to ensure that the maximum number of women who are likely to develop invasive cancer in the future are examined when detectable precursors or preinvasive lesions are present. Table 6 illustrates the effects of taking a smear at different ages on the risk of invasive cervical cancer, based on data from Chile.

Cervical cancer is an important health problem in Chile, and cervical cytology services are available, but until now screening has had little impact on the incidence of the disease, as it has been directed at the wrong target group (see Chapter 1). Table 6 indicates that if it is decided to take a single smear in a woman's lifetime, the smear should be taken from women aged at least 40, and preferably 45 years for maximum effect.

Table 6. Reduction in the cumulative incidence of invasive cervical cancer as a result of a single screen at different ages

Age of single screen (years)	Percentage reduction in cumulative incidence	No. of tests in population[a]
30	11	88 000
35	15	81 000
37	17	81 000
40	20	70 000
45	26	57 000
50	26	45 000
60	21	34 000

[a] Based on 1985 estimated population of Chile.

Economic aspects of screening

In Canada the cost of screening for cervical cancer has been estimated to be about 10 Canadian dollars per smear (or $45 if the fee for the appointment to take the smear is included) (Miller et al., 1991b).

Additional costs must be considered when an organized screening programme is being set up. These are associated with the need for quality control, evaluation and monitoring of the programme, centralization of cytology services, and establishment of an appropriate information system, as well as financing of public and professional education programmes. The costs associated with cytology laboratory services have been summarized elsewhere (WHO, 1988). However, when a country considers substituting an organized programme of cervical cytology for a system that depends on opportunistic screening, the resources available as a result of less frequent screening of low-risk women are likely to cover the costs of reaching and screening the older high-risk women until then largely unscreened, as well as the costs of organizing the programme (Miller et al., 1991b).

As the frequency of screening is increased from once in a woman's lifetime to annual screening, the marginal costs per year of life gained escalate. For example, it has recently been estimated by the Office of Technology Assessment in the USA that a single screen at 65 years of age would cost US $1666 per year of life gained (Muller et al., 1990). Screening every 5 years from 65 years of age would cost US $3119 per year of life gained, but screening every 3 years would cost US $9075 per year of life gained and annual screening US $48 868 per year of life gained. Changing to an organized system of cervical cancer screening and reducing the frequency of unnecessary rescreening can therefore be regarded as cost-effective.

Table 7. Cost-effectiveness of two different strategies for cervical cancer screening in Chile[a]

	Programme 1	Programme 2
Age	30–55 years	30–50 years
Frequency	3-yearly	10-yearly
Compliance	30%	90%
Reduction in mortality	15%	44%
Reduction in treatment costs	US $0.13 million	US $0.25 million
Cost per case detected	US $2522	US $556

[a] Source: Eddy (1986c).

Similar considerations should govern the introduction of screening in developing countries. Table 7 compares the cost-effectiveness of two different strategies for cervical cancer screening in Chile (Eddy, 1986c). It is clear that less frequent screening but with high coverage of the population at risk is a more cost-effective strategy.

Monitoring and evaluation of screening

Monitoring and evaluation are essential to ensure that the programme is both efficient and effective. Process measures, such as the number of smears taken, the number of positive smears reported, the number (and proportion) of women referred for diagnosis and therapy, the number of invasive cervical cancers diagnosed and the number of precursor and benign lesions detected, should be obtainable from the laboratory and treating institutions. Such data must be analysed by age to confirm that women in the target age group are being screened, and that the subsequent management is appropriate. However, such data cannot be used to evaluate the effectiveness of the programme in terms of the prevention of invasive cervical cancer, unless the data on cancers detected can be related to information derived from the total population, which requires a pre-existing cancer register or a register of cases of cervical cancer established for this purpose.

The simplest form of evaluation that will provide a measure of the effectiveness of the programme is to demonstrate a change in the incidence rate of cervical cancer (or in the number of advanced cases or mortality from the disease) in the population. More detailed evaluation requires the identification of all women who develop invasive cervical cancer in the target population and documentation of their screening history. Such documentation could be done by comparing new cases of cervical cancer in the target population with a register of women from the same population who have been screened. This will permit an estimate of the relative risk in women who have been screened and in those who failed to attend screening, and the

combined effect can then be compared with the prescreening period. Where such registers have not been established, a screening history should be obtained from all women with cervical cancer, though this may not be reliable as many women may be unable to recall whether a smear has been taken in the past.

Efficient monitoring requires a system of linked records. A population register (or available substitute) allows periodic call-back for rescreening at appropriate intervals. The cytology register, when linked with a cancer register (which could be ad hoc and specific to cervical cancer), permits women with cytological abnormalities to be recalled for repeat screening, diagnosis and therapy. Evaluation of the programme can then be carried out with regard to the assessment of:

- management of women with positive smears;
- false-negative smears;
- cancers which are detected during the interval between consecutive screens;
- groups missed in the target population.

Further details of the data requirements for efficient management and evaluation of cervical cancer screening programmes are given in Chapter 5.

Responsibility for cervical cancer screening

The efficient management of cervical cancer screening in a country or region should preferably be the responsibility of a designated official within a relevant organization. If cancer control has been designated to a special agency in a country, this official should have an appointment within that agency. Alternatively, it would be appropriate to designate an official within the ministry of health.

