

Report of the Department of
Health Cervical Screening
Committee

December, 1996

DEPARTMENT
OF HEALTH AND
CHILDREN
AN ROINN
SLAINTE AGUS
LEANAI

Contents

Chapter	Page
Introduction	3.
Principal recommendations	5.
Summary of main conclusions	6.
1. Principles of screening and how they apply to the prevention of cervical cancer	10.
2. The effectiveness of organised screening programmes	17.
3. Current screening activities in Ireland	24.
4. Review of implementation of recommendations of the Interim Report of the Working Party on Cervical Screening (1988)	27.
5. Costings within the cervical screening service	34.
6. Training of personnel participating in cervical screening	38.
7. The organisation of a cervical screening programme	40.
8. Quality assurance in the cytology laboratory	48.
9. Screening methodology	51.
10. Overall quality assurance of a screening programme	56.
Glossary	58.
Appendix	61.

Introduction

Aim of the Document

The Working Party was appointed as a committee of experts by the then Minister of Health, Dr John O'Connell T.D., in October, 1992 to review cervical screening with the following terms of reference: -

- To review the implementation of the recommendations of the Interim Report of the Working Party on Cervical Screening 1988;
- To review the general efficacy and cost effectiveness of the operation of the present systems; and
- To consider what further cost effective improvements can be made.

The members of the Working Party were: -

Dr Niall Tierney (Chairman), Chief Medical Officer, Department of Health.

Ms Shane Allwright, Department of Community Health, TCD.

Dr Jane Buttimer, Deputy Chief Medical Officer, Department of Health.

Ms Breda Carroll, The Academy of Medical Laboratory Science and St Luke's Hospital, Dublin.

Dr Robert Carroll, Consultant Histopathologist, St Luke's Hospital, Dublin.

Dr Mary Condren, Irish College of General Practitioners.

Dr John Devlin, Deputy Chief Medical Officer, Department of Health.

Mr John Doyle, Programme Manager, Community Care, EHB (to February, 1994).

Ms Deirdre Fitzsimons, Community Nursing Adviser, Department of Health.

Ms Dora Hennessy, Assistant Principal, Department of Health.

Dr Bernadette Herity, Faculty of Public Health Medicine, RCPI and University College, Dublin.

Dr William Kealy, Consultant Histopathologist, Cork University Hospital.

Dr Gerard Kidney, Irish College of General Practitioners.

Professor Mary Leader, Consultant Histopathologist, RCSI and Beaumont Hospital, Dublin.

Ms Anne MacMahon, Cytotechnologist, Irish Association for Clinical Cytology.

Ms Lenore Mrkwicka, Irish Congress of Trade Unions.

Dr Michael Mylotte, Consultant Obstetrician/Gynaecologist, University College Hospital, Galway.

Dr Maeve Peyton, Acting Director of Community Care and Medical Officer of Health, Eastern Health Board.

Professor Walter Prendiville, Consultant Obstetrician/Gynaecologist, RCSI and Coombe Women's Hospital, Dublin.

Ms Moira Staunton, Assistant Principal, Department of Health (to June, 1993).

Mr Martin O'Malley, Higher Executive Officer, Department of Health. (Secretary to May 1994).

Dr Winifred O'Neill, Senior Area Medical Officer, EHB (Medical Secretary).

The background to the appointment of the Working Party was a commitment given in the Programme for Economic and Social Progress that the working party on cervical screening (which issued an interim report in 1988) would be reconvened in order to consider what further improvements could be made in this area. In addition, the Programme for Competitiveness and Work undertook that consideration would be given to the recommendations of this Working Party in the context of the development of a detailed plan for women's health.

The Working Party was divided into three groups. Sub-group 1 chaired by Dr Buttimer reviewed what was happening in Ireland in relation to cervical screening, colposcopy and costing within the service. Dr O'Neill was seconded to the Department of Health to facilitate this task. Professor Frank O'Brien, Department of Accountancy, UCD provided advice and guidance on the costing method. Ms Fitzsimons surveyed the Community Care Areas. Sub-group II chaired by Professor Prendiville examined the evidence available on the effectiveness and need for screening. To facilitate this brief, Professor Prendiville organised a workshop to which Dr Ian Duncan and Professor Ciaran Woodman contributed. Sub-group III under the chairmanship of Professor Prendiville produced guidelines on how to take a cervical smear, essential equipment required for taking a smear, the most suitable reporting nomenclature for Ireland, and the management of cytological abnormalities. The Working Party also received documents on quality assurance in the laboratory from the Faculty of Pathology, RCPI and Professor Leader, RCSI, and on the organisation of a cervical screening programme from the Faculty of Public Health Medicine, RCPI. Reports from each sub-group were then presented to the whole group which met on eleven occasions. This document is based on the reports of these three sub-groups which also contain detailed references.

In addition, the Working Party would like to acknowledge the assistance provided by health boards, hospitals, community care staff, gynaecologists, pathologists, hospital doctors, laboratory technicians, general practitioners, the library and staff of the Department of Health. Without their contribution and interest it would not have been possible to complete our brief. The Working Party also wishes to acknowledge the assistance of the Eastern Health Board who agreed to second Dr Winifred O'Neill to assist us in our task which enabled us to comprehensively fulfil our brief. The Working Party wishes to express its appreciation for her work.

Principal Recommendations

1. A national cervical screening programme based on an age sex register should be established.
2. Women aged 25-60 years should be screened.
3. The minimum recommended screening interval is 5 years.
4. Smear taking should be carried out within the primary care network.
5. Participating laboratories should have a minimum throughput of 15,000 smears annually.
6. 5,000 cervical cases per technician per annum is an appropriate case load.
7. A colposcopy service should be established in all health board areas keeping in mind that colposcopists should practise in clinical situations that allow them to manage 100 cases of CIN per annum.
8. All personnel involved in the delivery of the programme must be trained to a high standard.
9. Comprehensive quality control must be an integral part of the programme at every level.
10. Counselling together with health promotion material alleviates anxiety prior to screening and consequently prior to colposcopy and treatment.
11. Adequate resources are essential to ensure that the targets set out in this report are achieved effectively and efficiently.
12. An expert advisory committee is necessary to oversee the setting up, implementation and monitoring of the cervical screening programme.
13. The Director of Public Health in each health board area should have overall responsibility for the cervical cancer screening programme and for its evaluation.

Summary of Main Conclusions

The main thrust of our conclusions is that cervical screening is a worthwhile preventive health measure when delivered as an organised screening programme. An extensive literature review revealed that it is difficult to quantify the effectiveness of opportunistic screening. However, it is generally agreed that opportunistic screening such as the current Irish screening service, is not effective in reducing overall mortality. In addition the report concluded

1. Invasive cervical cancer is usually preceded by an asymptomatic preinvasive stage of the disease. The condition being screened for in cervical screening programmes is the precursor of invasive cervical cancer rather than the disease itself. (Section 1.4).
2. Cervical cancer is unusual (amongst cancers) in being preventable by treatment during its preinvasive stage (CIN). (Section 1.5).
3. The risk factors for the disease are multifactorial and at present the exact cause of cervical cancer is uncertain. (Section 1.6).
4. Treatment of cancer of the cervix has an overall 5 year survival of 57%. (Section 1.14).
5. Cervical cytology alone has become the accepted screening method for the detection of preinvasive cervical neoplasia throughout most of the developed world. (Section 1.15).
6. Cervical cancer screening satisfies most of the WHO's criteria for screening. (Section 1.25).
7. The objective of an organised cervical screening programme is to reduce the incidence of, and the mortality from, cervical cancer in the target population. (Section 2.1).
8. The effectiveness of the current screening service, the coverage of the population at risk and the quality of the overall service are not clear. (Section 3.2).
9. Colposcopy is a procedure which can be easily undertaken in an OPD with the appropriate equipment. (Section 3.4).
10. Short waiting lists (not exceeding four weeks), individual appointments, appropriate clinic environment and adequate information help to reduce anxiety levels in clients and may contribute to improving compliance. (Section 3.6).
11. Long term cytological follow up is essential for patients treated at colposcopy. (Section 3.7).
12. The pathology workload has to be considered when introducing LLETZ into a colposcopy clinic. (Section 3.7).

13. Cytology/histopathology/colposcopy links on site must be ensured as far as possible. (Section 3.7).
14. Laboratories or group of laboratories participating in the proposed screening programme should have an adequate throughput of smears i.e. 15,000 smears annually. (Section 4.1).
15. Pathology manpower needs in relation to cervical screening should be addressed and training in cytopathology be provided for trainee histopathologists. (Section 4.2).
16. 5,000 cervical smear cases per technician per annum is considered an appropriate case load. (Section 4.3).
17. Hospitals should provide adequate clerical staffing. (Section 4.4).
18. The Working Party endorses the CIN reporting nomenclature. (Section 4.7).
19. Out-patient charges should no longer apply to the processing of cervical smears in laboratories. (Section 4.10).
20. The bulk of cervical smears are taken by general practitioners. Women should have a choice of service provider within the primary care network. Service providers should be properly resourced. Financial barriers for women within the GMS should be removed. (Section 4.12).
21. Good productivity and accuracy in screening are essential in achieving an efficient and effective service. (Section 5.6).
22. The approximate cost to the public service of the current cervical screening service is in the region of £1.6 million. (Section 5.13).
23. All personnel involved in the delivery of the programme should be trained to a high standard. (Section 6.1).
24. An adequate smear is one which reflects accurately the condition of the cervix. All doctors and nurses undertaking cervical screening should ensure that they are competent in smear taking. The Irish College of General Practitioners should continue to incorporate training in smear taking into vocational training and continuing medical education. Health boards should ensure that staff assigned to this work are properly trained. (Section 6.2).
25. Each participating laboratory should be staffed by a consultant histopathologist trained in cytopathology. (Section 6.3).
26. A Certificate in Competence in Cytology from a recognised training course which has the approval of the Irish Association of Clinical Cytology is desirable for medical laboratory technicians training in cytology. (Section 6.5).
27. Clerical staff within the laboratory should have appropriate skills. (Section 6.6).

28. An age sex register is a prerequisite for an organised population based screening programme. This is the basis for a call/recall system and subsequent evaluation of the programme. (Section 7.3).
29. An organised call/recall system is recommended for women aged 25-60 years. This raises data protection issues, the implications of which should be fully considered. (Section 7.4).
30. A minimum 5 yearly screening interval is advised with two smears to be taken within twelve months of entering the programme if they have never had a previous smear. (Section 7.5).
31. Opportunistic screening should be reviewed on an ongoing basis. (Section 7.6).
32. It is essential to ensure that smear taking, laboratory processing, colposcopy and treatment facilities are adequate and that colposcopy and treatment can be provided without delay. Quality control and evaluation must be an integral part of the service. (Section 7.7).
33. Compliance is a fundamental prerequisite for the success of a screening programme. (Section 7.8).
34. The Director of Public Health in each health board area or a person designated by him/her should have overall responsibility for the cervical cancer screening programme. (Section 7.9).
35. The implementation of a systematic screening programme is a major organizational exercise. An expert advisory committee is necessary. (Section 7.10).
36. There should be an effective standardised computerised call/recall system registering all appropriate data. (Section 7.11).
37. It is essential that adequate resources are provided initially and that continuing resources are ensured from the start for the effective implementation of the recommendations in this report. (Section 7.12).
38. Quality control is essential at all levels in the screening process. (Section 7.20).
39. Targets should be set for the cervical screening programme. (Section 7.21).
40. The incidence of invasive squamous cell cervical cancer should decrease by 60% within 10 years. Mortality from cervical cancer should decrease by 60% within 20 years. (Section 7.23).
41. The guidelines in quality assurance in the cytology laboratory should be followed. (Section 8).
42. Guidelines for taking cervical smears, reporting and recommendations for action following smear report should always be followed. (Section 9).

43. Ongoing measures to reduce the occurrence of inadequately taken smears etc. as well as health education and programme co-ordination are essential to facilitate overall quality assurance of the programme. (Section 10.1).
44. Colposcopists should practise in clinical situations that allow them to manage 100 cases of CIN per annum. (Section 10.5).

Chapter 1

The principles of screening and how they apply to the prevention of cervical cancer

Principles of screening

- 1.1. The principles of screening were first formulated in 1968 by Wilson and Jungner for the World Health Organisation (WHO) (Table 1). Cervical cytology screening antedated these principles and cervical screening programmes were not set up with these in mind. It is, therefore, interesting to see how cervical cytology screening measures up to these principles.

