(iv) Invasive carcinoma must be excluded by biopsies under colposcopic control.

Local destructive therapy may be used to treat CIN2 and 3, when the conditions defined in 4.5 are fulfilled. If they are not fulfilled, conisation as a combined diagnostic and therapeutic method is recommended. Treatment of invasive cancer is not discussed here.

Analysis of records from countries where screening programmes have been running for several years have shown a tendency towards conservative treatment whenever possible. This should be encouraged. In particular hysterectomy for small lesions should be discouraged.

4.6 COMPLICATIONS AFTER TREATMENT OF CERVICAL LESIONS

Complications may occur in 2–5% of patients receiving local therapies. They may be of short term character such as bleeding, discharge and infection or of long term nature such as subfertility, including tendency to abortion or premature delivery. Risk of complications probably depends on the technique used and the size of the cone. All complications should be recorded.

4.7 RESIDUAL AND RECURRENT LESIONS

Residual lesions are defined as the presence of abnormal cells in a cervical smear within 1 year of treatment. The potential for residual lesions to occur will depend on the clearance of endocervical margins after conisation.

4.8 FOLLOW-UP AFTER TREATMENT FOR PREINVASIVE CANCER

Most abnormal smears after treatment occur within 2 years. Thus close follow-up by repeat smears and/or colposcopy is essential after treatment. The recommended frequency for follow-up smears varies between centres, but twice in the first year and once in the second year is suggested. Women with normal smears 3 years after treatment for CIN may be returned to the screening programme.

Controlled trials comparing the various forms of local treatment and follow-up regimes are lacking. Such trials are encouraged.

5. Monitoring the Programme and Use of Resources

5.1 INTRODUCTION

CERVICAL CANCER screening programmes aim at (1) preventing cervical cancer with minimal negative side-effects, and (2) using available resources in an optimal way. It is possible to have an effective preventative programme which is not cost effective. Comparing the outcome of the screening activity with the aim of the programme is an important aspect of quality assurance. Lists of parameters which must be monitored and targets to be achieved in a cervical screening programme is given in Tables 5.1 and 5.2.

The parameters are divided into those that can be measured in the short term and those that can be measured in the long term. The description assumes a target age group of 25–65 years and a 3-year screening interval. Most of the short term parameters can be measured following the completion of a 3-year screening round. Some of them, however, require inclusion of observations from the next round. Observations for the long term parameters such as changes in mortality and in some cases also in incidence will be available only after a 10-year period.

Also specified in this chapter are the data gathering requirements needed for assessment of the programme. This is described in terms of collection of data on individual women and collection of statistical data.

Table 5.1. Monitoring the cervical screening programme. Prevention of cervical cancer. List of parameters to be measured and targets to be achieved in relation to time scale

Time scale	Parameters	Targets
Short term	Coverage	85% of all women
	Interval to reporting	Must not exceed 3 weeks
	Proportion of unsatisfactory smears	Must not exceed 5%
	Follow-up compliance	
	Treatment compliance	Follow-up and treatment to be activated within 3 months after an abnormal smear
	Sensitivity and specificity	
	Distribution of invasive cancers	
	Interval cancers	
Long term	Mortality rates	Reduction in mortality by 15% by the year 2000
	Incidence cancers	

5.2 PARAMETERS FOR MONITORING THE EFFECTIVENESS OF THE SCREENING PROGRAMME IN PREVENTING CERVICAL CANCER IN THE SHORT TERM

5.2.1 *Coverage*

If a screening programme starts in an area where the previous, spontaneous smears are not registered, all women in the catchment area should be invited to the first screening round, and the invitations should be distributed throughout the 3 year period. However, if the previous smears are registered, invitation may be restricted to women on the register who, at the time of invitation, have not had a smear during the past 3 years. Mobility of the target population must be taken into account when assessing coverage over a 3-year screening round. The coverage is calculated as the number of women with at least one smear in a 3-year period divided by the target population in the middle of the second year (mid year population).

Table 5.2. Monitoring the cervical screening programme. Optimal use of resources. List of parameters to be measured and targets to be achieved

Time perspective	Parameters	Targets
Short term	Smear consumption	Smears used outside the guide-lines should not exceed 10%
	Smear distribution	
	Excess use of smears	
Long term	Cost effectiveness analysis	

In an interview survey undertaken in 1991 of 1 224 000 women in the EC aged 25–54 years, 39% of the women reported that they had a smear test every year, 26% reported that they had a smear test every 2–3 years, 9% every 4–5 years, 21% less often, and 5% responded "don't know". If these figures hold true, on average 65% of EC-women are thus screened at least every third year.