In general, it is not appropriate for the director of the cytology laboratory to be made responsible for the overall management of the programme, because the responsibilities for the programme are far wider than for the laboratory, and cover aspects such as the identification of the target group, recruitment, screening, management of any cytological abnormalities detected and evaluation of the impact of the programme.

The programme manager should be aware that successful cervical cancer screening programmes have a number of common features:

- They are organized as public health programmes, and not simply as laboratory services for clinical investigations.
- They target the age groups at greatest and most immediate risk (i.e. above 35 years of age), concentrating on women who have never had a smear.

- They use population registers to identify women in the target group.
- The person in charge is named, can be contacted by telephone, and is held responsible for his or her actions (Editorial, 1985).

In order to run a successful programme, the manager requires skills in the fields of epidemiology, public health and management.

Chapter 4

CERVICAL SCREENING IN PRIMARY HEALTH CARE[1]

Setting up a screening service

The smear register

All primary health care practitioners should aim to identify, reach, invite, and screen the women in the target population in their practice area. If a register of the practice population is maintained, it should be possible to identify the target population from the recorded age or date of birth. If there is no pre-existing register, a mechanism should be introduced to set up a simple register for the purposes of cervical screening. This can be done using a simple card system. The card should identify the woman's name, address, date of birth, and a family contact, and provide space for the date of each cervical smear, the result, and details of any referrals necessary for treatment. Reports received from the cytology laboratory should be filed with and linked to the patient's card.

The administrative and documentation aspects of the smear register should be familiar to all staff members, but should be run mainly by one person.

Training of staff

All doctors, nurses, and allied health workers in the practice should be specially trained to take adequate smears using a vaginal speculum and to perform and interpret a pelvic examination if indicated by the patient's symptoms or by the appearance of the cervix. Training courses should be given in the department of gynaecology at the local district hospital, if necessary. In addition, all staff should have a good knowledge of family planning and contraception and well-woman screening procedures, coupled with a good knowledge of menopausal and postmenopausal problems.

Accommodation and equipment

Accommodation should include suitably equipped rooms that are clean, warm, well ventilated, and well lit, and that provide privacy and

[1] Based on an article by Chomet & Chomet (1990), with permission.

have comfortable couches. The equipment and supplies required for taking smears include gloves, spatulas, specula, and glass slides; facilities for sterilizing equipment are also needed. The purchasing, ordering and reordering of disposable items (such as spatulas and slides) and their storage and distribution in the practice must be carefully organized.

Relationship with the laboratory

A delivery system is required for transport of slides to the laboratory, and for transfer of reports from the laboratory to the practice. The laboratory must have adequate quality control procedures in place for cervical cytology (see WHO, 1988). The laboratory should also accept some responsibility in follow-up of patients found to have abnormal smears. Good liaison with the laboratory is an important part of the screening process.

Relationship with the treating institution

The success of cervical screening is dependent on appropriate treatment being available for any cytological abnormalities found on screening. If suitable accessible facilities for such treatment do not exist in the area (e.g. a department of gynaecology in the district hospital), screening will be of no value. There must be a mechanism in place to ensure that women with abnormal smears are referred to this institution for diagnosis and therapy; the responsibility for ensuring that the women understand this requirement is that of the primary health care practitioner. Further, it should be ensured that the results of any investigations, the necessity for repeat smears or for other forms of follow-up, and the results of treatment are reported back to the practitioner.

The target group for screening

All women in the age group determined as appropriate for the national cancer control programme, who are or have been sexually active, should be screened (see Chapter 1). In order to ensure that the available resources are used in a cost-effective manner, a stepwise approach to the introduction and expansion of screening is recommended (WHO, 1986). In countries where resources are limited, the aim should be to screen every woman in the target group once in her lifetime at about the age of 40 years. When more resources are available the frequency of screening should be increased to once every 10 years, and then once every 5 years, for women aged 35–55 years. If resources increase and a high proportion of the target group are being

screened, screening should be extended, first to older women (up to the age of 60) and then to younger women (down to the age of 25). If additional resources are available and a high proportion of the target group are being screened every 5 years, the frequency of screening should then be increased to once every 3 years for women aged 25–60 years.

Once screening has been extended up to the age of 60, screening is indicated for women over the age of 60 who have never been screened, or for those for whom a negative screening test has not been recorded in the last 10 years. If resources permit, two negative screening tests should be recorded for such women before recall for screening ceases. Screening is not indicated for women within the target group who have had a hysterectomy for a non-malignant condition if before that hysterectomy they had a normal smear and if the removed uterus and appendages were non-malignant.

Annual rescreening is contraindicated in every country in any age group. The resources needed for such screening will always be more appropriately used for other forms of health care as the marginal benefits of annual screening over 3-yearly screening are negligible and the costs are considerably higher. Screening women under 25 within a year of first having sexual intercourse is unnecessary as, even if a pre-cancerous abnormality is detected, the likelihood of it progressing to invasive cervical cancer below the age of 25 is very low (Miller et al., 1990). It may often be felt that screening women within an existing health infrastructure is cost-effective, thus screening women within the age range 20–25 years is sometimes advocated by maternal and child health programmes, in part because bringing women into screening at these ages may encourage their participation later. There is little evidence that such screening achieves these objectives, however, while it substantially increases costs because of the high frequency of cytological abnormalities in this age group that require diagnosis and are then treated, even though the majority of them would have regressed without treatment (see Chapters 2 and 3).