TABLE 1

WHO protocol for principles of screening

- | |
|---|
| <ul style="list-style-type: none">• The condition should pose an important health problem.• The natural history of the disease should be well understood.• There should be a recognisable early stage.• Treatment of the disease at an early stage should be of greater benefit than treatment started at a later stage.• There should be a suitable test.• The test should be acceptable to the population.• There should be adequate facilities for the diagnosis and treatment of the abnormalities detected.• For diseases of insidious onset, screening should be repeated at intervals determined by the natural history of the disease.• The chance of physical and psychological harm to those screened should be less than the chance of benefit.• The cost of a screening programme should be balanced against the benefits it provides. |
|---|

The condition should pose an important health problem

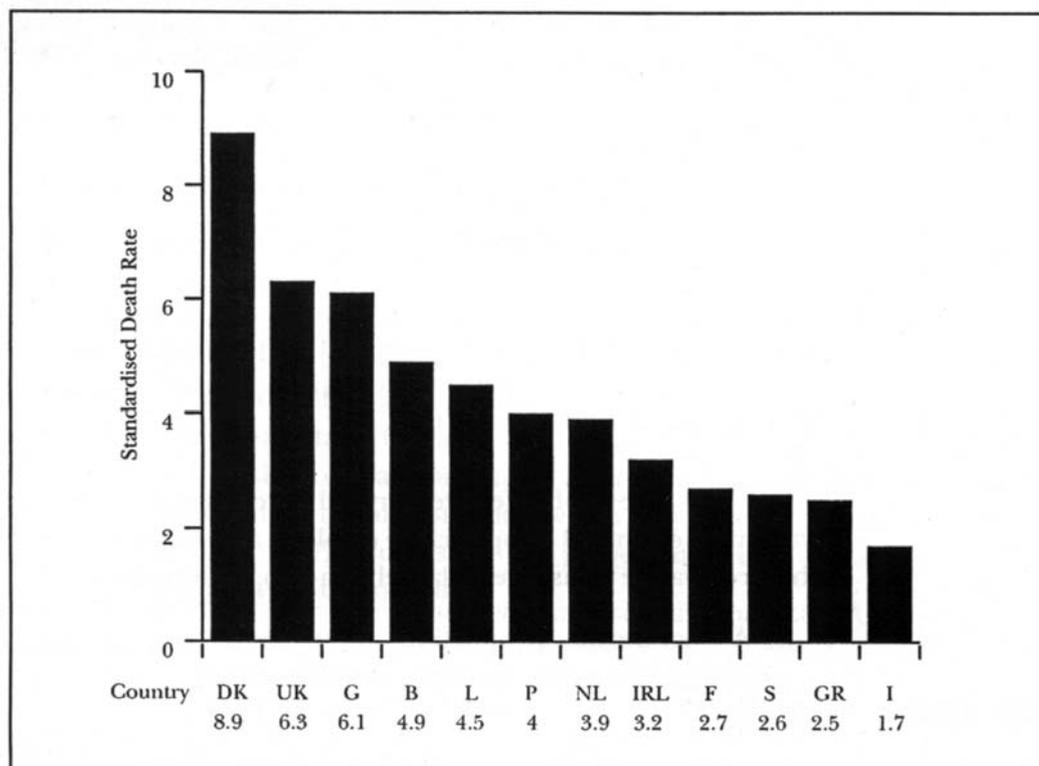
- 1.2. Screening programmes designed to reduce the incidence and death rate from cervical cancer have been established in most developed countries. Few developing

countries have yet been able to establish such programmes. Worldwide, nearly half a million women develop cancer of the cervix every year. Three quarters of these cases occur in the developing world where it is the commonest female cancer.

- 1.3. In Ireland there were 72 deaths certified as due to cancer of the cervix (ICD 180) in 1992. These account for 2% of all cancer deaths in Irish women and a crude mortality rate of 4.1/100,000. In addition there were 25 deaths certified as due to cancer of the uterus, part unspecified (ICD 179) and at least half of these are likely to have been due to cancer of the cervix. Age-standardised mortality rates for cancer of the cervix in the European Union (EU) are displayed in Figure 1. Deaths due to cervical cancer tend to occur more often in older women and women in the lower socioeconomic groups. Informed women in the higher socioeconomic groups are generally more concerned about their health and tend to avail of smear tests.
- 1.4. Incidence rates for cancer of the cervix in Ireland are based on the population of the Southern Tumour Registry of approximately 500,000 and due to small numbers the rate fluctuates from year to year (Table 2); it ranges from 11.8/100,000 in 1983 to 4.3/100,000 in 1988. As a general rule incidence rates for cancer of the cervix in developed countries are 2.5-3 times the mortality rates. The death rate is low but rising in younger women (less than 35 years old) in most countries. Numerous studies indicate that **invasive cervical cancer is usually preceded by an asymptomatic preinvasive stage of the disease** where precancerous cells are confined to the epithelium of the cervix. **The condition being screened for in cervical screening programmes is the precursor of invasive cervical cancer rather than the disease itself.** The precursor to invasive squamous cervical cancer is known as Cervical Intraepithelial Neoplasia or CIN.
- 1.5. **Cervical cancer is unusual (amongst cancers) in being preventable by treatment during its preinvasive stage (CIN).** If diagnosed late it has a high case fatality rate. It invades locally and is associated with exceptional morbidity and so despite its relative infrequency in comparison with other cancers (e.g. breast) it remains an important health problem.

FIGURE 1

Mortality – Cancer of the Cervix
Age standardised death rate per 100,000 (New Standard European Population)



Source: World Health Statistics WHO 1993.

TABLE 2

Cervical Cancer – incidence rates 1983-1990
Southern Tumour Registry

Year	No	Rate/100,000	* ASR/100,000
1983	33	12.5	11.8
1984	17	6.8	6.1
1985	21	7.9	7.9
1986	22	8.2	7.9
1987	12	4.5	4.8
1988	14	5.3	4.3
1989	23	8.6	7.7
1990	13	4.9	4.4
1991	27	10.2	8.6

* Age Standardised Rate per 100,000 ‘old’ standard world population

The natural history of the disease should be well understood

- 1.6. **The risk factors for the disease are multifactorial and at present the exact cause of cervical cancer is uncertain.** There may be several interlocking mechanisms involved. In particular the human papilloma virus types 16 and 18 are considered to be linked to the subsequent development of cervical cancer. An altered local immune

response is probably a necessary circumstance. The natural progression to cervical cancer is relatively well understood. High grade lesions e.g. CIN III have a high probability of progression to cervical cancer. Low grade lesions e.g. CIN I are less predictable in their behaviour and may even regress.

- 1.7. It may be reasonable to assume that progression through the grades of cervical intraepithelial neoplasia occurs in a gradual, incremental fashion, but there is no direct evidence for this.
- 1.8. The success of effective cervical screening programmes which detect cervical intraepithelial neoplasia by cytology and allow its treatment whilst still in the preinvasive phase, rests largely on two assumptions:
 - (i) A significant proportion of women with cervical intraepithelial neoplasia would eventually develop invasive carcinoma, if not treated.
 - (ii) Most invasive squamous cell carcinomas are preceded by a demonstrable intraepithelial phase.
- 1.9. However, there is little precise information on the rate of progression from cervical intraepithelial neoplasia to invasive carcinoma, mainly because of the moral and ethical impossibility of observing women with a known premalignant disease without intervention.
- 1.10. Although, two studies from Scandinavia reported progression rates of 65-70% in women with carcinoma in situ (CIN III) who developed invasive carcinoma over the course of 12 years a more recent study from New Zealand found that 36% of women who had persistent abnormal cytology following incomplete treatment for CIN III, developed invasive carcinoma after 20 years and 18% had developed carcinoma after 10 years. As these patients were partially treated, the disease could not be considered to have run its natural course.
- 1.11. With regard to duration of the preinvasive phase, it has long been accepted from epidemiological and cytological studies that cervical intraepithelial neoplasia takes at least 10 years to become invasive (although more recent analyses indicate that 3-10 years may be more realistic). The fact that women with CIN III are generally some 10-15 years younger than those with invasive carcinoma, is taken to support this suggestion.
- 1.12. Nevertheless, there have been worrying reports of young women developing invasive carcinoma of the cervix following recent negative cytology. Some of these smears may have been false negatives, which would have been found to contain malignant cells on review or there may have been a genuine progression from a normal cervix to invasive carcinoma during a short time.

There should be a recognisable early stage

- 1.13. As with all cancers cervical neoplasia is staged according to four broad categories defined by Federation Internationale de Gynecologie et d'Obstetrique (FIGO). Cervical cancer has the particular advantage of also having a detectable preinvasive stage where the

abnormality is confined to the epithelium of the transformation zone of the cervix. The preinvasive stage is commonly known as stage 0 and as such is confined to the epithelium and cannot spread outside of that epithelium until it develops the ability to invade and spread. Treatment of this condition which may be recognized by a cervical smear is virtually 100% successful in preventing cervical cancer and its associated morbidity and mortality.

Treatment of the disease at an early stage should be of greater benefit than treatment started at a later stage

Table 3
Stage and Prognosis

Stage	Description	Survival Rate %
0	Precancerous lesions	99-100
I	Cancer confined to the cervix	79
II	Cancer has spread beyond the cervix but not on the pelvic wall	47
III	Cancer has spread on to the pelvic wall	22
IV	Cancer has spread more widely	7
All stages		57

Source: Cancer Research Campaign Factsheet 12.

1.14. **Treatment of cancer of the cervix has an overall 5 year survival of 57%.**

Whether treatment is by radiotherapy or surgery it is associated with morbidity and occasionally mortality. It always involves the loss of fertility. The success rate approaches 100% when the problem is recognized and treated at its preinvasive or intraepithelial stage (stage 0) before the abnormal cells have developed the potential to spread beyond their natural intraepithelial boundaries. Treatment at this stage is simpler and of more benefit than treatment started at a later stage.

There should be a suitable test

1.15. The cervix is relatively accessible to inspection, cytology and colposcopic examination. **Cervical cytology alone has become the accepted screening method for the detection of preinvasive cervical neoplasia throughout most of the developed world.** In some European studies (Duncan) where both colposcopy and cytology have been compared as primary screening methods cytology has been found to be highly sensitive.

1.16. Undoubtedly, cytopathologists can recognize cells with mild, moderate and severe grades of dyskaryosis which have their counterparts in tissue preparations, but several observers have now called into question the correlation of the cytology report with the histology. It is now thought that when the degree of dyskaryosis seen on smears is mild, it does not mean that CIN I alone is likely to be present. CIN III has been variously reported in 17.5% to 41.4% of those patients. This percentage increases when moderately dyskaryotic cells are seen, while CIN III is virtually certain to be present when severe dyskaryosis is noted.

- 1.17. A suitable test may be described as one that is inexpensive, valid, reliable and safe. The cervical smear is relatively inexpensive.
- 1.18. The validity of the test may be measured by its sensitivity and specificity. Cervical smears programmes are not designed to detect cancer of the cervix. When they do so this is a bonus if the disease is at an early stage.
- 1.19. Cervical smears are designed to detect intraepithelial abnormalities that have a greater or lesser potential for progression (according to the degree of abnormality). While a single cervical smear test is sensitive a high degree of specificity can only be achieved by serial screening. Its specificity may be set according to pre-agreed thresholds of abnormality. If the objective is only to identify high grade lesions then the programme will be highly specific (there will be few women with CIN III smears who do not have lesions with a significant potential for progression). If on the other hand the policy is to look for and report every possible deviation from the standard normal cytological profile then a relatively high number of women could be selected who do not have a lesion with a significant potential for progression. It is difficult to establish precise specificity (and therefore positive predictive values) for cervical cytology because of several factors:
- (a) The unknown rate of CIN in our community.
 - (b) The variations in laboratory nomenclature and reporting.
 - (c) The imprecise knowledge of progression rates in women with low grade lesions.

The test should be acceptable to the population

- 1.20. Smear tests are acceptable to most women once they understand the potential benefits. Acceptability varies by culture, socioeconomic status and by age. By taking cognisance of women's reticence, in the provision of the service, smear tests can achieve reasonable levels of acceptability in most communities. An information and education programme would facilitate this process.

There should be adequate facilities for the diagnosis and treatment of abnormalities detected

- 1.21. It is envisaged that some expansion and reorganisation of existing cervical smear taking, laboratory and colposcopy services will be required in Ireland if a screening programme is instituted. However, by targeting screening to the most appropriate age groups at appropriate intervals, and by providing clear guidelines for referral to colposcopy, the additional services required may be quite limited.

For diseases of insidious onset screening should be repeated at intervals determined by the natural history of the disease

- 1.22. Review of various cervical screening programmes (e.g. International Agency for Research on Cancer (IARC)) indicate that the shorter the screening interval, the greater the reduction in invasive cancer. However reducing the screening intervals to less than 3 years, produces minimal benefit in mortality reduction with additional overtreatment and increase in costs.

TABLE 4**Reduction in incidence rates of invasive cervical cancer with various screening policies**

Policy	% Reduction	Number of Tests
Every 5 years		
35-64	70	6
25-64	82	8
20-64	84	9
Every 3 years		
35-64	78	10
25-64	90	13
20-64	91	15
Yearly 20-64	93	45

Source: Day N.E.J. *Epid. Comm. Hlth*, 1989, 43, 103-6.

The chance of physical and psychological harm to those screened should be less than the chance of benefit

- 1.23. Most women with abnormal smears will not develop invasive cancer. Assessing the balance between harm (unnecessary treatment and anxiety caused by false positives) and benefit (greatly improved survival of true positives) is difficult. However, modern assessment procedures and treatment have minimal side effects. Prompt referral for assessment and treatment, together with positive steps to educate women and health professionals can greatly minimize the anxiety engendered by a positive smear. In particular, counselling before and at the time of taking a smear is likely to reduce anxiety associated with a subsequent abnormal smear and should be standard practice. (See also section 3.6 regarding the points at which women should be given information and 7.28 regarding health education).

The cost of the screening programme should be balanced against the benefit it provides

- 1.24. In monetary terms the cost of a screening programme is considerably greater than the cost of treatment at clinical presentation. This does not take account of the emotional cost of preventable deaths nor the considerable morbidity associated with the disease.

Conclusion

- 1.25. **Cervical cancer screening satisfies most of Wilson and Jungner's criteria** as formulated for the World Health Organisation.

Chapter 2

The effectiveness of organised screening programmes

- 2.1 **The objective of an organised cervical screening programme is to reduce the incidence of and the mortality from cervical cancer in the target population.** In the absence of randomized controlled trials on the effectiveness of cervical screening, various epidemiological techniques have examined the impact of screening on a population after the programme was introduced. These include (a) temporal relationships, (b) geographic factors, (c) cohort studies and (d) case control studies.