The target for coverage in organised screening programmes in the EC should be at least 85% of the female population within a specified interval of 3–5 years.

5.2.2 *Interval to reporting*

The test result may be reported directly from the pathology laboratory to the smear taker and the women, or to the smear taker only who is then responsible for informing the women. The women may receive information on a negative test result only indirectly, e.g. "if you have not heard from us within 3 weeks you can assume that the test was normal". However, it is preferable that the women receive written information directly.

The reporting procedure should in any case be clearly stated in advance, and the time intervals to reporting should be monitored. These time intervals should be specified as number of days from the smears is taken until (i) the smear taker receives the result, and (ii) the woman receives the result.

The target for interval to reporting should not exceed 3 weeks; explanations should be provided if longer intervals occur.

5.2.3 *Proportion of unsatisfactory smears*

The performance of each smear taker should be monitored by annual tabulation of the proportion of unsatisfactory smears.

If the proportion of unsatisfactory smears for a given smear taker exceeds 5% explanations should be provided.

5.2.4 *Follow-up compliance*

The screening programme should include clear guidelines for the follow-up of abnormal smears. The compliance with the guidelines should be monitored, including explanations for non-compliance. The basis for tabulating of compliance may be the single abnormal smear, or the individual woman with more than one abnormal smear.

For the single abnormal smear the tables should show time to next smear/biopsy, and reasons for non-follow-up, such as death, emigration or failure of follow-up on the part of the smear taker.

A screening programme should aim at follow-up of all abnormal and unsatisfactory smears within 3 months. Reasons for non-follow-up should be provided for all abnormal and unsatisfactory smears which have not been followed-up within 3 months.

The proportion of women with one or more abnormal smears who have not been adequately followed-up should be recorded. Follow-up activity on unsatisfactory smears should be reported separately.

5.2.5 *Treatment compliance*

The screening programme should include clear guidelines for the treatment of CIN and for invasive cervical cancer. The guidelines should ensure that all cases needing treatment are offered this. The guidelines should also ensure that the treatment offered is the most conservative which is acceptable from a professional point of view.

The compliance with these guidelines should be monitored, including explanation for non-compliance.

5.2.6 *Sensitivity and specificity*

The sensitivity of the cervical smear test can be defined as the proportion of persons with CIN or invasive cancer who have an abnormal screening test. The specificity of the test can be defined as the proportion of healthy patients who are normal on the screening test.

Direct measurements of the sensitivity of cervical screening is difficult since pre-invasive cancers are usually asymptomatic and the total number of women with these lesions in the community is not known. The number can only be determined by biopsies taken simultaneously with the smears. Such a procedure is realistic only on a sample basis in special trials.

Various measures can be used to assess indirectly the sensitivity of the smear for detection of invasive cervical cancer. The screening history within 1 year of diagnosis can be traced for all cases of invasive cervical cancer. The sensitivity can then be measured as "invasive cases with a positive smear" divided by "invasive cases with a smear, independent of the smear result". In order to obtain comparable data from different screening programmes this tabulation should be restricted to invasive cases aged 25–64 years and diagnosed during the first year following completion of a screening round.

The specificity can be estimated from the number of women aged 25–64 for whom the first smear in the screening round is negative and women for whom the final diagnosis after follow-up is negative. The specificity is then the first group divided by the sum of the two groups. When and how a final diagnosis is made after a non-negative smear depends on the local guidelines for follow-up and of the compliance with these guidelines.

5.2.7 *Distribution of incident cervical cancer cases*

Although the aim of cervical cancer screening is detection of precancerous lesions, a certain number of invasive cancer cases may also be detected. These cases will typically be microinvasive or early invasive lesions which are still symptom free. The introduction of organised screening will then be followed also by a change in the stage distribution of invasive cervical cancers.

For the general surveillance of the programme the incident cervical cancer cases should also be tabulated by way of detection.

