



National
Cancer
Screening
Service


CervicalCheck
THE NATIONAL CERVICAL SCREENING PROGRAMME

1 September 2008 – 31 August 2009

Programme Report



WOMEN'S CHARTER

Screening commitment:

- CervicalCheck – The National Cervical Screening Programme offers a free complete quality assured programme of care
- You choose your smearer from a wide range of eligible service providers registered with the Programme
- You may change your preferred provider for subsequent Programme screening
- All Programme staff will respect your privacy, dignity, religion, race and cultural beliefs
- Your screening records will be treated in the strictest confidence
- You will always have the opportunity to make your views known and to have them taken into account
- Once you become known to the Programme you will be invited every three years for screening while you are aged 25 to 44 and every five years while you are aged 45 to 60
- Your smear test will be screened in an accredited quality assured laboratory
- Your result and any treatment recommendation will be provided to you and your nominated smearer by the Programme within four weeks.

We aim:

- To ensure pleasant and comfortable surroundings during screening.

If you require further treatment, we aim:

- To ensure that you will be offered an appointment at a quality assured colposcopy clinic (*within four weeks for high grade cell changes and within eight weeks for low grade cell changes*).

Tell us what you think:

- Your views are important to us in monitoring the effectiveness of our services and in identifying areas where we can improve
- You have a right to make your opinion known about the care you received
- If you feel we have not met the standards of this Charter, let us know by telling the people providing your care or in writing to the Programme
- We would also like to hear from you if you feel you have received a good service. It helps us to know that we are providing the right kind of service – one that satisfies you
- Finally, if you have any suggestions on how our service can be improved, we would be pleased to see whether we can adopt them to further improve the way we care for you.

Ways you can help us:

- Please make your appointment with a registered smearer on receipt of your invitation letter from the Programme
- Please bring your PPS number with you to your appointment
- Please read any information we send you
- Please try to be well informed about your health.

Let us know:

- If you change your address
- What you think – your views are important.

Freephone 1800 45 45 55
www.cervicalcheck.ie



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Contents



| | |
|---|----|
| CervicalCheck Women’s Charter | 1 |
| Overview of the National Cancer Screening Service | 5 |
| Introduction from the Director, National Cancer Screening Service | 7 |
| Message from the Head of Cervical Screening | 13 |
| Message from the Clinical Director, Colposcopy | 15 |
| Programme Overview | 17 |
| Programme Report | 29 |
| Glossary | 46 |

Overview of the National Cancer Screening Service



CervicalCheck – The National Cervical Screening Programme is part of the National Cancer Screening Service (NCSS).

The National Cancer Screening Service (NCSS) was established by the Minister for Health and Children in January 2007. The establishment followed the launch of 'A Strategy for Cancer Control in Ireland 2006' which advocates a comprehensive cancer control policy programme in Ireland by the Cancer Control Forum and the Department of Health and Children.

The Strategy set out recommendations regarding prevention, screening, detection, treatment and management of cancer in Ireland in coming years and recommended the establishment of a National Cancer Screening Service Board.

Governance of the former Irish Cervical Screening Programme (ICSP) Phase One was transferred to the Board of the National Cancer Screening Service on its establishment. The National Cancer Screening Service has been responsible for the establishment of CervicalCheck.

On 31 March 2010 the Board of the National Cancer Screening Service was dissolved. On 1 April 2010 the National Cancer Screening Service joined the National Cancer Control Programme (NCCP), part of the Health Service Executive (HSE). The National Cancer Screening Service continues its work operating as a business unit within the NCCP.

The functions assigned to the National Cancer Screening Service are as follows:

- To carry out or arrange to carry out a national breast screening service for the early diagnosis and primary treatment of breast cancer in women
- To carry out or arrange to carry out a national cervical cancer screening service for the early diagnosis and primary treatment of cervical cancer in women
- To advise on the benefits of carrying out other cancer screening programmes where a population health benefit can be demonstrated
- To advise the Minister, from time to time, on health technologies, including vaccines, relating to the prevention of cervical cancer
- To implement special measures to promote participation in its programmes by disadvantaged people

Since its establishment the National Cancer Screening Service has aimed to maximise expertise across screening programmes and improve efficiency by developing a single governance model for cancer screening.

The National Cancer Screening Service encompasses BreastCheck – The National Breast Screening Programme and CervicalCheck – The National Cervical Screening Programme. The NCSS is also responsible for the development and implementation of a national colorectal cancer screening programme.

Introduction from the Director, National Cancer Screening Service



On behalf of the National Cancer Screening Service (NCSS) it is my pleasure to introduce the first Programme Report of CervicalCheck – The National Cervical Screening Programme. This report provides screening statistics for the first 12 months of the CervicalCheck programme, 1 September 2008 to 31 August 2009. The report also provides an overview of activities and developments within CervicalCheck up to the time of publication.

CervicalCheck became available to over 1.1 million women aged 25 to 60 on 1 September 2008. The overall aim of CervicalCheck is to reduce the incidence and mortality rate of cervical cancer by detecting changes on the cells of the cervix before they become cancerous.

Over time, based on a target uptake of 80 per cent, a successful national, quality assured cervical screening programme has the potential to significantly reduce incidence and mortality rates in the screened population by as much as 80 per cent.

The performance of the CervicalCheck programme has exceeded all expectations. During the reporting period over 284,800 women were provided with a free smear test. I am also delighted to share that from 1 September 2008 to date (September 2010) CervicalCheck provided over 500,000 free smear tests to women in Ireland*.

Following extensive consultation in advance of the introduction of CervicalCheck, a contract for the provision of smearing services was delivered directly to GPs and medical practitioners nationwide. To date, over 4,150 GPs, practice nurses and medical practitioners in over 1,400 locations are registered to take smear tests as part of the programme.

The vast majority of smear tests (approximately 93%) were taken in the primary care setting, primarily in GP practices. The remainder of smear tests were carried out at colposcopy, gynaecology and STI/GUM clinics. Of those women that had their smear tests carried out in a primary care setting, approximately 92 per cent attended a GP practice and approximately eight per cent of women opted to have their smear test at a clinic other than a GP practice, such as a Family Planning, Women's Health or Well Woman Clinic.

* Full CervicalCheck programme statistics for the second year of operation (1 September 2009 to 31 August 2010) will be published in 2011 once fully evaluated and verified.



Tony O'Brien, Director

Cervical Cytology Services

It was widely accepted that the introduction of a national programme was long overdue. Following transfer of governance of the Irish Cervical Screening Programme (ICSP) Phase One to the NCSS on 1 January 2007, the NCSS was committed to delivering a national, quality assured programme to women at the earliest possible date.

At the time, women in Ireland had to tolerate lengthy delays for the receipt of smear test results. Those delays often extended up to and beyond a year in some cases. The data provided in this report shows how this situation has been transformed.

The establishment and introduction of CervicalCheck was not without its challenges.

Despite the well intentioned efforts of all concerned over the last 30 years in Ireland, a disorganised system of cervical cancer screening had clearly failed in terms of making any population impact on cervical cancer mortality.

To be effective in its goal of reducing the incidence and mortality from cervical cancer in women in Ireland, a national cervical screening programme needed to introduce a number of changes, some deemed radical, to the existing system of cervical screening.

As part of a national programme, such delays could no longer be tolerated. It became apparent that a priority for the NCSS would be to immediately proceed with a public procurement process for the provision of cytology services as part of the national programme.

The McGoogan Report on cervical screening in Ireland in 2004 clearly stated that any cytology laboratory wishing to participate in a national cervical screening programme should apply for accreditation before January 2006. Following publication of the McGoogan Report it was clear that accreditation would be a minimum requirement for a successful bidder.

The NCSS commenced a procurement process for the provision of a cytology service in December 2007. Following a rigorous, two stage public procurement process the contract for provision of cytology services was awarded to a US laboratory, Quest Diagnostics Inc. The laboratory successfully met all the required criteria set out under the procurement process including the holding of third party accreditation, the capacity and ability to process smear tests within a 10 day turnaround to facilitate the provision of results to women within four weeks and a minimum screening capacity of 25,000 smear tests per year at each proposed laboratory.

