

Report

on the

Irish Cervical Screening Programme



JULY 2004

Dr. Euphemia McGoogan

Senior Lecturer Pathology, University of Edinburgh
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introduction

I was invited by Dr Sheelah Ryan, Chief Executive Officer, on behalf of the Health Board Executive (HeBE), to undertake a review of the operation of the first phase of the Irish Cervical Screening Programme (ICSP) in the Mid Western Health Board as an overview. The purpose of the retrospective evaluation was to identify the improvements that may be needed to move forward nationally. My help was requested in clarifying the model, particularly in relation to policy, as the Department of Health in Ireland begins to grapple with the changes in the organisation of the Irish Healthcare system.

TERMS OF REFERENCE

- Evaluation of the present organisational elements in Phase 1 ICSP as defined by the Report of the Department of Health Cervical Screening Committee published December 1996
- Evaluation of the application of quality standards as defined by the Quality Assurance document of the National Expert Advisory Group on Cervical Screening 1999
- Review of Phase 1 in the context of preparedness for the organisational issues for a national rollout
- Defining the critical success factors for a national rollout of the cervical screening programme.

METHODOLOGY

Between July and November 2003, I visited Ireland on several occasions in order to meet stakeholders in the delivery of Phase 1 of the Irish Cervical Screening Programme to review overall progress and to identify successes and any barriers to roll out;

I met with Dr. Sheelah Ryan;

I met with Dr Marian O'Reilly and Programme Office staff;

I met with Dr Kevin Kelleher, Director of Public Health, Mid-Western Health Board;

I visited the cervical cytopathology laboratories in Galway, St Luke's Hospital, Dublin and Royal College of Surgeons of Ireland, Dublin;

I visited the Mid Western Regional Hospital Histopathology Laboratory and the Colposcopy Clinic in the Regional Maternity Hospital in Limerick;

I had meetings with several hospital managers;

I attended a meeting at the Department of Health and Children (DoHC) on 14th November 2003 at which the Deputy Chief Medical Officer, Principal Officer Secondary Care (Cancer Strategy), Principal Officer Community Care, Assistant Principal Officer Community Care, Assistant Principal Secondary Care Colposcopy, among others were present;

I have read many documents including: DoHC Report December 1996, First annual report of ICSP Phase 1 Mid-Western Health Board (MWHB), Colposcopy Survey 2001, Draft Task Force Report September 2002, ICSP Cytology Laboratory Survey 2002, Draft Service Agreement with cytology laboratories September 2002, General Practitioner contract (October 2000), Quality Assurance Document December 1999, Quality policy statement, ICSP Business Plan December 2003, ICSP Cytology Referral Form, ICSP Women's Charter and was given copies of the ICSP Video, and ICSP Leaflets.

I would like to express my appreciation for the warm welcome I have received on each of my visits. I found all the staff groups with whom I met open and frank and they provided me with all the information I required. This made my task so much easier.

Thank you to everyone.



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The invasive cervical cancer rate in Ireland is one of the highest in Western Europe. In order to achieve an 80% reduction in cervical cancer in the Irish population, there is a need for an organised population health based programme rather than continuing with opportunistic screening as at present. Phase 1 of the Irish Cervical Screening Programme in the Mid-Western Health Board worked well and provides a sound basis for national roll out. The main weakness was governance of the cytology laboratories. A transition period of 18 months or less is required to prepare for the invitational phase beginning. Work during this period needs to focus on rationalisation of laboratories, accreditation of laboratories, smear taker training, the Register and links to colposcopy, all of which are detailed in the text.

The cornerstone of the Programme must be quality assurance with clear governance and accountability, underpinned by both clinical and operational standards. A national Steering Group should be set up to oversee and provide professional direction for the Programme. Strong leadership is needed as is a secure funding policy from the Department of Health and Children for all aspects of the Programme. The significant resource currently utilised in cervical screening must be redeployed to provide a world class service for the women in Ireland.

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recommendations

1. The Programme

- 1.1 A national Cervical Screening Programme must be rolled out as soon as possible.
- 1.2 There is currently a significant resource deployed in making the cervical screening test available to women in Ireland on an opportunistic basis. Unfortunately, this has failed to achieve a significant reduction in the incidence and mortality for cervical cancer. Indeed there is a suspicion that the trend is upwards. The current resources must be reconfigured and change actively managed to deliver a national screening programme for women so that proper use is made of all the available resources to ensure a drop in morbidity and mortality from cervical cancer in Ireland.
- 1.3 Cervical Screening in Ireland should be managed as a single, national, organised (call / recall) programme with written standard operating procedures, targets and standards, clear governance and accountability. Only in this way can the best benefit be provided for Irish women in terms of a decrease in the incidence and mortality from cervical cancer.
- 1.4 The ICSP should be organised around four regional screening centres. A typical screening centre would serve a defined population through a network of professionals working in primary care, laboratories and colposcopy.
- 1.5 Synergies with other screening programmes should be explored. A key element to be addressed in terms of clarity with regard to governance for the Programme involves the synergies with Breastcheck in moving towards a public health population based screening programme model within the health reform process.
- 1.6 The natural home for a cervical screening programme is within a Population Health department. Given that the health service in Ireland is undergoing restructuring at present and the final structure is not yet clear to me, it is difficult for me to recommend exactly where the Irish Cervical Screening Programme should be located. However, wherever it is based, it is critical to ensure that the ICSP is appropriately organised and governed to achieve success.
- 1.7 A management structure with clear governance arrangements is required to ensure that the legal obligations to eligible women, health care professionals and staff participating in the Programme including Phase One are met.
- 1.8 DoHC directives regarding Programme Policy and Quality Assurance are required so that clarity and consistency is ensured.
- 1.9 The establishment of effective governance arrangements with immediate effect is necessary in order to provide overall leadership and direction in terms of policy development, standards, accountability and achievement of value for money for Phase One and the extension of the programme.
- 1.10 A single central Programme office and Programme Director is required with clear policy that everyone adheres to, responsibility, ring fenced funding and multi-annual budget planning. The ICSP Programme Director should have clear and effective lines of communication to the appropriate Director within the Department of Health and Children (DoHC).
- 1.11 A multi-disciplinary national ICSP Steering Committee with representation from management and the professional academic bodies, is needed to provide general oversight of the ICSP and effectively influence policy development and issues



pertaining to the Programme to reduce risk. The ICSP Programme Director should be advised by the Steering Committee.

- 1.12 A quality assurance (QA) programme should continue to be given priority in the ICSP. The QA programme must be updated on a continuing basis and in a formal manner. A culture of continuous quality improvement with openness and accountability should be encouraged among all stakeholders. Steps must be taken to improve the validity of the data used to measure the effectiveness of the cervical screening. The use of confidential enquiry and audit to identify system failures should be developed.
- 1.13 There are no structures in place to allow immediate review or revision of the QA document by a professional group. Given Ireland’s geographic location and population size and since the Irish cytology and colposcopy services already aspire to the standards of UK NHS Cervical Screening Programme (NHSCSP) and British Society for Colposcopy and Cervical Pathology (BSCCP), the ICSP should immediately adopt these standards as the minimum with review in the light of the experience of the first three years of invitational screening. Phase 1 ICSP has already aligned in an observer status at the NHSCSP QA Committee
- 1.14 Structures must be put in place to allow review or revision of quality standards by a National ICSP Quality Assurance Committee which should include representation from the Professional bodies, other key stakeholders such as the Cancer Registry, the Cancer Society and other cancer screening programmes and, most importantly, women.
- 1.15 The programme outcome should be monitored using the following critical measures of success:
- Incidence and mortality from cervical cancer in those women screened and those not screened. This should be measured accurately and not simply by estimate using (out of date) census data
 - Population coverage –the number of eligible women who have a smear test within the screening interval and the percentage in comparison to the eligible population age group
 - Cervical cancer rates for women who have had a smear test within the defined screening interval. Microinvasive cancers should be analysed separately.
- 1.16 A clearly defined screening policy should be developed and implemented which should be subject to ongoing review in the light of developing evidence, guidance, technology and government policy.
- 1.17 Introduce a 3-year routine screening interval for the national programme from 25 years until 35 years of age; and thereafter a 5-year screening interval for routine screening of women with 2 consecutive negative smears until the age of 60 years. If laboratory capacity allows, 3 yearly screening intervals may be extended to the 40 or even 45 years age group. Thereafter 5 yearly screening is adequate for women who have no history of abnormality. This screening policy was endorsed by the World Health Organisation (WHO) and the International Agency for Cancer Research (IARC) earlier this year.
- 1.18 Ireland must be ready to “go-live” with the invitational phase within 18 months of the decision to implement. A transition period of no more than eighteen months is required before the first invitational is rolled out nationally and the first cohort of women receives letters. Routine activity should continue in parallel during the transition phase except for those specified categories of smears that can cease

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recommendations

immediately. A summary of the key tasks to be completed during the transition phase are listed in Table 11. Investment is needed to match all of the tasks that must be completed during the transition period and there should be an agreed business plan.

- 1.19 Since women can enter the Programme by responding to an ICSP invitation letter or by direct referral at the discretion of the clinically responsible doctor, consideration should be given to a rapid national extension with conversion of opportunistic smears to Programme entry policy. After the transition period, smears taken outside of Programme policy and all subsequent opportunistic smears should be actively discouraged so that laboratory capacity can be concentrated on delivering results for programme smears.
- 1.20 A single standard screening test needs to be agreed. The Irish Cervical Screening Programme should move to liquid based cytology (LBC) as the routine screening test soon as possible. LBC brings an immediate reduction in the workload for smear takers, laboratories and colposcopy clinics due to a reduction in unsatisfactory smears (which require an immediate repeat test) and an increase in laboratory capacity since more slides can be screened each day by laboratory staff. If implementation of LBC is deemed to require an EC Procurement process, an early decision is particularly critical. Moving to LBC will require a national training programme for converting laboratory staff and smear takers to the new technology and this will take many months to implement. This should be fully implemented before the invitational phase starts in 18 months. This is yet another reason for a rapid decision by the DoHC.
- 1.21 Processes should be put in place to evaluate new technologies in cervical screening with respect to the ICSP such as computer assisted microscopy and biomarkers as well as HPV testing.
- 1.22 I have considered but decided I cannot recommend the use of HPV testing as the primary screening test in the ICSP at present. There is as yet insufficient evidence that HPV DNA detection as a screening test would deliver the same efficacy as cytology in organised screening programmes. We must await further data from trials in progress such as the Manchester ARTISTIC trial.
- 1.23 There is also currently insufficient evidence for the cost effectiveness of reflex HPV testing of low grade samples. I believe we must await the outcome of the NHSCSP pilot data and other large studies currently in progress in UK and Europe such as the MRC TOMBOLA trial.
- 1.24 Active management of the laboratories is required. This is a big challenge and will require major re-design. Governance of laboratories was a major issue outstanding in the Phase One pilot. However, it may be that HIQA would have a role in the external governance of the transition as well as the Programme as a whole. Agreed standard SOPs are needed for every aspect of the programme to enable appropriate audit and measurement against targets and standards.
- 1.25 Since it is a significant portfolio, laboratory redesign would benefit from the appointment of a short term (24 months) Project Manager to, among other tasks, manage the transition of the laboratories to meet the needs of the ICSP. This Project Manager should report to the Programme Director.