5.2.8 *Interval cases*

Estimations by the IARC collaborative group show that 91% of the squamous cell invasive cervical cancer cases can be avoided if women are screened every third year. The remaining 9% represent cases undetected at the time of screening and true interval cases. For women with a normal smear it is possible to tabulate the incident cancer cases, the accumulated person years

at risk and the observed incidence by time since last normal smear. These tabulations may be used as parameters of sensitivity for comparison between areas. It is more difficult, however, to assess the protective effect as this requires comparison of the observed incidence with the expected incidence in the absence of screening. It is difficult in Europe today to find reasonable data for the expected incidence in the absence of screening, and the expected incidence would therefore have to be estimated.

The interval cancers should be examined on an individual basis. The screening history of the cases should be listed and old specimens re-evaluated.

5.3 PARAMETERS FOR MONITORING THE EFFECTIVENESS OF THE PROGRAMMES FOR PREVENTING CERVICAL CANCER IN THE LONG TERM

5.3.1 *Mortality from cervical cancer*

The mortality rate from cervical cancer is calculated as the number of deaths in which cervical cancer is the underlying cause of death divided by the mid-year population. Reliable data are obtained only if the proportion of deaths with unknown cause of death is low, and if all deaths from uterine cancer are specified by site (cervix/corpus) on the death certificate. Mortality rates are normally calculated for 5-year age groups. Various indices are used to summarise the rates for a given year or period.

5.3.2 *Incidence of cervical cancer*

The incidence rate of cervical cancer is calculated as the number of incident cases of invasive cancer divided by the mid-year population. Reliable data require a population based cancer register with a clear distinction between cases of invasive cervical cancers (including microinvasive) and carcinoma *in situ* (CIN3). Incidence rates are also normally calculated for 5-year age groups, and summarised by various indices.

5.3.3 *Choice of control group*

In order to evaluate the effectiveness of screening programmes in preventing cervical cancer, comparison must be made between the mortality and incidence of cervical cancer in a screened and unscreened population.

For a given programme, this will give rise to problems with the selection of the control group of unscreened women, as cervical screening will have been offered to all women in the catchment area. Three possible control groups can be identified.

(1) Non-participants. Within a population there will be a proportion of women who do not participating in the screening programme. Non-participants are known to have an excess mortality and incidence of cervical cancer. It is therefore, not advisable to use data from non-participants to assess the effect of screening.

(2) Regional comparison. When organised screening programmes are implemented in a given region it will be useful to select one or more regions without organised programmes as control regions. Control regions should have sufficiently large populations to have stable mortality and incidence rates. The mortality and incidence rates should be known for both the screening regions and the control regions for at least 5 years before and 10 years after the introduction of the screening programme. Data should also be collected to monitor the amount of unorganised screening activity in the control regions.

(3) Historical comparison. The screening area may also constitute its own control regions. The mortality and incidence rates are then compared for the periods before and after implementation of the screening programme. The screening programme may, however, act on top of already increasing or declining trends in mortality and incidence. To assess the effect of the screening programme independently, mortality and incidence rates should therefore be available for at least 10 years before and 10 years after implementation of the screening programme. The trends should be accounted for in the analysis.

(4) Simulation. It is possible to estimate the expected number of invasive cervical cancer cases and deaths for cervical cancer following implementation of an organised screening programme. After implementation of the organised programme it is then possible to compare the observed number of cases and deaths with the expected numbers. Such predictions are uncertain, however, as several assumptions have to be made.

5.3.4 *Target for Europe*

The "Europe against Cancer" programme which was launched in 1986 set the target of reducing the mortality from cancer including cervical cancer, by 15% by the year 2000.

This is a target stated in terms of historical comparison. These data may, however, not be generated easily for all of Europe, as the proportion of deaths recorded with unspecified uterine cancer was still relatively high in the mortality statistics from some countries in 1990.

5.4 PARAMETERS FOR MONITORING USE OF RESOURCES IN THE SHORT TERM

In many areas of Europe the introduction of an organised screening programme for cervical cancer does not imply introduction of new activities, but only reorganisation and redistribution of already ongoing activities. The consumption and distribution of smears therefore constitute important components of the short term parameters on optimal use of resources whereas the cost effectiveness of the programme can be calculated in the long term.

5.4.1 *Consumption of smears*

The number of smears per woman used during the 3-year screening round should be tabulated by 5-year age groups. Production of these figures does not require registration of every smear, and equivalent figures might thus be available for the same region for the 3-year period preceding the screening round. Comparison between regions may also be possible.

5.4.2 *Distribution of smears*

The proportion of women with more than one smear during the 3-year screening round should be tabulated by 5-year age groups. If this proportion exceeds the proportion of women with at least one non-negative smear, short interval rescreening is occurring. This excess activity can be pinpointed further by tabulation by smear taker, etc.