The decision by the NCSS to outsource the provision of cytology services to a US based laboratory was met with opposition. Quest Diagnostics Inc. has been instrumental in ensuring that the objectives initially set by CervicalCheck have been achieved. Uptake levels have remained consistently high, all analysis has been carried out in fully accredited laboratories and each smear test sample has been analysed twice by two separate cytotechnologists.

The CervicalCheck Women's Charter (page 1) makes a commitment to women that 'result and any treatment recommendation will be provided... by the programme within four weeks'. In early 2009 there was an unprecedented surge in the demand for smear tests. This coincided with the launch of a national CervicalCheck public awareness campaign, European Cervical Cancer Awareness Week and the death of reality TV star Jade Goody. This surge in demand challenged the capacity of the cytology laboratories to analyse smear test results within 10 days of receipt, leading to a temporary increase in waiting times for results. However, by June 2009 the percentage of test results received within two weeks had returned to 97.5 per cent.

Encouraging Participation in Screening among Women

To accommodate the initial expected interest in CervicalCheck, during its first year of operation, the programme operated an open access system of screening. Any woman who wished to avail of a free smear test could arrange an appointment with any one of the over 4,150 CervicalCheck registered smertakers. On 1 September 2009, after 12 months of operation, CervicalCheck moved to an organised call, re-call system of invitation, in line with best international practice. From 1 September 2009 women were required to have an invitation from CervicalCheck to avail of a free smear test.

Those women that presented for screening since 1 September 2008 were now part of a quality assured, organised screening cycle and will be re-called when their next smear test is due.

While the move to a call, re-call system of invitation was opposed by some members of the medical community, it is the proven basis for a successful population-based screening programme.

CervicalCheck has a national register of in excess of 1.1 million eligible women aged 25 to 60 and over each screening round will send women an invitation for their free smear test by post.

Following the introduction of the call, re-call system of invitation on 1 September 2009 there was an inevitable temporary dip in the numbers of women attending for screening. This was to be expected as women, smertakers and the programme adjusted to the new system of invitation. From January 2010 the level of monthly screening steadily increased.

As the programme entered its third year of operation, it was timely to introduce the final phase of encouraging client participation – direct programme entry by smertakers.

Direct programme entry was introduced on 1 September 2010 as a means of recruiting new eligible women, in particular from minority populations and 'harder to reach' women into the programme. Registered CervicalCheck smertakers can facilitate a smear test for new eligible women (aged 25-60) without the woman having a letter of invitation. A new online facility through www.cervicalcheck.ie enables smertakers to check a woman's eligibility before taking the test.

CervicalCheck continues to operate a vigorous, organised call, re-call system in tandem with direct programme entry by smertakers.

Screening Age Eligibility

CervicalCheck offers free smear tests to women aged 25 to 60. There are a number of exemptions to the screening age range including:

- Women over the age of 60 who have never had a smear test
- Women under the age of 25 who have attended a colposcopy service and require follow-up
- Women who are post organ transplant
- Women who have Human Immunodeficiency Virus (HIV)
- Women who are on renal dialysis

When CervicalCheck was introduced there was a call from some members of the public and medical community to reduce the screening age from 25 to 20. Based on evidence to date, there is no additional public health benefit in starting screening below the age of 25. In women under the age of 25, minor changes in the cells of the cervix are common but invasive cancer is extremely rare.

In the UK, the independent Advisory Committee on Cervical Screening undertook a comprehensive review in May 2009 on the appropriateness of 25 as the starting age. This meeting was attended by the NCSS. The Advisory Committee recommended that there should be no change to the screening commencement age of 25 years.

In July 2010 the Northern Ireland Department of Health and Social Services and Public Safety announced its intention to raise the cervical screening entry age from 20 to 25.

Population-based screening in women under the age of 25 may lead to many women receiving unnecessary treatment for lesions that would never have developed into invasive cancer.

The women CervicalCheck invites for screening are the main priority of the programme. While some of the operational decisions made by the NCSS in shaping CervicalCheck have drawn opposition, I am absolutely confident that each decision, however challenging, has benefited the women who take part in the programme.

Each challenge encountered in the establishment and implementation of CervicalCheck has been successfully overcome and today the programme operates in line with the highest international standards.

As CervicalCheck enters the third year of its first screening round, I am immensely proud of the performance of the programme which is exceeding all expectations.

The positive predictive value (PPV) of referral for colposcopy measures the proportion of women with positive smear test results who are correctly diagnosed. It is one of the most important diagnostic measures of a screening programme as it reflects the probability that a positive test has detected the underlying condition being tested. During the reporting period CervicalCheck recorded in excess of 86 per cent PPV for high grade abnormalities and in excess of 95 per cent for low grade abnormalities.

The combination of high levels of screening, quick delivery of results, high PPV performance and quality assured colposcopy services reflects the effectiveness of the programme in detecting and treating abnormalities on the cells of the cervix in women who are generally without symptoms.

I wish to thank the Minister for Health and Children, Ms Mary Harney, TD and her colleagues in the Department of Health and Children for their commitment to the establishment of the CervicalCheck programme, particularly during times of fiscal restraint.

I would also like to pay tribute to Dr Marian O'Reilly, Director of the former Irish Cervical Screening Programme (ICSP) and Head of Cervical Screening and Deputy Programme Manager John Gleeson. Together with their team, they have been dedicated to the expansion of population-based cervical screening to women on a national level, to ensure every woman living in Ireland aged 25 to 60 had access to fully quality assured cervical screening.

On 31 March the Board of the NCSS was dissolved. On 1 April 2010 the National Cancer Screening Service joined the National Cancer Control Programme, part of the Health Service Executive (HSE). I wish to express my gratitude to the former Chairperson Dr Sheelah Ryan for her role in shaping and establishing CervicalCheck.

I wish to acknowledge the invaluable contribution of each and every member of the National Cancer Screening Service and the CervicalCheck team based in Limerick who work daily to deliver and maintain a programme that is making a very real difference to women's lives. In particular I would like to acknowledge the contribution of each member of the NCSS Quality Assurance Committee and Groups, the Cervical Executive Management Team and the Cervical Operations Group.

Women living in Ireland deserve a cervical screening programme that is fully quality assured at every step of the screening process, that provides smear test results without lengthy delays and that can offer timely access to a standardised system of colposcopy care for those women who require it. CervicalCheck could not have achieved the levels of success it has to date without the support of the medical community. I wish to take this opportunity to thank all involved to date in developing and delivering a successful programme.

CervicalCheck is a cancer screening programme of which all involved can and should be proud. Regular smear tests at recommended intervals can prevent cervical cancer. Some women will be offered up to 11 routine smear tests and will remain part of the CervicalCheck programme for 35 years and we must continually focus on maintaining a high uptake of cervical screening in the years ahead.

The most important goal for CervicalCheck is to ensure that all women who participate in the programme can remain confident in the service it delivers and reassured by the quality of care they receive. CervicalCheck has one aim – to reduce the incidence and mortality from cervical cancer among every woman aged 25 to 60. By continuing to work together, I have no doubt that this aim will be achieved.



Tony O'Brien
Director
National Cancer Screening Service
Autumn 2010

Message from the Head of Cervical Screening



In Ireland there are on average 180 cases of cervical cancer per year and 73 deaths. The average age at diagnosis is 46 years. The average age at death is 56 years. Cervical screening is a preventative health measure as smear tests can detect early changes in the cells of the cervix. The earlier cell changes are found the easier they are to treat.

CervicalCheck became available to over 1.1 million women aged 25 to 60 on 1 September 2008.

Free smear tests are provided to women aged 25 to 44 every three years. Following receipt of two consecutive 'no abnormality detected' results at three yearly intervals, women aged 45 to 60 will be screened every five years.

A woman can choose to have her smear test free of charge with any registered smearer, in any location of her choice, including GP practices, Family Planning, Women's Health and Well Woman Clinics.

Quality assurance is the foundation on which a successful programme is built. To achieve maximum public health benefit from a population-based cervical cancer screening programme, every aspect of the service delivered to women must be fully quality assured. In January 2010 the National Cancer Screening Service published its 'Guidelines for Quality Assurance in Cervical Screening'. The guidelines are the result of a collaborative process undertaken between representatives of each step of the cervical screening process – Programme Administration, Primary Care, Cytopathology, Colposcopy and Histopathology.