The Screening Programme Register

- 1.26** A complete register of all women in Ireland aged 25 – 60 years must be established using a unique identifier for each woman to minimise the clinical risks of duplicated records.
- 1.27** The unique identifier number for women should be the Personal Public Service (PPS) number as described in the National Health Information Strategy published in July 2004. This should be made mandatory for all laboratory requests, referrals to colposcopy and further investigation or treatment records in order to ensure all clinical information is held in a single record for each woman.
- 1.28** All relevant clinical history should be held on the central cervical screening register information system. This should be defined, reviewed and audited at regular intervals.
- 1.29** A methodology of recording on the Register all previous smear / colposcopy history for women joining the programme should be established. Everyone should co-operate to identify women who have been screened in the past. All current database owners should clean up their data as best they can, especially merging all duplicate records for women into a single file with her PPS number attached. The issue of consent requires to be explored with a view to enabling the Programme to access clinical histories in existing cytology laboratory databases.
- 1.30** Responding to an invitation or agreeing to have a cervical screening test incorporates signed consent not only for the test but also full buy-in to all aspects of the programme. Clear information about the programme must be made available to women at the time of invitation or taking the test.
- 1.31** Women can enter the Programme following an ICSP invitation letter or by direct referral at the discretion of the clinically responsible doctor. Direct referral would only be appropriate during the transition phase for entry to the Register.
- 1.32** The information on the Register must be kept completely confidential. However, all stakeholders (laboratory, Colposcopy Clinic, Primary Care and the Programme Register Office) should be able to access a woman's history at specific points in time in order to ensure the overall cost effectiveness and the affordability of the Programme. This will avoid the necessity for colposcopists to have a printed copy of the referral smear result for each patient. Laboratories will be able to see the results of previous smears or biopsies for the woman that may have been reported elsewhere and give an appropriate clinical management recommendation.
- 1.33** IT linkages between laboratories, colposcopy clinics, smear takers and the Register must be implemented and tested.

Smear Takers

- 1.34 Formal registration of smear takers should be implemented.
- 1.35 There should be no routine annual tests. I recommend stopping immediately repeating the smear one year after a first test and all routine repeat cytology at the first colposcopy visit.
- 1.36 In order to facilitate cessation of opportunistic screening, clinical protocols in maternity services, gynaecological outpatients and STD clinics should be updated to remove any reference to taking opportunistic smears once the invitational programme is rolled out. This is required to free up laboratory capacity to deal with programme smears and allow equity of access for all women as well as value for money.
- 1.37 Consideration should be given to carrying out smear taker ICSP QA visits since primary care staff are pivotal to a successful cervical screening programme.
- 1.38 Any review of the GMS contract should include consideration of the fee for taking Programme smears. The success of the Cervical Screening Programme is reliant on primary care staff actively promoting uptake among eligible women and adherence to guidelines.

Hospital Based Services

- 1.39 There must be a decision about the number and location of cervical cytopathology laboratories, histopathology laboratories and colposcopy clinics so that there is appropriate capacity for the programme now and in the future. I recommend a model similar to that for Breastcheck. Services should be based in four centres, two in Dublin, one in the south and one in the west. The cytopathology laboratory, colposcopy clinic and histopathology service should work closely together as a regional team to ensure the catchment population is screened appropriately and quality standards are met.
- 1.40 There should be direct funding for cervical cytopathology, cervical histopathology and colposcopy services - either within a hospital setting or, if necessary, as stand alone. The requirements of the Programme must be clearly defined and costed and funds earmarked for Programme use.
- 1.41 All laboratories providing services for the programme should apply for external laboratory accreditation before January 2006. Application for CPA(UK)Ltd accreditation means that the laboratory is ready for an external inspection i.e. a quality manager is appointed, standard operating procedures are written and implemented, all relevant quality assurance standards are in place and statistical information is available.

The Cytopathology Service

- 1.42 Each laboratory should serve a defined catchment area so that reporting profiles can be compared to the incidence of disease in that regional population. In order to plan for capacity, Primary Care smear takers should be registered on a geographical basis with a particular laboratory. However, the national screening laboratories must work together as a team, operating as a single service with standardised protocols to provide a contingency so that there can be a smooth delegation of work to another laboratory / laboratories where there is capacity if one laboratory develops unacceptable turnaround times.



- 1.43 During the transition period when liquid based cytology training is being undertaken, laboratories may utilise the skills of staff in other local cytology laboratories in a hub and spoke arrangement so as to make best use of equipment and availability of trained cytology staff.
- 1.44 National laboratories should comply with all national standards.
- 1.45 The protocol for internal quality control procedures should be standardised across all laboratories and implemented urgently to avoid continuation of unnecessary work within the laboratory. The responsibility for recalling women at the appropriate interval should be passed to the Register thus freeing up laboratory time for assessment of slides.
- 1.46 Only Programme policy smears should be processed at national screening laboratories.
- 1.47 The national laboratory structure should be based upon the model described in Table 12.
- 1.48 I note with some concern that over 25% of staff are aged 50 years and over and are due to retire in the next 10-15 years. Consideration should be given to improving recruitment and retention of cervical cytopathology laboratory staff. Innovative ways to address the discrepancies in the take home wages between cytopathology and staff in other laboratory disciplines should be explored.
- 1.49 Consideration should be given to employing Advanced Practitioners to address staffing issues in cytopathology laboratories.
- 1.50 Training in third level is required to improve recruitment of medical laboratory scientists.
- 1.51 A defined productivity standard per medical laboratory scientist would assist capacity planning based on projected workload for the catchment area.
- 1.52 Cervical smear reports must contain a classification using the dyskaryosis terminology, a recommendation for management and where not negative, a descriptive text.

The Colposcopy Service

- 1.53 There should be four national colposcopy centres aligned to cervical cytopathology and histopathology laboratories with geographically spread outreach clinics for easier access by the population.
- 1.54 Outreach clinics should be managed by the national colposcopy centre and quality standards included in those of the centre. All colposcopists should meet the agreed national standards.
- 1.55 Colposcopy should be an outpatient service - and women attending should not be considered as "patients" unless an abnormality is identified.
- 1.56 It is important that colposcopists meet regularly with the cervical cytopathologists (and Advanced Practitioners) and histopathologists to discuss the best management of difficult cases and to review discrepant clinical findings.

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recommendations

The Histopathology Service

- 1.57 There should be four national cervical histopathology services aligned to cytopathology and colposcopy.
- 1.58 A lead histopathology consultant should be identified in each laboratory with responsibility for liaising with the ICSP and adherence to quality standards.
- 1.59 Quality assurance standards should be agreed immediately and ICSP QA visits implemented. National histopathology laboratories should implement all national standards.
- 1.60 All cervical biopsies should be classified using the SNOMED system and forwarded to the Register.



2.1 Incidence of and mortality worldwide

Cancer of the cervix is the second most common cancer among women worldwide, with an estimated 471,000 new cases and 235,000 deaths in the year 2000. Almost 80% of the cases occur in the developing countries, where, in many regions, it is the most common cancer among women, responsible for about 15% of all new cancers. Cervical cancer is less common in economically developed countries, where in the year 2000, it comprised about 4% of cancers in women, ranking sixth in importance.

Effective cytological screening programmes have resulted in dramatic falls in incidence and mortality of cervical cancer rates over the last 20 years with the UK setting an important example. The very effective call and recall system in the UK, having operated since 1988, has seen a progressive fall in mortality at the rate of 7% per annum with over 100,000 lives saved in the intervening period. This is notwithstanding an increase in pre-invasive lesions over the same period. However, before the introduction of screening programmes in the 1960's and 1970's, the incidence was much as we see in developing countries today.

2.2 Incidence and mortality in Ireland

In 1995 the age-standardised incidence rate for Ireland was 9.5 per 100,000 compared to 13.9 per 100,000 in the UK. Despite the differences in incidence, mortality was almost the same in both countries (4.6 compared to 5 per 100,000 in the UK) indicating that Irish women were being diagnosed with their cancer at a later stage when medical intervention was less likely to achieve a cure. Currently 77 women die in Ireland each year from cervical cancer. Because cervical cancer affects relatively young women, it is an important cause of lost years of life.

2.3 Demographics

Incidence shows a rapid rise to a peak at a comparatively young age. Average age of onset worldwide is at about 25 years, there is a rapid rise between 30 and 40 and a peak at ages 44 to 49 years. In countries with established screening programmes invasive cancers are identified at an earlier stage and the peak is at 35 - 40 years. After the peak, the decline is fairly rapid but there is another small peak at 70-75 years. Cervical cancer also has quite marked differences in incidence, according to demographic variables such as social class, marital status, ethnicity and religion. There is a consistent association between risk and early age at initiation of sexual activity, increasing number of sexual partners of females and other indicators of sexual behaviour. The part played by sexual behaviour and history of male partners has also been recognised as significant in increasing risk. These findings are strongly suggestive of a causative role for a sexually transmitted agent. This agent is now identified as the group of high-risk types of human papillomavirus (HPV). It is quite likely that the observed demographic variables with risk of cancer of the cervix are very largely the result of differences in exposure and biological response to HPV.

2.4 Aetiology

Almost all cervical cancer is caused by a persistent infection by specific high risk types of HPV. HPV is a ubiquitous hardy DNA virus that can infect various surfaces in the body including the hands (warts), the feet, (plantar warts or veruicca) and the larynx as well as the anogenital tract of both men and women. There are about 100 different types of HPV and these are divided into groups of low, intermediate and high risk types. Anogenital HPV infection is usually transmitted during sexual intercourse and is so common that most sexually active men and women will have experienced an HPV infection at some point in their lives. The low risk types are usually responsible for visible warts on the vulva or penis and are not normally associated with the development of cancer. Most people never know that they have been infected with a high risk HPV since these infections are usually without symptoms and individuals clear

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the virus without needing any treatment or experiencing any problems. Only a very small number of women are not able to clear the virus and the virus may produce abnormalities in the cells of the cervix. In an even smaller number of cases, the virus will persist and eventually lead to cervical cancer. However, cancer takes many years to develop (10 to 15 years) and will only happen if the virus is not cleared during this period.

Persistent HPV infection leads to two categories of pre-invasive squamous lesions: productive, self-limited HPV infection (low grade lesions), and lesions with the potential, if left untreated, to progress to invasive cancer. Persistent HPV infection produces a large variety of morphologic changes in the cervix readily identifiable by routine light microscopy and at colposcopy.

While persistent infection with high-risk types of human papillomavirus is necessary, it is not a sufficient on its own to cause the development of cervical cancer. Co-factors such as immunosuppression (for example due to smoking or HIV infection) and other molecular deficiencies are likely to be involved.

2.5 Pathogenesis

Cervical cancer progresses through a number of early stages (cervical intraepithelial neoplasia – CIN) that are asymptomatic and invisible to the naked eye but can be identified by cytology and at colposcopy. CIN lesions do not invade below the surface epithelium and therefore do not threaten the life of the woman. CIN is divided into three grades (CIN1, CIN2 and CIN3). Low grade disease (CIN1) is now regarded as almost entirely composed of transient productive HPV infection.

Most CIN1 lesions regress spontaneously and only a small proportion progress to invasive cancer. It is estimated that about half of CIN3 lesions progress to invasive cancer if left untreated. Unfortunately we are currently not able to differentiate between those lesions that will progress to cancer and those that will regress.

In countries with cervical screening programmes, the peak incidence of CIN 3 is between 25-29 years, a full 10 years earlier than the peak incidence of invasive cancer. Thus progression to invasive cancer takes 10-15 years from the development of CIN3. However, it is possible that some lesions may progress more rapidly. While rapidly progressive cancers are described, these fast-growing lesions probably represent one extreme of the distribution of progression times rather than being a different type of disease and are probably not amenable to prevention by routine screening programmes.

2.6 Histological types and stages of cervical cancer

The majority of cases of cervix cancer are squamous cell carcinomas arising in the transformation zone around the cervical os. Adenocarcinomas arising in the endocervical canal epithelium are much less common, comprising around 20% of cancers in screened populations. Cytological screening, at least as traditionally carried out with a wooden spatula, has had little effect in reducing the risk of adenocarcinoma of the cervix since these tumours occur within the cervical canal and are not readily sampled when scraping the outer cervix and the cervical os.

