— 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.

of sampling the transformation zone, and be able to correctly interpret a report on a cervical smear. The smear taker also has a duty to monitor the frequency with which unsatisfactory smears are obtained and seek further training if necessary.

6.3 CLERICAL AND SECRETARIAL STAFF

Clerical and secretarial staff should be computer literate and have general office skills. They should be made aware of the importance of confidentiality and accuracy in transfer of patient details. They should be instructed in clinic and laboratory registration systems, filing and retrieval of reports, handling of specimens and health and safety within the laboratory. They should also be taught relevant medical terminology. Additional "in service" training should be given within the laboratory for clerical staff to meet these skill levels.

6.4 CYTOTECHNOLOGISTS

6.4.1 *Skill levels*

Cytotechnologists undertaking the screening of cervical smears should have achieved certain skill levels within the cytology laboratory prior to undertaking unsupervised screening of cervical smears. They should be able to screen and interpret cervical smears, prepare a descriptive report on all smears that are negative for precancerous changes, and identify problem and abnormal smears referring them for higher opinion according to the practice of the laboratory. They should be trained in confidentiality, the reception and recording of patient data, computerised systems, and relevant medical terminology. They should be able to carry out general laboratory procedures such as slide staining, mounting, labelling, filing and retrieving of slides and patient data. They should adhere to health and safety procedures. They should also participate in quality control programmes and continuing education.

6.4.2 *Training*

The trainee should have attained a high school education or university degree dependent on the requirement of the individual member state.

In order to gain the skill levels described above the cytotechnologists should attend a training centre that meets the requirements set out in section 6.4.3.

The training should be given within a framework of general medical laboratory technology and non-gynaecological cytology or supplement an existing programme of training. The trainee should receive a minimum of 80 hours formal theoretical instruction including lectures, seminars and tutorials.

In addition to the theoretical instruction the trainee should receive 6 months supervised practical microscopy instruction and during this period should screen a minimum of 2000 smears. The training should cover the syllabus described in Table 6.1.

It is acknowledged that after this relatively short period of training a cytotechnologist would not gain sufficient experience to screen smears without supervision. To achieve the additional experience a total of 7000 slides should be examined under close supervision. This extra training may be obtained at the training centre or as "in service" training.

The trainee should pass an examination which has been set by an accredited training school or encouraged to sit an aptitude test (see 6.4.4.) before undertaking primary screening.

6.4.3 *Training centres for cytotechnologists*

Centres for the training of cytotechnologists in cervical cancer screening should meet the following standards.

Table 6.1. *Curriculum*

- General
  - Historical review of clinical cytology
  - Principles of mass screening for cervical cancer
  - Ethics and medico legal aspects as applied to cervical cytology
  - Organisation of the cytopathology laboratory
  - Record keeping systems, registration of specimens, call/recall systems etc.
  - General terminology in cytopathology and reporting
  - Laboratory health and safety
  - Concepts of carcinogenesis and epidemiology of cervical cancer
- Cytopreparatory techniques
  - Cytology screening techniques
  - Collection and preparation of cell samples from the female genital tract
  - Theory and practice of fixation: the commonly used fixatives
  - Theory and practice of staining with particular reference to the Papanicolaou and haematoxylin and eosin techniques
  - The use of mountants — resinous and aqueous
  - Assessment of smear quality
  - Common artifacts and contaminants
  - The use, care and maintenance of the light microscope
- Female genital tract
  - Anatomy, physiology and histology of the female genital tract
  - Cell structure and function
  - Cytomorphology of
    - Normal epithelial cells of the female genital tract
    - Reserve cell hyperplasia and squamous metaplasia
    - Inflammation, degeneration and regeneration
    - Iatrogenic changes including radiation and chemotherapy
    - Hormone status: normal and abnormal patterns
    - Microbiology of the female genital tract and viral cytopathic changes
    - Neoplasia: general features and an understanding of the process
  - Cytomorphological and histopathological basis of
    - Cervical intraepithelial neoplasia
    - Microinvasive and invasive squamous carcinoma of the uterine cervix
  - A basic knowledge of the cytomorphology and histopathological basis of
    - Adenocarcinoma and glandular intraepithelial neoplasia of the endocervical canal
    - Adenocarcinoma and relevant common lesions of the endometrium
    - Relevant common lesions of vulva, vagina, tubes and ovaries
  - Principles of investigations and management of patients with abnormal cervical smears.

This curriculum should form part of a comprehensive syllabus for training in general cytotechnology

The training centre should have a permanent staff including a nominated anatomopathologist specialising in cytopathology and a nominated cytotechnologist, both of whom should have a minimum of 5 years experience in cervical cancer screening. The centre must be able to offer a wide range of teaching material and in order to obtain this the centre should have a minimum work load of 15 000 smears per year. The training centre may draw on workloads of smaller affiliated laboratories to meet this requirement. The centre should also have a slide bank of selected cases available for trainees.