(a) Temporal relationships

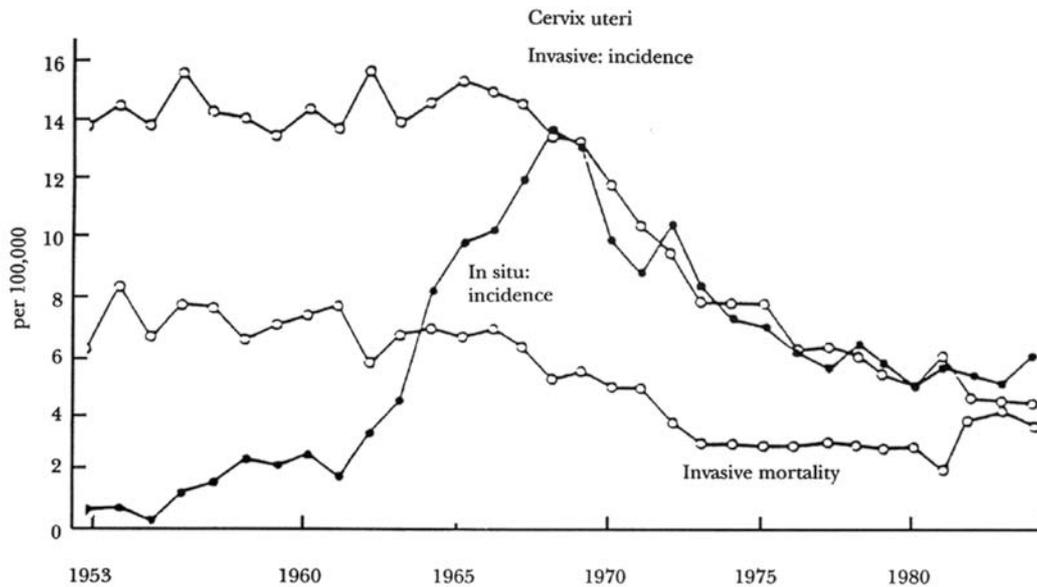
- 2.2 There are many factors which influence incidence and/or mortality from cervical cancer such as
- (a) lifestyle and behaviour of the population;
 - (b) the structure and process of the screening programme; and
 - (c) the availability of health services to manage those who have been detected by the programme.

There is considerable variation with respect to these factors where screening has been implemented and this should be kept under consideration when the data are being evaluated.

- 2.3 In Finland the incidence of CIN III and cervical cancer was documented from 1953-1984 surrounding the introduction of a systematic screening programme. Following its introduction the number of cases of CIN III (In situ incidence in figure 2) increased (as would be expected) and mortality from the disease and the incidence of cervical cancer fell. Eventually the number of cases of CIN III also fell (see figure 2).

FIGURE 2

Annual age-adjusted incidence and mortality rates of invasive cervical cancer and detection rates of carcinoma in situ lesions in Finland from 1953 to 1984



Finnish Cancer Registry.

Source: Hakama and Louhivouri.

- 2.4 Whilst this diagram is an impressive illustration of the apparent effect of a properly organized systematic screening programme it is not irrefutable. The incidence of cervical cancer would appear to be falling in many countries. It is also falling in countries without systematic screening programmes. However, the confounding influence of the cohort effect, opportunistic screening programmes and variable data collection quality make these trends difficult to interpret.
- 2.5 While there are variations in the data due to a number of factors as outlined above, it is possible to give general estimates of the effectiveness of cervical screening programmes. The detection of preinvasive lesions increases initially by the order of 60%. It is more difficult to interpret the mortality and incidence trends because mortality rates were declining in some countries before the introduction of screening. The overall data, however, indicate that incidence and mortality from invasive cervical cancer are reduced by 65% and 55% respectively once the programme is well established (such as after a 10 year interval).

(b) Geographic factors

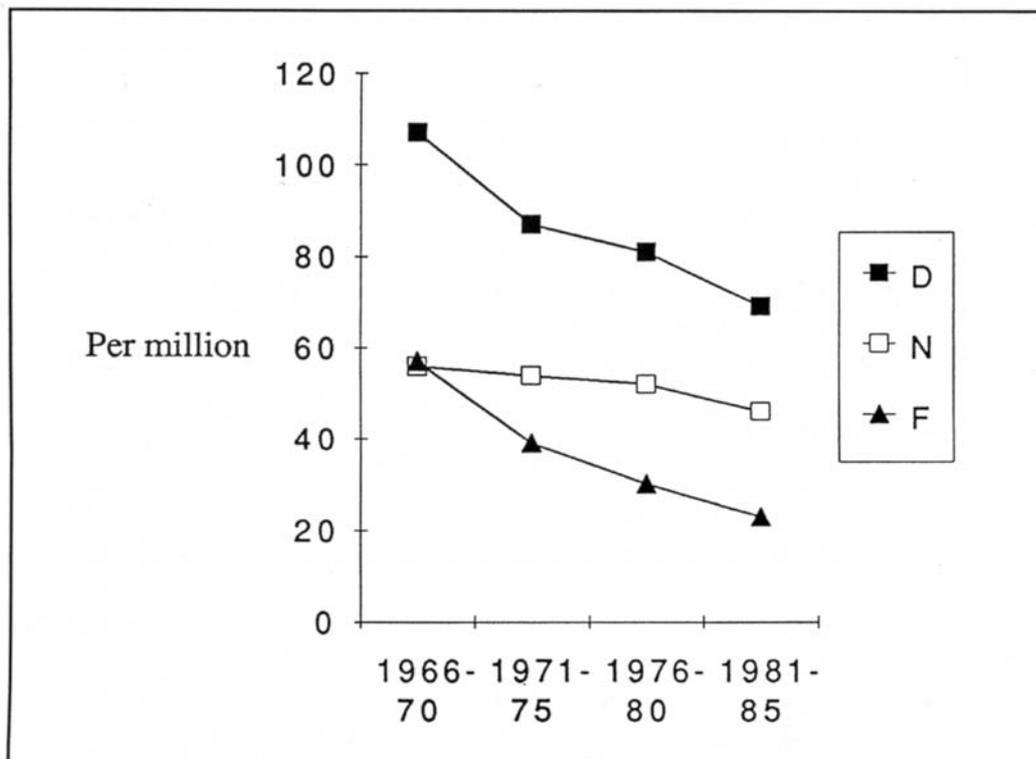
- 2.6 Mortality and incidence rates have fallen very substantially in those countries in Scandinavia with a systematic screening programme when compared to those countries with opportunistic programmes (see figures 3 and 4). These show that Denmark, Finland, Iceland and Sweden achieved a more marked reduction in incidence and mortality than did Norway. Norway did not have a systematic screening programme. Again, however, global data would suggest a slight fall in the rates. Within individual countries some regions have implemented more comprehensive programmes than others and this has been associated with

significantly better mortality and incidence rates than either national or other regional rates. This example is best illustrated by comparing data from Grampian and Tayside in Scotland with other regions (e.g. Glasgow) in Scotland or England.

- 2.7 However, the cohort effect confounds evaluation of geographical trend comparison. Interpretation of geographical comparisons and temporal trends is confusing. Younger generations may have different risks. In other words the risk of cervical cancer may actually be very low in some societies and, therefore, the need for a screening programme may also be low.

FIGURE 3

Effect of organised screening on the mortality from cervical cancer in the Nordic countries

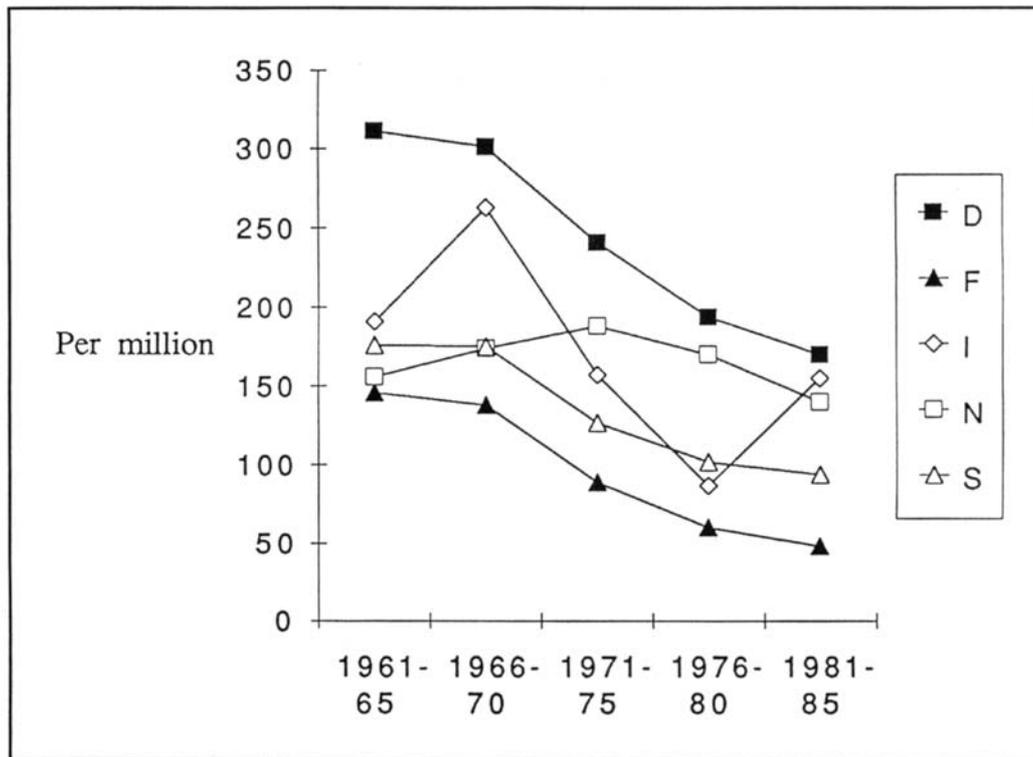


Trends in the age-adjusted (world standard) mortality rates from cervical cancer in 1966 to 1985 in Denmark (D), Finland (F) and Norway (N).

M. Hakama, K. Magnus, F. Pettersson, H. Storm and H. Tilinius. Effects of Organised Screening on the Risk of Cervical Cancer in Nordic Countries in Miller – AB (et al) Cambridge University Press 1991: 153-162.

FIGURE 4

Effect of organised screening on the risk of cervical cancer in the Nordic countries



Trends in the age adjusted (world standard) incidence rates of invasive cancer in 1961 to 1985 in Denmark (D), Finland (F), Ireland (I), Norway (N) and Sweden (S).

M. Hakama, K. Magnus, F. Pettersson, H. Storm and H. Tilinius.
 Effects of Organised Screening on the Risk of Cervical Cancer in Nordic Countries. Miller – AB
 (et al) Cambridge University Press 1991: 153-162.

(c) Cohort Studies

- 2.8 There are several such studies in the literature. They reveal a reduction in risk (as measured by odds ratios or relative risk models) for those who have been screened compared to those who have not (see tables 5, 6 and 7).
- 2.9 One of the problems with cohort studies is that, as with all observational studies, the exposure (in this case screening) is self-selected. This means that those who elect to go for screening may differ from those who refuse. Those who refuse are almost invariably at higher risk irrespective of the absence of screening. The result of this is that cohort studies, as well as case control studies, tend to overestimate the benefit of screening. Data from the Finnish mass screening programme (Hakama and Rasanen-Virtanen, *AJE*, 1976, 103, 512-7) support this. Table 5 shows that the relative risk of cervical cancer for the 15% of women who did not attend screening was 1.6 that of the unit risk for the total Finnish population just prior to the period of intensive screening. The relative risk for attenders, compared to the same population, was 0.2. The incidence rate for attenders was one-eighth that of non-attenders.

TABLE 5
Finnish mass screening programme for cervical cancer:
probability of contracting cervical cancer between ages 30 and 59

Population group	P(30-59)
Control*	0.010
Target population, total	0.004
Attender after first negative smear	0.002
Non-attender after first invitation	0.016

* Total Finnish population prior to period of intensive screening.

Source: Hakama and Rasanen-Virtanen (1976).

Screening intervals

- 2.10 There are a number of cohort and case control studies which estimate the risk of invasive cervical cancer in women who have been screened and relate this risk to the time interval since their last negative smear. The data was empirically summarised and the results are outlined in Table 6.

TABLE 6
Screening Intervals and risk of Cervical Cancer

Years since last Negative Smear	Relative Risk	Relative protection (years)
1	0.1	10
2	0.15	7
3	0.2	5
4	0.3	3
5	0.4	3
6	0.5	2
7	0.6	2
10	0.7	1
> 10	1	1

- 2.11 Table 6 demonstrates that there is a protective effect from screening and that this is linked to the time interval since the last negative smear. If a woman has had a negative smear within one year, the relative risk of her developing cervical cancer is 0.1 (one tenth) that of a woman who has never has a smear. The period of relative protection (inverse of relative risk) reduces with the time interval since the smear was taken and there is no protective effect after 10 years. In general these studies indicate a significant duration of relative protection of approximately 5 years while there is some residual protection up to 10 years since the smear was taken.

- 2.12 The IARC Working Group (1986) examined the relationship between screening schedules and the reduction in cervical cancer rates (Table 7). It is clear that

intensive screening such as that performed annually offers the greatest reduction in cervical cancer rates (93%), however, the number of smear tests rises to 45 per woman and the efficiency of the screening programme reduces considerably. On the other hand, screening every 10 years is efficient with the reduction in cervical cancer being of the order of 61%.