Cervical cancer is staged according to the extent of invasion of the surrounding tissues and organs. International criteria have been set by FIGO (International Federation of Gynaecological Oncology) for measuring the spread of cervical cancers (staging) in a standard way. See Table 1.



Microinvasive squamous cancers are well-defined lesions with only minimal spread below the basement membrane to the deep tissues. They are generally asymptomatic and are detected at screening. Since the invading cells are unlikely to have reached blood or lymph vessels lying in the deep tissues, these cancers have an excellent prognosis and an extremely low incidence of distant spread or recurrence after treatment. In well-screened populations, microinvasive cancers form a large proportion of the total invasive disease and should therefore be considered a success of screening. This should be taken into account when publishing cervical cancer incidence rates.

Table 1 FIGO STAGING OF CERVICAL CANCER

Stage 0	Pre-invasive (CIN3)
Stage 1a	Microinvasive - not visible
Stage 1b	Clinically apparent lesion confined to the cervix
Stage 2	Invasion beyond cervix but not reaching lateral pelvic wall or lower 1/3 vagina
Stage 3	Invasion lateral pelvic wall / lower 1/3 vagina
Stage 4	Involving bladder+/-or rectum or beyond pelvis.

2.7 Survival Rates

Stage of disease at diagnosis is generally the most important factor determining the survival of cancer patients. Diagnosis at a symptomatic stage (Stages 2-4) has a poorer prognosis (See Table 2). Regular screening generally results in diagnosis at an earlier stage and a better survival, as does rapid access to appropriate treatment.

Table 2 FIGO (1985) 5 Year Survival

Stage 0 (CIN3)	100%
Stage 1a	97%
Stage 1b	78%
Stage 2	57%
Stage 3	31%
Stage 4	8%

2.8 Terminology for pre-invasive cytology and histology

Historically, the terminology used to classify these pre-invasive cellular changes has undergone periodic revision to incorporate advances in the scientific, clinical, and cultural understanding of cervical cancer. Many different classification schemes are in use worldwide and within Europe and there are, in addition, a myriad of local modifications to these schemes. Meaningful communication between pathologists and gynaecologists depends on a clear, shared understanding of the terminology being used. In the late 1980s, the UK and Ireland adopted the British Society for Clinical

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Cytology (BSCC) dyskaryosis terminology for cytological smears and the CIN (cervical intraepithelial neoplasia) terminology for histological lesions (see Table 3). The recently updated US Bethesda terminology is the classification most used outside UK and Ireland. The inter-observer and intra-observer variation in the use of all of these classifications is well recognised. The cytology result broadly indicates the expected histological grade but may underestimate the severity of the lesion in the cervix.

Table 3 Comparison of terminologies used in cervical cytopathology and histopathology

DYSKARYOSIS CLASSIFICATION (Cytology)	CORRESPONDING CIN CLASSIFICATION (Histology)
Unsatisfactory	- -
Negative	Normal
Borderline Changes	- -
Mild dyskaryosis	CIN1
Moderate dyskaryosis	CIN2
Severe dyskaryosis	CIN3
?Invasive squamous carcinoma	Squamous carcinoma
Adenocarcinoma	Endocervical / endometrial adenocarcinoma

2.9 Diagnosis and Treatment of pre-invasive disease (CIN)

The diagnosis of pre-invasive lesions (CIN) depends on obtaining a biopsy from women with abnormal cervical cytology, using a colposcope (magnifying binoculars) to define the abnormal area on the cervix. Once diagnosed, certain management protocols come into play depending on the grade of CIN and the referral cytology.

Women with low-grade cytological abnormality are often managed conservatively by follow up since the majority of these lesions regress spontaneously (regression rates of over 60%). In some healthcare settings conservative management is augmented by an HPV test at 12 months with a finding of a positive high risk HPV DNA type at 12 months being an indicator for colposcopy referral. Colposcopists are divided whether or not to treat these low-grade lesions but excision biopsy is usually undertaken if the lesion persists for several colposcopy visits.

The cumulative evidence indicates conclusively that lesions histologically confirmed as CIN2 or CIN3 have a progression rate of up to 40%. Therefore, treatment of these lesions is required and should be instigated soon after these lesions are diagnosed. Treatment for all grades of CIN is normally performed as an outpatient procedure at a colposcopy clinic and has minimal morbidity. It involves removing the abnormal surface epithelium together with some of the underlying tissue. This can be achieved by several methods including laser excision, loop excision, and diathermy as well as surgical excision.

Follow up post treatment is required since about 10% of women experience some recurrence.



3.1 General principles

In general health professionals and the public have a poor understanding of public health screening programmes. "Screening" is the use of presumptive methods to detect unrecognised health risks or diseases in order to permit timely intervention. The World Health Organisation (WHO) pioneered the development of criteria for screening programmes. In 1968 Wilson & Jungner defined the aims and principles of screening that have been the mainstay of research into and the application of screening ever since.

The Wilson & Jungner principles are listed in Table 4: Ideally all their criteria should be met before screening for a condition is initiated. These principles bring with them implications for an ethical approach to healthy individuals participating in the screening process. In medical practice, the special nature of the relationship between a patient and her physician has resulted in the need to build up a core of ethical principles which govern this relationship.

Table 4 Wilson and Jungner. Principles for screening programmes

- The disease should pose an important health problem for the individual and the community
- The natural history should be well understood with a recognisable early stage
- An appropriate and acceptable screening test should be available and offered at suitable intervals
- Treatment at an early stage should be advantageous
- There should be adequate facilities for the diagnosis and treatment of abnormalities identified
- The chance of physical or psychological harm must be less than the chance of benefit
- The costs of the screening programme should be balanced against the benefits it provides.

The benefit of the screening programme should outweigh any physical or psychological harm (caused by the test, diagnostic procedures or treatment). Even if the screening test is in itself harmless, a "positive" or "equivocal" result may cause unnecessary anxiety and the subsequent investigations and treatment can be hazardous. Ensuring the safety of screening is important because large numbers of individuals will be screened, creating a potential for greater numbers to be harmed, emotionally or physically by the process of screening.

An important distinction between screening and other medical care is that the screening encounter is not normally originated by the individual; rather the provider of screening (governments, public health units, or individual physicians) initiates the process. In screening, however, those who are approached to participate are healthy individuals and most of them never become patients. The provider of screening believes that as a result of screening, the health of the community will be better. There is therefore an ethical responsibility on those planning to introduce screening to be in a position to expect an overall benefit in the community.

Some additional ethical issues are also important. The first is the need to minimise the harm and anxiety that may affect certain individuals. This requires that the screening

methods selected should have the lowest proportion of false-positives possible. The second is to ensure that a useful remedy is available for all individuals who test positive. There should be no one for whom a definitive diagnostic test is not available. If this is not the case, screening will merely generate groups of anxious individuals for whom there is no benefit.

With these objectives there is a need to ensure that those who have an abnormal screening test return for a diagnosis and, if found to have a significant lesion, attend for treatment. A screening programme must ensure that there is sufficient contact with the individuals being screened to make them aware of the implications of an abnormal test to ensure appropriate follow up. Provision must be made to ensure that they have somewhere to return to for further medical advice and if necessary, counselling. Failsafe follow up procedures must be in place for non attenders.

3.2 Value for money and equity of access

All other options for managing the disease should have been considered (e.g. improving treatment, providing other services), to ensure that no more cost effective intervention could be introduced or current interventions increased within the resources available. The opportunity cost of the screening programme (including testing, diagnosis and treatment, administration, training and quality assurance) should be economically balanced in relation to expenditure on medical care as a whole.

Wilson and Jungner stated that the aim of screening programmes is to sort out those people who probably have the disease from those who probably do not. A screening test is not intended to be a diagnostic test. Screening procedures are generally easier to perform and cheaper than diagnostic procedures but their results require confirmation through definitive diagnostic tests.

Equity of access to screening services is another important consideration. All those who stand to gain from screening should have access to the procedure. A screening service should not be a service that relies on individuals seeking out particular tests or procedures that they have heard may be of value. Instead, those who organise the service have an obligation to ensure that those who have not heard of the test/procedure but who stand to benefit from it are adequately informed and located to enable them to be screened.

In order to achieve this, adequate staffing and facilities for testing, diagnosis, treatment and programme management should be available throughout the country prior to the commencement of a national screening programme.

There should be evidence that the complete screening programme (test, diagnostic procedures, treatment / intervention, management) is clinically, socially and ethically acceptable to health professionals and the public.

Public pressure for widening the eligibility criteria, for reducing the screening interval, and for increasing the sensitivity of the testing process should be anticipated. Decisions about these parameters should be scientifically justifiable to the public.



3.3 Organisation of screening programmes

All national programmes also have certain common values and structures (see Table 5 and Figure 1)

Table 5 Values common to all nationally managed screening programmes

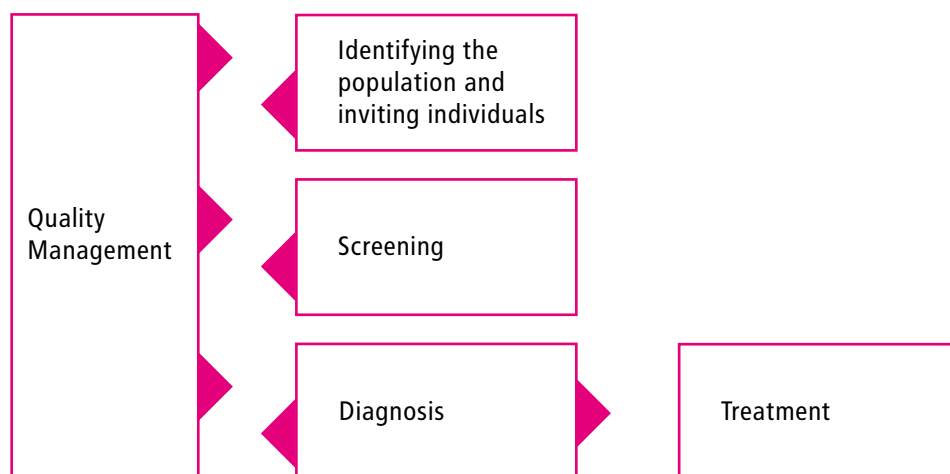
(Taken from J Muir Gray. Screening in Scotland. NSC Programme Director's report 2002-2003)

- People should be offered the opportunity to enter a screening programme, and given the necessary information and support to make an informed choice based on their values
- Professionals involved in screening programmes need development and support
- Screening programmes aim to maximise benefit, minimise harm, and make the best use of the resources available
- Screening programmes need to work in partnership with related clinical services to provide a seamless experience for people needing treatment
- Explicit and valid evaluation is essential both to fulfil a responsibility for accountability and provide a baseline for quality improvement
- Programmes are committed to continuous improvement in performance and standards
- Research can contribute to quality improvement and should be encouraged.

Nationally managed screening programmes are not directly responsible for treatment services but because they are identifying healthy people, some of whom will eventually be referred to treatment services; there is a responsibility to do everything possible to ensure that treatment services are of high quality.

These stages can be identified in every screening programme and the management of the programme is primarily responsible for organisation, co-ordination, evaluation and quality improvement. Quality assurance has four objectives:

- To reduce the risk of error
- To manage errors competently and sensitively when they do arise
- To support continuous improvement in performance
- To set and re-set standards.

Figure 1 Structures common to all screening programmes

Features common to all nationally managed screening programmes are listed in Table 6

Screening is a programme, not a test, and screening programmes need high quality information systems to measure their impact and their quality.