5.4.3 *Excess consumption of smears*

Smears taken in accordance with the guidelines are (1) one smear per woman aged 25–64 years within a 3-year period, and (2) follow-up smears for each abnormal and unsatisfactory smear.

Optimal use of resources is achieved if the proportion of smears taken in accordance with the guidelines is close to 100%.

The proportion of smears taken outside the guidelines should not exceed 10%.

5.5 PARAMETERS FOR MONITORING USE OF RESOURCES IN THE LONG TERM

5.5.1 *Cost-effectiveness analysis*

When the long term parameters of cervical cancer mortality and incidence are available, an opportunity exists for undertaking an analysis of the cost-effectiveness of the screening programme. This means calculating the costs per life year gained or per cancer free life year gained in the population under study.

As the organisation of a cervical cancer screening programme primarily implies redistribution of resources it should be made clear whether we aim at analysing the cost-effectiveness of this redistribution, or whether we aim at analysing the cost-effectiveness of cervical cancer screening as such. For analysis of redistribution, the gained life years can be estimated from the mortality rates for the catchment area compared with the mortality rates for regional or historical "controls". For analysis of cervical cancer screening as such, the gained life years have to be estimated from the mortality rates for the catchment area compared with mortality rates reflecting the more theoretical situation of no screening activity.

5.6 DATA GATHERING REQUIREMENT

The parameters listed above can be tabulated only if the necessary data are available. These data include both registrations made on an individual basis and statistical data. It should be stressed that only minimum data requirements are listed. Extension of the list both in terms of parameters measured and variables identified could be valuable. The requirements listed do not cover registration of all activities, e.g. colposcopies.

5.6.1 *Data on individuals*

Comprehensive registration systems exist in some areas with organised screening programmes, and computerised pathology registration is established in many hospitals. If a computer system exists, this system will able to provide the necessary data. If the existing system cannot provide the data, it will probably be most expedient to adapt the existing system. Double registrations in two systems, or in a system and on a form, will be a heavy burden and is counter productive.

Direct registration on a computer has the advantage that the data can be validated at entry. This refers especially to validation of personal identification, specimen identification, and diagnostic codes.

The following items of information are essential:

(*i*) *Women.* At the beginning of a screening round, all women in the target population aged 25–64 years (defined by birth cohorts) should be registered. Women who immigrate to the area during the screening round should be added to the file. For each woman the following data should be available:

— personal identification
— date of birth
— date of entry to area (start of screening round or later)
— date of exit from the area
— reasons for exit (death, emigration)
— name (current only)
— address (current only)
— administrative data (e.g. GP identification)
— date of invitation
— date of first reminder
— date of second reminder
— date of active wish not to be contacted.

(*ii*) *Pap-smears.* All Papanicolaou-smears taken in the area during the screening round (both inside and outside the target population) should be registered with the following data:

— personal identification
— specimen identification
— reason for smear (if known, i.e. screening or diagnostic)
— resident in area at date of specimen (yes/no)
— date of birth (may be only year of birth)
— date of specimen
— specimen result (see below)
— specimen taker
— specimen evaluator.

It should be possible to place the specimen result in one of the following categories, see Table 3.1:

— invasive cancer (squamous, glandular, other)
— cervical intraepithelial neoplasia (CIN3)
— adenocarcinoma *in situ* (GIN3)
— CIN2/moderate dysplasia
— CIN1/mild dysplasia (includes koilocytotic atypia)
— other intraepithelial neoplastic lesions
— squamous or glandular abnormality (not amounting to neoplasia)
— other abnormal changes
— satisfactory within normal limits
— unsatisfactory.

These categories are hierarchically structured. This means that the most severe category shall be used if it is possible to place a given smear in more than one category.

(*iii*) *Biopsy specimens.* All biopsies and other histological specimens from the cervix uteri taken in the area during the screening round (both inside and outside the target population) should be registered with the following data. In rare cases an invasive cervical cancer may be diagnosed only clinically. These cases should also be included in the registration:

— personal identification
— specimen identification
— specimen type
— resident in area at date of specimen (yes/no)
— date of birth (may be only year of birth)
— date of specimen
— specimen result (see below)
— specimen taker
— specimen evaluator.