Ensuring that the target group is screened

Personal invitations

If practical, the best method for organizing the attendance of women in the target group for screening is by personal invitation. For women who are literate, this can be in the form of a letter. For those who cannot read, the invitation could be delivered personally by an allied health care worker, or by a woman in the village or area who has agreed, on a voluntary or paid basis, to deliver invitations to women in the target group. Whatever form the message takes, it should be carefully worded to enable the recipient to understand the importance

and benefit of being screened and to encourage other women in the target group to do the same.

The women in the practice area should have already been characterized as being in the target group or not. If the practice is setting up a register from scratch, it may be necessary to seek the collaboration of village elders in identifying members of the target group. It may also be necessary, in many cultures in developing countries, to obtain the approval of husbands before their wives are screened. The necessity for screening, and the reason why some women are in the target group whereas others are not, may have to be explained through appropriate health education. Once the register has been set up, it can be used to identify women in the practice area who are due to be rescreened, providing the means have been found to identify those new to the area as well as those leaving.

Each invitation should usually contain a specific time and date for a smear. The woman should be encouraged to request an alternative appointment if that offered is not convenient.

Casual attenders

When a woman of appropriate age attends the practice for reasons unconnected with cervical cytology, it should be routine to check whether, and how recently, she has been screened. If the woman is due for a smear, as far as possible it should be done during the visit, but if she is menstruating, she should be given a future appointment. In any case the woman's details should be entered into the practice register.

Maternal and child health/family-planning clinics

As indicated above, the majority of women attending MCH/FP clinics in developing countries will be younger than the target age group. The exception will be women who are still having children over the age of 35 or 40 years, who should be offered a smear. However, the clinics may be used to issue invitations to the mothers or aunts of the women using their services, the majority of whom will be in the target group. Given the extended family networks in many developing countries, this mechanism for recruiting women into screening should be actively promoted.

Special events

As discussed in Chapter 3, in some countries special health fairs have been organized to recruit women into screening programmes.

Although the numbers of people attending these fairs have been quite large, they suffer from two important disadvantages. First, it may be difficult to ensure that only women in the target group are screened, so that resources may be expended on those not eligible for the programme. Secondly, it may be difficult to trace the women subsequently to ensure that those found to have cytological abnormalities attend for diagnosis and treatment. Accordingly, the full name, address, and next of kin should be noted for all women screened at such fairs. The use of mobile units is discussed in Chapter 3.

Special surveys

With the collaboration of the local public health service, surveys may be undertaken to identify women in the target age group in the population. These women can then be offered appointments to attend for screening or screened on the spot in their homes. Such surveys will provide the mechanism to set up a register for organization of subsequent screening.

Recording and reporting

Report forms

Details on the taking of smears and the process for recording the results and for patient follow-up are described in an earlier publication (WHO, 1988). Slides should be labelled with the patient's name, identification number, the name of the clinic, and the date of the smear. Accompanying forms should also have the patient's date of birth, address, result of last smear, history of use of contraceptives, and any previous cytological abnormality, as well as her practitioner's name and address. These forms will usually be provided by the cytology laboratory, who will often use the lower half of the form for reporting the results of the cytological examination.

Informing women of their results

All women who are screened should be informed of their smear results. If the woman is literate, this can be in the form of a letter. The format and content of this letter need careful consideration. If the result is normal, this should be clearly stated, and information given on when the next smear is due. If the smear is reported as unsatisfactory, the woman should be advised to reattend for a further smear to be taken. If the result is abnormal but not precancerous (e.g. a cytological abnormality due to inflammation), the letter can be reassuring but may indicate that the woman should attend for appropriate therapy.

The laboratory will usually indicate the management that should be offered for abnormal smears. For smears indicating mild dysplasia, rescreening within 6 months will often be recommended. For smears indicating a more severe precancerous lesion or possible cancer, referral for further diagnosis and therapy will be recommended. Explicit instructions must then be given to the woman when she attends for diagnosis and therapy. It is the responsibility of the practice to initiate the process to obtain follow-up smears when recommended, as well as to ensure that the woman does attend for diagnosis and therapy when that has been recommended.

For illiterate women, the above information will need to be given verbally, either by an allied health worker or a voluntary health worker.

Every effort should be made to ensure that reports on the results of smears reach the women concerned in a timely fashion. Reporting in an easily comprehensible manner will encourage them to attend for further screening as required.

Management of women with abnormal smears

Cytological screening is designed to detect the presence of preclinical cervical dysplasia or neoplasia of the cervix. The presence of these abnormalities will be variously reported, but all are encompassed in the term "abnormal" smear. Expressed simply, an abnormal smear is one that shows cytological abnormalities. For women with normal smears, screening should be continued at the recommended intervals. However, women with abnormal smears should be removed from the screening programme and referred for appropriate diagnosis and treatment. It is the responsibility of the person obtaining the smear to ensure that appropriate follow-up action is taken on the basis of the cytology report.