Those responsible for screening programmes have an ethical responsibility to ensure implementation and maintain quality control of the screening tests and that the effectiveness of screening programmes is continually monitored. There should be a plan for managing and monitoring the screening programme and an agreed set of quality assurance standards.

**Table 6 Common features of nationally managed screening programmes**

- Cover a defined population
- Have a simple set of objectives
- Develop valid and reliable criteria to measure performance and produce an annual report
- Organise quality assurance systems to help professionals and organisations prevent errors and improve performance
- Communicate clearly and efficiently with all interested individuals and organisations
- Co-ordinate the management of these activities, clarifying the responsibilities of all individuals and organisations involved

Screening programmes focus on performance measurements as their main indicator of quality but it is also very important to measure outcome. It is essential to be able to identify all the individuals affected by a condition for which screening has been organised including those who did not attend for screening because it may be that the population that is most at risk is that which is not receiving screening. No matter how good the quality of the screening programme, its impact on the population will be significantly reduced if it is not covering a high enough proportion of the population at greatest risk.

For this reason registers play an essential part in programme management and monitoring. There is a need for population registers to be developed and maintained and for those offered screening to be given information describing why this is important. Understandable public concern about confidentiality has led to changes in data management which have made registers more difficult to organise and sustain.

Each screening programme has to develop training specifically for the professionals involved in a particular type of screening. There is however, much common ground and it is important for those professionals involved in more than one programme (e.g. Primary Care clinicians) to understand the general principles of screening and how the different programmes relate to one another. In particular it is important to develop the knowledge and skills of public health professionals to provide generic screening education resources that could be used for any professional group.

4

screening for cervical cancer control

4.1 General principles

The World Health Organisation (WHO) and the International Agency for Research on Cancer (IARC) published Guidelines for Screening for Cancer of the Uterine Cervix in 1986. Revised guidelines were written earlier this year and are due for publication in December. A summary is available in the IARC website (iarc.fr). The European Union guidelines published in 2003 are broadly similar to the IARC /WHO guidelines. It is now accepted that an 80% reduction in cervical cancer can be achieved in an organised call-recall Programme implementing quality standards.

WHO recommended that for cervical screening to be effective, it is especially important that the programme be organised according to an agreed policy. The essential elements of such a policy are shown in Table 7

WHO also recommended that cervical screening must be run as an organised system with objectives, criteria to measure progress towards those objectives, standards and targets.

The outcome indicators to measure effectiveness of the programme are a fall in incidence and mortality from cervical cancer. A secondary indicator could be a shift in the stage of invasive stage and fewer with distant spread round the body. The detection of high grade CIN may also be used as a surrogate for invasive cancer.

Screening for CIN, the pre-invasive stage of cervical cancer meets the above criteria. The effectiveness of screening programmes based on cytological smears in reducing the incidence of and mortality from carcinoma of the cervix has been well established for some decades as evidenced by experience in Scandinavia in the 1960s and more recently - and dramatically - in the UK.

As explained above, cervical cancer progresses through a number of early stages in which some of the cells of the cervix become abnormal although they are not yet cancerous. Cervical screening is the process of identifying these abnormal cells so that they can be removed before they become cancer. It is a very important part of a woman's routine healthcare and all women between the ages of 25 and 60 with a cervix should be offered regular screening.



Table 7 IARC Guidance for Cervical Screening Programmes

CRITERIA FOR A CERVICAL SCREENING PROGRAMME

- the target population has been identified
- individual women are identifiable
- measures are available to guarantee high coverage and attendance, such as a personal letter of invitation
- there are adequate field facilities for taking smears and adequate laboratory facilities to examine smears
- there is an organised programme for quality control of smear taking and laboratory interpretation
- adequate facilities exist for diagnosis and for appropriate treatment of confirmed neoplastic lesions and for the follow-up of treated women
- there is a carefully designed and agreed referral system, and an agreed link between the women, the laboratory and the clinical facility for the diagnosis of an abnormal screening test, the management of any histological abnormality found and providing information about normal screening tests
- Evaluation and monitoring of the whole programme is organised in terms of incidence and mortality rates at the level of the total target population among those attending, and among those not attending
- Quality control of these epidemiological data should be established.

Evidence based information, explaining the consequences of testing, investigation and treatment, should be made available to potential participants to assist them in making an informed choice.

The three principal factors influencing how much benefit can be obtained in any population are

- The proportion of eligible women who are screened. This should be measured accurately and not simply by estimate using (out of date) census data
- The sensitivity of the screening test in detecting high grade pre-invasive disease (i.e. CIN3 and not CIN1). This is a combination of the quality of smear taking, slide preparation and laboratory assessment
- The adequacy of colposcopic investigation and treatment of any disease detected.

4.2 Monitoring and evaluation

Cervical screening must be run as a system with objectives, criteria to measure progress towards those objectives, standards and targets. There should be a plan for managing and monitoring the screening programme and an agreed set of quality assurance standards. At the initial roll out of a cervical screening programme, these can be adopted from similar existing cervical screening programmes. However, standards and targets need to be reviewed regularly in the light of experience and reset for the individual programme.

The effectiveness of the screening programme is the degree it achieves its objectives; the quality of the programme is the degree to which it conforms to pre-set standards of good screening.

4

screening for cervical cancer control

At a national level changes in cancer incidence and mortality among those attending and among those not attending are valid measures of effectiveness. For the population served by health authorities or individual laboratories, however, incidence and mortality data are less valid. Other measures of the cervical screening process, for example, the percentage of the population who have had a screening test, or the false positive rate have to be used. A common dataset for the programme evaluation should be agreed and an annual report should be produced.

Any impact on incidence and mortality will take several years to appear. Incidence may take up to two screening rounds (6-10 years) to show its full effect. Mortality may take much longer since women dying from cervical cancer in the first 6-10 years will generally already have developed their cancer and would not have benefited from the screening programme.

Steps must be taken to improve the validity of the data used to measure the effectiveness of the cervical screening. The use of confidential enquiry and audit to identify system failures should be developed.

Cancer Registry data needs to be linked with other measures of programme effectiveness.

To measure and improve the quality of the programme, it is necessary to have not only explicit standards but also an information system which allows the necessary data to be collected and a quality assurance system which allows action to be taken should any programme fail to meet those standards.

Quality assurance must be run as a national system so that the same standards, definitions and data are being used across the whole country. A national Quality Assurance Team with relevant professionals should be established to ensure appropriate standards are set. There should be a culture of transparency, openness and accountability.

4.3 Definitions of sensitivity and specificity

Sensitivity is the ability of the test to detect women who harbour a significant abnormality in the cervix while specificity is the ability of the test to correctly identify normal women.

Both are important in screening programmes. The higher the quality of the programme the higher its sensitivity and specificity. Attempts to increase sensitivity (reduce false negatives) invariably result in decreasing specificity (increasing false positives including unsatisfactory or borderline smear rates). Thus attempts to reduce the number of false negatives may lead to more normal women being recalled for repeat tests or referred to colposcopy.

4.4 Age to start screening

The incidence of carcinoma of the cervix is very low under the age of 24 years. In Europe, age to start screening varies widely, with Finland and Holland inviting women to their organised programme from the age of 30. The NHS Cervical Screening Programme in England recently recommended that women under the age of 25 should not be screened. For developing countries, screening may commence at age 35 years in order to maximise best use of resources since invasive cervical cancer is infrequent below the age of 35 years. WHO / IARC do not recommend screening below the age of 25 since this is not cost effective.



4.5 Population coverage and frequency of screening

The design of a screening programme defines two key parameters for achieving these objectives, coverage of the target population and the screening interval. Compliance with these parameters is crucial in maintaining the effectiveness of the programme and in measuring cost-effectiveness in order that appropriate resources may be directed to increasing population coverage. The potential percentage reduction in cumulative incidence can only be obtained if a high proportion of the population (over 80%) comply with screening. Significant deviation from the recommended screening interval or target population may reduce programme effectiveness either by using excessive resources as in the case of annual re-screening for CIN or by allowing the disease to 'escape' the period at which early intervention can lead to treatment and/or cure.

The optimal screening interval is one that provides the most favourable ratio between degree of disease control and cost of screening. Determining the frequency of screening is aided by an understanding of the natural history of cervical cancer, including the duration of the asymptomatic (CIN) phase (10-15 years). The International Agency for Cancer Research and WHO in 2004 recommended a screening interval of 3 years in younger women since there is almost as much benefit from screening three yearly as for annual screening. Since the protection from a cervical smear is higher in older women, the routine screening interval can be increased to 5 yearly after the age of 35 years if the previous two screens are negative.

More rapidly progressive lesions do occur but it appears unlikely that the majority of such lesions would be detected by more frequent screening.

4.6 Age to stop screening

Invitation for routine cervical screening in women who have been actively screened and always been negative usually stops at age 60-65 years. The European guidelines recommend 64 as the upper age limit for routine invitation.

There have been suggestions that women who have never had an abnormality on cytology and have been active participants in screening could stop screening at 55 years or even 50 years but there is no good evidence to support this strategy at present.

Since the incidence of cervix cancer in all countries shows relatively high rates of invasive cancer in older women, there is a consensus that women over the age of 60 who have never been screened or have not been screened for many years should be encouraged to have at least 2 smears, and only if both are negative should they stop screening.

5

the routine screening test

5 The Wilson & Jungner principles of screening require that there should be a simple, safe, precise and validated screening test. The test should be acceptable to the population. The distribution of test values in the target population should be known and a suitable cut-off level defined and agreed for "positive" results. There should be an agreed policy on the further diagnostic investigation of individuals with a "positive" or persistent equivocal and unsatisfactory test results.

5.1 The Conventional cervical smear

The conventional cervical smear (Pap test) has been used as the routine screening test for many decades and has been responsible for the dramatic reductions in invasive cancer in well screened populations. It consists of scraping the cervix with a suitable sampler and spreading the material obtained onto a glass slide then fixing it with a preservative fluid or spray. It is well recognised that the sensitivity of this method is only around 55% mainly due to sampling and preparation issues. It is the regular screening during the long period that CIN3 is present before cancer develops accounts for the success of cervical screening programmes. The reasons for this low sensitivity are well understood and include limited transfer of cellular material onto the glass slide so that the smear may not be representative of the material removed from the cervix.

5.2 Liquid Based Cytology (LBC)

More recently cervical screening programmes across the world are introducing a new technology for collecting cellular material from the cervix and preparing slides. This new technology is called Liquid Based Cytology (LBC) since the cellular material removed from the cervix is placed into a transport fluid and sent to the laboratory as a cell suspension. The two main commercial LBC systems currently available on the market are ThinPrep (Cytoc, Boxborough, MA, US) and SurePath (TriPath Imaging Inc.). These utilise very different technologies and have differing resource requirements. The collection methods also differ between the systems.

While the laboratory consumables are more expensive than those for the conventional smear, the evidence is that LBC markedly reduces the unsatisfactory rate while increasing or at least maintaining the identification of high-grade lesions. Thus there are fewer repeat tests and more appropriate referrals for colposcopy. In addition, the laboratory throughput may increased by about 40% allowing greater productivity.

The recent pilots in England showed robust evidence for cost effectiveness in terms of life years saved. The National Institute for Clinical Excellence has recommended that the NHS Cervical Screening Programme in England and Wales convert to LBC for its routine screening test. Scotland took a similar decision in 2002 and is now fully converted to ThinPrep as its routine screening test. Scotland chose to implement only one LBC system to facilitate training and external quality assurance, allow more cost effective national procurement and to avoid confusion among smear takers.

5.3 Automation Assisted Screening

Automation assisted screening (using computers to scan the slides) is aimed at increasing sensitivity (and specificity) by identifying abnormal samples especially those with only a few or very small abnormal cells. It has proved extremely difficult to train computers to identify abnormal cells on conventional smears.

