2. Organisation of the Programme

2.1 INTRODUCTION

WHEN ORGANISING a cervical cancer screening programme, many different aspects of the programme have to be reviewed and evaluated in advance. These aspects include (I) identification of the catchment area, (II) definition of the target population, (III) specification of the screening interval, (IV) review of ongoing opportunistic screening, (V) the integration of the screening programme into the health care system, (VI) the introduction of methods for reaching the target population and increasing coverage, (VII) identification of person responsible for programme, (VIII) resource implications, (IX) mechanisms for data gathering and (X) establishment of an effective fail safe system. These aspects are discussed below.

2.2 DEFINITION OF THE CATCHMENT AREA

The catchment area should be administratively well defined, and statistical data on the number of female residents at a given point in time, by year of birth, should be available. Personal data on deaths and migration are essential to allow follow-up and evaluation. Population registries can in general provide such data.

A high rate of migration will cause problems in the follow-up and in the production of statistics. Stability of the population is therefore needed and the catchment area of the programme should be large enough to ensure stability. In those countries where population registers are based on administrative areas of small size, communication between them is essential.

It is difficult to obtain adequate data for evaluation if a large proportion of smears are taken or biopsies are performed outside the catchment area under study. The catchment area should therefore be large enough to include the resources needed not only for smear taking, but also for smear evaluation, follow-up of abnormal smears and treatment. Otherwise specific reference centres outside the area must be identified and communication established.

The catchment area should normally include not less than 250 000 persons for optimal administrative efficiency.

2.3 DEFINITION OF THE TARGET POPULATION

Populations at risk should only be defined in terms of age. Attempts to define sub-groups at high risk are theoretically appealing but not practically possible in Europe. This document is based on the EC recommendation that screening should be offered to women in the age group 25–65 years. Cervical smears should not be taken from well women attending contraceptive clinics, ante-natal clinics or post-natal clinics unless the women are over 25 years of age and have not had a smear within the previous 3 years. However, it must be emphasised that women with symptoms or signs which may be related to cervical cancer are eligible for a smear test at any time.

In deciding on local policy several special groups have to be considered.

(i) Women treated for cervical intraepithelial neoplasia and invasive cervical cancer should be registered for statistical purposes as a special group.

(ii) Women who have never been sexually active are generally considered to be at low risk from cervical cancer, although this has recently been disputed. In some centres these women are excluded from screening.

(iii) It must be specified in the screening programme whether or not hysterectomised women are included.

(iv) In some centres, women under the age of 25 attending for treatment for sexually transmitted diseases are offered screening, but this is not included in the EC recommendations.

(v) It has been suggested that women over the age of 65 who have never had a smear should be offered a smear test, but this is not included in the EC recommendations.

2.4 SPECIFICATION OF THE SCREENING INTERVAL

Observational studies, whether case control or cohort, have been used to estimate the relative benefit associated with different screening intervals. To decide on the optimum age group on which to target screening and the optimum screening interval, one needs information on age specific rates and on the duration before onset of invasion in which precursor lesions are detectable.

The incidence of invasive cervical cancer at different ages follows a particular pattern. In unscreened populations, this is similar whether the disease is very common or relatively rare. One can compare Cali in Columbia with the West Midland region in the U.K. for the late 1960s (Table 2.1).

Estimations of the length of time during which precursor lesions are detectable before invasive cancer occurs have been confused by an overconcentration on the natural history of precursor lesions detected at screening. It is now clear that many of these lesions, particularly mild (CIN1) or moderate (CIN2) dysplasia in younger women, will not progress, and will in fact regress. In order to assess the risk of invasion, one has to determine the rapidity with which an invasive lesion can arise from an epithelium after a normal cytological smear report has been issued.

A large number of screening programmes has reported on this issue, and many of these results were included in an overview published by the International Agency for Research on Cancer. The organised programmes included in this overview gave a consistent picture, summarised in Table 2.2. The results in this table provide the theoretical basis for screening for cervical cancer, defining statistically the window in which precursors of potentially invasive lesions can be caught.

The incidence of invasive cancers among women who have had at least two normal smears, returns to the rate in unscreened women about 10 years after the last normal smear. Thus, the protection afforded by screening is high in the first 3–5 years; it has, however, virtually disappeared after 10 years. One can conclude therefore that the value of a screening test is in essence to protect against invasive disease occurring in the next 5 years. Moreover, when the incidence pattern of cervical cancer is taken into account, a smear taken between 35 and 60 years of age is 30 times more effective in detecting a lesion destined later to become invasive than a smear taken at age 20 years, and about 10 times more effective than a smear taken at age 25 years.