TABLE 7

**Screening for Cervix Cancer in Developing Countries
Effects on cervical cancer incidence of different screening policies, starting at age 20***

Screening schedule	Cumulative rate, 20-64 per 10 ⁵	Reduction in rate %	No. of tests	No. of cases prevented per 10 ⁵ tests
None	3311.5			
Every 10 years, 25-64	1298	61	4	503
Every 10 years, 35-64	1476	55	3	612
Every 10 years, 45-64	1895	43	2	708
Every 5 years, 20-64	544	84	9	308
Every 5 years, 30-64	630	81	7	383
Every 3 years, 20-64	303	91	15	201
Every year, 20-64	216	93	45	69

* From IARC Working Group (1986); assuming incidence rates from Cali, Colombia. The first screening test is assumed to be 70% sensitive. D.M. Parkin, Cancer Screening, UICC 1991.

2.13 These tables would suggest impressive protection from cancer afforded to those who are screened when compared to those who have not been screened. However, a cervical smear does not actually protect a woman from getting cervical cancer. The actual test merely reveals or rules out a potentially cancerous or precancerous lesion. It is the treatment of this lesion which is protective for the few who actually have an abnormality.

(d) Case Control Studies

2.14 The literature was reviewed to determine the effectiveness of cervical cancer screening programmes are demonstrated by case control studies. These studies compare cases (women who developed cervical cancer) and controls (women without cervical cancer) with respect to their prior history of screening for cervical cancer. Such studies have merits in that they are inexpensive, can be performed rapidly and there is an explicit comparison group. They, however, have many disadvantages such as the selection of control groups, and information supplied by participating women may be biased. Case control studies cannot determine the absolute risk of a woman developing cervical cancer as the epidemiology of the disease may be affected by the screening test. These studies may overestimate the benefit of screening in situations where (i) cases of invasive disease detected by screening are excluded because this results in a deficit of screen-detected cases and (ii) the effect of a possible selection bias because women at highest risk of developing cervical cancer are least likely to attend for screening. In spite of these difficulties and the fact that cervical screening has already been introduced in many

countries, case control studies are used in the evaluation process because randomized controlled trials have not been conducted.

- 2.15 In general, case control studies demonstrate that women who develop cervical cancer (cases) are less likely to have had a smear test than those women without cervical cancer (controls). Approximately two thirds of controls have had at least one screen compared to only 40% of cases. The overall relative risk of a woman who has had a smear developing cervical cancer is only 39% that of a woman who has never had a smear. Relative risk is also dependent on the time interval since the smear was taken (as demonstrated in Table 6).

Chapter 3

Current screening activities in Ireland

Cervical screening

- 3.1 The pattern of cervical screening emerging from this review is one of opportunistic screening for women attending general practitioners, post natal examinations, family planning and S.T.D. clinics, and self-referral to community clinics (Table 7 in the Appendix). It is not possible to identify and target vulnerable groups without an age/sex register and call/recall facilities. The laboratory cytology service processed 154,224 cervical smears in 1992 (Table 1 in the Appendix). As this figure includes repeat smears the number of women attending for cervical screening is actually less and unknown. The demographic profile demonstrates that the majority of women screened in 1992 were < 45 years of age (Table 4 in the Appendix) and most of the deaths in this country are still in the older age group. Medical card holders are less likely to be attenders (14%) (Table 6 in the Appendix) and may be hindered by the current financial barriers.
- 3.2 Recommendations on screening intervals vary somewhat among smear-takers and are likely to be less than 3 years overall. Screening rates average at 13 per 100 women (Table 8 in the Appendix). The number of smears taken in 1992 was sufficient for screening 100,000 women per annum and was more than sufficient for screening all women aged 25-50 years in Ireland every fifth year. **The effectiveness of the current screening service, the coverage of the population at risk and the quality of the overall service are not clear.**

Colposcopy services

- 3.3 When an abnormal smear report has been issued i.e CIN II, CIN III, or persistent CIN I, the client must be referred for further investigation as follow up and treatment of abnormal smears are essential for the prevention of cervical cancer. The Intercollegiate Working Party on Cervical Cytology Screening 1987 recommended that no woman with CIN should be treated without prior colposcopy and biopsy.
- 3.4 **Colposcopy is a procedure which can be easily undertaken in an outpatient's department (OPD) with the appropriate equipment** and so adequate equipment for treating abnormalities is worthwhile to prevent hospital admissions. A clinic should be equipped with a colposcope, colposcopy couch, equipment for one or more of the following local destructive methods of treatment - cryocautery, radical diathermy, cold coagulation and laser vaporization or excisional biopsy e.g. LLETZ or laser.
- 3.5 Colposcopy services are currently available in five health board areas and will be available in two more in the near future. Ease of access to this

service to facilitate compliance must be balanced with the concept of adequate patient throughput when establishing a clinic. Training in colposcopy takes time and requires a significant through-put of patients i.e. 4 new patients per week and an ongoing case load of 100 cases per year in order to remain proficient. In some centres, the colposcopy clinics will take some time to develop into busy clinics. For the country as a whole, consultant manpower in colposcopy is sufficient to provide a colposcopy service for the women currently identified as having an abnormal smear. There would be an inevitable increase in the demand for diagnostic and treatment services arising out of a more comprehensive cervical cytology screening programme.

- 3.6 In 1992 the colposcopy service performed 7,916 assessments (Table 3 in the Appendix) and 2,272 of these were new patients. Waiting lists for colposcopy are four weeks or less in the majority of clinics. Long waiting lists for colposcopy are not to be recommended. In the UK the DHSS has recommended that women referred for colposcopy should be seen within one month. The Working Party recommends that women referred for colposcopy should be seen within four weeks. It has been reported that women attending for a first colposcopy appointment have anxiety levels higher than that experienced the night before surgery. Marteau considers that anxiety is more strongly related to anticipation of the procedure than the outcome. Efforts should be made to reduce delays in reporting smear results and waiting time for colposcopy. Duncan is of the opinion that there are at least four points at which women should be given information about cervical screening including colposcopy: before an initial smear, after an abnormality has been detected, when they have been referred for colposcopy and when they attend for colposcopy. Ideally, information should be oral and written. A colposcopy booklet has proved to be effective in reducing stress. **Short waiting lists (not exceeding four weeks), individual appointments, appropriate clinic environment and adequate information also help to reduce anxiety levels in clients and may contribute to improving compliance.**
- 3.7 LLETZ is the most commonly used method of treatment in Ireland. The excision of the transformation zone as in the LLETZ technique would appear to be a definite advantage in detecting microinvasive lesions, excluding glandular abnormalities, and ascertaining that the actual margins of the transformation zone are clear as well as facilitating clinical audit. Published literature indicates that treatment failure rates are small but can vary between methods of treatment and colposcopy centres. They are likely to be low in centres of excellence. **Long term cytological follow up is essential for patients treated at colposcopy clinics.** Clinics utilising LLETZ require less OPD resources than clinics using destructive methods of treatment. However, **the pathology workload has to be considered when introducing LLETZ into a colposcopy clinic.** Sixty two per cent of the colposcopy clinics have access to local cytology laboratories. **Cytology/histology/colposcopy links on site must be ensured as far as is possible in any future development of the colposcopy service.** Otherwise formal links must be established and maintained between the three services. Opportunity for training with supervision in the technique of colposcopy and

participation in continuing medical education is essential for the ongoing development of the specialty.

Chapter 4

Review of implementation of the recommendation of the interim report of the working party on cervical screening (1988)

Laboratory services Interim Report Par 9

- 4.1 *The Interim Report recommended that laboratory services for cervical cytology should be located in three regional laboratories i.e. St Luke's Hospital, Dublin, Cork University Hospital and University College Hospital, Galway, serving the health boards. The report recognised the need to continue a cervical cytology service to provide for major obstetrical and gynaecological departments, particularly where colposcopy facilities were located. These services were orientated towards a diagnostic rather than a screening service. The Interim Report also recommended that smears taken by general practitioners and clinics should be referred to the designated laboratory.*

Current position

- The laboratory cytology service processed 154,224 smears (approximately 175,000 slides in 1992 (Table 1 in the Appendix)) as this figure includes repeat smears the number of women attending for cervical screening is actually less and is unknown.
- The three regional laboratories are not receiving smears from the recommended catchment areas.

Conclusion

The Working Party considers that **laboratories or group of laboratories participating in the proposed screening programme should have an adequate throughput of smears i.e. 15,000 smears annually**, a histopathologist with a special interest in cytopathology, be based in laboratories linked to teaching pathology departments and have formal links with histology and colposcopy services. Adequate space and good quality control are also essential.

Staffing levels Interim Report Par 10

- 4.2 *The Interim Report recommended a histopathologist with a special interest in cytology for each regional laboratory.*

Current Position

- Cervical cytology is considered a sub specialty of histopathology, so there are no wholtime cytopathology consultant posts in the country. Also non gynaecological cytology is continuing to increase as the specialty is constantly expanding.

- Medical manpower is very variable as sessions in cytopathology vary around the country.
- There is low input at consultant level in some laboratories where there is high cytology output.

Conclusion

The Working Party considers that **pathology manpower needs in relation to cervical screening should be addressed and training in cytopathology be provided for trainee histopathologists**, on a daily on going basis within their teaching departments.

Technicians Interim Report Par 10

4.3 *The Interim Report recommended that the international figure of 50-100 slides per day could be achieved in adequately and efficiently managed computerised laboratories.*

Current Position

- Table 2 in the Appendix shows laboratory technician staffing structures and the annual caseload for technician wholtime equivalent primary screener within normal hours. Laboratories which receive smears from gynaecology clinics are processing more abnormal slides and so the case load for screening is likely to be lower than would be expected in a laboratory, the main workload of which is population screening.
- A technician's case load of 50-100 slides per day is not being achieved. Processing of smears varies from one laboratory to another and workloads are not strictly comparable as in some laboratories screeners are involved in other activities. The Working Party was of the opinion that the organisation of screening in the United States is not comparable to Ireland. In the US more tiers of screening are required to arrive at a diagnosis on the initial screen.

Conclusion

5,000 cervical smear cases per technician per annum is considered an appropriate case load (excluding maternity and diagnostic laboratories) to ensure a quality service. It was agreed that a teaching component would also need to be taken into account. The advantage of employing some part-time and jobsharing staff should be considered by laboratories. The recommendation in Chapter 8 on quality assurance in the cytology laboratory must also be taken into account.

Clerical assistance Interim Report Par 10

4.4 *The Interim Report recommended appropriate clerical support staff for cytology laboratories.*

Current position

- Clerical and support staff is frequently below international standards.

Conclusion

The Working Party considers that **hospitals should provide adequate clerical staffing** designated specifically to cytology to allow technicians concentrate on their work. Adequate clerical staffing for colposcopy clinics should also be ensured.

Training in cytology screening Interim Report Par 10

4.5 *The Interim Report recommended that adequate training be provided for screeners to ensure an effective and efficient service.*

Current position

- Any loss of current staff causes considerable disruption without an ongoing plan for training.
- In the past, there was no accredited training school in cytology in Ireland which has hindered laboratory service.

Conclusion

The Working Party recommends the establishment of a complete training programme in laboratory screening and welcomed the initiation of the programme currently taking place in the Dublin Institute of Technology, Kevin Street. Further development of in-service training will be required in cytology laboratories. Continuing training for all staff is essential as part of quality control in screening. (See also Chapter 6 of this report).

Internal quality control procedures Interim Report Pars 6 (i), 9

4.6 *The Interim Report recommended that only one slide per smear per client should be used. It considered that the quality of smears submitted for analysis should be monitored and laboratories should provide feedback on inadequate smears so that the individuals who took such smears could be notified and take corrective action. The report also recommended that a fully completed standard form should accompany smears being submitted to laboratories. Adherence to strict quality control procedures in all laboratories was also recommended.*

Current position

- As recommended by the Interim Report, quality control is being given due recognition by some laboratories and large laboratories are able to achieve this to a greater extent.
- Almost all laboratories other than UCH, Glaway are referred 1 slide per smear.

Conclusion

The Working Party considers that one slide per cervical smear is adequate and this needs to be addressed to reduce reporting delays by replacing existing double slide holders with single slide holders in laboratories supplying kits. Guidelines on internal and external

quality control in Chapter 8 of this report should be followed. Each laboratory should do an annual audit. Numbers of inadequate smears should be recorded and smear takers with recurring inadequate smears should be informed. See also Chapter 6 of this report regarding training.

Unified nomenclature in cervical cytology Interim Report Par 13.4

4.7 *The Interim Report recommended that laboratories adopt a common classification for reporting smears. Smears should be classified by the terms negative, inflammatory, insufficient. The work dyskaryosis, meaning abnormal nucleus, should be used to describe those changes occurring in ecto and endocervical epithelium.*

Current Position

- The reporting classification is broadly in line with the recommendations of the Interim Report.

Conclusion

The Working Party endorses the CIN Reporting Nomenclature following consultation with the Institute of Obstetricians and Gynaecologists, the Faculty of Pathology, the Irish College of General Practitioners, the Irish Association of Clinical Cytologists and the Association of Clinical Pathologists. See also Chapter 9 of this report.

Computerisation of the laboratories Interim Report Par 12A & 12B

4.8 *The Interim Report recommended computerisation of the three regional cytology screening laboratories to facilitate the management of the service. The report recommended that the cytology laboratories have a standardized computer system. The system chosen should be of sufficient size to store 5-10 years' records, and have the ability for future expansion and integration with the cervical cytology services. The terminal network would vary according to the size of the laboratory. The Department of Health should be consulted with regard to the installation or development of any computerised system for the laboratory cytology service. The report recommended that the information being collected with the smears and its analysis be standardized between the designated laboratories. This was to facilitate the regular evaluation of the service on a local area and on a national level basis and thus monitor whether or not the service was meeting its objective. The design of a uniform computerised notification form was also advised.*

Current position

- Computerised record systems are in situ in St. Lukes.
- Computerisation of cytology laboratories in UCH Galway and Cork University Hospital is inadequate.