For a screening programme to be effective, it is essential that there is high uptake among the cohort of women invited for screening. CervicalCheck has set an ambitious target of 80 per cent uptake by the end of the second round of screening in August 2014.

From 1 September 2008 to 31 August 2009 CervicalCheck provided free smear tests to 284,833 women. Over 11,000 women were referred to colposcopy for further investigation.

The majority of the 284,833 women screened were in the younger age groups with numbers falling with increasing age. The highest level of uptake was among women aged 25 to 29, representing 20.8 per cent of all women screened. The second highest level was among women aged 30 to 34, representing 19.3 per cent of all women screened. The lowest level of uptake was among women aged 55 to 60, representing 6.8 per cent of all women screened. The programme will put increased emphasis on encouraging women in this age group to participate in screening.



Dr Marian O'Reilly, Head of Cervical Screening

The CervicalCheck Smearer Training Unit co-ordinates and delivers education and training in smearing. Less than one per cent (0.5%) of smear tests taken during the reporting period recorded a result that was unsatisfactory which meant the test needed to be repeated.

Almost 85 per cent of satisfactory smear test results in the period were negative or normal. Of the remainder, 13.9 per cent showed low grade abnormalities and 1.4 per cent showed high grade abnormalities. These women received the appropriate treatment at a CervicalCheck colposcopy service and will receive the necessary follow-up required.

While the purpose of cervical screening is to detect changes on the cells of the cervix before they become cancerous, 100 women were diagnosed with cervical cancer during the reporting period.

I am delighted that almost 285,000 women were provided with a free smear test by CervicalCheck during its first year of operation. I pay tribute to the smearer community – all registered GPs, practice nurses and medical practitioners – for their participation, promotion and support of the programme.

For a screening programme to be effective in its goal of reducing the incidence and mortality from cervical cancer it is essential that women attend for regular screening when invited. Cervical cancer is a preventable disease and I look forward in the years ahead to seeing a significant and real reduction in the morbidity and mortality from cervical cancer in Ireland.

A handwritten signature in black ink that reads "Marian O'Reilly". The signature is written in a cursive, flowing style.

Dr Marian O'Reilly
Head of Cervical Screening
National Cancer Screening Service
Autumn 2010

Message from the Clinical Director, Colposcopy



It is essential that cervical screening is offered in an organised manner. Women must be screened regularly, every three to five years, to ensure that population-based screening can have maximum impact on the incidence and mortality from cervical cancer in women in Ireland.

The CervicalCheck programme is centred on meeting the needs of eligible women by ensuring equal access and a quality assured service to all women aged 25 to 60. The women the programme invites for screening are its priority.

No screening test is 100 per cent accurate so we must ensure that every aspect of the cervical screening service delivered to women in Ireland is of the highest possible standard.

A smear test is not a diagnostic test. It is not designed to detect a cervical cancer. The purpose of a smear test is to detect changes in the cells of the cervix. Over time, if left undetected and untreated, such cell changes can become cancerous.

Colposcopy services play a key role in cervical screening by ensuring optimal management of women with smear test detected abnormalities through accurate diagnosis and effective treatment. The first two years of operation have seen significant advances made in the delivery of colposcopy services.

Additional resources were put in place by the NCSS to establish multidisciplinary teams for colposcopy services. The implementation of defined processes has delivered increased capacity and significant improvements in the quality of the service offered to women.

An infrastructure was developed to enable the effective audit of performance against the standards set for colposcopy services as part of the CervicalCheck programme. Information and data was collated centrally and analysed to produce the results presented in this report.

Web based multidisciplinary clinicopathological (CPC) meetings were established to facilitate the real time review of cytological, colposcopic and histological outcomes of selected women.

Significant improvements were achieved despite unprecedented demands placed on colposcopy services in early 2009 due to a heightened awareness of the importance of cervical screening among women.



Dr Gráinne Flannelly, Clinical Director, Colposcopy

The purpose of cervical screening is the detection and removal of abnormalities in the cells of the cervix before they become cancerous. The increased capacity created by the NCSS in colposcopy services has considerably increased the number of high grade diseases detected during the reporting period.

The process of improving colposcopy services in Ireland is ongoing and I look forward to seeing the benefits of continued improvements for those women who require these services. While waiting times for colposcopy at some services are still in excess of NCSS guidelines, it is the priority of the programme to improve performance to within the standards set by the programme at all locations by the end of the third screening year.

I wish to acknowledge the hard work and dedication of all those who have contributed to improving colposcopy services in Ireland, including the teams at each of the colposcopy services providing support to the CervicalCheck programme, management teams at each of the host hospitals, the Health Service Executive (HSE) Integrated Services and the staff of the National Cancer Screening Service.

A handwritten signature in black ink that reads "Gráinne Flannelly". The signature is written in a cursive, flowing style.

Dr Gráinne Flannelly
Clinical Director, Colposcopy
CervicalCheck – The National Cervical Screening Programme
Autumn 2010

Programme Overview



Background

The NCSS was responsible for establishing and implementing CervicalCheck – Ireland’s first national cervical screening programme for the over 1.1 million eligible women living in Ireland aged 25 to 60 years.

The Irish Cervical Screening Programme (ICSP) Phase One had been in operation in the Mid-West in Counties Limerick, Clare and north Tipperary since 2000. Following the establishment of the National Cancer Screening Service (NCSS) in January 2007, governance of the ICSP was transferred to the Board of the NCSS and directed by the Cervical Executive Management Team.

The primary objective of cervical screening is to reduce the incidence and mortality from cervical cancer by detecting cell changes before they become cancerous. In Ireland there are on average 180 new cases of cervical cancer diagnosed per year. Half of all new cases are in women aged under 46 years, and the average age at death from cervical cancer is 56.

The NCSS launched CervicalCheck – The National Cervical Screening Programme on 1 September 2008. Efforts and preparations were made to ensure that a quality assured, organised, cost effective programme be made available free of charge to all eligible women living in Ireland.

A contract for the provision of smearing services was developed and published in draft format in January 2008 inviting comment and feedback from potential service providers including the Irish College of General Practitioners, the Irish Medical Organisation, women’s interest groups, women’s health groups and individual GPs and medical practitioners. On completion of this consultation process and discussion with potential smear takers, the NCSS published and made available a final contract for the provision of smearing services as part of the national programme.

During October and November 2007, the NCSS also carried out consultations with a variety of interested stakeholders providing them with an opportunity to contribute views regarding a national programme. Today there are over 4,150 smear takers in over 1,400 locations. This invaluable support from the primary care community has enabled CervicalCheck to be a truly national programme.

The key objective of CervicalCheck is to deliver a quality assured screening service to women living in Ireland in line with best international practice.

Members of the Cervical Executive Management Team



Majella Byrne,
Deputy Director,
NCSS



Pat Cafferty,
Planning and Risk Manager,
NCSS



Sheila M Caulfield,
Head of Communications and
Stakeholder Relations, NCSS



Dr Marian O'Reilly,
Head of Cervical Screening,
CervicalCheck



John Gleeson,
Deputy Programme Manager,
CervicalCheck



Dr Gráinne Flannelly,
Clinical Director, Colposcopy,
CervicalCheck



Tony O'Brien, Chair
Director NCSS
Deputy Director of NCCP



Dr Therese Mooney,
Head of PEU, NCSS



Dr Alan Smith,
Medical Director, Screening Policy,
NCSS

Secretariat: Sheila Corcoran Baxter, Shane Neary, Eileen O'Connor



Chairs and Members of QA Committees and Staff

Cessation of Opportunistic Screening

Smear tests performed as part of CervicalCheck should replace those previously performed opportunistically and at times, inappropriately. Screening is for women who are not experiencing symptoms. Despite the best efforts of the medical community, the opportunistic cervical screening carried out prior to the introduction of CervicalCheck had no population impact in terms of reducing cervical cancer mortality in Ireland.

Quality Assurance

To achieve maximum public health benefit from a population-based cervical cancer screening programme, every aspect of the service delivered to women must be fully quality assured. Quality assurance is the foundation on which a successful programme is built. From initial invitation, through screening and treatment every individual involved in each step of the screening process must adhere to the highest standards set by the programme.