Table 2.1. The incidence of cervical cancer in high and low risk unscreened populations. Age standardised rate and age specific rates per 100 000 women (1963–1967)

	All ages	Age group (years) 20–24	25–29	30–34	35–39	40–44	45–49	50–54	55–59	60–64
Cali, Columbia	75.6	4.3	15.4	47.9	98.8	154.5	191.4	186.2	236.9	277.0
Birmingham, United Kingdom	13.6	0.7	2.8	8.7	24.6	38.5	41.7	37.7	33.1	27.1
Cali/Birmingham	5.5	6.1	5.5	5.5	4.0	4.0	4.6	4.9	7.2	10.2

Table 2.2. Incidence of invasive squamous cell carcinoma of the cervix uteri following two or more normal smears, as a proportion of the incidence in a comparable unscreened population

Time since last smear (months)	Proportional incidence
0–11	0.06
12–23	0.08
24–35	0.12
36–47	0.19
48–59	0.26
60–71	0.28
72–119	0.63
120+	−1.00

Table 2.3 illustrates the effectiveness of different screening policies on the incidence of cervical cancer assuming 100% compliance. The information it contains is useful when deciding screening policy as it enables the policy maker to determine the protection offered by a particular screening programme and the resources needed to implement the programme. One can also use the information in Table 2.3 to project the results of different screening policies. A compliance of about 80%, and a screening interval of 2–5 years, should give an overall reduction of 65 to 70% in cervical cancer mortality.

The EC recommendations state that cervical cancer screening should be offered at least every fifth year, and if resources are available, every third year. Screening more frequently than every 3 years should be discouraged as it is not cost-effective. In case of limited resources, screening every fifth year with high quality and high compliance is preferable to screening every third year.

Table 2.3. The effectiveness of different screening policies. Proportionate reduction in incidence of invasive squamous cell carcinoma of the cervix uteri assuming 100% compliance, based on Tables 1.1 and 1.3

Policy	Age group	% Reduction in cumulative rate in age group	Numbers of smears per woman
Every 10 years	25–64	64	5
Every 5 years	35–64	70	6
Every 5 years	25–64	82	8
Every 5 years	20–64	84	9
Every 3 years	35–64	78	10
Every 3 years	25–64	90	13
Every 3 years	20–64	91	15
Every year	20–64	93	45

In deciding on the local policy for screening the following exceptions have to be made.

(i) Women treated for cervical intraepithelial neoplasia and invasive cervical cancer should have a Papanicolaou smear taken as frequently as is considered clinically necessary.
(ii) Women with symptoms of cervical cancer such as bleeding or discharge should have immediate access to a cervical smear test and other diagnostic procedures as necessary.

2.5 REVIEW OF ONGOING OPPORTUNISTIC SCREENING

The amount of opportunistic screening in a catchment area will depend on both local and national health care policies. In countries where independent private health insurance schemes are common, opportunistic screening will prevail. The extent and the characteristics of the opportunistic screening must therefore be taken into account when an organised screening programme is planned.

As a starting point, it is important to determine whether the existing screening activity is overall sufficiently protecting the target population so that only minor changes and/or improvements are needed, or whether the screening activity is sufficient with regards to quality and/or coverage of the population.

2.6 INTEGRATION OF AN ORGANISED SCREENING PROGRAMME INTO THE HEALTH CARE SYSTEM

A comprehensive review should be made of the local facilities before an organised screening programme is implemented. It is necessary to know exactly who are the smear takers, the smear evaluators, the availability of diagnostic work up, including colposcopy, and what are the lines of referral between these. It is also essential to ensure that facilities for treatment are adequate and colposcopy and treatment can be provided without delay.

In different European countries, and even within the same country, smear taking is provided by a number of different health professionals. The most common providers of smears are general practitioners in Great Britain, Denmark, and the Netherlands, gynaecologists in Germany and France, midwives and gynaecologists in Italy and Greece. Smears may also be taken in special screening clinics, or by general practice nurses. This variability is obviously dependent on local arrangements and constraints, such as professional responsibilities regulated by law, direct access to gynaecologists, or payment systems for GPs.

The evaluation of smears may also take place both in public

and private laboratories with the annual number of smears processed by the laboratory varying between a few hundred and tens of thousands. Treatment of precancerous lesions may be performed in public and private hospital clinics, or by gynaecologists and other specialists in private practice.

It is essential for the success of an organised programme that is accepted both by the population at large and by persons earning their living from screening. It may be productive to think in terms of a system where the already ongoing activities are integrated into the organised programme.

Such an integrated programme is now running in several Danish counties. The idea is to have a comprehensive register of all women living in the county and of all smears taken in the county. Invitations to the screening programme are then restricted to all women on the registers who have not had a smear within the last 3 years. Full benefit is thus made of the already ongoing activity. As a result, 50–60% of the resources can be saved compared with a programme where all women are invited. The Danish model of an integrated screening programme is shown in Fig. 2.4.