Two commercial systems were extensively studied in the 1990s: PAPNET (Neuromedical Systems Inc. (NSI), Suffern, New York, USA) which has gone into receivership and the AutoPap System (Neopath Inc., Redmond, Washington, USA). Newer devices are emerging targeting liquid based cytology smears. The ThinPrep Imager (Cytoc, Boxborough, MA, US) and FocalPoint (Formerly AutoPap) (TriPath Imaging Inc.) have



been approved by the FDA in the US for routine screening. Each system is designed to work on its own method of LBC preparation only. The ThinPrep Imager scans the slide and selects the 20 most suspicious fields. These fields are presented down the microscope to the cytotechnologist reviewing the slide. The FocalPoint system after scanning the slide presents the laboratory with a risk assessment of the slide containing abnormal cells. The FDA has approved the system at a 20% sort rate. This is the 20% lowest risk slides can be archived without human review. The remaining slides are subject to full manual review. A new version of the TriPath system with the ability to relocate suspicious fields down the microscope (FocalPoint GS) has not yet received FDA approval.

The few randomised prospective studies and also the other performance studies have shown that automation assisted screening may be feasible as a part of routine primary screening. It appears to perform at least equally well compared to manual screening in organised well working screening programme. It is estimated that these devices would increase throughput of primary screening by up to 100%.

5.4 HPV testing as a primary screening test and for triage of low grade abnormalities.

HPV testing can be performed on the residual material in the LBC vial. There have been suggestions of using testing for the presence of HPV DNA as a more sensitive primary screening test for the presence of high grade CIN since the negative predictive value is very high. Unfortunately, the high frequency of positive HPV tests among younger women results in poor specificity (many normal women will receive a positive result). Thus HPV testing as a primary screening method is unsuitable for use under the age of 30 years of age.

The specificity of HPV testing is considered as too low for use as a primary screening test in population-based screening since HPV infections most often clear spontaneously. HPV testing is likely to result in a considerable number of women who do not harbour high-grade disease being referred for colposcopy and biopsy. Counselling and management of normal women with persistent HPV positive tests but who show no evidence of CIN on cytology or at colposcopy is a major problem especially since only a tiny percentage of such women will ever progress to cervical cancer. Currently there is no treatment available for persistent HPV infection and the result of this screening test could simply be unnecessary anxiety.

Before HPV can be considered for primary screening of women over 30 years of age several issues would require to be addressed including cost, widespread dissemination of information about HPV, and the appropriate screening algorithm for women younger than 30 years. Costs of HPV testing are currently higher than for cytology but could potentially be balanced by increasing the screening interval for HPV negative women. The Manchester ARTISTIC trial is designed to answer some of these questions.

However, using HPV DNA testing to triage those LBC samples that show a low grade cytological abnormality may help identify those women who are normal and can be returned to routine screening. This makes use of the negative predictive value for a HPV test which is extremely high. A study in the UK on women over 30 years suggested that a combination of HPV testing and cytology could support longer screening intervals for those negative on both. The MRC TOMBOLA trial is designed to answer these questions.

HPV testing is also being studied to see if women who test negative following treatment for CIN can be returned to routine screening earlier than on current protocols.

5

the routine screening test

5.5 Other molecular tests using markers of disease progression

Much recent work has gone into identifying test systems potentially more specific than HPV that might indicate early evidence of progression to high-grade CIN or cancer. Such tests may allow selecting women at increased risk for cervical cancer with a high predictive value. Certain bio-molecular pathways, subsequent to HPV infection, that lead eventually to the development of CIN3 and cancer, are investigated and some potentially useful molecules have been identified (for example p16 ink4a and mcm5).

The potential advantages of molecular markers in future clinical practice include more accurate and reproducible classification of histological cervical lesions; clearer distinction between cervical and endometrial lesions; better prediction of prognosis and the selection of best treatment procedures. Ultimately these molecular markers may be used in triage of women with minor cytological abnormalities and may even be used for primary screening for cervical progressive cancer precursors.

However, the detection and utilisation of such molecular markers is still in the research stage.



6.1 Cytopathology service

The role of the cytopathology laboratory is well described in the 1996 DoHC document.

Cervical smear test reports include a coded result, a recommendation for when the next smear should be taken or clinical management and where not normal, a descriptive text. In order to recommend the appropriate next management of women, access to accurate information about previous screening tests and clinical history are necessary.

A new grade of non medical laboratory staff - the Advanced Practitioner in Cervical Cytopathology has recently been introduced. This grade is recognised by the Royal College of Pathologists and the Institute of Biomedical Scientists in the UK. Medical Laboratory Scientists must undergo rigorous training and sit an examination before becoming qualified to apply for an Advanced Practitioner post. Staff employed on this grade must work under the general supervision of a consultant pathologist but they can report abnormal smears and give clinical advice about management of women with abnormal results. Advanced Practitioners have been successfully introduced in the UK and have offset the major shortage of consultant pathologists and proved to be value for money.

CPA(UK)Ltd laboratory accreditation is mandatory in the UK for all cytopathology laboratories. Regular (at least annual) proficiency testing (a form of external quality assurance) organised at a regional (national in Wales and Scotland) is also mandatory for all medical and technical staff reporting cervical smears. Rapid review of all negative and inadequate slides is the standard internal quality control method and the sensitivity of all screeners must be calculated according to a defined protocol and documented. For pathologists, the positive predictive value of smears reported as high grade (i.e. subsequently confirmed as high grade on histology) is the quality assurance method of choice. The documented outcomes of internal quality control and external quality assurance as well as the reporting profiles of the laboratory are all monitored at regular intervals during the Quality Assurance Team visits.

Liquid based cytology has replaced the conventional cervical smear as the routine screening test. Implementation is complete in Scotland and is in the process of being rolled out in England and Wales.

6.2 The Colposcopy Service

Colposcopy is the diagnostic investigation of women with abnormal cervical smears or persistent unsatisfactory or borderline smear results. The role of the colposcopy clinic is well described in the 1996 DoHC document. The British Society for Colposcopy and Cervical Pathology (BSCCP) has subsequently introduced quality standards for colposcopists including a minimum workload for each colposcopist in terms of number of new cases each year and an upper limit to the percentage of biopsies reported as within normal limits. Nurse specialists have also been introduced in some clinics as a cost effective means of supporting gynaecologists in the routine colposcopy clinic workload.

It is important that colposcopists meet regularly with the cervical cytopathologists (or Advanced Practitioners) and Histopathologists to discuss the best management of difficult cases and to review discrepant clinical findings.

6.3 The Histopathology Service

The role of the histopathology laboratory is also well described in the 1996 DoHC document. Successful cervical screening requires good diagnostic pathology for the cervical biopsies taken at colposcopy. It is essential to have a definitive diagnosis

6

the role of hospital services in screening

before any decision can be made regarding the optimal management for a woman with an abnormal screening test.

The pathologist is responsible for prompt, accurate reporting of cervical tissues obtained through biopsy and surgical procedures. Each pathology report must communicate information sufficient to ensure that each patient receives appropriate clinical management. Standard (CIN) terminology should be used.

The results for all cervical biopsies including the cervical histology result from hysterectomy samples should be sent to the screening Register to allow appropriate follow up, cessation of recall where appropriate and statistical analyses.

Furthermore, due to the critical importance of quality assurance to successful cervical cancer prevention, the pathologist is also responsible for detecting and analysing the errors that routinely occur in screening programmes by comparing histological findings to those from previous screening tests. This process, termed cytological/histological correlation, is required to confirm that women in target demographic groups are receiving appropriate clinical management.



7.1 The background

The national Irish cervical screening programme commenced with a phase one development of the programme following the report of the Department of Health Cervical Screening Committee (Dec. 1996) that concluded that cervical screening is a worthwhile preventive health measure when delivered as an organised screening programme.

The first phase of the Irish Cervical Screening Programme was established in the Mid-Western Health Board in October 2000 with an aim to develop and implement a population based, organised, call / recall cervical screening programme in a defined area and to test all of the operational issues before implementing the national programme (see Table 8). The eligible population was defined as women aged 25 to 60 years in the Board area and the screening interval was set at 5 years.

An Expert Advisory Group on Cervical Screening was established in 1997 and its terms of reference are listed in Table 9. A Steering Group established in January 1999 to oversee the implementation of the programme in the Mid-Western Health Board with representation from the Board and the Department of Health and Children community health and secondary care divisions. This Steering Group has stood down now that its remit has been completed.

Table 8 Operational Issues that required to be addressed (from DoHC Report 1996)

1. Development of a Population Register
2. The ICSP computerised register Information System
3. Administration of call recall and GP payments
4. Health Promotion
5. ICSP Documents
6. Links with the Cytology Laboratories
7. Links with smear takers
8. Links with the Colposcopy Clinic
9. Links with the Histology Laboratory
10. Quality Assurance

A national QA document drawn up by the Expert Advisory Group was published in 1999. The document is divided into four components (Table 10)

Following the establishment of the Phase 1 ICSP, the Expert Advisory Group identified the urgent need to address the permanent organisational and accountability structure requirements for the national programme. The Department of Health and Children subsequently requested the CEOs of the Health Boards in August 2001 to examine the feasibility and implications of a roll out of the programme, such examination to include consideration of governance arrangements for the programme.

The stakeholders in the Programme included the primary care doctors and nurses;

cervical cytopathology services; the colposcopy investigation and treatment service and the histopathology diagnostic service.

The screening test used in Phase 1 ICSP was the conventional cervical smear test and cervical smear reporting was provided mainly at University College Hospital Galway and St Luke's Hospital, Dublin cytopathology laboratories. The Royal College of Surgeons of Ireland laboratory assisted with a small pilot of liquid based cytology (ThinPrep) samples in 2003. Cervical biopsy reporting (histopathology) was undertaken by the Mid Western Regional Hospital Histopathology Laboratory in Limerick. Colposcopy services were provided by the Regional Maternity Hospital Colposcopy Clinic in Limerick.

Table 9 Terms of Reference of the Expert Advisory Group on Cervical Screening

TERMS OF REFERENCE

- To advise the Minister on:
 - The piloting of the programme
 - The resolution of any difficulties which may emerge
 - Developments and best practice including quality assurance and new Technologies in cervical screening, treatment etc.
 - The development of protocols where appropriate
 - The setting up and implementation of the national cervical screening programme
 - Progress in the implementation of the recommendations of the Report of the Department of Health Cervical Screening Committee.
- To support the persons responsible at regional level for the cervical screening programme
- To liaise as appropriate with the National Forum on Cancer and with the health boards in relation to the development of the national cervical screening programme.

Table 10 The components of the national QA document 1999

- Quality Assurance Targets for the General Practitioner & Smear Takers
- Quality Assurance Targets for the Laboratory
- Quality Assurance Targets for the Colposcopy Service
- Quality Assurance Targets at the Register Office



7.2 Organisational Elements, Achievements and the Application Of Quality Standards

Overall the Phase one pilot has proved very successful. I am impressed with the planning, implementation and achievements to date.

7.2.1 Programme Director

The success of Phase 1 has been due in no small measure to the appointment of a skilled public health consultant as Programme Director. Dr Marian O'Reilly has a good understanding of screening and she has built up an efficient team in the Central Programme Office as well as building up good relationships with the external stakeholders.