Counselling

Counselling for women with abnormal smears is necessary to ensure that they attend for diagnosis and treatment. Care must be taken to ensure that women with a precancerous abnormality recognize that this is a readily treatable condition. If care is not taken over these psychological aspects of management a readily treatable condition could, through lack of care, become an untreatable condition. In developed countries, there is evidence that an important cause of advanced cancer in women who have been screened is failure to attend for appropriate management (Miller et al., 1991b); care must be taken to ensure that this does not occur in developing countries.

Repeat cytology

If the smear is reported as being technically unsatisfactory, it should, if possible, be repeated within 6 months unless there is clinical evidence of a cervical lesion. Repeat cytology is also appropriate for the majority of women with abnormal smears but without a definite cytological diagnosis of neoplasia. Those women who are reported on cytological screening to have abnormal cells consistent with benign cervical lesions, mild dysplasia (CIN I), or human papillomavirus (HPV) infection with or without evidence of mild dysplasia should be advised to have a repeat cytological smear within 6–12 months. If at that time the degree of abnormality appears to be unchanged, screening should be repeated within 24 months after detection of the initial abnormality. Women with persistent cytological abnormalities at that time, or women who at any time show evidence of cytological progression, should be referred to the district gynaecology department for diagnosis. Women reported on cytological screening to have abnormal cells consistent with moderate dysplasia (CIN II), or severe dysplasia or carcinoma *in situ* (CIN III) with or without evidence of HPV infection should be referred at once for diagnosis and treatment.

Management and treatment of women with cytological abnormalities

If a clinical lesion is detected on the cervix when the smear is taken, a tissue biopsy should be performed, whatever the findings on the smear. If a diagnosis is established of moderate or severe dysplasia , or carcinoma *in situ*, treatment should be recommended. Depending on the age of the patient, her desire to have children in the future, the likely compliance with follow-up, the presence of other disease, the extent of the lesion, and the availability of equipment, treatment may involve electrocoagulation, cryosurgery, laser therapy, therapeutic conization, or hysterectomy.

If microinvasive cervical cancer is diagnosed, after appropriate evaluation the recommended therapy in most circumstances would be a hysterectomy. In certain patients, conservative therapy with a therapeutic cone biopsy may be considered. Invasive cervical cancer requires specific investigation and management; the condition is usually managed with either radiotherapy or a radical hysterectomy with pelvic lymphadenectomy.

Follow-up

If a patient has received treatment for cervical cancer, then she should never return to the screening intervals recommended for women who have not been found to have a cytological abnormality. If the treatment was for intraepithelial disease, the patient should be recommended

to undergo two further cytological evaluations at 6-month intervals. If both of these evaluations are negative for persistent or recurrent disease, then annual cervical screening should be performed. If the treatment was for invasive cancer, then follow-up should be according to the recommendations of the national cancer control programme.

Chapter 5

INFORMATION SYSTEMS FOR CERVICAL CANCER SCREENING

Introduction

As indicated in Chapter 3, special information systems will need to be established to achieve the maximum benefit from the resources invested in cervical cancer screening. This chapter outlines the requirements for information systems for cervical screening. Although based on a document largely produced for a developed country (Miller et al., 1991b), there are elements that can be incorporated now in programmes in developing countries, especially with the more ready availability of computer systems.

Population-based information systems

A population-based information system is an essential component of organized screening programmes. Such information systems must be capable of supporting a variety of goals and objectives, including individual information retrieval and sophisticated aggregate and comparative data analyses.

The goals of information systems for cervical cancer screening programmes are:

- *To enrol the at-risk population.* Data on the entire target population, including women who have never been screened, must be stored on the database.
- *To maintain information.* Information on the screening history of each woman must be maintained on the database; in addition, the information must be organized and the data elements defined to facilitate analysis and planning.
- *To provide follow-up.* The information system must support communication with individuals concerning smear results, the need for screening, rescreening or follow-up.
- *To support quality assurance.* The design of the information system must permit qualitative assessment of the overall programme.
- *To track utilization.* A critical measure of the value of the information system will be its capacity to monitor screening patterns to determine levels of both underscreening and overscreening.
- *To monitor compliance.* Compliance with recommended screening and appropriate follow-up must be monitored by the information system to assist in evaluating the success of the overall programme as well as targeted outreach programmes.

The specific objectives of information systems for cervical cancer screening programmes are:

- to locate women in the target population who have never been screened or have been underscreened;
- to provide data to identify special targeted groups such as elderly women;
- to record cytological abnormalities detected on screening;
- to assist in follow-up and treatment;
- to reduce overscreening;
- to provide reference data to cytopathologists;
- to assist in follow-up communications to the target population;
- to support a schedule of screening;
- to evaluate compliance with screening;
- to define high-risk groups;
- to facilitate evaluation and planning of the programme;
- to determine the cost-effectiveness of the programme.