In June 2007 the NCSS established a Quality Assurance (QA) Committee in preparation for the introduction of CervicalCheck. The role of the Committee was to review

international standards; recommend best practice; monitor and evaluate achievement of the recommended standards and monitor and support adherence to standards by service providers. The QA Committee reports to the Director of the National Cancer Screening Service who has overall responsibility for quality assurance in the programme.

Three speciality groups, Smear taker/Primary Care Group, Cytology/Histology Group and Colposcopy/Gynae Oncology Group support the QA Committee and link with international bodies and professional advisers. The QA Committee is independently chaired by Mr Simon Kelly, former Chief Executive of the National Standards Authority of Ireland.

In January 2010 the National Cancer Screening Service (NCSS) published its 'Guidelines for Quality Assurance in Cervical Screening'. The guidelines represent a collaborative process undertaken between representatives of each step of cervical screening to ensure adherence to quality assurance across all aspects of the programme.

The NCSS convened an international expert peer review of the proposed quality assurance standards for CervicalCheck in August 2009. The published guidelines represent a consensus view from the experts involved.



Members of the Cervical Screening International Peer Evaluation Group

Screening Intervals

In line with best international practice, screening is provided every three years to women aged 25 to 44 and then, once a woman has had two consecutive 'no abnormality detected' results, every five years between the ages of 45 and 60. The vast majority of abnormalities detected will be precancerous changes, not cervical cancer.

Screening Age Rationale

Based on evidence to date, there is no additional public health benefit in starting screening below the age of 25. Screening in women under the age of 25 may lead to many women receiving unnecessary treatment for lesions that would never have developed into invasive cancer.

Certain exemptions apply where some women over the age of 60 and under the age of 25 are considered eligible. Such exemptions may include women of any age who are post colposcopy or who have had a previous abnormal smear test result and are within the recommended follow-up period, women over the age of 60 who have never had a smear test and women aged 20 and over who are on renal dialysis, have Human Immunodeficiency Virus (HIV) or are post organ transplant.

Encouraging Participation in Screening among Eligible Women

The aim of the first phase of encouraging women to participate in the screening programme began with the launch of CervicalCheck on 1 September 2008. During the first 12 months of operation, CervicalCheck offered eligible women open access to screening to meet what was anticipated to be an unprecedented demand for cervical screening services.

The second phase of client participation was introduced on 1 September 2009 with the programme moving to an organised call, re-call system of invitation in line with best international practice.

The first two phases of promoting participation in CervicalCheck proved effective in encouraging women to attend for a free smear test. Initially the move to an organised call, re-call system of invitation in 2009 was met with opposition from some members of the medical community.

However, as proven internationally, it was necessary to introduce and establish a call, re-call system of invitation to ensure an organised and efficient approach to screening.

As the programme entered its third year of operation, it was timely to introduce the final phase of encouraging client participation – direct programme entry by smertakers.

Direct programme entry was introduced on 1 September 2010 as a means of recruiting new eligible women, in particular from minority populations and 'harder-to-reach' women, into the programme in support of the aim of achieving 80 per cent coverage of the eligible population.

From 1 September 2010, registered CervicalCheck smertakers were able to facilitate a smear test for new eligible women (aged 25-60) without the woman having a letter of invitation. A new online facility through www.cervicalcheck.ie enables smertakers to check a woman's eligibility before taking the test.

CervicalCheck continues to operate an organised call, re-call system in tandem with direct programme entry by smertakers.

Uptake

Since its launch the response from women nationwide to CervicalCheck has been exceptional, with uptake remaining consistently high. During the first year of screening (1 September 2008 to 31 August 2009), CervicalCheck provided free smear tests to 284,833 women. In total, 285,012 smear tests were performed.

Of the 285,012 smear test results, less than one per cent (0.5%) recorded unsatisfactory results, meaning the test had to be repeated. Almost 85 per cent of satisfactory smear test results recorded during the reporting period were negative or normal. Of the remainder, 13.9 per cent showed low grade abnormalities and 1.4 per cent showed high grade abnormalities. Of all the smear tests results received in the reporting period, 11,112 resulted in a woman being referred to colposcopy.



Smertaker Training Unit Team



Smertaker Training Unit and Clinical Trainers

Smertaker Training Unit

A Smertaker Training Unit with responsibility for the co-ordination and delivery of all smertaker educational initiatives was established.

The unit together with its team of smertaker training co-ordinators, clinical trainers and GP Advisor facilitates learning through the delivery of accredited smertaker training modules in partnership with the Irish College of General Practitioners, the Royal College of Surgeons in Ireland, and the National University of Ireland, Galway. The unit also facilitates learning through the organisation of clinical updates and the development of related educational resources including a Guide for Smertakers, A Simple Guide to the Language Used in Cervical Screening and a training DVD.

Cytology Arrangements

A procurement process for the provision of cytology laboratory services was undertaken in December 2007. The NCSS was not obliged to operate a public procurement process however chose this route to ensure transparency and fairness in securing a quality assured cytology laboratory suitable for a national cervical screening programme.

The objective of undertaking a public procurement process was to deliver the best quality service for women in Ireland. The rigorous procurement process was conducted in two stages and in order to qualify for the tender evaluation stage, each applicant was required to meet certain criteria, namely:

- Hold third party accreditation from a recognised accreditation body to International Standard ISO17025 or ISO17011
- Capacity to screen a minimum of 25,000 cervical smear samples per annum at each proposed laboratory
- Capacity and ability to process smear tests within a 10 day turnaround in order to facilitate the delivery of results to women within four weeks of their smear test

Each submission was considered equally against a range of quality-led criteria. On completion of the procurement process, Quest Diagnostics Inc. was appointed the provider of cytology laboratory services to CervicalCheck. The original contract was awarded for two years (until 31 July 2010), with an option to extend for a further two years or return to market.

Due to the change in economic and market conditions since the original tender process was undertaken, the NCSS chose to return to market and conduct a further public procurement process.

Similar to the criteria in the first cytology tender process carried out in 2007-2008, each applicant was required to meet certain quality criteria including the holding of third party accreditation, the capacity to screen a minimum of 25,000 cervical smear samples per annum and the capacity and ability to process smear tests within a 10 day turnaround to facilitate the continued delivery of results to women within four weeks of having their smear test.

As a public body the NCSS has a duty to ensure it continues to receive best value for money for all purchases of goods and services. This process ensured that value for the Irish taxpayer is maximised while maintaining a

competitive environment and continuing to provide women in Ireland with a cervical cancer screening programme that operates in line with the highest international standards.

On completion of the procurement process, Clinical Pathology Laboratories Ltd. (CPL) through its company Medlab Pathology was awarded a contract to provide cytology laboratory services for CervicalCheck. A condition of the contract is that a cytology laboratory will be established in Ireland to analyse CervicalCheck smear tests within 18 months of commencement of the contract. In addition, the existing contract with Quest Diagnostics Inc. was extended for a further two years.

Cervical Screening Co-ordinators

A population-based cervical screening programme encompasses three key elements – smertaking, cytology services and colposcopy services.

Smertaking is generally carried out in the primary care setting. CervicalCheck appointed a Smertaker Co-ordinator to liaise with the in excess of 4,150 registered smertakers on behalf of the programme. Her role is to promote best practice in cervical screening, identify and resolve smertaking performance issues, assist in the monitoring and compliance of contracts and provide support and information to all registered smertakers.

A Colposcopy Co-ordinator was appointed to facilitate communication between the CervicalCheck programme, the 15 colposcopy services that provide support to the programme, the Health Service Executive (HSE) Integrated Services Directorate and various other stakeholders. In addition she provides ongoing communication and

programme updates. A focus of the role is to ensure compliance with the Service Level Agreement (SLA) to maintain the high level of quality assurance required in the delivery of colposcopy services for the women of Ireland.



Cervical Screening Co-ordinators

All smear tests taken are sent to a cytology laboratory for analysis. A Laboratory Co-ordinator was appointed to liaise with and co-ordinate cytology laboratory services provided to the programme. In addition, she provides support to laboratory staff and monitors adherence to laboratory quality standards, regulations and practices.

The three co-ordinators work closely together to maximise operational effectiveness and ensure women receive a high quality, professional service.

Colposcopy Services

The majority of women who have a CervicalCheck smear test will have a reassuringly normal result however, up to five per cent of all women screened will receive a result that requires further investigation.