Conclusion

The Working Party endorses the recommendation of the Interim Report and also recommended integrated computer systems linking cytology, histopathology and

colposcopy. This would facilitate communication and ensure follow up of abnormal smears. The Group also considered that adequate good quality laboratory equipment is essential for delivering a high quality cervical screening service. Hospitals and health boards should review their laboratory equipment. The development of a computerised system should be agreed by the health board, agencies and the Department of Health.

Reporting on cervical smears Interim Report Par 6 (ii)

4.9 *The Interim Report recommended that the interval between the taking of a smear and the issue of the result should not exceed one month. A report should be issued on positive and negative smears. The Interim Report advised that it was the responsibility of the laboratory to report the result to the referring doctor and to the family doctor, if any, unless the patient requested otherwise. Where smears were taken at a public health clinic, the referring doctor was deemed to be the Director of Community Care. The report advised that the woman should be informed that the result was normal or that she should consult her family doctor or clinic. Discussions should be held between the three main laboratories regarding the design of a uniform, computerised notification form. The referring doctor should be given adequate information about the patient's smear.*

Follow-up on abnormal smears Interim Report Par 6 (iii)

4.10 *The Interim Report advised that the ultimate responsibility for the follow up of positive smears lay with the referring doctor, with appropriate assistance provided by the laboratory. Where the referring doctor was the Director of Community Care s/he should ensure that follow up took place through the doctor of the patient's choice. Particular attention should be given to the correct interpretation of abnormal smear report. Laboratories should provide assistance to doctors in this area in order to reduce demand for unnecessary colposcopy procedures. The Working Group recognised that colposcopy facilities were unable to meet the demand. They recommended that adequate colposcopy facilities be provided.*

Current position

- Seventy five per cent of laboratories processed smears within one month in 1992 with delays of 10 weeks and 12 weeks reported by two laboratories.
- The results of smears are not always returned to the smear taker.
- Laboratory notification forms are not uniform.
- Current consultant manpower in colposcopy was considered sufficient for the existing service.

Conclusion

The Working Party endorses the Interim Report's recommendations on reporting follow up and on the use of a uniform computerised notification form. The Group considers that where smear results are not returned to the smear taker this should be addressed urgently. Laboratories should report the result to the smear taker and notify the woman to contact the

smear taker for the results. It is the responsibility of the smear taker to ensure follow up of abnormal smears. One slide per smear could facilitate the reduction of waiting lists. The colposcopy service may need to be expanded if a national programme is implemented, although compliance with appropriate referral criteria could eliminate some of the current inappropriate referrals.

Laboratory charges Interim Report Par 11 (ii)

4.11 *The Interim Report recommended that the Health (Out Patient Charges) Regulations 1987, be amended to provide for a £5 charge.*

Current position

- Forty five per cent of laboratories were not charging for processing a cervical smear in 1992. All were in the public sector.
- A number of changes in statutory outpatient charges occurred during 1993 and 1994. Since 1 March, 1994 outpatient services are provided free of charge. In July, 1994 a small number of hospitals charged for processing smears.

Conclusion

Notwithstanding the recommendations in Chapter 7 regarding an organised screening programme, the Working Party considers that **outpatient charges should no longer apply to the processing of cervical smears in laboratories.**

Taking of smears Interim Report Par 6 (i)

4.12 *The Interim Report reported that smears were taken by general practitioners in their surgeries, by doctors at family planning clinics, by gynaecologists in hospitals and in their own practices and by public health nurses in health board clinics. The report considered that smears taken by inadequately trained personnel were generally of poor quality and may have to be repeated. The report emphasised that it was particularly important that health boards ensured that nurses assigned to this work were properly trained. The report recommended that adequate training be provided for all staff engaged in this work.*

Current position

- In 1992, 42% of smears were taken by general practitioners, 28.5% in hospitals, 9.9% in family planning clinics, 6.4% in community clinics and 1.4% in STD clinics. See Table 7 in the Appendix.
- The range of reported inadequate smears is variable and can be up to 10.6%. This is partly dependent on the definition of adequacy.

Conclusion

Quality assurance of cervical screening is equally influenced by the smear taker, laboratory processing, follow up and treatment of abnormal smears. The Working Party endorses the

Interim Report's recommendation on training in smear taking and continuing education. See also Chapter 6 regarding training of personnel participating in cervical screening.

Availability of cervical screening Interim Report Par 8

4.13 *The Interim Report considered that women should have a choice where they have a cervical smear taken. Most women requested their general practitioner to carry out a smear. Some women preferred to attend a family planning clinic or the public health clinic for this service. The report considered that an element of choice was an important factor in encouraging women to have a smear taken, particularly as some women prefer to have the smear taken by another woman. The report recommended that cervical screening should continue to be available to women through general practitioners, family planning clinics and at public health clinics with properly trained staff.*

The organisation of cervical screening varied from one health board to another and from one practice to another. Since the bulk of cervical smears were taken by general practitioners, the organisation of cervical screening on a wider scale must involve the general practitioner at the preparatory stage and in its development.

Current position

- The element of choice of service is not available in all areas, with only 55% of community care areas offering clinics.
- Family planning clinics are limited in number and tend to be located in the larger centres of population.
- Availability of cervical screening is fairly good with the majority of general practitioners available to provide cervical screening, but the availability may not be uniform in all areas.
- Financial barriers to cervical screening exist for women within the GMS.

Conclusion

The Working Party recognises that the bulk of cervical smears are taken by general practitioners. It recommended that women should have a choice of service provider within the primary care network. Service providers should be properly resourced. Financial barriers for women within the GMS should be removed.

Chapter 5

Costings within the cervical screening Service 1992

- 5.1 Cervical screening has evolved in an ad hoc way in Ireland. The service is interwoven with other aspects of health care to such a degree that costing of the complete service is likely to be as difficult as that reported by the House of Commons Committee of Public Accounts on Cervical and Breast Screening in England in 1992.
- 5.2 With this in mind, unit costings were sought on two public health cervical screening clinics, two cytology laboratories, two colposcopy clinics and costings on Punch biopsies and LLETZ in one histopathology laboratory. Labour costs were relatively easy to obtain and the costs of supplies were also relatively well ascertained in most cases. However, overhead costings proved to be the most difficult to establish and overall could only be considered to be approximate.

Public health cervical screening clinics

- 5.3 The unit cost of a cervical smear taken at a public health clinic varied from £7.70 in the North Western Health Board to £15.91 in the Eastern Health Board. The North Western Health Board is a walk-in clinic, advertised in a local newspaper, staffed by two public health nurses and smear results are sent directly to the general practitioner by the laboratory. The Eastern Health Board clinic is by appointment, staffed by two nurses and follow up of smears is facilitated by an area medical officer.
- 5.4 The difference in unit costs is largely due to labour and increasing the level of attendance at the Eastern Health Board clinic could reduce the gap. Quality of service also has to be taken into consideration as well as the number of women attending given that many clinics also take the opportunity to provide health education. Nevertheless, monitoring inadequate smears and ensuring follow up of abnormal smears as recommended in the Interim Report is vital in cervical screening so the extra labour costs in the Eastern Health Board clinic are likely to be serving a purpose. The total cost of a three hour session of cervical screening in terms of labour and supplies is almost the same for both clinics (£120-£123) assuming that overhead costs of heat, light, electricity, insurance etc. are going to be borne by the overall health centre regardless of whether cervical screening takes place or not. If the health centre space could otherwise be utilised, the cervical screening clinic is an opportunity cost to other health centre clients. So it is likely that health centre overheads attributed to a cervical screening clinic will be less in health centres which are utilised to their maximum.

Laboratory processing of a smear

- 5.5 The cost of processing a cervical smear in St. Luke's was costed at £8.55 and, as some of the overheads were estimated, this costing cannot be considered to be exact.

The National Maternity Hospital, Holles Street, has calculated the technician time and consumables used for a cervical smear as costing £6.68. This is very similar to the equivalent aspect of St. Luke's laboratory. Factors which may cause variations in costings include case load, reagent costs, staining procedures, slide quality, overhead costs and using two slides per cervical smear. Two slides per smear has the effect of almost doubling the cost per unit. A wholtime consultant in cytology would raise the total unit cost to approximately £10.22 in St. Lukes.

- 5.6 Reported costing of screening cervical smears vary somewhat in other countries. In the UK, Data Tree has developed a computerised package for all pathology disciplines and has reported a cervical smear cost of £4.97 in Glan Clwyd Hospital in Wales. The House of Commons Report, previously referred to, estimated that laboratory screening would cost £15.50 but emphasised that this was a crude calculation. In Canada the cost of screening has been estimated to be 10 Canadian Dollars (£5 Ir) per smear or 45 Dollars (£23 Ir) if the fee for the appointment to take the smear is included. **Good productivity and accuracy in screening are essential in achieving an efficient and effective service.** In the UK the National Co-ordinating Network Costing Project reported a cost ranging from £4.68-£5.30 per cervical smear, including departmental overheads, but this increased to £8.90 when general hospital overheads were included.

Colposcopy clinics

- 5.7 Costings were sought on two colposcopy clinics, the Coombe Women's Hospital which utilises LLETZ as the method of treatment and University College Hospital, Galway where Punch biopsy and laser are undertaken. Overhead costs were not feasible to ascertain in either centre and supplies in University College Hospital, Galway were estimated. The cost of a single visit to the colposcopy clinic in terms of labour and supplies was £31 in Coombe Women's Hospital and £46 in UCH Galway. A hospital considering initiating a colposcopy clinic and assuming that suitable rooms and equipment are already available, might consider it useful to know that one single clinic held in the Coombe in 1992 cost £382 in terms of supplies and labour and £514 in a double clinic in UCH Galway, keeping in mind that supplies in both hospitals were estimated costings as distinct from actual costs. A study in the UK considered the mean cost per patient of investigation, treatment and follow up to be £289 (1986/7 prices). A recent costing project in the Oxford region in the UK reported £24.95 as the average cost of a colposcopy attendance visit, but emphasised that there was a wide range around this figure. Clinics with higher attendances have a lower unit cost per visit.

Histopathology costings

- 5.8 Costings for labour and supplies only were Punch biopsy £19, LLETZ £47, Cone biopsy £63, Wertheims Hysterectomy £183, and Hysterectomy for residual CIN £68. These were costed in the National Maternity Hospital, Holles Street, using Welcan Units (measurement on a time unit basis indicating workload).

TABLE 8**Approximate cost to Public Service of Current Cervical Screening Service 1992**

			Cost £
Laboratories (121,885 Smears)	@ £8.55	= 1,042,116	1,042,116
Public Clinics (9559 Smears)	@ £7.70-£15.90	= 73,604	151,988
Colposcopy Assessment (7916)	@ £31.20- £46	= 247,058	364,136
Punch Biopsies (1684)	@ £19	= 31,996	31,996
LLETZ Biopsies (588)	@ £47	= 27,636	27,636
Cone Biopsies (140) (Histology)	@ £63	= 8,820	8,820
Hysterectomies (Histology) (77)	@ £68	= 5,236	5,236
Wertheims (Histology) (50)	@ £183	= 9,150	9,150
		1,445,616	1,641,078

- 5.9 The above costings do not include the cost of smear taking by general practitioners (65,000 smears), family planning clinics (15,268 smears) and cytology in private laboratories (32,340 smears) which are paid for by those using the services. Smears taken in hospitals amounted to 43,953 in 1992 and the ratio of public to private is unknown as is the cost. The smear taker for 17,500 smears was unknown. Hospital stay and surgical procedures for those requiring general anaesthetic for cone biopsies and hysterectomies are also excluded. Again it must be emphasised that overhead costs are not adequately represented in the total cost which is very much an approximate cost.

Cost containment

- 5.10 The threshold for recommending investigation and treatment of an abnormal cervical smear is a major factor in controlling costs. Mild cytological abnormalities have the option of being managed conservatively or referred for colposcopy. The possible disadvantages of referring large numbers of women at low risk of invasive cervical cancer for colposcopy include increased financial cost, crowded clinics and longer waiting lists, diversion of gynaecologists from other activities, increased histology workload, increased demand for treatment sessions and reduced benefit/cost ratio. From the patients' viewpoint the possible disadvantages may include, time and travel costs, greater anxiety and risk of unnecessary treatment for a lesion which has a low risk of progression and possible complications. Conservative management would appear to be reasonably safe and the most efficient option.

Conclusion

- 5.11 It has only been possible to cost limited aspects of the cervical screening service. Labour consistently accounts for the major part of the overall expenditure. Frequency of screening, appropriate case load, quality control and policy on referrals for investigation and treatment throughout the cervical screening services would appear to be the major areas which influence costs. Overhead costs have proved difficult to establish and are likely to be different in the various establishments. In many instances they are going to be incurred by the overall

hospital or building whether the particular aspect of the cervical screening service is taking place or not.

5.12 In conclusion, costings were somewhat underestimated, since overhead costs were approximate in some cases and not possible in others.

5.13 **The approximate cost to the public service of the current cervical screening service is in the region of £1.6 million.**

This costings project was undertaken by Dr Winifred O'Neill with the advice and guidance from Prof Frank O'Brien, Department of Accountancy, UCD.

Chapter 6

Training of personnel participating in cervical screening

Introduction

- 6.1 In order to ensure a reliable and efficient standard of screening, **all personnel involved in the delivery of the programme should be trained to a high standard.** Facilities must be available for training health care professionals in smear taking, and in the analysis of cervical smears. Clerical staff must be trained in the administration of the screening programme.