In order to ensure that the students' training is of high quality the centre should have separate lecture accommodation and screening laboratory, a library of books and journals, good quality binocular microscopes, discussion microscopes and pro-

jection facilities. The training programme should comply with the ECTP proposals for training and it is recommended that there is continuous assessment of students and an exit examination equivalent to the ECTP aptitude test. In the absence of an equivalent examination students should be encouraged to take the ECTP Test of Aptitude.

6.4.4 *ECTP test of aptitude in cervical cytology for cytotechnologists*

In order to set a basic recognised standard of cervical screening throughout the European Community, the ECTP recommends that cytotechnologists who undertake cervical screening take the ECTP aptitude test or an equivalent examination.

6.5 ANATOMOPATHOLOGISTS

6.5.1 *Special responsibilities*

The trained anatomopathologist specialising in cytopathology should take responsibility for the cervical cancer screening service provided by the laboratory including budgetary management where appropriate. This includes undertaking responsibility for all cervical smear reports issued by the laboratory. The anatomopathologist should also personally examine and report on all abnormal and problem cases. Other responsibilities should include implementation of a quality assurance programme, provision of in service training, audit of laboratory practice, liaison with clinical colleagues, monitoring of health and safety within the laboratory and introduction of a programme of research and development.

6.5.2 *Training*

The training should be obtained at a training centre which meets the standards set out in 6.5.3, and would normally be a minimum of 6 months duration. During this time, 2500 cervical smears should be examined. On completion of training the anatomopathologist should be competent to perform primary screening and give an independent opinion on cervical smears that have been prescreened by a cytotechnologist.

The anatomopathologist should take an examination equivalent to the aptitude test for anatomopathologists proposed by the ECTP before assuming responsibility for a cervical cancer screening service.

6.5.3 *Training centres for anatomopathologists*

The training centre should meet the conditions already described for cytotechnologists (see 6.4.3) with the addition that it must provide the trainee with the opportunity of attending gynaecological clinico-pathological meetings on a regular basis which should include relevant histology.

7. Quality Assurance in the Cytology Laboratory

7.1 INTRODUCTION

QUALITY ASSURANCE in cervical cytology is designed to achieve an acceptable reliability and consistency in the results produced in the cytology laboratory.

Internal quality assurance (IQA) refers to the procedures introduced by the staff in the laboratory to monitor results and ensure that they are of a sufficiently high standard to be released.

External quality assurance (EQA) refers to systems of objectively checking laboratory results or reports by an external agency for the purpose of promoting a high standard of performance and establishing comparability between laboratories.

We consider that both schemes are essential for sound laboratory practice.

7.2 INTERNAL QUALITY ASSURANCE

In order to ensure a high standard of laboratory practice the following internal quality control procedures should be instituted:

(1) Specimen collection. The smear should be correctly labelled and matched with the request form. The request form should be checked to ensure that all relevant information has been given.

(2) Preparation and staining. Interpretation of cytological material depends on the quality of preparation and staining. A schedule of technical methods for processing and staining cervical smears should be maintained and updated.

(3) Primary screening. Quality control of primary screening is difficult to achieve on an ongoing basis when pressures of work can intervene. The following methods can be considered.

(a) Selected rescreening. This involves rescreening of cervical smears from patients in selected clinical categories, e.g. abnormal bleeding, postcoital bleeding or a clinically suspicious cervix.

(b) Double screening. This is a reliable method of internal monitoring if it is undertaken by experienced supervisory staff and a high level of vigilance maintained at all times. All diagnostic samples should be double screened.

(c) Review of previous cytology. This is important for internal monitoring as it can highlight failure to recognise an unsatisfactory or suboptimal smear, failure to observe abnormal cells, or errors of interpretation. It should be undertaken in all cases where: (i) current cytological material shows unsuspected abnormalities, (ii) a positive histological diagnosis is reported, (iii) cells evaluated to be abnormal but not confirmed by histology.

(d) A satisfactory staff/workload ratio is essential for good IQA. It is estimated in some countries that one cytotechnologist can undertake the primary screening of approximately 7000 cervical smears annually. One supervisor is required for every three primary screeners.

(e) It is common practice to rescreen a random sample (10%) of negative smears. This should be discouraged as it is an inefficient way of detecting screener errors.

7.3 EXTERNAL QUALITY ASSURANCE

7.3.1 *Slide exchange schemes*

Pilot studies have been carried out in the U.S.A., the U.K. and the Netherlands on the value of slide exchange schemes. In this system a group of 4–5 laboratories will form a cluster. One