Women who have changes in the cells of their cervix detected by smear test are referred to a colposcopy service. Colposcopy services as part of CervicalCheck are delivered through a multidisciplinary team approach and provide the facilities for diagnosis, treatment and follow-up of women with an abnormal smear test result.

The aim of colposcopy is to reduce the risk of a woman developing cervical cancer and return her to normal smear test screening as part of the CervicalCheck programme.

Colposcopy services are an integral part of a population based screening programme. Between approximately two and five per cent of all women screened will require access to a colposcopy service.

The introduction of CervicalCheck provided an opportunity to focus on the development and organisation of colposcopy services in Ireland.

In December 2007 members of the NCSS Colposcopy/Gynae Oncology Group arranged to visit colposcopy services nationwide. The purpose of the visits was to analyse and review current practices and to consider ways of achieving a standard of excellence in those clinics which aspired to become part of the national programme.

This service-by-service analysis examined facilities, staffing, systems management, information management, information technology and governance. An assessment report was provided following each visit and was agreed by the local service providers and the NCSS Colposcopy/Gynae Oncology Group.

The result of the assessment showed that existing public services were at different stages of operational development and accordingly, some services were more prepared to meet the needs of CervicalCheck.

Fifteen services nationwide were selected to provide colposcopy support to the programme. These services are based in the Adelaide & Meath Hospital, Dublin Incorporating the National Children's Hospital, Tallaght; St Finbarr's Hospital, Cork; The Coombe Women and Infants University Hospital, Dublin; Louth County Hospital, University College Hospital Galway; Kerry General Hospital, Letterkenny General Hospital, Limerick Regional Maternity Hospital, Mayo General Hospital, The National Maternity Hospital, Dublin; The Rotunda Hospital, Dublin; Sligo General Hospital, South Tipperary General Hospital, Waterford Regional Hospital and Wexford General Hospital.

Whether these locations continue to provide colposcopy services into the future will be based on compliance with Service Level Agreements (SLAs) that will govern the relationship between the NCSS and colposcopy service providers.

The NCSS is confident that adequate provision of service is available for those women (2-5%) who require access to a colposcopy service. The NCSS has supported the development of services in each location. The overall configuration of services is likely to evolve over time and as the programme develops.

The NCSS is responsible for the monitoring and audit of colposcopy services to ensure the quality assured standards (as outlined in the NCSS 'Guidelines to Quality Assurance in Cervical Screening') are adhered to.

During 2009 a computerised management system was implemented by the NCSS Information and Communications Technology team (ICT) with each of the 15 colposcopy services, allowing a bilateral exchange of information.

Measurable standards have been developed in conjunction with the Programme Evaluation Unit of the NCSS to enable audit. It is anticipated that the colposcopy management systems will be updated in 2010 to enable local reporting against these standards.

Web-based multidisciplinary clinicopathological (CPC) meetings have been established in many clinics. These meetings use a web-based meeting resource and digitised cytopathology, colposcopy and histopathology images to enable real time discussions on defined cases between cytopathologists, histopathologists and clinicians.

By year end 2009, all colposcopy services provided as part of the CervicalCheck programme were delivered by British Society for Colposcopy and Cervical Pathology (BSCCP) certified colposcopists or by trainee colposcopists under the supervision of a BSCCP certified colposcopist. Each service now has a defined team led by a clinical lead with responsibility for the clinical governance of the service.

The target for 2010 is to increase colposcopy service capacity from 10,000 new referrals in 2008 to over 16,500 new referrals in 2010. In tandem with this target, the NCSS is focussed on bringing waiting times for colposcopy appointments to within the standards set by the CervicalCheck Women's Charter at all 15 colposcopy services.

Histopathology

Biopsy samples taken at colposcopy are analysed by histopathologists. Histopathology provides the final diagnosis of cervical neoplasia and is the basis on which treatment is planned. Histopathology is required to diagnose the degree of abnormality detected in women with persistent low grade abnormalities including HPV lesions, as well as high grade lesions. Histopathology may also detect glandular abnormalities, high grade cervical intraepithelial neoplasia (CIN) or invasive cancer.

The introduction of CervicalCheck and resulting high level of cervical screening has increased the demand on histopathology services at some hospitals. The HSE has established a Histopathology Working Group with representation from CervicalCheck and the Faculty of Pathology, Royal College of Physicians of Ireland to evaluate the situation and make recommendations for improvements.

The NCSS aims to ensure that histopathology services delivered as part of CervicalCheck are provided by accredited laboratories adhering to agreed quality assurance standards. The necessary resources required will be reallocated to ensure each participating laboratory can meet the quality assurance standards required by the programme.

Public Information Campaign

The National Cancer Screening Service launched a national CervicalCheck public information campaign led by the Communications Department and encompassing television, outdoor, convenience and print advertising in February 2009.

The aim of the campaign was to raise awareness of the CervicalCheck brand, the availability of the service to eligible women aged 25 to 60 and to highlight the recommended screening intervals.

The creative concept demonstrated the subtle exterior changes a woman's appearance will experience over time, as she ages from 25 to 60. This exterior change reflects the potential inner changes a woman's body may be experiencing if there are precancerous cells present.

Targeting women aged 25 to 60, the TV advertisement aired in rotation across RTE 1, RTE 2, TV3, Living, Sky, MTV, E4, Paramount and 3e. Outdoor advertising was carried out nationally and incorporated a range of advertisement posters (large 48 sheet billboards, 6 sheets at bus shelters and city lights posters on bins and in supermarkets) and advertisements in washrooms.



The CervicalCheck TV creative idea was commended with two advertising awards at the prestigious Shark Awards 2009, picking up a Silver Shark in the Irish TV category and a Gold Shark in the International Craft category. The advert was the only Irish submission to receive recognition at the Global Awards ceremony in the US. The Global Awards are dedicated to the best in worldwide healthcare communications and the CervicalCheck advert was awarded a Finalist Certificate for Television.

A CervicalCheck website (www.cervicalcheck.ie) was developed to provide information to women about the programme, cervical screening and having a smear test. In addition, the site contains a list and contact details for all registered smertakers. There is a dedicated section for health professionals containing evidence papers, information materials, registration information and details on the Smertaker Training Unit.

In addition a suite of information leaflets for women was developed in conjunction with the National Adult Literacy Agency (NALA) and made available through all registered smertakers.

Crystal Clear Award

The CervicalCheck programme was shortlisted in the Best Health Promotion Project category of the Crystal Clear Health Literacy Awards in spring 2010 for promoting awareness of the programme. The award recognised the importance of developing materials with simple, sensitive and easy to understand language to help address barriers to screening.

Communications and Screening Promotion

The NCSS implements an extensive communications approach aimed at informing, educating and encouraging women to participate in the CervicalCheck programme. This approach includes public relations, advertising and screening promotion.

It is a priority for the NCSS to ensure that its programmes are accessible to all eligible women in the population. Some women, particularly those considered 'harder to reach' experience barriers that hinder their access to screening services for varied reasons including fear, embarrassment, anxiety, intellectual and physical disabilities, literacy difficulties and language barriers.



The NCSS has a designated team of Screening Promotion Officers who operate on a national basis. The overarching objective of the screening promotion strategic framework is to maintain and further develop an equitable, quality assured, innovative and women centred approach to increasing awareness and uptake of the CervicalCheck programme, particularly among 'harder to reach' or marginalised women.

The team has implemented specific initiatives based on international evidence and learnings from other programmes to reduce barriers and encourage eligible women to participate in the CervicalCheck programme. The team worked closely with groups as varied as regionally-based partnerships, RAPID co-ordinators, community development projects, the social inclusion section of the HSE, family resource centres, women's networks, traveller primary healthcare projects, community network groups, charities and representative groups for asylum seekers and refugees, women with special needs and migrant women's groups.

Such collaboration provides invaluable platforms for the delivery of focused screening promotion and peer education to women in general, and particularly to those considered marginalised and 'harder to reach'. In the mid west, a pilot cervical screening peer education training programme was developed for community development workers. This programme has proven successful in encouraging women to attend for cervical screening and the team is currently developing a similar programme on a national level.



European Cervical Cancer Prevention Week

The NCSS supported European Cervical Cancer Prevention Week (January 2009 and January 2010) by partnering with the Irish Family Planning Association (IFPA) to promote European Cervical Cancer Prevention Week in Ireland.