It shall be possible to place the specimen result in one of the following categories:

— cervical cancer, adenocarcinoma
— cervical cancer, squamous cell carcinoma
— cervical cancer, not otherwise specified
— cervical cancer, only clinically diagnosed
— primary cancer of other site
— carcinoma *in situ* CIN3
— adenocarcinoma *in situ* GIN3
— severe dysplasia CIN3
— moderate dysplasia CIN2
— mild dysplasia CIN1 including koilocytotic atypia
— mixed lesions

— dysplasia, not otherwise specified
— positive, not otherwise specified
— atypical (not amounting to intraepithelial neoplasia)
— normal
— unsatisfactory
— not-classifiable.

These categories are hierarchically structured. This means that the most severe category shall be used if it is possible to place a given biopsy in more than one category.

(*iv*) *Treatment.* All treatments of cervical malignancies made in the area during the screening round (both inside and outside the target population) should be registered with the following data:

— personal identification
— resident in area at date of treatment (yes/no)
— date of birth (may be only year of birth)
— date of treatment or diagnostic procedure
— treatment or diagnostic procedure (see below)
— treating physician.

Treatments or diagnostic procedures should be registered in the following categories:

— radiotherapy
— chemotherapy
— radical hysterectomy
— total hysterectomy
— amputation of cervix
— conisation (may be further specified)
— local destructive treatment, i.e. coagulation, cryotherapy
— other relevant procedures.

5.6.2 *Statistical data*

The following data are required.

(*i*) *Population statistics.* Population figures are necessary to calculate the coverage and the mortality and incidence rates. We suggest the use of the mid-population in the second year of a 3-year screening round. Population figures for the screening area should be available by 1-year age groups.

(*ii*) *Smear taking activity.* In order to compare the consumption of smears in the screening programme with the consumption before organised screening commenced, or with the consumption of smears in other regions, data should be available on the total number of smears in these periods/regions. The smears should be tabulated by 5-year age groups.

(*iii*) *Deaths from cervical cancer.* In order to monitor mortality, the number of deaths from cervical cancer should be collected for the catchment area for the 10 years proceeding the implementation of the screening programme, and for the 10 years after. Number of deaths from areas selected for regional comparison should be collected from 5 years before and 10 years after the implementation of the screening programme. Number of deaths from unspecified uterine cancer should also be collected.

(*iv*) *Incident cases of cervical cancer.* The number of incident cases of invasive cancer should be collected as specified for number of deaths. The incident cases should preferably be tabulated by stage at diagnosis.

5.7 CONFIDENTIALITY

The guidelines on confidentiality in cancer registries which have been agreed by the International Agency for Research on Cancer and the International Association of Cancer Registries can usefully be applied for screening programmes. The national legislation relating to the confidentiality of population data and medical records has to be taken into account in establishing guidelines for data access and transfer. Recipients of identifiable data should sign commitments to respect confidentiality. Provided that adequate safeguards are set up the community ought not to restrict access to data.

5.8 TABLES

A lay out for tabulation of data required for monitoring cervical screening is given in Appendix A.

6. Training of Participating Personnel

6.1 INTRODUCTION

IN ORDER to ensure a reliable and efficient standard of screening, all personnel involved in the delivery of the programme have to be trained to a high standard. Facilities must be available for training of medical and paramedical personnel in smear taking, and the analysis of cervical smears. Clinical staff must be trained in the administration of the screening programme.

In 1990, the European Commission and the Europe against Cancer programme commissioned a working party to formulate basic training programmes for medical and paramedical personnel participating in cervical screening in EC-countries. A working party was formed which has now drafted a set of proposals* for training and proficiency testing for cytotechnologists and anatomopathologists undertaking cervical screening. These proposals have the support of all national cytology societies in the EC and are presented in abbreviated form in this chapter.

It has been proposed that certificates for certain groups or personnel should be issued by central authorities.

6.2 SMEAR TAKERS

Medical and paramedical personnel must be trained in the technique of smear taking as described in section 3.3. The principles underlying the cervical cancer screening programme and the physiology of the female genital tract should be clearly understood. Smear takers should also know how to use a speculum and visualise and assess the appearance of the cervix with the naked eye. They must also understand the importance

*Copies of the proposals for training are available from the Secretary, European Community Training Programme for Cervical Cancer Screening (ECTP.CCS), Department of Cytopathology, St. Mary's Hospital, London W2.1PG, U.K. Tel: 44 71 725 1710, Fax: 44 71 402 0401.