7.2.2 Central Programme Office / Register Office

The target population Register has been established, as many duplicate records as possible eliminated and procedures established to maintain the Register. To date about 87,000 women have their demographic details incorporated into the Register representing approximately 90% of eligible women (inevitably some women under 25 years and women who are now over 60 years are included on the Register and there are some duplicate records for which there is insufficient or erroneous data and thus cannot be merged). Thus Phase One has been extremely successful in establishing the Register. A cervical screening database containing test results and when the next smear is due or clinical referral recommendations (clinical management) has been implemented. A computerised information system for call/recall and failsafe follow up has been developed and tested. Once registered with the Programme, women are automatically monitored by the call/recall and failsafe follow up systems to ensure that they return for a repeat test at the appropriate interval.

Information Technology has been developed to meet all Programme standards and appropriate support has been established. Information Technology data quality has been implemented. Data quality has been markedly enhanced through the inclusion of the Personal Public Service number for women as their unique identifier. This was viewed as a significant risk reduction measure.

Purchase, supply and distribution of smear test consumables and disposable speculae to primary care has been organised.

QA of all aspects of the programme has been an integral part of Phase 1 ICSP from the start and the Cervical Screening Register Office / Programme Office has met all the standards set in the 1999 QA document but these now require revision. A QA Manager was appointed and has led the implementation of ISO standards for administration throughout the Office. The QA Manager attends the English NHSCSP QA meetings in observer status. The central office achieved ISO 9001-2000 standard of the National Standards Authority of Ireland in March 2004.

7.2.3 Promotion of the Programme

By May 2004, uptake in the eligible cohort in Phase 1 had reached 71.5% within the previous five years (with only 3.5 years of Phase 1 completed). Entry to the Register has been via a number of routes: women responding to an invitation letter from the central administrative office in Limerick, attending their General Practitioner, attending a colposcopy clinic or referred for entry to the Programme at the discretion of another doctor. There has been significant promotion of the programme at smear taker level. Almost 30% of women responded to their invitation letter in a timely manner – a commendably good result at the start up of the pilot programme. Revisions to the wording of invitational letters should be tested and several examples piloted to find the most effective format for first invitation and recall letters. Literature has been developed and distributed nationally. Information and awareness campaigns targeting women are ongoing.

7.2.4 Smear takers in Primary Care and in other settings

A contract for General Practitioners and Family Planning / Well Women doctors as independent smear takers has been implemented with a fee per item payment system. The current fee is €46.33 per programme smear. Nearly €2 million was paid to doctors registered with the programme in the first three years. In 2002, 27% of smears were taken by primary care nurses and this had risen to 35% in 2003 and this trend is likely to continue in the future. The trend in the UK has been to a nurse led service with over 70% of smears being taken by nurses. Given that contracts are with General Practitioners, the governance needs to be reviewed in the context of future contracts since smear taking until now has been perceived as a medical function.

A registration procedure for doctors and nurses as smear takers is in place. A smear taker training programme, targeting inexperienced smear takers and certified by RCSI in 2003, has been implemented and a resource manual published. The Nursing and Midwifery Development Units in some health boards are taking on the running of this training in their area. ICSP is working with ICGP to develop a model training programme for smear takers with a view to incorporating a distance learning module.

There have been no Smear Taker QA visits to date and no lead clinician has been appointed. There has been no progress to establish clinical audit of the programme at the primary care level nor has audit of the screening history of women who develop cervical cancer been implemented.

There are many other smear takers in gynaecological outpatients and maternity services and in Sexually Transmitted Diseases clinics. Taking a cervical smear appears to have been included in routine clinical protocols preceding the Phase 1 Programme and should now be discontinued. While these services are a useful means of enrolling women onto the Register, further opportunistic smears must be avoided in the future. Once the invitational programme is commenced, opportunistic smear taking must be removed from clinical protocols in maternity services, Gynaecological outpatients and STD clinics otherwise unnecessary repeat smears from these sources will swamp the laboratory capacity.

7.2.5 Cytopathology laboratory services

The Cytopathology laboratory service has a complexity of funding streams (consultant appointments, cancer services, the ICSP, etc). The Department of Health and Children also fund the laboratory service providers through the acute hospital services. While these sources are hugely important, the professional development of the laboratory needs to be co-ordinated in a way that supports the needs of the Programme.

Laboratories are managed locally within the hospitals and a local laboratory management committee drives quality assurance standards and coordination with the ICSP.

Almost 57,000 smear tests from 30,000 unique women were processed in the first three years. UCHG has processed 37,220 and St Luke's Hospital 14,148 smear tests in the first three years. 50% of tests were annual repeat tests following first smears in accordance with the original policy.

The RCSI cytopathology laboratory participated in an operational trial of 5,000 liquid based cytology preparations (ThinPrep) in 2002-03 and reported on costs and logistics.

A contract was developed with an external fully accredited laboratory to take on cytology screening to deal with backlogs that developed.



The first baseline survey of the cytology laboratories in Ireland was carried out in 2002. This provides a clear overview of the national situation. There were 14 laboratories reporting cervical smears in Ireland in 2001, half of the laboratories were in the Dublin area, three in the south and two in the west. Only 5 laboratories had an annual workload over 15,000 smears per annum minimum standard and between them they reported over 70% of the national workload. (3 in ERHA and one each in SHB and WHB). Only three laboratories had a workload over 25,000 smears per annum. 15% of the workload nationally is reported in overtime.

Staffing complements were difficult to assess since some pathologists worked in more than one hospital and cytology staff often had duties in adjoining histopathology laboratories. Better data collection and analyses is required.

Of the data available for pathologists, 10 out of 19 reported less than the 500 minimum smear reports per annum (mainly as a function of the small workload of some laboratories). Likewise for medical scientific staff the data available shows that few screen the minimum number of 5,000 conventional smears per annum and the range was estimated at between 122 and 4989 smears per annum. Training and continuing education standards appear to be well met in general. The age profile of medical scientific staff is a concern since over 25% of staff are due to retire in the next 10-15 years.

There is no standard practice at present for clinical management recommendations for the interval till the next routine smear. Only 2 laboratories followed the 1996 guidance for a 5 yearly interval and some laboratories chose not to give any recommendation at all. Most laboratories request an annual repeat smear after the first smear received from that woman in their own laboratory since there is no way of accurately identifying whether a previous smear had been taken elsewhere.

Qualitative data about the internal quality control procedures and outcomes is less well documented. Internal quality control processes are reported to be in place but these are varied and most are inadequately documented. Individual screeners' sensitivities were only available in 4 laboratories. The most common method of internal quality control is rapid review of all negative and inadequate smears. This however, is complicated by the myriad of double screening protocols in place. Most laboratories try to undertake biopsy / smear correlation but this is nearly impossible if the woman did not attend the colposcopy clinic attached to the same hospital. The positive predictive values (PPV) for smears reported as moderate and severe dyskaryosis were therefore mainly estimates and individual pathologist's PPV not calculated. Calculation of PPV is required for laboratory accreditation and this issue needs to be resolved through the implementation of defined regional services.

Most laboratories participate in the Irish Association for Clinical Cytology external quality assurance scheme. The results for this are confidential and assessed at laboratory rather than individual level. A technical (staining quality) external quality assurance scheme is also in operation and most laboratories participate.

The quality of laboratory accommodation varies between hospitals.

Some QA standards for cytopathology laboratories were defined in the 1999 QA document. Subsequently NHS Cervical Screening Programme performance indicators for laboratories have been adopted. A QA lead for cervical cytopathology has been appointed on a consultancy basis to carry out QA visits to service providers and monitor performance indicators and to identify to management gaps in defined QA standards.

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QA visits have commenced but have proved more difficult to implement than those in colposcopy. Prior to the visit by the ICSP QA Team, a questionnaire is sent to the laboratory to complete and a protocol for the visit agreed. Management are included in these visits so that any resource needs identified for that service can be brought to the attention and agreed with the hospital managers. This could be a very positive influence. Following the visit, a draft report is sent to the laboratory for comment before a final agreed report is issued. To date no final report has been signed off. In some settings commercial interests for private cytology may be a disincentive to sharing qualitative QA data.

Strong professional leadership will be required to create a culture of openness and transparency with a focus on laboratory quality assurance, particularly external quality assurance. I gained the impression that morale in the cervical Cytopathology laboratories was low but I saw evidence of real commitment to provide as good a service to women as possible and a genuine willingness to change in order to achieve this. Active leadership is required nationally and within laboratories to make this happen. There appears to have been a lack of confidence among laboratory staff and a degree of apprehension about the ICSP QA Team visits. However, this is a critical step to ensure overall quality and safety of the Programme and is one of the most fundamental aspects still to be addressed.

Historically, laboratories have usually been poorly equipped, staffed and resourced and have had to fight to retain what little resources they had. Cytology staff do not have the opportunity to earn additional money through on-call payments that are available to staff in other laboratory disciplines and therefore staff recruitment and retention has suffered. Unfortunately this might also encourage backlogs with a need to do overtime to supplement their basic salary.

Many laboratory practices are out of date resulting in duplication of effort and exacerbating build up of backlogs. Practices to deal with historical situations are often continued indefinitely and add to the day to day work of the laboratory. In particular, much time and effort goes into local failsafe follow up procedures.

Staff are dedicated to delivering a good service for women and many of the redundant practices have resulted from attempts to improve the sensitivity of smear results being issued. For example, in some laboratories a large proportion of slides may be fully re-screened two, three or four times before the result is issued. This includes negative smears. The proportion of smears double screened ranged between 10 and 100%. Some laboratories fast track (give priority) to smears received from certain types of clinic or women (for example repeat smears at colposcopy from women referred following an abnormal smear). This can inappropriately further delay the reporting of routine smears. Waiting times for smear results (as at 01/12/03) ranged from 1 to 13.5 weeks with only 5 laboratories meeting the national standard of less than 4 weeks.

Most laboratories use the conventional cervical smear but some laboratories in Dublin have implemented LBC using the ThinPrep system.

The ICSP has encouraged the cytology laboratories to seek formal external laboratory accreditation with an agency such as CPA(UK)Ltd. Application for CPA(UK)Ltd accreditation means that the laboratory is ready for an external inspection i.e. a quality manager is employed, standard operating procedures are written and implemented, all relevant quality assurance standards are in place and statistical information is available. Unfortunately I gained the impression that laboratory staff believe that such laboratory accreditation is unachievable in the short term. There has been a lack of available resource to complete the documentation required, achieve the



quality standards and failsafe procedures to meet CPA standards before an application can be sent for accreditation. Only a few laboratories have applied for accreditation and no laboratory has been successful in achieving accreditation to date.

The workforce is generally very highly qualified. However, there are recruitment and retention issues and some laboratories are carrying unfilled vacancies. No Advanced Practitioners are in post.

There has been no accountability of laboratories or the relevant hospital managers to the ICSP. There have been delays in filling funded vacancies and budget under-spends are not returned to the ICSP. Hospitals and laboratories are reluctant to have any gaps in service delivery or standards made public.

7.2.6 Colposcopy Service

One clinic in Limerick acted as service provider for the Mid-Western Health Board area. It has 1,000 attendances including 380 new patients per year. The Department of Health and Children fund the colposcopy service provider through the acute hospital services. A local committee drives coordination with the ICSP.

A colposcopy computer system specification for all clinics was delivered in 2002.

The first baseline survey of the colposcopy clinics in Ireland was carried out in 2001 to determine the national situation.

QA standards have been defined for the colposcopy clinics. There has been agreement among colposcopists to align with the British Society for Colposcopy and Clinical Pathology (BSCCP) standards.

A QA lead colposcopist was engaged on a consultancy basis to carry out QA visits to service providers and to identify to management, gaps in defined QA standards. Eleven of the nineteen colposcopy clinics have received a QA visit to date. These visits appear to have been well received. There is little or no duplication of service and staffing and these clinics appear to be value for money.