Information systems for cervical cancer screening programmes should be designed:

- to identify the target population;
- to identify individual women in the target population;
- to permit individual women in the target population to be contacted:
  - to remind them to attend for screening once they reach the recommended age;
  - to remind them to reattend for screening at the recommended intervals;
  - to request that they visit their physician if a cytological abnormality is discovered;
- to check that action has been taken by the woman and her physician following the discovery of a cytological abnormality;
- to provide long-term follow-up for patients who have received treatment following the diagnosis of a cytological abnormality;
- to permit linkage of smear results at the individual level;
- to provide data on a woman's screening history to her physician;
- to collect data for assessment of the efficiency of laboratory quality control systems;
- to permit evaluation and monitoring of the total system;
- to permit the comparison of data at a regional, national and international level.

The development of the information system will be facilitated by the introduction of permanent individual identification numbers for patients. However, the establishment of a database to support a cervical cancer screening programme need not be dependent upon unique individual identification numbers and should not be delayed where such numbers are not yet in use.

Information system design

The design of the information system must incorporate the views and data requirements of all groups involved in the programme. In other words, wide-ranging consultation and participatory planning are essential. With appropriate interaction on system design, the system can be structured so as to serve the current and future needs of the programme. For example, data concerning screening facilities (location, hours, wheelchair accessibility, linguistic capabilities of staff, etc.) might be identified as necessary by the target population, while epidemiologists would list a different set of requirements.

The process of planning and developing the information system should include all those involved in the programme and should be sensitive to the needs of diverse interest groups, including:

- the target population, including representatives from women's organizations, women's health groups, and all minority groups (immigrants, ethnic minorities, the disabled);
- professional institutions and associations;
- cancer societies and cancer control agencies;
- the government, including representatives from public health units, women's health agencies and health promotion agencies;
- researchers, including epidemiologists and academic researchers in health care and public policy.

Policy issues and use of data

Policy makers should understand the need for an information system. The main advantages of such a system are that it facilitates the day-to-day running of the programme, permits its performance to be assessed and enables any necessary improvements to be made; it can also be used for evaluation and research. The uses to which data are put are of just as much concern as is the design of the system from which information is derived. One of the primary concerns is the question of access to information and the protection of individual privacy. Extensive consultation is necessary to ensure that personal privacy is protected, that legislation concerning access to information is adhered to, and that appropriate protocols are developed for the use of linked and aggregated data. Other policy issues will also require similar consultation and review.

Components of information systems

Information systems developed in support of health programmes usually contain a number of common elements, including: the target population file, a registration file, a laboratory test database, data

linkage capabilities (e.g. for linkage to cancer registers, registers of births, marriages and deaths), and mechanisms for monitoring and evaluation. Despite the likelihood of many of the data elements being similar when programmes are developed in different regions, opportunities to improve evaluation and delivery of the programme may be lost if the data are not standardized. However, the process of standardization should not be allowed to delay the implementation of regional systems, providing they have the necessary internal elements and external linkages, such as to the cancer register.

Other aspects of information systems

As part of the process of consultation needed to set up information systems for cervical cancer screening, a range of information management issues will have to be considered. Although this chapter does not include specific recommendations on topics such as ethical issues, use of "smart card" technology, and the control of access to information for research purposes, it is anticipated that the consultative process will provide the mechanism for addressing them.

Implementation of well-designed and monitored information systems can enhance the benefits of an organized screening programme. Such systems can help to ensure quality control by linking screening and treatment with outcomes, increase efficiency, identify and prevent overscreening, support programme evaluation, and be used for research purposes; data can also be fed back to yield further improvements in the programme.

Monitoring and evaluation of the programme

The general objective of cervical cancer screening programmes is to reduce the incidence and mortality from the disease. The specific objectives to achieve this are:

- to provide accessible and acceptable screening services;
- to recruit eligible women, ensuring in particular that those at high risk are screened;
- to ensure adherence to recommended screening schedules;
- to ensure satisfactory collection and examination of smears;
- to ensure effective communication of smear results;
- to ensure appropriate follow-up if cytological abnormalities are found.

The components of programme evaluation should be compatible with these objectives and should include population-based information systems as well as quality control systems, both internal and external.

In the absence of population-based information systems, specific surveys may provide some of the necessary information; these could include surveys of the awareness of the need for screening among women in the target population, especially those at high risk, and surveys of the attendance for screening by women and the advice given by their physicians.

Specially designed epidemiological studies, most economically of the case–control type, can also be used for programme evaluation, but should in general be part of a specific research project and subject to peer review.

The data requirements for efficient programme evaluation include:

- data on the target population;
- a register of all smears, with identification as to whether it is a first smear or a repeat (these records must be capable of being linked to provide a longitudinal screening history for each woman. This requires information to be obtained on all changes of name, and preferably the use of unique personal identification numbers);
- a separate register of all abnormal smears, with data on follow-up, management and outcome;
- data on all precancerous lesions diagnosed, classified by the recommended terminology;
- data on all invasive cervical cancers diagnosed, classified by stage;
- data on deaths from cervical cancer;
- information on costs and personnel, relevant to every aspect of screening.

For evaluation and monitoring purposes, the data must be maintained in a form that permits identification and linkage at an individual level, and the information system should be so designed that it is accessible for such purposes, as well as for research and the routine requirements of the programme. Nomenclature, procedures and measurements should be standardized, and the data on the target population should be provided according to age, geographical area, laboratory and the woman's physician. This will permit the identification of women in the population who are not being screened, who are likely to include those at highest risk, for whom special efforts will be needed to bring them into the programme. Such linkages will enable the success of the measures taken to recruit such women to be determined.