The Europe-wide initiative is organised by the European Cervical Cancer Association (ECCA) and aims to raise awareness of cervical cancer, how it can be prevented and the importance of having regular smear tests.

The Pearl of Wisdom is the international emblem of cervical cancer prevention. Twenty thousand pins were distributed together with information about CervicalCheck. The purpose of the campaign was to encourage discussion about cervical cancer and to remind women to make an appointment for a free smear test when they receive their letter of invitation from CervicalCheck.

In January 2010 the IFPA received a Pearl of Wisdom Award from the ECCA for its commitment to raising awareness about cervical cancer prevention in Ireland.

Consultation Process with Groups Representing 'Harder to Reach' / Marginalised Women

The NCSS has a statutory remit to implement special measures to promote participation in its screening programmes by marginalised or 'harder to reach' populations.

Recognising the unique knowledge base of community networks and smartakers, the NCSS invited submissions for participation in a consultation process to help develop initiatives for CervicalCheck to maximise and sustain uptake amongst these 'harder to reach' women.

Submissions were sought from interested parties and a workshop consultation process took place in March 2010. Information was sought on existing healthcare initiatives that are effective in reaching these populations, in addition to international models of best practice that could be adapted and implemented as part of BreastCheck, CervicalCheck and the future colorectal cancer screening programme.

Human Papilloma Virus

The NCSS has a remit to advise the Minister for Health and Children from time to time on health technologies, including vaccines. In 2007 the Minister requested the advice of the Board of the NCSS on the role of Human Papilloma Virus (HPV) vaccines in the prevention and control of cervical cancer.





NCSS Scientific Advisory Group on HPV Testing

On completion of its review, which included an NCSS requested Health Technology Assessment (HTA) undertaken by the Health Information and Quality Authority (HIQA), the Board of the NCSS recommended that the HPV vaccine has the potential to play an important long-term role in the prevention of cervical cancer and that a vaccination programme should be put in place.

However, HPV vaccines do not eliminate the need for a cervical cancer screening programme as currently available HPV vaccines do not offer protection against all types of HPV that cause cervical cancer. Screening will also be necessary to protect women who have not been vaccinated. In due course it is anticipated that the impact of HPV vaccination on the incidence of cervical cancer will result in changes to the operational structure of a population based cervical screening programme.

NCSS Scientific Advisory Group on HPV Testing

The NCSS established a Scientific Advisory Group on HPV Testing. Chaired by Professor Ciaran O'Neill, Economist and Professor of Health Technology Assessment, National University of Ireland Galway, the Group will evaluate appropriate HPV testing strategies that could be adopted and implemented by CervicalCheck.

Members of the Group represent experts in the fields of women's health, gynaecology, cancer epidemiology and histopathology. The Group's findings will inform the future direction of CervicalCheck.



CervicalCheck Staff

Programme Report



Introduction to the Statistics

CervicalCheck became available to women nationally on 1 September 2008. The figures reported in this section relate to the screening period 1 September 2008 to 31 August 2009. During this period the programme operated an open access system of screening where any eligible woman (aged 25-60) could arrange a smear test with a registered smearer of her choice, without a letter of invitation from CervicalCheck.

The response to the programme has been very positive with over 284,000 women attending for screening during the reporting period. When CervicalCheck has completed two full screening rounds (six years of operation) it will be possible to calculate the coverage of the programme.

Quality assurance underpins every aspect of the CervicalCheck programme. The programme's performance is measured against Key Performance Indicators (KPIs) as outlined in the NCSS 'Guidelines for Quality Assurance in Cervical Screening'. Many KPIs cannot be measured before the first round of screening (three years) has been completed. The programme has measured outcomes against many of the remaining KPIs. This is the first time many of these parameters have been reported on in an Irish context.

The first year of CervicalCheck saw 284,833 women receiving a cervical smear test. Most of these women were in the younger age groups with numbers falling with increasing age.

Table 1: Number of Women Screened by Age Group

| Age Group | Number of Women Screened | % |
|--------------|--------------------------|--------------|
| < 25* | 6,432 | 2.3 |
| 25-29 | 59,310 | 20.8 |
| 30-34 | 54,854 | 19.3 |
| 35-39 | 48,044 | 16.9 |
| 40-44 | 38,587 | 13.6 |
| 45-49 | 30,500 | 10.7 |
| 50-54 | 22,811 | 8.0 |
| 55-60 | 19,446 | 6.8 |
| ≥ 61* | 4,849 | 1.7 |
| Total | 284,833 | 100.0 |

* *Screening age range* – based on evidence to date, there is no additional public health benefit in starting screening below the age of 25. Screening in women under the age of 25 may lead to many women receiving unnecessary treatment for lesions that would never have developed into invasive cancer. Certain exemptions apply where some women over the age of 60 and under the age of 25 are considered eligible. Such exemptions may include women of any age who are post colposcopy, women over the age of 60 who have never had a smear test and women aged 20 and over who are on renal dialysis, have HIV infection, are post organ transplant or who have had a previous abnormal smear test result and are within the recommended follow-up period.

Table 2 shows the geographical spread of screening activity based on the location of the GP practice or clinic against the eligible population of each county*. The former Irish Cervical Screening Programme (ICSP) Phase One provided cervical screening to women living in Counties Limerick, Clare and north Tipperary from October 2000 to August 2008. Many women in these counties have availed of free smear tests prior to September 2008. Consequently

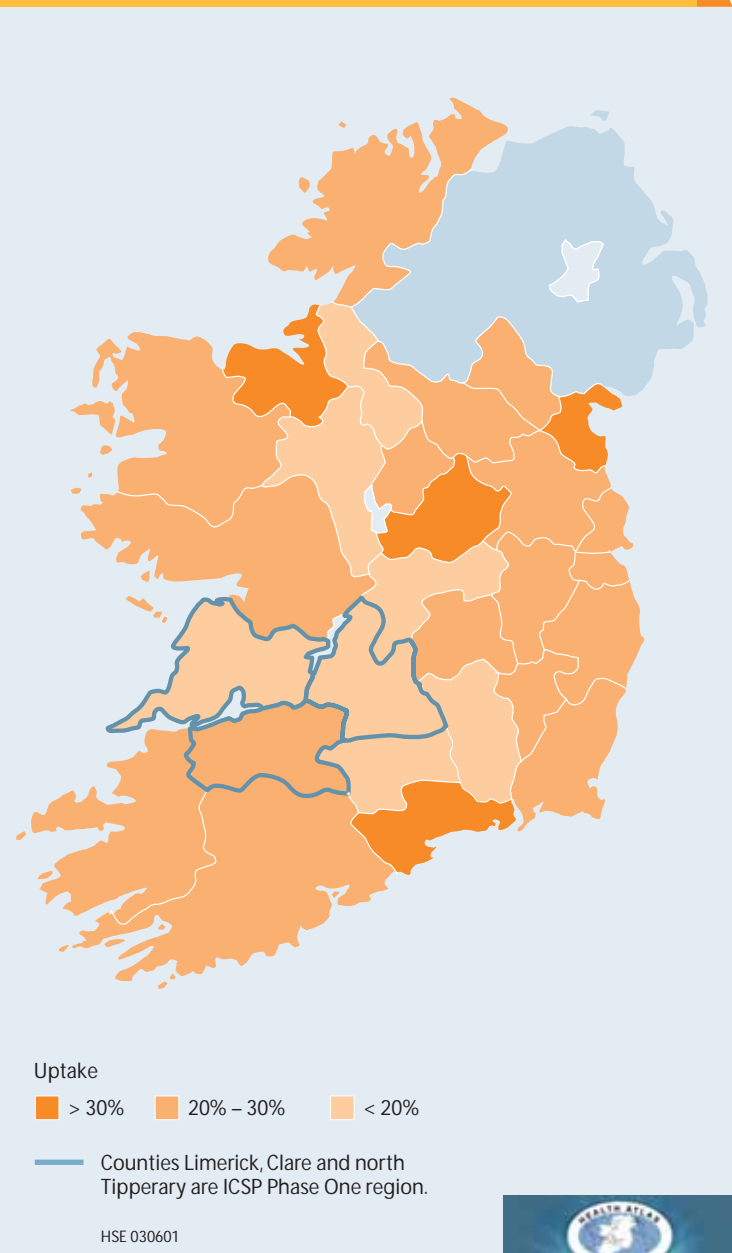
the numbers screened in these counties reflect the previous availability of organised screening.