Performance indicators are monitored to meet QA standards. Equipment, clinical standards and relationships with hospital management were viewed as good but opportunities for improvement were identified in staffing, facilities and external communications. Subsequent to the QA visits to the Dublin clinics, the ERHA planners have rationalised colposcopy services in Dublin. I understand that one clinic has closed and its resources used to bolster another clinic to better meet needs of women in Dublin.

The routine taking of cervical smears from every woman who has been referred to the clinic is unnecessary and a waste of resources. The colposcopist should have access to the Register for the results of referral smears so that clinical appearances of the cervix can be properly interpreted. Repeat smears at the first visit should only be required in those few women with an abnormal referral smear who show no colposcopic abnormality.

7.2.7 Histopathology Service

Mid Western Regional Hospital Histopathology Department was the diagnostic service provider to Phase 1 ICSP. The Department of Health and Children fund the laboratory service providers through the acute hospital services. A local committee drives coordination with the ICSP.

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Although the ICSP QA lead for cervical Cytopathology doubles for histopathology, no standards have been agreed for the Programme histopathology services, and there have been no ICSP QA visits to date.

While there is a specialist cervical histopathologist in Limerick, in most histopathology laboratories the reporting of cervical biopsies is shared among all pathologists with no single pathologist taking a specialist interest in cervical pathology - particularly with respect to liaising with the Programme and providing quality assurance data. It is worth noting that histopathology was the last set of standards published by the NHS Cervical Screening Programme. These were published in 1999 (NHSCSP Publication No 10), three and a half years after the first publication of standards for cytopathology laboratories. NHSCSP histopathology standards are now in place in the UK.

However, there has been some progress. SNOMED coding has been agreed for all cervical biopsy results and the interface between Limerick Histopathology Laboratory and the Register Office has been established successfully. Unfortunately there is a backlog of results to be coded and sent to the Register which is delaying analyses of the programme standards. This also compromises failsafe follow up and must be addressed.

As with cervical cytopathology, the ICSP has encouraged the histopathology laboratories to seek formal laboratory accreditation with an External Agency such as CPA(UK)Ltd. As with cytopathology laboratories, only a few histopathology laboratories have applied for accreditation and none have been inspected to date.



8. A NATIONAL ROLLOUT OF THE CERVICAL SCREENING PROGRAMME

There remain many opportunities and challenges for the national Cervical Screening Programme in Ireland. The UK NHS CSP concentrated on improving coverage and failsafe systems in its first screening round (1988-1993) and on improving quality in the next screening round. The challenge for Ireland is to achieve both in the first screening round. The programme must be high quality but affordable, be shown to give value for money and give equal access to all eligible women.

8.1 Preparedness for a national rollout and the critical success factors

Experience from the first phase of the Irish Cervical Screening Programme in the Midwest is that a number of issues need to be resolved, namely:

8.1.1 Governance Structures, Management and Accountability

A home must be found for the ICSP in the current health reorganisation. I recommend it is based within Population Health since the natural home for a cervical screening programme is within a Population Health department. Given that the health service in Ireland is undergoing restructuring at present and the final structure is not yet clear to me, it is difficult for me to recommend exactly where the Irish Cervical Screening Programme should be located. However, wherever it is based, it is critical to ensure that the ICSP is appropriately organised and governed to achieve success.

A management structure with clear governance arrangements is required to ensure that the legal obligations to eligible women, health care professionals and staff participating in the Programme including Phase One are met.

The establishment of effective governance arrangements with immediate effect is necessary in order to provide overall leadership and direction in terms of policy development, standards, accountability and achievement of value for money for Phase One and any extension of the programme.

A key element to be addressed in terms of clarity with regard to governance for the Programme involves the synergies with Breastcheck in moving towards a public health population based screening programme model within the health reform process. A robust programme model is required to allow for national expansion, one that would fulfil the criteria for a national public health programme and lead to a reduction in morbidity for Irish women. All international evidence shows that population screening programmes are cost effective when organised as a Public Health Programme, underpinned by clear standards, managed clinical networks, clear accountability across organisational boundaries, clearly documented individual and organisational roles and responsibilities (defined in written protocols) as well as a dynamic policy and quality assurance system. The model of service delivery should facilitate the required accountability to ensure a quality assured screening service. A single central Programme office with clear lines of policy that everyone adheres to, responsibility, ring fenced funding and multi-annual budget planning is required.

At the current time, the Programme works within existing services. Integration with service providers has proved difficult because of competing priorities. This has led to a serious lack of accountability to the Programme. A contract of service for the programme must be agreed before programme work is undertaken. The hospital could bid into the programme for this or the Programme could directly contract the staff and service. Consideration could be given to the Programme establishing independent structures for service delivery in contracting its own staff and facilities particularly for the cervical cytopathology laboratory service.

There are no structures in place to allow immediate review or revision of the QA document by a professional group. Given Ireland's geographic location and population

size and since the Irish cytology and colposcopy services already aspire to the UK based NHSCSP and BSCCP standards, the ICSP should immediately adopt these standards as the minimum with review by the ICSP QA Steering Committee in the light of the experience of the first three years of invitational screening. Phase 1 ICSP has already aligned in an observer status at the NHSCSP QA Committee.

QA visits should be completed and any resulting recommendations adopted. Formal registration of smear takers should be implemented.

8.1.2 Professional Direction - National Committees

A multi-disciplinary National ICSP Steering Committee with representation from management and the professional academic bodies is needed to effectively direct policy development and issues pertaining to the Programme to reduce risk. A National ICSP Quality Assurance Committee with external representation is needed to adopt and review standards. Both committees should have a 2-3 year timeframe. Consideration should be given to requesting nominees from professional academic bodies. These individuals should represent their institutions and have delegated authority to make decisions on behalf of their professional body where appropriate.

A clearly defined screening policy should be developed and implemented which should be subject to ongoing review in the light of developing evidence, guidance, technology and government policy. Processes should be put in place to evaluate new technologies in cervical screening with respect to the ICSP such as computer assisted microscopy and biomarkers as well as HPV testing.

8.1.3 Programme Direction

The post of Executive Director whose job plan should include the management responsibilities for adoption of a business-model approach for the Programme should be established. The Director would, when necessary, enter into contract arrangements with service providers within existing structures to meet the needs of the Programme or when appropriate to enter into arrangements with private individuals or agencies.

Accountability from primary care and hospital services (laboratories and colposcopy clinics) will require review of existing and some new contracts in the light of incoming health reforms. Ring fenced funding and direct sessional contracting for the Irish Cervical Screening Programme would assist in accountability in its dealing for service delivery in the hospital sector.

The Director should report to the Director of Population Health and would be advised by the Steering Committee for policy and to the Quality Assurance Committee for standards development.

8.1.4 The Population Screening Register

A complete Register of all women in Ireland aged 25 – 60 years using their unique PPS identifier must be established. The central cervical screening Register information system does not currently hold all the relevant clinical history for each woman. A methodology of recording on the Register all previous smear / colposcopy history for women joining the programme must be agreed and implemented as soon as possible.

The issue of consent requires to be explored with a view to enabling the Programme to access existing cytology laboratory databases. Responding to an invitation or direct referral for a cervical screening test carries with it implied consent for the test and full buy in to all aspects of the programme.



All database owners should clean up their data as best they can, especially merging duplicate records for women. This task needs to be as automated as possible and may need outsourcing. Everyone should co-operate to identify women who have been screened in the past.

The use of the personal public service number (PPS) (1998 Social Welfare Act) should be made mandatory for all laboratory requests for programme smears and for smears from women requesting entry to the Register. This will allow keeping all the cervical screening records for one woman in one file on the Register and facilitates recall at an appropriate time as well as failsafe follow up. The introduction of a standard cytology request form which includes the PPS number will facilitate this and all cytology reports should include a management recommendation to ensure appropriate failsafe follow up.

All stakeholders (laboratory, Colposcopy Clinic, Primary Care and the Programme Register Office) should be able to access a women's history in order to ensure delivery of appropriate healthcare. This avoids the necessity for colposcopists to have a printed copy of the referral smear result for each patient. Laboratories should be able to see the results of previous smears on the woman reported elsewhere and thus give the appropriate management recommendation. IT linkages between laboratories, colposcopy clinics, smear takers and the Register must be implemented and tested.

8.1.5 Uptake of screening

The screening interval should be agreed. I recommend an interval of 3 years for women aged 25 to at least 35 years (extended possibly up to 45 years if laboratory capacity allows). Thereafter 5 yearly screening is adequate for women who have 2 consecutive negative smears and no history of abnormality.

Uptake of screening and entry to the Register must be encouraged together with a cessation of all ad hoc and opportunistic smears. Repeat smears at the first colposcopy visit following an abnormal smear result should be stopped and all annual smears banned except in the follow up for abnormal smears or treatment – including repeat after first ever smear. This is required to free up laboratory capacity to deal with programme smears and allow equity of access for all women as well as value for money.

Promotion to health care professional (primary care, labs, hospital clinic staff, colposcopy, practice nurses, GUM, maternity services, gynaecologists,) including realistic time scales for implementation and recommendations of what should happen in the meantime. The transition period timescale before first round invitation letters are sent out should be agreed and routine activity except for repeat opportunistic smears should continue in parallel.

Since women can enter the Programme by responding to an ICSP invitation letter or by direct referral at the discretion of the clinically responsible doctor, consideration should be given to a rapid national extension with conversion of initial opportunistic smears to Programme entry policy. Subsequent opportunistic smears however, must be discouraged.

8.1.6 The screening test

Currently two types of screening test are in use: the conventional Pap smear and ThinPrep (LBC). A single standard screening test needs to be agreed. I recommend moving to liquid based cytology since it brings an immediate reduction in the workload for smear takers, laboratories and colposcopy clinics due to a reduction in unsatisfactory smears (requiring an immediate repeat) and an increase in laboratory

capacity since more slides can be screened each day by laboratory staff. This may require an EC Procurement process so an early decision is critical. Moving to LBC will require a national training programme for converting laboratory staff and smear takers to the new technology and this will take many months to implement – yet another reason for a rapid decision.

Serious consideration should be given to choosing only one LBC system at present to allow a more cost effective national procurement. If more than one LBC system is accepted for implementation it may prove expensive or impossible to organise a satisfactory national external quality assurance programme for the four laboratories and for smear takers. Cognisance should be taken of the potential need for sharing workload between laboratories in the event of one laboratory developing a significant backlog and to the risk of samples being unsuitable for analysis if collected by a smear taker using one methodology and sent to a laboratory using the different methodology since the sample collection methods are not compatible.

Consideration should be given to evaluating the use of computer assisted cytology in the ICSP since this would further increase laboratory productivity.

8.1.7 Service quality and delivery

There must be a speedy policy decision by the DOHC about the number and location of cervical cytopathology laboratories, histopathology laboratories and colposcopy clinics so that there is appropriate capacity for the programme now and in the future. The cytopathology laboratory, colposcopy clinic and histopathology service should work together as a team. I recommend services be based in four centres, two in Dublin, one in the south and one in the west. It may be appropriate for a hub and spoke arrangement for outreach colposcopy services to be set up so that women do not have to travel too far for colposcopy investigations and treatment.

All laboratories providing services for the programme should apply for external laboratory accreditation before January 2006.

The Irish Hospital Services Accreditation Board has been requested by the DoHC (April 2004) to advise on an external accrediting body for the cytology service. A process of seeking accreditation is essential before the invitational Programme is implemented.

The Health Information and Quality Authority (HIQA) due to be established in autumn 2004, will be addressing standards in all health care providers. I am presuming HIQA will have the responsibility of declaring External Quality Assurance accreditation for all screening programme stakeholders and ICSP EQA visits and external accreditation will fall under HIQA. I would recommend that a laboratory accreditation system similar to CPA(UK)Ltd is used by HIQA. However, if CPA(UK)Ltd or equivalent laboratory accreditation is approved, this is a process driven accreditation and there will be therefore a continuing need for outcome monitoring – for example via ICSP QA visits.