The criteria for assessing the success of screening programmes relate to the objectives of the programme; these include:

- increase in awareness of the need for screening in the population at risk;
- increase in participation rates for screening;
- identification and recruitment of women who have never been screened;

- improvement in the performance of cytology laboratories;
- reduction in the number of unnecessary medical procedures;
- reduction in incidence and mortality from cervical cancer.

Thus evaluation should include not only outcome measures, most importantly incidence and mortality from cervical cancer, but also process measures, so that if a programme is not effective the corrective actions needed can be taken.

The primary responsibility for programme evaluation should usually be assumed by the government, although this may vary depending on the country. However, governments may seek the assistance of non-governmental organizations in reaching the objectives. In this regard, it would be desirable for governments to appoint an advisory committee of experts from a variety of disciplines. Acting on the advice of this committee, governments may be able to delegate to the various organizations responsible for different programme components the responsibility for any corrective action necessary.

Chapter 6

DOWNSTAGING FOR CERVICAL CANCER

Introduction

In most developing countries, a high proportion of cases of cervical cancer are diagnosed at an advanced stage. There are many reasons for this, including a lack of knowledge among women of the relevance of symptoms of the disease, a fatalistic attitude towards cancer and the possibility of being cured, and a lack of availability of health care in rural areas, combined with a low priority for women's health issues. Although some benefit might be obtained from public education directed to women informing them of the symptoms of cervical cancer, such an approach would be unlikely to reduce significantly the mortality from the disease unless accompanied by a more active attempt to detect the disease at an early stage. The approach proposed for developing countries without the laboratory facilities or resources to envisage cytological screening of all adult women in the foreseeable future is called "downstaging" (Stjernswärd, 1990).

Definition of downstaging

Downstaging for cervical cancer is defined as "the detection of the disease in an earlier stage when still curable, by nurses and other non-medical health workers using a simple speculum for visual inspection of the cervix" (Stjernswärd et al., 1987). The approach must be regarded as still experimental. Thus at a WHO meeting held in Geneva, in November 1985, it was recommended that the feasibility of downstaging should be studied and that the approach should only be contemplated in areas where cytological screening would not be possible for many years and where the majority of cases of cervical cancer are diagnosed at an advanced stage (WHO, 1986).

The need for downstaging

Where adequate treatment for cervical cancer is available in developing countries, it is essential that there is a mechanism for detecting the disease at an early stage and referring patients as necessary. At present, most treatment efforts in these countries have little or no effect on mortality from cervical cancer, because the majority of cases are diagnosed at a late stage, when the disease is incurable. Early referral, linked to adequate treatment of cancers of the cervix, breast and mouth, is of greater prognostic importance than any treatment

effort, however sophisticated, applied at a late stage of the disease (Stjernswärd, 1990).

The Indian Council of Medical Research, in collaboration with the World Health Organization, is conducting feasibility studies, in which female paramedical workers are trained to recognize cervical erosions (Stjernswärd et al., 1987). Unfortunately, only a few results from these studies are available (Sehgal et al., 1991), so it is not yet clear whether downstaging is practical, or whether it can contribute to the control of cervical cancer in developing countries. The approach was discussed during a workshop of the UICC Project on Evaluation of Screening for Cancer (Miller et al., 1990), where it was emphasized that there is no evidence that downstaging is effective. In view of the costs associated with locating and examining women, it was suggested that a more cost-effective approach might be to combine a cervical smear with the speculum examination of all women included in downstaging programmes.

In the state of Kerala, the stage of disease at the time of diagnosis has changed over the past 10 years, following the introduction of a downstaging programme in which women are informed of the symptoms of the disease and report to health workers for examination if they appear. Thus, the proportion of cases diagnosed at stages I and II (when treatment is usually successful) has risen from 15% to 45%, while the proportion of those diagnosed at stages III and IV (when treatment is usually ineffective) has fallen from 85% to 55% (WHO Workshop on Cancer Control Programme, 1992).

A possible approach to downstaging

Women to be examined

As for cervical cytological screening, it is important that the age groups examined are those where the incidence of cervical cancer is high. The maximum range can be considered to be 35 years of age and above, though when a programme of downstaging is first introduced, it would be preferable to restrict the age range to 45–64 years to reduce the number of women to be examined and to have the maximum initial impact.

Personnel needed for the examinations

The clinical examination should be performed by female primary health care workers who have been trained over a period of at least one week in the department of gynaecology in a district hospital to

perform a speculum examination of the cervix and to distinguish between a clinically normal cervix, a cervix with simple erosion, and a cervix with suspected invasive cancer. They should understand the symptoms as well as the signs of the disease, and they should be able to take a specimen for culture and a cervical smear for diagnostic purposes (see below). The gynaecologists responsible for training these health workers should ensure adequate exposure to women with clinically normal, as well as abnormal, findings (invasive cancer, ectopia, cervicitis), since the purpose of the examination is to distinguish the normal from the abnormal, not to make a diagnosis. Some female primary health care workers may already have carried out speculum examinations of the cervix in order to insert intrauterine devices as part of the family-planning programme. However, such workers should still be specially trained to recognize the symptoms and signs of invasive cervical cancer.