2.7 HOW TO REACH THE TARGET POPULATION AND INCREASE COVERAGE

Compliance is a fundamental prerequisite for the success of a screening programme. Low coverage reduces the number of cancer cases prevented, and special efforts should be made for recruiting women who have never had a smear.

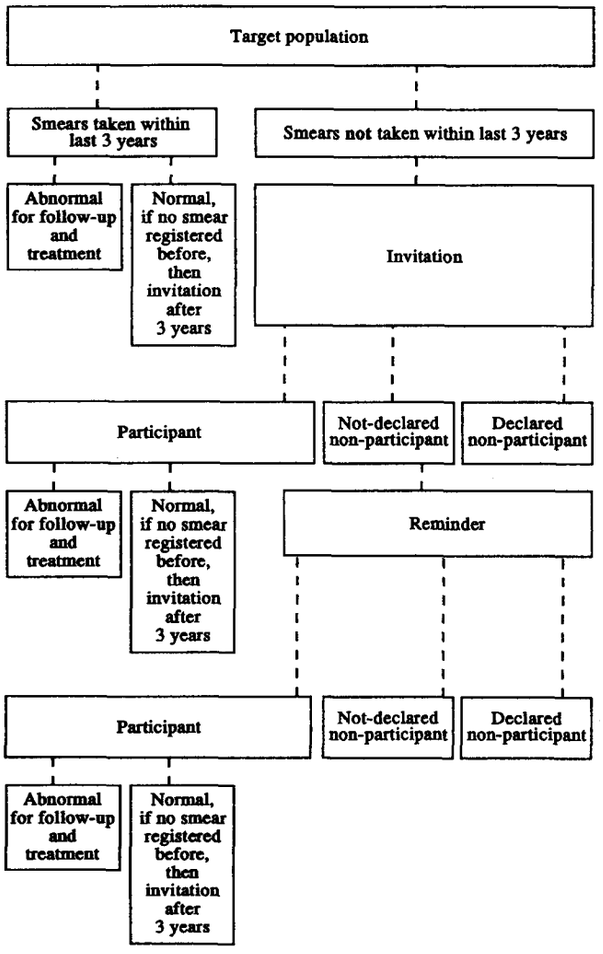

Fig. 2.4. Danish model for integrated screening programme.

2.7.1 *Barriers*

The extent to which women participate in screening is associated with age, socioeconomic status and marital status. The non-compliers are elderly, unmarried or divorced, and of low socioeconomic status. Usually they have never had a smear, and their contact with the health service has not been recent. Non-compliers have higher incidence and mortality risks. The barriers related to cultural and socioeconomic problems are likely to change in future generations.

Fear of gynaecological examination, fear of cancer, concern about the sex of the smear taker, non-confidence in the method, and in the health care system in general, are obstacles which are difficult to remove and largely dependent on the cultural and social background. The tools for removing them need to be tailored in each region. The same is true for potential barriers decreasing the accessibility such as distance from well women clinics, waiting-time required for the test, etc.

Scarce data exist about participation rates and cost to the patient of the test, but it is remarkable that screening in Sweden and Finland combines free access with high attendance.

2.7.2 *Tools for increasing the compliance*

Compliance can be increased by improving the reputation of the programme within the population and encouraging the non-responders to participate through a personal letter. Personal invitations should be signed by a well known person who is held in high regard, i.e. the woman's GP or outstanding members of the community. The style of the letter should be friendly, informative and non-patronising and must be suited to each country's population both nationally and locally. As many women invited for cervical screening are still having regular menstrual bleeding it is not advisable to give a predetermined appointment on a specific date, or if this is given it should be easy to change the date.

Invitation letters should clearly identify where, when and by whom a woman may have her smear taken. Inclusion of a contact telephone number, simple information about the taking of the test, when and from where the results are available all encourage women to accept their invitations. A concise statement of the local programme aims and recall intervals helps women to feel empowered to undertake responsibility for their own health. It is most important to stress that the aim is to treat lesions before they become invasive.

In small towns and in the countryside the organisations of the social life such as churches, markets and womens organisations, provide opportunities for advertising and promotion.

Advertising through mass media has an effect for a short period of time and should be planned at regular intervals in order to reinforce the message. Newspapers, magazines, television and radio can offer free spaces for publicity. Sponsors for advertising should be considered. These approaches are not mutually exclusive and should be tailored according to local situations.

Economic incentives for GPs have been shown to be effective in the U.K. in improving coverage, which in some regions has reached more than 80%. Incentives for women such as free offers, complimentary tickets, gifts, etc. could be considered in some areas and in general marketing techniques could be considered for increasing the compliance.