Smears are taken in too many diverse clinical settings and samples are sent to a diversity of laboratories. This makes call / recall and failsafe follow up difficult. Biopsy / Smear correlation (quality assurance) is also impeded.

Training for all personnel providing services to the programme must be given a high priority and each individual stakeholder must comply with the training and continuing education standards agreed. Training should be certified by a professional authority e.g. RCSI / ICGP or equivalent. Training of laboratory staff for LBC should start as soon as possible and be co-ordinated with smear taker LBC training so that the change from conventional smears to LBC follows the ability of laboratory staff to evaluate LBC samples.



The fee agreed with GPs for smear taking services Phase 1 ICSP has proved expensive in terms of the Programme as a whole. Women should have the choice of a female smear taker and primary care nurses in filling this role may prove to be more cost effective smear takers. Any review of the GMS contract should include the fee for Programme smears.

8.2 STEPS IN TRANSITION TO FULL IMPLEMENTATION

There should be a transitional phase lasting no more than 18 months during which all preparations must be put in place and this should start immediately. There are big challenges to be met in this period which is why there must be no delay to starting. Transition can be followed by first full invitational round of the Irish Cervical Screening Programme. During the 18 month period all stakeholders should adjust their practices and prepare themselves for full implementation of the programme. There is a need for transition to be managed in a professional way with authority to implement changes. I recommend the appointment of an Implementation Project Manager on a short term contract to support the Programme Director in the coordination of training to service providers during the transition phase. The key tasks to be completed in the Transition period are summarised in Table 11. Significant investment is required to ensure these tasks are completed in time for national roll out within 18 months.

Table 11 Summary of tasks that must be completed during the transition phase.

- Maintain uptake of screening but cease routine repeat after first-ever smears, repeat at first colposcopy visit and all other inappropriate annual recall. Prepare for replacement of ad hoc opportunistic smears with call recall
- Appoint a Programme Director
- Submit a business plan and job description for a project manager
- Appoint a Project manager for the transition period
- Establish a Steering Committee
- Agree screening age group and screening interval
- Implement NHSCSP quality standards as a minimum for all areas of the Programme
- Agree internal quality control procedures for laboratories
- Agree move to LBC modality as the single screening test
- Agree that national Register should hold all relevant clinical information on women's screening history
- Make women's history on the register available to laboratory staff, GPs and other Programme personnel
- Establish confidentiality rules and code of practice for access to register with regular random audit of access to records
- Decide the geography of the 4 regional screening centres
- Decide which laboratories will become the four national screening laboratories
- Ensure laboratory accreditation, training and capacity planning/ throughput
- Decide which colposcopy clinics will become the four national centres
- Ensure colposcopy accreditation, training and capacity planning / throughput
- Prepare call and recall as focus with mapping of uptake in the four regions
- Review current funding arrangements and plan for redistribution of resources where appropriate to ensure affordability and cost effectiveness
- Establish a training programme for all personnel in the programme
- Clarify consent issues
- Consider fees for smear taking within GMS contract.



8.3 IDENTIFICATION OF THE IMPROVEMENTS THAT MAY BE NEEDED TO MOVE FORWARD NATIONALLY.

8.3.1 Cervical cytopathology as service.

A major challenge is the re-organisation of the cytopathology laboratories (internal and external) to meet the capacity needs of the programme. (See appendix 1 Capacity calculations) Turnaround times are currently wholly unacceptable in many laboratories. Women should receive the result of their screening test within four working weeks.

Laboratory throughput must be increased. A defined productivity standard per medical laboratory scientist would assist capacity planning based on projected workload for the catchment area.

Cervical cytopathology requires to be rationalised to four national screening cytology laboratories with specific catchment areas defined by the primary care practices registered with the Programme laboratory on a county basis. Identification of laboratories must be on the basis of seeking external accreditation and meeting ICSP (NHSCSP) QA standards. Laboratories should have a minimum annual throughput of 25,000 ideally moving to 80,000 within a short timescale. Only Programme policy smears should be processed at the national screening laboratories.

During the 18 months transitional phase, it is likely that the national screening laboratories will require the assistance of other currently existing cytopathology laboratories to help manage the conventional smear workload while the screening laboratories are training to convert to liquid based cytology. Work could be allocated to existing cytology laboratories or to any other cytology laboratory on the basis of that laboratory's ability to deliver the specified service to the required level of quality.

Once the invitational programme is established, some of the screening laboratories may find it necessary to consider a short-term hub and spoke model whereby all programme samples are sent to a central slide preparation facility for processing. Some of the slides would be forwarded to a peripheral laboratory for microscopic assessment. The screening laboratory would be responsible for all data management and quality assurance. This centre facility would be the nucleus for a single reporting laboratory in due course.

Retention of staff might benefit from the career progression that would result from the introduction of the Advanced Practitioner in Cervical Cytopathology grade of Medical Laboratory Scientist. After a rigorous training programme and passing an examination, Advanced Practitioners are able to report abnormal smears and give clinical advice under consultant supervision. They are a very cost effective grade of staff since they can dedicate all of their time to the cytopathology service and thus the number of consultant pathologist sessions required can be markedly reduced. A staffing structure for the national screening laboratories requires to be agreed – a model staffing structure is presented in Table 12

Standard protocols for internal quality control should be agreed and implemented to avoid unnecessary work within the laboratory. The responsibility for recalling women at the appropriate interval should be passed to the Register thus freeing up laboratory time for assessment of slides. Call and recall should be focused with mapping of uptake in regions and sub-regions.

8.3.2 Colposcopy service as service provider for the Programme.

Colposcopy should be an investigation, diagnosis and treatment service based in an outpatient setting – and women attending should not be considered as patients unless an abnormality is identified. Colposcopy services should be rationalised to 4 national centres aligned to cervical cytopathology and histopathology services with geographically spread satellite clinics for access to the population. Satellite clinics should be managed centrally by the national colposcopy centres and quality standards included in those of the national centre.

Each clinic should have a Lead consultant in charge of the service with a dedicated colposcopy sister and dedicated clerical staff using the colposcopy information system. The employment of suitably qualified Nurse Colposcopists should be considered. Local hospital management should be responsible for the service based on being accountable to ICSP QA standards.

Regular clinicopathological conferences (multidisciplinary meetings) should be held with review and discussion of discrepancies between cytopathology and colposcopy or biopsy findings. Case conferencing for difficult cases should be the norm.

Table 12 Model structure of a national cytology screening laboratory

- At least two consultant pathologists to provide between them a total of 13 sessions per 25,000 cervical smears per annum
- A named lead consultant histopathologist with an interest in cervical cytology - minimum 7 sessions per week to cervical cytology with responsibility for the quality of the service and accountable to the Director of the ICSP
- At least one other consultant histopathologist with an interest in cytology - minimum 5 sessions per week to cervical cytology
- If an Advanced Practitioner grade of staff is employed then total histopathology consultant minimum time could be reduced to 5 sessions between the two histopathologists
- A chief medical laboratory scientist to provide medical laboratory scientist professional leadership and other defined responsibilities including liaising with the ICSP
- Access to a laboratory Quality Manager for accreditation purposes (the QM sessions can be shared with other laboratory specialties)
- A Training Officer - a senior medical laboratory scientist to organise training and QA (should also participate in checking and / or primary screening)
- Primary screening – 1 basic grade medical laboratory scientist or above per 5,000 conventional smears or 7,000 LBC samples
- Checking - 1 senior medical laboratory scientist per 2-3 primary screeners
- Laboratory aid grade staff may be employed for sample preparation
- Clerical staff will be required not only for data entry and result generation but also for IT linkage requirements for the ICSP.



8.3.3 Histopathology service

There is a need to rationalise services for cervical biopsies taken at colposcopy clinics. There should be four national histopathology centres aligned to cytology and colposcopy services. Good practice dictates that the histopathologist reporting a cervical biopsy should have access to the referral smear result and, where there is a discrepancy between the biopsy and the cervical smear results, the actual cytology slide should be available for review. Thus the histopathology laboratory must work closely with the cervical cytopathology laboratory with which it is aligned and with its colposcopy clinic staff. A lead histopathologist for cervical biopsies should be identified with responsibility for liaising with the ICSP. Consent should be sought at the time of surgery for all histopathological reports for cervical biopsies and hysterectomy specimens to go on the Register.

All biopsy results should be coded using SNOMED or the ICD classification. If the local hospital management continues to be responsible for the service it must be accountable to the ICSP for the QA standards. Hysterectomy samples will continue to be reported in other laboratories but the cervical SNOMED codes should be made available to the Register.

There should be a process of correlation with colposcopy and cytology including an audit of invasive cancers. The histopathology service should adopt the NHSCSP standards as a minimum immediately.

appendix 1

LABORATORY CAPACITY IMPLICATIONS OF PROPOSAL TO SCREEN 25-34 YEARS THREE YEARLY AND 35-60 YEARS FIVE YEARLY

Using 2002 CSO CENSUS FIGURES

FEMALES IN IRELAND (IN THOUSANDS)

25-34	308.9
35-44	283.1
45-54	238.9
55-64	174.2
Grand total	1005.1

25-34 yr olds: 308,900 - 3yearly is 103,000 at 100% and **82,400** at 80% annually

35-64 yr olds: 696,200 - 5yearly is 139,240 at 100% and **111,392** at 80% annually

Total annual capacity required is: 193,792 at 80% annually

Limitations:

- CSO statistics go beyond the 25-60 age group to include those up to 64 years and are therefore an overestimate
- Cytology capacity must include;
 - 10% repeats for unsatisfactory tests (conventional) or 2% (LBC);
 - 5% repeats for abnormal tests and
 - 2-4% (2% international figure - 4% phase 1 evidence) post colposcopy surveillance

Therefore, additional annual capacity of 19% (worst-case scenario) to 9% (best-case scenario) is required.

25-34 yr olds: 3yearly = 82,400 at 80% of target group annually

Plus 9% (7,416) = 89,816

Plus 19% (15,656) = **98,056**

35-64 yr olds: 5 yearly = 111,392 at 80% of target group annually

Plus 9% (10,025) = 121,417

Plus 19% (21,165) = **132,557**

Grand total annual cytology capacity requirements 25-64 year age group in this instance is from: **211,233 to 230,613 assuming 80% coverage.**



**LABORATORY CAPACITY IMPLICATIONS OF PROPOSAL
TO SCREEN 25-44 YEARS THREE YEARLY
AND 45-60 YEARS FIVE YEARLY**

25-44 year olds = 592,000 - 3 yearly is 197,400 annually at 100% uptake
and **157,920** at 80% uptake

45-64 year olds = 413,100 - 5 yearly is 82,620 annually at 100% uptake
and **66,096** at 80% uptake

Total annual capacity required is: **224,016**

Assuming an additional annual capacity of 9-19% as before.

25-44 year olds: 3 yearly	=	157,920 at 80% of target group annually
Plus 9% (14,213)	=	172,133
Plus 19% (30,005)	=	187,925

45-64 year olds: 5 yearly	=	66,096 at 80% of target group annually
Plus 9% (5,949)	=	72,045
Plus 19% (12,558)	=	78,654

Grand total annual cytology capacity requirements 25-64 year age group in this instance is from: 244,178 – 266,579

CURRENT AND FUTURE LABORATORY CAPACITY.

In 2002, a total of 230,000 conventional smears were processed in the Irish laboratories. 70% were performed in 5 laboratories. Moving to LBC and streamlining internal quality control practices should allow an additional throughput of at least 50% i.e. up to 345,000 capacity across all laboratories.