The examination

Good visualization of the cervix is essential. This requires adequate light (natural or artificial) and a warm vaginal speculum lubricated with water. The procedure and the reason for it should have been carefully explained to the woman, who should have been made as comfortable as possible. Privacy is important, but a female friend or relative may be of assistance in providing reassurance. If the nature of the woman's residence means that it is impossible to perform an examination, arrangements should be made for her to attend a fixed (or temporary) health centre, where, if at all possible, a couch or bed should be available for the examination.

Use of cervical cytology

Cervical cytology is unnecessary for women with suspected invasive cancer, as cervical smears may be negative in the presence of invasive cancer, which can only be diagnosed with certainty by an appropriately directed punch biopsy.

For women with abnormal findings but who are not suspected of having cervical cancer, a number of clinical conditions may be relevant, including various infections. If the necessary facilities are available, cultures may facilitate decisions on appropriate therapy; a cervical smear may also be taken, providing there is a laboratory that can process it. Such cultures or smears may reduce the number of women who have to be referred for gynaecological assessment. However, if they are not available, all women with abnormal findings should be referred for further assessment, unless the facilities for such assessment are so limited that only those with suspected cancer can be evaluated.

Referral for diagnosis

The primary health care worker performing the examination should be responsible for ensuring that women in need of further assessment are seen by the department of gynaecology. An adequate explanation of the need for assessment should be given to the woman herself and to an appropriate member of her family or a close friend. The primary health care worker should arrange to visit the woman's home during the week following the examination to ensure that she has attended as advised. The department of gynaecology should also ensure that the primary health care worker is informed of the diagnosis, in order to reinforce her skills.

Frequency of examination

As downstaging is currently an experimental procedure, it is uncertain how frequently it should be repeated. Since downstaging will only be introduced in areas without the laboratory facilities or resources for cervical cytological screening, it seems unlikely that annual examinations could be contemplated. As far as possible therefore, countries adopting this approach should attempt to examine women in the target group as frequently as is feasible, such as every 2, 3 or 5 years.

Evaluation

In areas where downstaging programmes have been initiated, every means should be taken to evaluate their effectiveness. Data should be collected on the number of women examined, their age, the findings on examination, the proportion who attend for diagnostic assessment, the diagnostic findings, the stage of the cancers detected, and the proportion of cancers of the total treated that were detected as a result of the programme. For cancers not detected in the programme, information should be obtained on whether the woman had been previously examined in the programme, and if so whether she failed to attend for assessment and diagnosis or whether the cancer developed after the examination; if the woman had not been previously examined, it should be determined whether she should have been included in the programme and why she had not been so included.

It should not be expected that the programme will have an immediate impact on improving the stage distribution of cases in an area, because some of the cases detected initially may be relatively advanced. Only after the programme has been in operation for several years will it be possible to judge its effectiveness, unless it becomes apparent very early on that women are not complying with it. If this is the case, various remedial approaches through appropriate health education should be attempted before the programme is dismissed as a failure. It

may be possible to demonstrate that the programme has an effect on the woman's quality of life. For example, some of the women in areas where the programme is introduced may not have had access to health services since they stopped having children. This access will be re-established through the programme, attitudes to the disease, its detection, diagnosis and treatment will be changed, morbidity may well be reduced and pain relief (if needed) provided. On a long-term basis, attempts should be made to evaluate the success of the programme in terms of a reduction in the number of deaths from cervical cancer.

Conclusion

Downstaging for cervical cancer is an experimental procedure that is not known to be beneficial in control of the disease. However, for countries that have no possibility of introducing cytological screening for cervical cancer in the foreseeable future, downstaging should be considered in the context of general approaches to early detection of the disease. Downstaging is intended to make use of the available health care resources in an area to improve the stage distribution of diagnosed cases of cervical cancer, with the aim of reducing morbidity from the disease and potentially reducing mortality also. It should be directed to the age group at highest risk to ensure the cost-effective use of resources (women aged 35 or preferably 45 years and above). Experience in visual inspection for oral cancer has shown that a major barrier to an effective programme is in ensuring that those found to have abnormalities do attend the local facility for diagnosis and therapy (Warnakulasuriya et al., 1984). It is therefore important that, if it is decided to introduce a downstaging programme into an area, appropriate arrangements are made to evaluate the effectiveness of the programme.

REFERENCES

Anderson GH et al. (1988) Organisation and results of the cervical cytology screening programme in British Columbia, 1955–85. *British medical journal*, **296:** 975–978.

Boyes DA et al. (1982) A cohort study of cervical cancer screening in British Columbia. *Clinical and investigative medicine*, **5:** 1–29.

Carmichael JA et al. (1984) The cytological history of 245 patients developing invasive cervical carcinoma. *American journal of obstetrics and gynaecology*, **148:** 685–690.

Chomet J, Chomet J (1990) Cervical screening in general practice: a "new" scenario. *British medical journal*, **300:** 1504–1506.

Eddy DM (1986a) Setting priorities for cancer control programmes. *Journal of the National Cancer Institute*, **76:** 187–199.