The percentage of eligible population screened by county ranges from 12.6 per cent to 38.1 per cent. The average percentage of eligible population screened was 26 per cent per county.

Table 2: Percentage of Eligible Women Screened by Smartaker Location

| County | Eligible Population Screened (%) |
|-------------|----------------------------------|
| Carlow | 30.0 |
| Cavan | 25.8 |
| Cork | 28.2 |
| Donegal | 28.0 |
| Dublin | 25.0 |
| Galway | 28.0 |
| Kerry | 22.2 |
| Kildare | 20.8 |
| Kilkenny | 18.7 |
| Laois | 24.6 |
| Leitrim | 17.6 |
| Longford | 26.0 |
| Louth | 30.2 |
| Mayo | 26.1 |
| Meath | 20.4 |
| Monaghan | 21.0 |
| Offaly | 16.4 |
| Roscommon | 19.2 |
| Sligo | 31.2 |
| Waterford | 35.9 |
| Westmeath | 38.1 |
| Wexford | 24.6 |
| Wicklow | 22.4 |
| Clare** | 12.6 |
| Limerick** | 23.6 |
| Tipperary** | 19.8 |

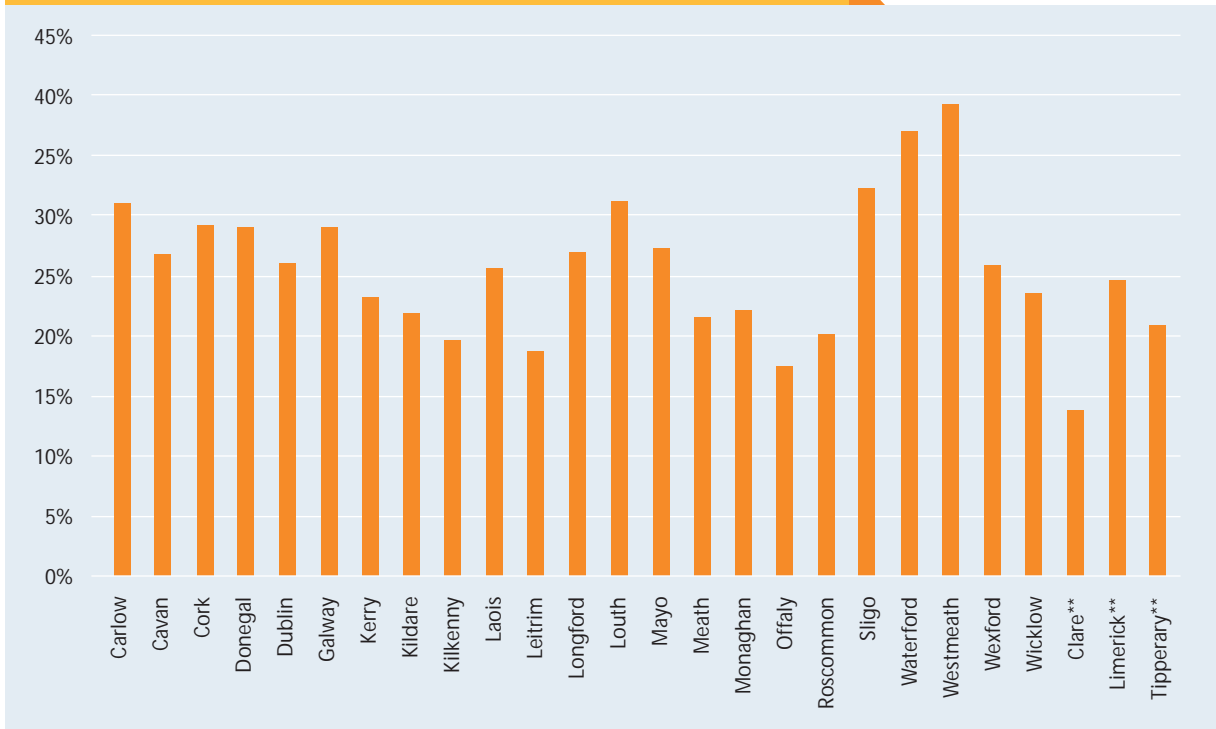
Figure 1: Map Showing Percentage of Eligible Women Screened by Smartaker Location (analysed using Health Atlas Ireland)*



* Population data based on Census 2006 numbers extrapolated to 2009

** ICSP Phase One region

Figure 2: Percentage of Eligible Women Screened by Smartaker Location



* Population data based on Census 2006 numbers extrapolated to 2009

** ICSP Phase One region

Most women (92.89%) had their CervicalCheck smear tests carried out in a primary care setting. Many women would already have been attending gynaecology or colposcopy services and would have been included in the CervicalCheck programme when they had a smear test at this visit.

Of those women who had their smear tests carried out in a primary care setting, 92.04% attended a GP practice. Less than eight per cent (7.96%) of women opted to have their smear test at a clinic other than a GP practice, such as a Family Planning, Women's Health or Well Woman Clinic.

Table 3: Percentage of Women Attending for a Smear Test by Clinic Type

| Primary Care Setting | | Colposcopy (%) | Gynaecology (%) | STI/GUM (%) | Total |
|----------------------|-------------|----------------|-----------------|-------------|-------|
| GP Practices (%) | Clinics (%) | | | | |
| 85.50 | 7.39 | 5.21 | 1.84 | 0.06 | 100% |

Laboratory Turnaround Time

One of the criteria for selection of a laboratory for the provision of cytology services was the capacity and ability to process smear tests within a 10 day turnaround to facilitate the provision of results to women within four weeks of having their smear test. Table 4 shows how the laboratories performed over the four quarters of the reporting period.

In early 2009 there was an unprecedented surge in the demand for smear tests. This coincided with the launch of a national CervicalCheck public awareness campaign, European Cervical Cancer Awareness Week and the death of reality TV star Jade Goody from cervical cancer.

This surge resulted in increased levels of awareness of cervical cancer and challenged the capacity of the laboratories to analyse samples in a timely manner.

Following consultation with the programme and co-operation with the laboratories the delay in turnaround time has been addressed and by the fourth quarter the percentage within target had returned to 97.5 per cent.

Overall for the reporting period 78.1 per cent of test results were received by the programme within two weeks and 92 per cent of test results were received within three weeks.

Adherence to CervicalCheck Women's Charter

The CervicalCheck Women's Charter (page 1) offers women the following commitment that 'results and any treatment recommendation will be provided... by the programme within four weeks'.

Table 5 shows that this was challenging to achieve in the first two quarters of the programme. However, in early 2009 steps were taken to improve this situation and steady improvements have been made throughout the year. By the end of August 2009 just over 74 per cent of women were receiving their result within four weeks and over 94 per cent received their result within six weeks of having their smear test taken.

CervicalCheck aims to achieve the target of providing results to over 90 per cent of women within four weeks by the end of the first screening round in August 2011.

Table 4: Laboratory Turnaround Time from Receipt of Sample at Laboratory to Results Returned to the Programme

| Time from Receipt of Sample to Results Returned to Programme | Percentage Within Target | | | | Overall |
|--|--------------------------|----------------------|----------------------|----------------------|----------|
| | Sep 08 - Nov 08 (Q1) | Dec 08 - Feb 09 (Q2) | Mar 09 - May 09 (Q3) | Jun 09 - Aug 09 (Q4) | |
| Within 2 Weeks | 99.7% | 80.2% | 59.4% | 97.5% | 78.1% |
| Within 3 Weeks | 99.9% | 89.5% | 86.6% | 99.7% | 92.0% |
| Total Number of Smear Tests Received | 21,446 | 54,922 | 69,209 | 78,240 | 223,817* |

* This refers to smear test notifications received at the laboratories between 1 September 2008 and 31 August 2009

Table 5: Percentage of Women Sent Results of Smear Test within Four or Six Weeks of Smear Test Date

| Time from Smear Test to Letter Printed Date | Percentage Within Date Range | | | |
|---|------------------------------|--------------------------|--------------------------|--------------------------|
| | Sep 08 - Nov 08 (Q1) (%) | Dec 08 - Feb 09 (Q2) (%) | Mar 09 - May 09 (Q3) (%) | Jun 09 - Aug 09 (Q4) (%) |
| Within 4 Weeks | 7.9 | 16.1 | 35.0 | 74.1 |
| Within 6 Weeks | 23.5 | 32.8 | 87.6 | 94.3 |

Cytology

Cytology findings reported in Tables 6 and 7 are based on smear test results received by the programme in the period 1 September 2008 to 31 August 2009, rather than the smear test date. Of the 285,012 smear tests taken, less than one per cent (0.5%) recorded a result that was unsatisfactory leading to a repeat smear test (Table 6). The outcomes of the remaining 283,491 satisfactory smear tests are reported in Table 7.