Smear takers

- 6.2 **An adequate smear is one which reflects accurately the condition of the cervix. All doctors and nurses undertaking cervical screening should ensure that they are competent in smear taking.** This can be achieved by nurses with organised training and by doctors as part of vocational training, or by continuing medical education. The smear taker also has a duty to monitor the frequency with which unsatisfactory smears are obtained and to seek further training if necessary. It is recommended that **the Irish College of General Practitioners should continue to incorporate training in smear taking into vocational training and continuing medical education. Health boards should ensure that staff assigned to this work are properly trained.**

Pathologists

- 6.3 **Each participating laboratory should be staffed by a consultant histopathologist trained in cytopathology.** His/her role should include undertaking responsibility for all cervical smear reports issued by the laboratory, examination of abnormal cases, 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.
- 6.4 Each trainee is required to examine and report on 2,500 cervical smears during a six month period in cytopathology, as recommended by the European Guidelines for Quality Assurance in Cervical Screening and those specialising in cytopathology require a minimum of 2 years cytopathology.

Medical laboratory technicians in cytology

- 6.5 **A certificate in Competence in Cytology from a recognised training course which has the approval of the Irish Association of Clinical Cytology is desirable for medical laboratory technicians training in cytology.** Compliance with EU accreditation requirements is desirable. Medical laboratory technicians working in cytology should participate in quality control programmes and continuing education.

Clerical staff

- 6.6 **Clerical staff within the laboratory should have appropriate skills** such as computer literacy, general office skills, awareness of the importance of confidentiality and accuracy in transfer of patient details. Induction should include instruction in clinic and laboratory registration systems, filing and retrieval of reports, handling of specimens and health and safety within the laboratory and relevant medical terminology. Where necessary, additional “in service” training should be given within the laboratory for clerical staff to meet these skill levels.

Colposcopy

- 6.7 Registrars in Gynaecology usually receive training in the technique of colposcopy on a one to one basis as part of their general professional training. Tuition courses can be availed of in the Royal College of Surgeons in Ireland (RCSI), Dublin and in the U.K. See also section 3.5 regarding training in colposcopy.

Chapter 7

The organisation of a cervical screening programme

Introduction

- 7.1 When organising a cervical cancer screening programme, many different aspects of the programme have to be reviewed and evaluated in advance. These aspects are discussed below.

Definition of the catchment area

- 7.2 In order that evaluation can be carried out the catchment area should be large enough to include the resources needed, not only for smear taking, but also for smear evaluation and follow up of abnormal smears and treatments.

Definition of the target population

- 7.3 The European Guidelines for Quality Assurance in Cervical Cancer Screening recommend that screening should be offered to women in the age group 25-65 years. The availability of a population register is a fundamental requirement for the establishment of any screening programme. As CIN III rarely develops de novo after 45 years the Working Party considered that screening could be safely discontinued for women aged 60 who have been regularly screened and who have had normal smears. **An age sex register is a prerequisite for an organised population based screening programme. This is the basis for a call/recall system and subsequent evaluation of the programme. An organised call/recall system is recommended for women aged 25-60 years.**

Although women over 60 years are not part of the defined target population they should be encouraged to attend for screening, especially if they have never or rarely had a smear. Other women may need a cervical smear who are not part of the target population.

Data protection issues

- 7.4 In order to operate an effective cervical screening programme it is necessary to establish a population register which will include, so as far as is practical, the names and other relevant data on persons in the target group. In the Irish context the only such population register is that compiled by the Department of Social Welfare for the purposes of operating the various social welfare schemes. While it is accepted that the Department of Social Welfare's records may not have complete coverage of the target group in question, it is nevertheless the case that no other available register approaches that of the Department of Social Welfare in regard to completeness and accuracy. The Working Party is conscious that any proposal to extend the use of the Department of Social Welfare's data base, albeit for an uncontroversial purpose such as cervical screening, raises important issues related to

data protection and the Working Party is aware that the Department of Health and the Office of the Data Protection Commissioner have been in contact to discuss these issues. The Working Party understands that, in conjunction with the Department of Social Welfare, the Department of Health is examining a system which would include the following elements:-

- the generation by the Department of Social Welfare of a master computer file containing the names and addresses of women in the target group;
- a mail shot containing an information pack prepared by the Department of Health, and issued to women in the target group by the Department of Social Welfare. This would also include a covering letter from the Department of Social Welfare explaining the background to the use of their data base and including a free post envelope together with advice on the appropriate action to be taken by women who did not wish to participate in the screening programme. (This is an example of an “opt out” approach under which women in the target group are first approached to see if they object to having certain details transferred to the health sector in connection with a screening programme, i.e. if they do **not** object, consent is assumed);
- the deletion, by the Department of Social Welfare, of the names of women who indicated that they did not wish to participate in the programme;
- a general publicity campaign launched by the Department of Health at the time of the mail shot outlining the background to, and benefits of, screening;
- a freephone information service which persons requiring further information could contact;
- the transfer of the final file to the Department of Health by the Department of Social Welfare. The Department of Health would then prepare individual sub files based on area of residence for circulation to the relevant health board. Each health board would only receive the relevant sub file in respect of its functional area.

The file prepared by the Department of Social Welfare would include the following information:- (a) name, (b) address, (c) date of birth, (d) maiden name (if appropriate) and (e) either the RSI Number or a unique identifier derived from the RSI Number. It would be necessary to repeat this procedure annually for women reaching the age of 25. The names of women who reach the age of 60 would be deleted by the health boards.

The Working Party appreciates that the approach being considered involves issues of general concern which should be considered and debated. Clearly, there is a ‘trade off’ in terms of the achievement of an effective screening programme and the price to be paid is the wider use of information held on individual citizens. It is the view of the Working Party that this price is acceptable – subject to this satisfactory safeguards. In this regard, the Working Party recommends that discussions between the Department of Health and Social Welfare and the Data Protection Commissioner be concluded as quickly as possible to facilitate the commencement

of an organised screening programme which meets reasonable concerns in regard to data protection.

Specifications of the screening interval

- 7.5 The EU 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 three years should be discouraged as it not cost-effective. Screening every fifth year with high quality and high compliance is preferable to screening every third year, where resources are limited. **A minimum of 5 yearly screening interval is advised for women between 25-60 years with two smears to be taken within twelve months of entering the programme if they have never had a previous smear.** A substantial number of women are already being screening opportunistically, the number, therefore, who would require a second smear within twelve months of entering the programme is unknown, but should not be significant.

Review of ongoing opportunistic screening

- 7.6 **Opportunistic screening should be reviewed on an ongoing basis.**

Integration of an organised screening programme into the health care system

- 7.7 At a national level the proposed Directors of Public Health should advise the Health Boards and assist the Department of Health on an integrated approach to the management and control of cervical screening programmes. The current opportunistic screening should be integrated into the organised programme. **It is essential to ensure that smear taking, laboratory processing, colposcopy and treatment facilities are adequate and that colposcopy and treatment can be provided without delay. Quality control and evaluation must be an integral part of the service.**

Coverage and compliance of the target population

- 7.8 **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 never had a smear. Every effort must be made to overcome other barriers which may affect compliance with cervical screening e.g. fear of cancer, older age and lower socio-economic status. Compliance can be increased by ongoing co-ordinated health promotion campaigns at regional and local level and through specific invitation letters.

Management of the programme

- 7.9 **The Director of Public Health in each health board area or a person designated by him/her should have overall responsibility for the cervical cancer screening programme.** Cervical screening is a multidisciplinary activity involving GPs, pathologists, cytotechnicians, gynaecologists, nurses, surgeons, administrators, epidemiologists, economists etc. All these professionals need coordination. A

committee should be established to monitor and update the local policy. The chairman of the committee should be the Director of Public Health or his/her nominee.

Overall programme responsibility

- 7.10 **The implementation of a systematic screening programme is a major organisational exercise. An expert advisory committee to oversee the setting up, implementation and maintenance of the cervical screening programme should be appointed by the Department of Health.**

Computerisation

- 7.11 **There should be an effective standardised computerised call/recall system registering all appropriate data** and which should also incorporate any opportunistically taken smear. Ideally it should be integrated with the cytology/histology laboratories and colposcopy clinics.

Resource implications and economic evaluation

- 7.12 International experience has reported that an organised programme may be more costly but more effective than opportunistic screening. **It is essential, therefore, that adequate resources are provided initially and that continuing resources are ensured from the start for the effective implementation of the recommendations in this report.** A monitoring system should be designed to document the costs. Parameters such as the cost per woman or per smear are necessary for improving the overall planning of the strategy.
- 7.13 Screening competes for scarce resources with other health interventions. Data should, therefore, be provided to the decision makers about the costs and health effects of the programme, including the costs of diagnosis, treatment and organisation.
- 7.14 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 with the utilisation of computerised mathematical models allows one to select the most cost-effective option of running the programme.
- 7.15 **A comparison of current opportunistic screening for cervical precancer with a projected organized systematic call and recall cervical screening programme. (The figures used in the models below are not intended to be accurate, rather they are intended to illustrate how the cost of different programme options may be estimated).**

TABLE 9

Cost Estimates of various Cervical Screening Programme Options
OPTION 1: Age 25 to 50

	Current (1992) (Opportunistic)	£	Projected (Organised)	£
Age group screened	20-60		25-50	
No. of women (1991)	853,000		610,000	
Screening interval	(1-5years)		5 years	
No. of screening invitations	* n/a		122,000	
Uptake	* n/a		70% (estimate)	
No. of smears per annum	154,000 (actual)		85,400	
Cost at £25 per screen		3,850,000		2,135,000
No. of abnormalities (assume 7%)	10,780		5978	
Follow up: Community	8,508 (assumed)		2,989 (50%)	
Cost (5 smears at £25)		1,063,500		373,625
Colposcopy (organised – assume 50%)	2,272 (actual)		2,989 (50%)	
Approx Cost (£400 including treatment and 5 follow up smears over time)		908,800		1,195,600
Total cost per annum		5,822,300		3,704,225

*n/a = Not applicable

In the costing study £25 was considered to be the approximate cost of taking (£16) and screening (£9) of a smear. Treatment and follow up costs, including 5 follow up smears, was costed at £400 by Prof. Ciaran Woodman in the UK.

7.16 TABLE 10

Cost Estimates of various Cervical Screening Programme Options
OPTION 2: Age 25 to 60

	Current (1992) (Opportunistic)	£	Projected (Organised)	£
Age group screened	20-60		25-60	
No. of women (1991)	853,000		716,000	
Screening interval	(1-5 years)		5 years	
No. of screening invitations	* n/a		143,200	
Uptake	* n/a		70% (estimate)	
No. of smears per annum	154,000 (actual)		100,240	
Cost at £25 per screen		3,850,000		2,506,000
No. of abnormalities (assume 7%)	10,780		7,016	
Follow up: Community	8,508 (assumed)		3,508 (50%)	
Cost (5 smears at £25)		1,063,500		438,500
Colposcopy (organised – assume 50%)	2,272 (actual)		3,508 (50%)	
Approx Cost (£400 including treatment and 5 follow up smears over time)		908,800		1,403,200
Total cost per annum		5,822,300		4,347,700

*n/a = not applicable

7.17 Thus it would seem that the ongoing costs of an organised screening programme are less than those of the current opportunistic set up. However, it should be noted that most of the costs of the current opportunistic screening are borne by the women themselves, whereas, an organised programme would imply most of the costs being funded centrally. In addition, there would be the initial starting up costs. This would include establishing a register, computerisation, call and recall costs, measures to facilitate quality control as well as overall coordination.

Establishment of a fail safe system

7.18 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. See also 9.10

Morbidity and mortality data

7.19 Comprehensive morbidity and mortality data are essential for monitoring a cervical screening programme. Thus the National Cancer Registry is an important information system as it is now registering reported cases of CIN III and invasive cancers. An organised cervical screening programme should integrate morbidity

and mortality data with information from the call/recall systems in order to evaluate the effectiveness of the screening programme.

Quality Control

- 7.20 **Quality Control is essential at all levels in the screening process**, from smear taking to laboratory and colposcopy services.

Targets

- 7.21 The overall aim of a cervical screening programme is to reduce the incidence and death rate from cervical cancer while optimising the use of available resources. The effectiveness of the programme is measured by comparing the outcome of screening activity against predefined objectives and targets. **Targets should be set for the cervical screening programme.** Targets should be measurable and realistic and the parameters that follow are intended for measurement in the short and longer terms. They were set after taking into account the WHO Health For All Policy, the Europe Against Cancer Programme (Commission of the E.U.) and data from the international literature on cervical screening.

Short term targets

- 7.22 (a) Coverage of the identified target population should be at least 80% when the screening programme is fully operational.
- (b) The interval from screening to reporting of the result should not exceed one month.
- (c) In five years time the proportion of unsatisfactory smears should not exceed 5%.
- (d) Follow up of abnormal and unsatisfactory smears, including appropriate treatment, should be within three months of the initial smear tests.

In the initial phase of a cervical screening programme, it is difficult to set targets relating to particular aspects of screening. These targets should be reviewed when the programme is established and include the sensitivity and specificity of the test, interval cases etc.

Longer term targets

- 7.23 Longer term targets depend upon the satisfactory achievement of short term targets and relate to a reduction in morbidity and mortality from cervical cancer.
- (a) **The incidence of invasive squamous cell cervical cancer should decrease by 60% within 10 years**
- (b) **Mortality from cervical cancer should decrease by 60% within 20 years.**
- 7.24 The long and short term targets listed above are numerical and mortality should be readily measurable from the available data sources (e.g. National Cancer Registry,

mortality statistics, computerised call/recall system etc). However, it will take ten years before the National Cancer Registry will have accurate data on the incidence of cervical cancer. In addition, the first round of screening would include incidence and prevalence cases of invasive cervical cancer. The second round should be mainly incidence, therefore, there will be a natural reduction in invasive cervical cancer in the second round of an efficient, organised screening programme. The targets outlined above should be evaluated in that context.