Eddy DM (1986b) A computer-based model for designing cancer control strategies. *Journal of the National Cancer Institute monographs*, **2:** 75–82.

Eddy DM (1986c) *Development of the National Cancer Control Programme in Chile. Assignment report.* Geneva, World Health Organization (unpublished document CAN/HQ; available on request from Division of Noncommunicable Diseases and Health Technology, World Health Organization, 1211 Geneva 27, Switzerland).

Editorial (1985) Cancer of the cervix: death by incompetence. *Lancet*, **2:** 363–364.

Hakama M et al. (1985) Evaluation of screening programmes for gynaecological cancer. *British journal of cancer*, **52:** 669–673.

Hakama M et al. (1991) Effect of organized screening on the risk of cervical cancer in the Nordic countries. In: Miller AB et al., eds. *Cancer screening*. Cambridge, Cambridge University Press: 153–162.

IARC Working Group on Cervical Cancer Screening (1986) Summary chapter. In: Hakama M, Miller AB, Day NE, eds. *Screening for cancer of the uterine cervix*. Lyon, International Agency for Research on Cancer: 133–144 (IARC Scientific Publications, No. 76).

Kinlen LJ, Spriggs AI (1978) Women with positive cervical smears but without surgical intervention. *Lancet*, **2:** 463–465.

Miller AB et al. (1990) Report on a workshop of the UICC Project on Evaluation of Screening for Cancer. *International journal of cancer*, **46:** 761–769.

Miller AB et al. (1991a) The natural history of cancer of the cervix, and the implications for screening policy. In: Miller AB et al., eds. *Cancer screening*. Cambridge, Cambridge University Press: 141–152.

Miller AB et al. (1991b) Report of a National Workshop on screening for cancer of the cervix. *Canadian Medical Association journal*, **145:** 1301–1325.

Muller C et al. (1990) *Costs and effectiveness of cervical cancer screening in elderly women—background paper*. Washington DC, US Government Printing Office (US Congress, Office of Technology Assessment. OTA-BP-H-65).

National Cancer Institute Workshop (1989) The 1988 Bethesda system for reporting cervical/vaginal cytological diagnoses. *Journal of the American Medical Association*, **262:** 931–934.

Parkin DM, Läärä E, Muir CS (1988) Estimates of the worldwide frequency of sixteen major cancers in 1980. *International journal of cancer*, **41:** 184–197.

Richart RM (1980) The patient with an abnormal pap smear: screening techniques and management. *New England journal of medicine*, **302:** 332–334.

Sehgal A et al. (1991) Screening for cervical cancer by direct inspection. *Lancet*, **338:** 282.

Stjernswärd J (1990) National training of radiotherapists in Sri Lanka and Zimbabwe: priorities and strategies for cancer control in developing countries. *International journal of radiation oncology, biology, physics*, **19:** 1275–1278.

Stjernswärd J et al. (1986) National cancer control programs and setting priorities. *Cancer detection and prevention*, **9:** 113–124.

Stjernswärd J et al. (1987) Plotting a new course for cervical cancer screening in developing countries. *World health forum*, **8:** 42–45.

Warnakulasuriya KAAS et al. (1984) Utilization of primary health care workers for early detection of oral cancer and precancer cases in Sri Lanka. *Bulletin of the World Health Organization*, **62:** 243–250.

WHO (1984) *Guiding principles for formulation of national cancer control programmes in developing countries*. Geneva, World Health Organization (unpublished document CAN/84.1; available on request from Division of Noncommunicable Diseases and Health Technology, World Health Organization, 1211 Geneva 27, Switzerland).

WHO (1986) Control of cancer of the cervix uteri. A WHO Meeting. *Bulletin of the World Health Organization*, **64:** 607–618.

WHO (1987) Genital human papillomavirus infections and cancer: memorandum from a WHO Meeting. *Bulletin of the World Health Organization*, **65:** 817–827.

WHO (1988) *Cytological screening in control of cervical cancer: technical guidelines*. Geneva, World Health Organization.

WHO Workshop on Cancer Control Programme (1992) *Report to the Ministry of Health*. New Delhi, Ministry of Health.

Yu SZ, Miller AB, Sherman GJ (1982) Optimising the age, number of tests, and test interval for cervical screening in Canada. *Journal of epidemiology and community health*, **36:** 1–10.

Well-organized screening programmes for cervical cancer are vital to reduce the incidence and mortality from the disease. With early detection, treatment is relatively inexpensive and almost always successful. In many countries, however, cervical cancer screening programmes have had little or no effect on mortality because resources have been used inappropriately, without achieving adequate coverage of the women at risk.

The guidelines in this book, which are based on experience gained in cervical cancer screening programmes throughout the world, are intended for planners and managers responsible for initiating or expanding such screening services. Emphasizing the need for cervical cancer screening to be part of an overall national cancer control programme, they cover programme issues such as the natural history of the disease and its implications for screening policy, service delivery, information systems, and programme evaluation. The book also discusses the concept and potential role of downstaging in countries that will be unable to provide screening programmes based on cytological examination in the foreseeable future.

Price: Sw. fr. 12.—
Price in developing countries: Sw. fr. 8.40

ISBN 92 4 154447 3