2.8 IDENTIFICATION OF PERSON OR PERSONS WITH RESPONSIBILITY FOR THE PROGRAMME

Cancer screening is a multidisciplinary activity involving clerks, nurses, midwives, cytotechnicians, pathologists, gynaecologists, surgeons, GPs, epidemiologists, economists, etc. All these professionals need coordination. A committee should be created to monitor and update the local policy. The chairman of the committee should be elected or named by the health authority as programme manager. Specific responsibilities should be assigned to the chairman for organisation, mass media relationship, budget, quality assurance, evaluation, etc. The responsible persons should be officially appointed, and they should have authority for implementing the decisions of the committee. Consensus on a screening programme is not a sufficient condition for its success, but is highly desirable.

2.9 RESOURCE IMPLICATIONS AND ECONOMIC EVALUATION

Continuity of financial resources for the programme should be ensured at the start. A monitoring system should be designed to document the costs at appropriate times. The collection of these data should be performed either by continuous monitoring of the costs or by periodic surveys of the financial system. Parameters such as the cost per woman or per smear are necessary for improving the organisation and planning the strategy.

Screening competes for scarce resources with other health interventions. On a longer time scale, data should therefore be provided to the decision makers about costs and health effects of the programme, including the costs of diagnosis, treatment and organisation.

Economic evaluation can be performed as a cost-effectiveness analysis (cost per year of life saved) or as a cost-utility analysis (also taking quality of life into consideration). Simulation of different scenarios such as those illustrated in Table 2.3, with the utilisation of computerised mathematical models allows one to select the most cost-effective option for running the programme.

2.10 MECHANISMS FOR GATHERING DATA

Before cervical screening can be implemented mechanisms for gathering essential data for the day to day operation of the programme and for statistical purposes must be in place. A comprehensive registration system for women at risk is a prerequisite for an organised screening programme as is a system for registering the Papanicolaou smear reports. Ideally the systems should be computerised and linked.

A register of biopsies and the histology reports from women referred for treatment are also required and a regional cancer register should be in place. Minimum data requirements are itemised in Chapter 5.

2.11 ESTABLISHMENT OF A FAIL SAFE SYSTEM

The value of the cervical screening programme will be diminished if action is not taken whenever an abnormal smear report is issued. The responsibility for ensuring this action is taken lies with the person who took the smear. However, smears may be taken in many different situations and there is a need for a back up system (fail safe system) to ensure that there is appropriate follow up of every woman with an abnormal smear. Fail safe measures are recommended in Chapter 4.

3. Screening Methodologies

3.1 INTRODUCTION

FOR THE past 50 years, the Papanicolaou smear test has been used to screen for preinvasive and early invasive cancer in asymptomatic women. This test involves removing a sample of cells from the epithelium of the transformation zone of the cervix and examining the cells with a light microscope.

Abnormal cells present in the sample can be recognised by the experienced cytologist. In this chapter we describe (i) methods for collecting cervical smears (ii) methods of processing the smear and (iii) preparation of the smear report.

3.2 EQUIPMENT REQUIRED FOR TAKING A CERVICAL SMEAR

(i) There should be an examination couch for vaginal examination of patient in either the left lateral or dorsal position with good illumination from an adjustable halogen spot light.
(ii) Disposable vinyl or latex gloves should be available.
(iii) Various sizes of specula must be available. They may be of a disposable pre-sterilised plastic type or sterilised non-disposable stainless steel. These must be thoroughly cleaned before being re-sterilised by steam sterilisation in an autoclave for a minimum of 15 min at 121°C or in a hot air oven at 180°C for 120 min. Chemical disinfectants are not sufficient to prevent the spread of infection.
(iv) Other essential items are: frosted ended glass microscope slides 7.6 × 2.5 cm; a lead pencil; fixative (95% alcohol and carbowax or 5% acetic acid) in a dropper bottle slide jar or as commercially available cytospray; a slide box for transportation and a request form.

3.3 PROCEDURE FOR TAKING A CERVICAL SMEAR

(i) Explain to the patient the procedure, what to expect and give reassurance. Ask about her general health and whether she has any symptoms such as irregular bleeding or discharge.
(ii) Label the slide clearly in pencil on the frosted end with the patient's name, date of birth and identification number. Other methods of marking may be removed during processing of the slide.
(iii) Ensure that the woman is lying comfortably on the examination couch in either the dorsal or lateral position so as to visualise the cervix clearly and position the light.
(iv) Select the largest speculum that can be inserted comfortably and bring to body temperature. Insert the speculum along the axis of the introitus and when halfway up the vagina rotate 90° and open when fully inserted. Lubricants