- 7.25 The most appropriate time to measure the effectiveness of the programme will, therefore, be after 15-20 years. When comprehensive data are available on the incidence of invasive cervical cancer, the targets for the next 15-20 years should be reviewed.
- 7.26 When interpreting the mortality data it must be borne in mind that at least half of the deaths due to cancer of the uterus are likely to have been due to cancer of the cervix.

Health education

- 7.27 Information on cervical screening is available in the booklets “The Hysterectomy Book” and “The Menopause” distributed by the Health Promotion Unit of the Department of Health and in two leaflets “The Cervical Smear Test” and “Early detection saves lives – Take good care of yourself” produced by the Irish Cancer Society.
- 7.28 The Working Party considered that there is a need for further health promotion explaining the nature of cervical cancer, the risk factors, the purpose of screening, the likelihood of a negative result (about 93%), the meaning of a negative result (low risk, but no risk), the meaning of being recalled, the importance of regular screening (a single smear is not a guarantee of being free from cancer or its precursors), when and how the results will be made available, age and appropriate screening interval and the treatment of abnormalities. It is envisaged that this would help to alleviate anxiety prior to screening and consequently prior to colposcopy and treatment.

Chapter 8

Quality assurance in the cytology laboratory

- 8.1 Quality assurance in cervical cytology is designed to achieve an acceptable reliability and consistency in the results produced in the cytology laboratory. A satisfactory staff/workload ratio, adequate clerical backup and computerisation are essential to facilitate good quality assurance:
- 8.2 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.
- 8.3 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.

Internal quality assurance

- 8.4 Each laboratory should have written guidelines for all aspects of the cytopathology service including quality control, from the time of receipt of the specimen to the discharge of the report. This should include detailed information on: reception of specimens; logging of specimens; guidelines in management of opened specimens; unlabelled slides, inadequately filled request forms, broken slides etc.; staining of slides including reagents, regular changing of reagents, cover-slipping etc. Guidelines should be available on reporting terminology including advice on further management of abnormal, inadequate, or suboptimal smears. A standardised system for the typing, checking and mailing of reports to referral doctors, and a monitoring system to ensure dispatch and receipt of all reports to correct destinations should be ensured.
- 8.5 The following methods of quality control in primary screening can contribute to overall quality assurance:
- (a) Double screening of all abnormal smears and the previous cytology.
 - (b) Proportional rescreening of normal smears e.g. 10% (if workload permits) or 30 second screening of all smears is desirable. The Working Party considers the latter to be a more worthwhile exercise.
 - (c) Selected rescreening which involves rescreening all smears from high risk groups e.g. where there is a history of abnormal bleeding, postcoital bleeding or a clinically suspicious cervix.
 - (d) When tissue material (derived from sources such as amputated cervixes, hysterectomy specimens, "colposcopy" biopsies or "colposcopy" smears) is positive for CIN/carcinoma, previous cytology reports should be checked and if negative for preceding 5 years (or part thereof), these respective smears should be reviewed by Consultant Histopathologist/Cytopathologist.

- (e) Likewise when biopsy material is present and has not confirmed the abnormality, the precipitating smear should be reviewed and compared with the biopsy material.
- (f) Regular review sessions in the cytology laboratory are valuable as well as conferences between the cytopathologist, colposcopist and the relevant cytology technicians of all cases referred for colposcopy to assess false positive and false negative reporting.
- (g) Audit at year end of all cases referred for colposcopy with correlation between colposcopy, cervical biopsy and cytology is necessary and hospitals should facilitate cytology laboratories in their search for outcome records.
- (h) Biennial refresher courses for all cytology technicians and cytopathologists. Proper funding and time must be provided for this.

External quality control

- 8.6 Regular review of proficiency testing of all staff (technical and medical) is essential as most laboratory errors occur at the primary screening level. A variety of different techniques can be used, e.g. slide exchange schemes or proficiency testing. An example of one such scheme is as follows:

The external quality control officer brings 10 cervical smears every 12 months to each participating laboratory. All staff involved in screening (technical and medical) are required to screen all ten smears without conferring. The results are collected by the quality control officer and subsequently reviewed. Strict confidentiality of results must be ensured.

A cytology technician or cytopathologist who shows a persistent problem with significant undercalling or overcalling is discretely advised to attend a refresher course before being allowed back on screening duties.

Quality control audit

- 8.7 The quality control audit must embrace all aspects of cervical smear reporting including assessment of adequacy of sampling of the cervix, adequate processing and staining of slides of cervical smears, the screening and interpretation of smears and reporting of findings and appropriate follow up systems.
- 8.8 Laboratories participating in a national Cervical Screening programme would require for quality control purposes:
- (a) A Quality Control Officer (Cytopathologist/Histopathologist).
 - (b) Sufficient throughput per screener.
 - (c) Computerisation of each laboratory to facilitate recall and retrieval of all previously examined material.

- (d) Computerisation links between laboratories participating in the National Cervical Screening Service to facilitate retrieval of reports of cervical smears and cervical biopsies from other centres.
- (e) Storage facilities to enable all laboratories to keep all slides for 7 years and all abnormal slides indefinitely.
- (f) Funding and staffing levels to enable staff to undertake quality control and attend refresher courses on a regular basis.
- (g) Standard request and reporting form.

Chapter 9

Screening methodology

- 9.1 **Guidelines for taking cervical smears, reporting and recommendations for action following smear report should always be followed.**

Equipment required for taking a cervical smear

- 9.2 (a) There should be an examination couch for vaginal examination of the patient in either the left lateral or dorsal position with good illumination from an adjustable halogen spot light.
- (b) Disposable vinyl or latex gloves should be available.
- (c) 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 cleansed before being re-sterilised by steam sterilisation in an autoclave for a minimum of 15 minutes at 121°C or in a hot air oven at 180°C for 120 minutes. Chemical disinfectants are not sufficient to prevent the spread of infection.
- (d) Other essential items are: frosted ended glass microscope slides 7.6 x 2.5cm; 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.
- (e) Aylesbury wooden spatula should routinely be used.

Appropriate timing

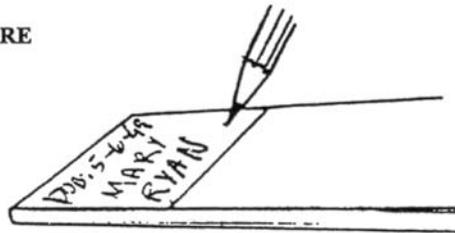
- 9.3 Ideally a cervical smear should be taken in the second part of the menstrual cycle to facilitate optimum cytological conditions. Postnatal smears are not recommended in the asymptomatic woman.

9.4 Taking cervical smears

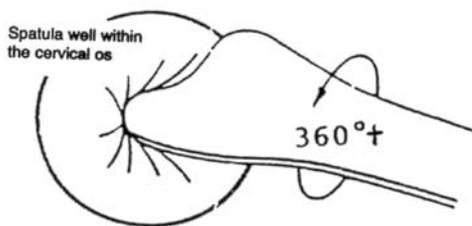
- Bivalve Vaginal Speculum
- Slide with ground glass end
- Lead Pencil
- Ball Point Pen
- Request form
- Good Illumination
- Slide Mailer
- Fixative/Carbowax

PROCEDURE

1 Put the patients name and number or date of birth on the ground glass end of the slide using lead pencil (other markers are washed off by processing fluids). If smear is vaginal, mark it 'V'. Please leave space for Laboratory Number.

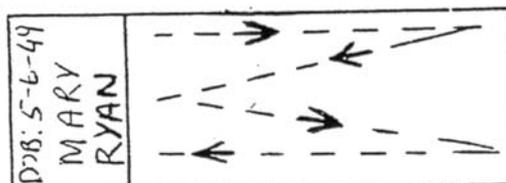


2 Do not clear cervix or wipe away any attached mucus until smear has been taken. Position patient, adjust light and **insert the warm speculum**. Lubricate with minimal tap water or water sol. lubricant. Use no antiseptics or greasy lubricants.

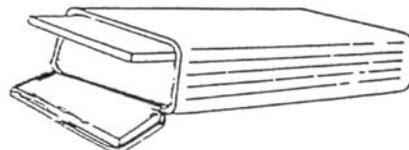


3 Insert the spatula into cervical os using the bilobed end unless the cervix is very patulous or scarred, when the spade should be used. Firmly rotate the spatula through at least **360°** ensuring that the scrape spans the squamocolumnar junction at all times. A brush sampler may be used where the squamo columnar junction is high or where an endocervical abnormality is suspected.

4 Spread material thinly on the glass slide. Use gentle longitudinal strokes rather than a circular motion. The aim is to get a single cell layer on as much of the slide as possible without damaging the cells.



5 Place the slide on a horizontal surface and immediately dip in or apply fixative generously. Avoid exposure to direct sunlight. Allow to dry for a minimum of 20 minutes before inserting into container.



6 Complete the request form with a ball point pen, pressing firmly on the hard backing surface. Ensure that all copies are legible.

7 Put the slide in a Slide Mailer for dispatch with request form. One slide per Slide Mailer only.

Classification of intraepithelial abnormalities

- 9.5 The Papanicolou system was widely used in Europe and the United States until two decades ago when the CIN system was introduced. The CIN classification was designed to rationalize the cumbersome and cytologically orientated Papanicolou system which confined itself to cytological abnormalities and was divided into 5 classes. The CIN system allows for equivalence between cytology, colposcopy and histology and has been very widely accepted in Europe, the UK, Australia and in Ireland. It allows cytologists, colposcopists and histologists to communicate in the same language and is considered to be a pragmatic and clinically useful system.
- 9.6 The Bethesda system of reporting has developed in more recent years and is popular in the United States. This Working Party having sought expert advice considered that the CIN method should be continued in Ireland at this time for the following reasons: -
- (a) It has taken a long time for the CIN system to replace the Papanicolou classification and is now accepted nationwide by the cytology, pathology and colposcopy fraternities in Ireland.
 - (b) The Bethesda system has not been completely accepted in the USA and has not spread widely elsewhere. In particular the UK has not adopted Bethesda and all indications are that it will not. Currently the majority of Irish cytologists/colposcopists and pathologists are UK trained. Our postgraduate training and research has strong links with the UK and this is likely to continue for the foreseeable future.
 - (c) It is possible that the Bethesda system could increase the number of women referred for colposcopy who do not have significant abnormalities.

Cervical smear report

- 9.7 **The cervical smear report should contain three descriptive categories and one recommendation as follows: -**

A: The smear is satisfactory or unsatisfactory for analyses.
If unsatisfactory, the reason why should be stated e.g.

- Slide broken/lost
- Cell fixation inadequate
- Blood contamination/excess
- Inflammatory problems
- Inadequate cellular content
- Smear preparation too thick

B: Description of cells

- Normal
- Borderline nuclear abnormality
- Mild squamous dyskaryosis (CIN I)
- Moderate squamous dyskaryosis (CIN II)
- Severe squamous dyskaryosis (CIN III)

Glandular dyskaryosis	present
	absent
	suspected
Invasive disease	suspected

C: Other comments concerning the cellular content

Inflammation present
 Koilocytosis present
 Normal glandular cells seen
 Metaplastic cells seen

Free text-----

D: Recommendation for action as a result of examination of this smear

- Routine repeat cytology
- Refer for colposcopy
- Repeat cytology twice within twelve months
- Suggest investigation and or treatment of suspected atrophy or inflammation/infection followed by repeat cytology.

Follow up smears should always be taken at least one month apart in order to provide satisfactory cytological specimens.

Management of cytological abnormalities and referral thresholds

9.8 The basis for selecting one or other of the four recommendations should depend upon the cytologist/cytopathologist following an agreed protocol of referral practice. This Working Party recommended the following: -

Algorithm for management protocol of abnormalities

<u>Cytological Diagnosis</u>	<u>Recommended action</u>
Moderate or severe dyskaryosis (CIN II, III), Carcinoma, or suspected glandular dyskaryosis	Refer for colposcopy
Mild dyskaryosis (CIN I) Or Borderline nuclear abnormality	Repeat cytology twice within 12 months. Refer for colposcopy if dyskaryosis persists. Refer back to routine cytology screening programme if both smears negative. Annual cytology if smears remain borderline. Follow up smears should not be taken too soon (minimum 1 month between smears) in order to provide a satisfactory cytology specimen.

Inflammatory changes only (no nuclear abnormality)	Routine recall screening
Negative smear	Routine recall screening

Women who have been treated for CIN should have two or three follow up smears, the first of which should not be before four months. Annual cytology thereafter for two years followed by five year cytology review in those yielding negative smears.

Follow up of an abnormal smear report: fail safe measures

- 9.9 The initial responsibility for recommending action to a smear report lies with the laboratory but the final decision rests with the smear taker. A single smear is not a guarantee of being free from cancer or its precursors. However, by taking part in a systematic screening programme the risk of any woman developing cervical cancer should be significantly reduced. The following fail safe measures as recommended by the EU are advised.
- (a) An abnormal smear report should be clearly marked with the phrase “further action required”.
 - (b) A copy of the smear report must be sent to the smear taker and the patient’s general practitioner if s/he is not the smear taker. The woman should receive a letter advising her to contact her doctor within a specified time.
 - (c) A record of all smears taken must be kept by the smear taker who must ensure all reports are received within 4 weeks of smears being sent to the laboratory for processing.
 - (d) If it appears that no action has been taken (i.e. referral for colposcopy or repeat cytology) following an abnormal smear report, the Director of Public Health should contact the original smear taker to ensure appropriate action within 2 months. A record of the attempts that have been made to contact the woman concerned should be kept.

Chapter 10

Overall quality assurance of a screening programme

- 10.1 The natural history of cervical cancer including progression through the precancerous stages is relatively well but not yet fully understood. Also the taking of a cervical smear, its interpretation and the action implemented constitute an inexact science. Smears may be inadequately taken, false positives and false negatives can occur on screening, lesions with a significant potential for progression may be missed or undertreated and finally over treatment of lesions with an insignificant potential for progression can also occur. **Ongoing measures to reduce the occurrence of inadequately taken smears etc, as well as health education and programme co-ordination are essential to facilitate overall quality assurance of the programme.**

Quality of smear taking

- 10.2 It is anticipated that training, sufficient resources and the availability of educational material e.g. 'How To Take A Smear' (section 9.4), will reduce the number of imperfectly taken smears. The Working Group also recommends the British Society for Clinical Cytology (BSCC) booklet and video 'Taking Cervical Smears' for smear takers. With regard to the reporting of smears, the Working Party advocates that each cytological report should include a statement concerning the adequacy of the preparation as in the Cervical Smear Report section 9.7 of this report.

Quality of cytology screening

- 10.3 A screening programme that does not include properly constructed quality assurance within its structure is unlikely to be either effective or efficient and increases the possibility of treating large numbers of women with insignificant intraepithelial lesions. Quality assurance of screening can be facilitated by: -
- (a) the adoption of standardised cervical smear reports, specific inter and intralaboratory quality assurance strategies with audits and the appointment of a quality control officer.
 - (b) close communication between the smear taker, laboratory technician, cytopathologist, colposcopist and histopathologist.

Appropriate referral for investigation of lesions with a significant potential for progression

- 10.4 The severe cytological abnormalities e.g CIN III have a greater degree of correlation between cytology and colposcopy and histology. The relatively high risk of progression to invasive disease of CIN III (and to a lesser degree CIN II) means that there is unanimous support amongst clinicians for the current practice of referring all women with a cytological suspicion of CIN II or III for colposcopic evaluation and treatment of the transformation zone from where the abnormal cells were shed. It is largely at the milder end of the spectrum of cytological abnormality that

difficulties in management strategies arise, in trying to achieve a balance of risks between: -

- not missing a clinically important lesion (i.e. with a significant risk of progression to cancer) and
- overtreating or unnecessarily treating a clinically unimportant lesion (i.e. with an insignificant risk of progression to cancer).

Appropriate treatment of lesions with an insignificant potential for progression

- 10.5 Several factors contrive to result in unnecessary treatment. Laboratories are concerned to reduce their false negative rate. Also laboratories vary somewhat in the nomenclature they use in reporting cytological abnormalities within the CIN system, particularly at the milder end of the spectrum of intraepithelial abnormality, hence the need for inter and intra laboratory quality control. Clinicians are equally concerned at the possibility of missing a lesion which may subsequently develop into an invasive lesion. Patients are often keen to have any abnormality removed or destroyed immediately. Finally, LLETZ is a relatively easy technique to learn. It is particularly easy to remove more tissue than is necessary. The necessary equipment is cheap and readily available. Over treatment is more likely to occur in countries where colposcopy is undertaken by a larger number of gynaecologists and other non-gynaecologically trained colposcopists whereby expertise may be diluted. In Ireland colposcopy is undertaken in dedicated clinics by a handful of gynaecologists with a special interest in the subject and the risk of a woman being treated by the occasional colposcopist is really very small. Ideally **colposcopists should practise in clinical situations that allow them to manage a 100 cases of CIN per annum.** However, the threshold for treatment can vary amongst colposcopists.
- 10.6 To reduce the possibility of overinvestigation responsibility for recommended action following screening of an asymptomatic screened population should rest with the cytopathologist in charge of the laboratory.

Glossary

The following terms and definitions are used in this report.

Cervical Intraepithelial Neoplasia (CIN)	<p>Cervical Intraepithelial Neoplasia is not cancer. It is a histological (examination of a tissue biopsy) diagnosis. It describes varying degrees of abnormality of the cells within and confined to the epithelium (cervical lining or 'skin').</p> <p>There are three grades of CIN.</p>
CIN I	<p>Mildly abnormal cell characteristics exist. The specificity of cervical smears which suggest the possibility of CIN I is low. The chance of progression to CIN III and or cancer is relatively small and the likelihood of regression is relatively high.</p>
CIN II	<p>Moderately abnormal cell characteristics exist. The specificity of cervical smears which suggest the possibility of CIN II is high. The chance of progression to CIN III and or cancer is relatively high and the likelihood of regression is relatively low.</p>
CIN III	<p>Severely abnormal cell characteristics exist. The specificity of cervical smears which suggest the possibility of CIN III is very high.</p>
Cervical Cancer	<p>Cancer arising from the uterine cervix. By definition malignant cells have spread beyond their natural boundaries (e.g. for squamous carcinoma the malignant squamous cells have spread beyond the squamous epithelium). In other words they have at least broken through the basement membrane of the cervical epithelium. The very great majority (circa 95%) of cervical cancer is of the squamous variety.</p>
Cervical Cytology	<p>Microscopical examination of cells scraped from the surface of the epithelium of the cervix.</p>
Colposcopy	<p>Low power magnification, light illuminated examination of the cervix.</p>
Cone Biopsy	<p>May be performed using a knife, diathermy loop (LLETZ-Cone) or laser beam. It is sometimes performed under general anaesthesia. The procedure is associated with well recognized short and long term morbidity. The chance of long term morbidity is related to how much endocervical tissue is excised.</p>
Dyskaryosis	<p>Term used in cytology to describe nuclear abnormalities in cervical cells. Dyskaryotic cells are classified as mild, moderate and severe and correlate with CIN I, CIN II and CIN III.</p>

Effectiveness	Is the extent to which a screening programme when deployed in practice meets its defined objectives.
Efficacy	Is the extent to which an intervention/programme produces a beneficial result under ideal conditions. Ideally the determination of efficacy is based on the results of a randomized controlled trial.
Efficiency	Is a measure of the result achieved in terms of money, resources and time expended on a procedure of known efficacy and effectiveness.
Incidence (rate)	May refer either to CIN or cervical cancer. It is the number of new cases of CIN/cervical cancer that occur in a defined period divided by the population at risk of experiencing the event during this period.
Local Destructive Techniques	Laser, cryocautery, cold coagulation and radical diathermy. These methods aim to destroy rather than remove the transformation zone.
LLETZ	Large Loop Excision of the Transformation Zone.
Negative predictive value	Is the proportion of test-negative women who do not have CIN. It is a measure of the likelihood that someone with a negative test is actually disease free.
Positive predictive value	Is the proportion of test-positive women who are truly positive. It can be considered a measure of the likelihood that a woman with a positive test truly has CIN.
Prevalence (rate)	May refer to CIN or cervical cancer. It is the total number of women who have CIN/cervical cancer at a particular time (or during a particular period) divided by the population at risk of having CIN/cervical cancer at this point in time or midway through the period.
Screening Programmes	
Systematic screening	Where the target population is invited to have a cervical smear at regular intervals.
Controlled spontaneous	Where there are recommendations guiding the number and frequency of screens that are performed opportunistically.
Opportunistic Screening	Where women have a smear when the opportunity arises (gynae clinics, GP visits, FPC visits).
No screening	This situation exists in some developing countries.
Sensitivity	Is the proportion of women with CIN in the screening population who are identified as having CIN by the screening test. It is a measure of the probability that any given case will be identified by

the test.

Specificity

Is the true proportion of women who do not have CIN or cervical cancer who are so identified by the screening test. It is a measure of the probability of correctly identifying a non-diseased woman by the test.

Transformation Zone

A junctional arc of epithelium lying between the ectocervical and the endocervical epithelium situated at or near the opening of the cervix.

Appendix

TABLE 1

Laboratories in Health Board Areas providing Cervical Cytology

Laboratory 1992	Cervical Cytology Cases processed	
	Number	%
EASTERN HEALTH BOARD		
St Luke's Hospital	27,903	
St James's Hospital	3,424	
Coombe Hospital	11,407	
Holles St Hospital (1991)	10,288	
Rotunda Hospital	4,916	
Beaumont Hospital	5,329	
Mater Hospital	1,466	
Blackrock Clinic	956	
University College Dublin	897	
Royal College of Surgeons in Ireland	6,410	
Lab Test	14,292	
Executive Medical Care	1,823	
James Connolly Memorial Hospital	758	
St Joseph's Raheny	821	
Mount Carmel	1,690	
St. Vincent's Elm Park	624	
TOTAL	93,004	60.3
WESTERN HEALTH BOARD		
UCH Galway	27,631	
Portiuncula	2,800	
TOTAL	30,431	19.7
SOUTHERN HEALTH BOARD		
Cork University Hospital	10,573	
Cork Bon Secours Hospital	3,250	
Cork Mercy Hospital	764	
Cork Pathology Services	2,200	
TOTAL	16,787	10.9
NORTH EASTERN HEALTH BOARD		
Our Lady of Lourdes Hospital, Drogheda	3,262	2.1
NORTH WESTERN HEALTH BOARD		
Sligo General Hospital	6,240	4.1
MIDLAND HEALTH BOARD		
Tullamore General Hospital	4,500	2.9
OVERALL TOTAL	154,224	100.0

TABLE 2

Laboratory Technician Staffing Structure 1992

Laboratory	Technologists	Technicians	Case load per Whole Time Equivalent (WTE)
St Luke's Hospital	1	6	5,000
Coombe Hospital		5+.5	
Holles St Hospital		2+ (.5x2)	4,437
Rotunda Hospital		1	3,277
St. James's Hospital	1	2+.5	8,500 (slides)*
Beaumont Hospital		1	
Blackrock Clinic	0.5		
University College, Dublin		.5	
Royal College of Surgeons		.75	
Executive Medical Care		1	
St Vincent's Hospital		.5	
UCH Galway	1	5	5,000 (8,000 slides)
Portiuncula		.5	
Cork Regional	1 (combined)	3	4,100 (7,000 slides)*
Cork Mercy		1	
Drogheda		2 combined posts	
Sligo General		1 combined post	5,280

* total Cytology

Table 2 shows the laboratory technician staffing structure. Caseload per whole time equivalent technician is not applicable in laboratories where staff are in combined posts or on night rosters. RCSI has a caseload of 6,410 (75% of WTE) and Beaumont 5,329 which includes screening but not slide preparation.

TABLE 3

Hospitals in Health Board Areas providing Colposcopy 1992

Hospital	Colposcopic Assessments	New Referrals	Clinics
EASTERN HEALTH BOARD			
NMH Holles Street *	3,118	594	193
Coombe *	1,839	563	150
+Rotunda/Mater *	300	130	52
+St James's (Genito Urinary Medicine)*	180	180	
WESTERN HEALTH BOARD			
UCH Galway *	515	198	46
Portiuncula *	130	98	100
+Castlebar	50	50	24
SOUTHERN HEALTH BOARD			
St Finbarr's Cork *	914	243	80
SOUTH EASTERN HEALTH BOARD			
Airmount Waterford	457	159	109
St Joseph's, Clonmel	177	19	37
Wexford General	7	7	-
NORTH EASTERN HEALTH BOARD			
Drogheda *	142	31	16
Louth County (1991)	87	N/A	N/A
OVERALL TOTAL	7,916	2,272	807

Table 3 shows the total number of colposcopic assessments, new referrals and number of clinics held in 1992.

* These clinics have access to cytology in local laboratories.

+ Approximate figures

DEMOGRAPHIC DATA

TABLE 4

Age Group	1988	1992
	%	%
< 35	57.0	50.1
35-44	24.1	26.4
45 +	17.1	21.5
Unknown	1.8	2.0
	100.0	100.0

TABLE 5

Parity	1988	1992 (St Lukes)
	%	%
Unknown	0	8.5
0	10.9	14.4
1	17.2	14.7
2-4	50.1	49.1
> 5	21.8	13.3
	100.0	100.0

Table 4 shows the age group of women availing of Cervical Screening in 1988 and 1992. The data in 1992 was supplied by six laboratories. In 1988 the screening rates for specific age groups were 17/100 women in those aged < 35 years, 13.9/100 for the 35-44 year age group and 6.9/100 for women aged over 45 years.

Table 5 shows the parity of women screened (1988 Survey). Data for 1992 was available only from St Lukes.

TABLE 6

Health Services Eligibility	1988	1992
	%	%
G.M.S	16.0	14.0
Hospital Services Card	22.0	
Health Act	7.3	39.9
Private/VHI	39.4	
Unknown	14.3	46.0
	100.0	100.0

TABLE 7

Service Provider	1988	1992
	%	%
G.P.	28.6	42.2
Hospital	50.3	28.5
Family Planning Clinic	12.2	9.9
Community Clinic	8.0	6.4
STD/Other	0.5	1.4
Unknown	0.4	11.5
	100.0	100.0

Tables 6 and 7 show the health services eligibility of attenders and source of cervical smears.

TABLE 8

Health Board of Origin	1988	Screening Rates/100 women
	%	
Eastern	43.0	15.0
Mid-Western	4.5	6.9
Midland	6.4	15.4
North Eastern	7.7	12.6
North Western	3.7	8.0
South Eastern	11.6	14.7
Southern	11.4	10.2
Western	11.7	17.2
	100.0	100.0

Table 8 shows health board of residence and the screening rates per 100 women in the population in 1988.