Almost 85 per cent of satisfactory smear test results in the period were found to be negative or normal. Of the remainder, 13.9 per cent showed low grade abnormalities and 1.4 per cent showed high grade abnormalities i.e. moderate dyskaryosis, severe dyskaryosis, query invasive squamous carcinoma or query glandular neoplasia.

Of all smear tests carried out in the reporting period 11,112 resulted in a woman being referred to colposcopy. This corresponds to a referral rate of approximately 3.9 per cent for screened women based on cytology alone. However, a number of women were referred to colposcopy services from the programme based on clinical indications.

At this point it is not possible to determine the precise number although it is likely that the referral rate of 3.9 per cent is an underestimate with the true value likely to be over four per cent.

Table 6: Cytology Findings for Smear Test Results

| Smear Tests | | Cytology Findings | | | |
|---------------------------------------|---------|--------------------------------------|-----|----------------------------------|------|
| Total Number of Smear Tests Processed | | Unsatisfactory/Inadequate Smear Test | | Satisfactory/Adequate Smear Test | |
| | N | N | % | N | % |
| | 285,012 | 1,521 | 0.5 | 283,491 | 99.5 |

Table 7: Cytology Outcomes for Satisfactory Smear Tests Results

| Cytology Results | N | % |
|-----------------------------------|---------|--------|
| NAD (no abnormality detected) | 240,074 | 84.68 |
| ASC-US | 26,091 | 9.20 |
| AGUS | 1,923 | 0.68 |
| LSIL | 11,338 | 4.00 |
| HSIL (moderate) | 2,545 | 0.90 |
| HSIL (severe) | 1,460 | 0.52 |
| Query Invasive Squamous Carcinoma | 32 | 0.01 |
| AGC | 28 | 0.01 |
| Total Satisfactory Smear Tests | 283,491 | 100.00 |

Colposcopy

The majority of women screened will have a reassuringly normal result. However, further investigations are required in some women. Fifteen colposcopy services were selected to deliver diagnostic and treatment services to these women and a dedicated project team was established to ensure the delivery of a standardised quality assured level of care with timely access for all women.

Information is collected routinely at each service using a dedicated computerised colposcopy management system. Data was extracted from each service and collated centrally for the purpose of this analysis. The results are presented for the first year of the programme from 1 September 2008 to 31 August 2009.

During the reporting period three distinct groups of women attended the colposcopy services:

- Women who had been referred to colposcopy following a cervical smear test as part of the CervicalCheck programme and who consented to central transfer of their information as part of this process
- Women who were referred following a non-programme smear test or for clinical reasons and who opted into the CervicalCheck programme through a consent process at colposcopy
- Women who were referred following a non-programme smear test for whom no consent for transfer of clinical information was recorded

Appointment and demographic attendance data are presented for all women. Clinical and outcome information is presented for consented women only. As the programme matures it is anticipated that the vast majority of women attending colposcopy will have consented to CervicalCheck.

Appointments

From 1 September 2008 to 31 August 2009 28,925 colposcopy appointments were offered, of which 19,294 (66%) were attended. While the number of appointments cancelled and rescheduled was relatively high, the number of defaulted appointments was relatively low (7.6%) (Tables 8 and 9).

Of the 13,058 new referrals to colposcopy during the year, information on the age of the woman was available for 12,307. The mean age at referral was 33.6 years. The majority of women were aged between 25 and 45 years, with 7.5 per cent over 50 and 12.5 per cent aged less than 25 years.

According to the standards for colposcopy for the CervicalCheck programme the rate of defaulted appointments where no prior notice was given (DNA) should be kept to a minimum and maintained below 15 per cent. The recorded rate for the first year of the programme was 7.6 per cent which met this standard (Table 9).

The rate of DNA appointments is presented according to the type of visit and the age of the woman (Table 10). The DNA rate is higher for return visits than for first visits. In general, younger women were more likely to default than older women (Table 10).

Table 8: Outcome of Appointments at Colposcopy Services

| Reason | First Visits | | Follow-ups | | Total | |
|----------------------|--------------|-------|------------|-------|--------|-------|
| | N | % | N | % | N | % |
| Attended | 10,094 | 77.3 | 9,200 | 58.0 | 19,294 | 66.7 |
| Cancelled | 2,212 | 16.9 | 5,164 | 32.5 | 7,376 | 25.5 |
| DNA* | 727 | 5.6 | 1,459 | 9.2 | 2,186 | 7.6 |
| Outcome Not Recorded | 25 | 0.2 | 44 | 0.3 | 69 | 0.2 |
| Total | 13,058 | 100.0 | 15,867 | 100.0 | 28,925 | 100.0 |

* DNA refers to a woman who did not attend the appointment offered to her and who gave no advance notification of her non-attendance

Table 9: Rate of Defaulted Appointments for Colposcopy Measured Against Colposcopy Standards

| Performance Indicator | Achieved | Target |
|---|----------|--------|
| The percentage of women who do not attend and who do not notify the clinic should be maintained at a low level to maximise the efficiency of the clinic and to avoid the loss of women to follow-up | 7.6% | <15% |

Table 10: DNA Rates for Appointments Offered to Women by Age Group

| Age at First Offered Appointment | Number of First Appointments | First Visit DNA Rate (%) Offered | Number of Follow-up Appointments | Follow-up Visit DNA Rate (%) Offered |
|----------------------------------|------------------------------|----------------------------------|----------------------------------|--------------------------------------|
| < 25 Years | 1,539 | 7.5 | 2,111 | 12.9 |
| 25 - 29 Years | 3,512 | 6.0 | 4,532 | 8.9 |
| 30 - 34 Years | 2,713 | 5.1 | 3,329 | 9.4 |
| 35 - 39 Years | 1,708 | 3.9 | 1,946 | 7.5 |
| 40 - 44 Years | 1,192 | 5.2 | 1,333 | 8.3 |
| 45 - 49 Years | 723 | 3.2 | 802 | 7.6 |
| 50 - 54 Years | 499 | 3.8 | 438 | 6.2 |
| 55 - 60 Years | 282 | 2.8 | 251 | 4.8 |
| 61+ Years | 139 | 2.9 | 112 | 6.3 |

Reasons for Referral

Women were referred to colposcopy on the basis of an abnormal smear test result or for clinical reasons such as symptoms of abnormal vaginal bleeding or a suspicion of an anatomical abnormality of the cervix.

Of the 13,058 new referrals to colposcopy services, consent was available for the CervicalCheck programme for 9,856 women. The reasons for referral to colposcopy for these women are presented in Table 11. Figure 3 illustrates the reason for referral according to the month – the increased numbers of referrals during the latter half of the year result from increased levels of uptake of screening during these months.

An abnormal smear test result precipitated referral in 8,429 (85.5%) women and the presenting smear abnormalities

are presented in Table 12. Of these, 3,229 were referred following detection of a high-grade abnormality, 4,583 were referred following detection of a low-grade smear test result (LSIL or ASC-US) and 113 women were referred with persistently unsatisfactory or inadequate results. A smear test showing AGUS (borderline glandular abnormalities) was the reason for referral in 297 cases (3.5%). This represented a change in policy to one of direct referral following a single AGUS instead of the previous policy of repeat cytology in three months.

High grade referral smear tests include cytology outcomes of AGC, CIN grade not specified, HSIL and possible invasion (AGUS treated as high grade when considering waiting times). Low grade referral smears include cytology outcomes of ASC-US and LSIL.

Figure 3: The Reason for Referral to Colposcopy by Month

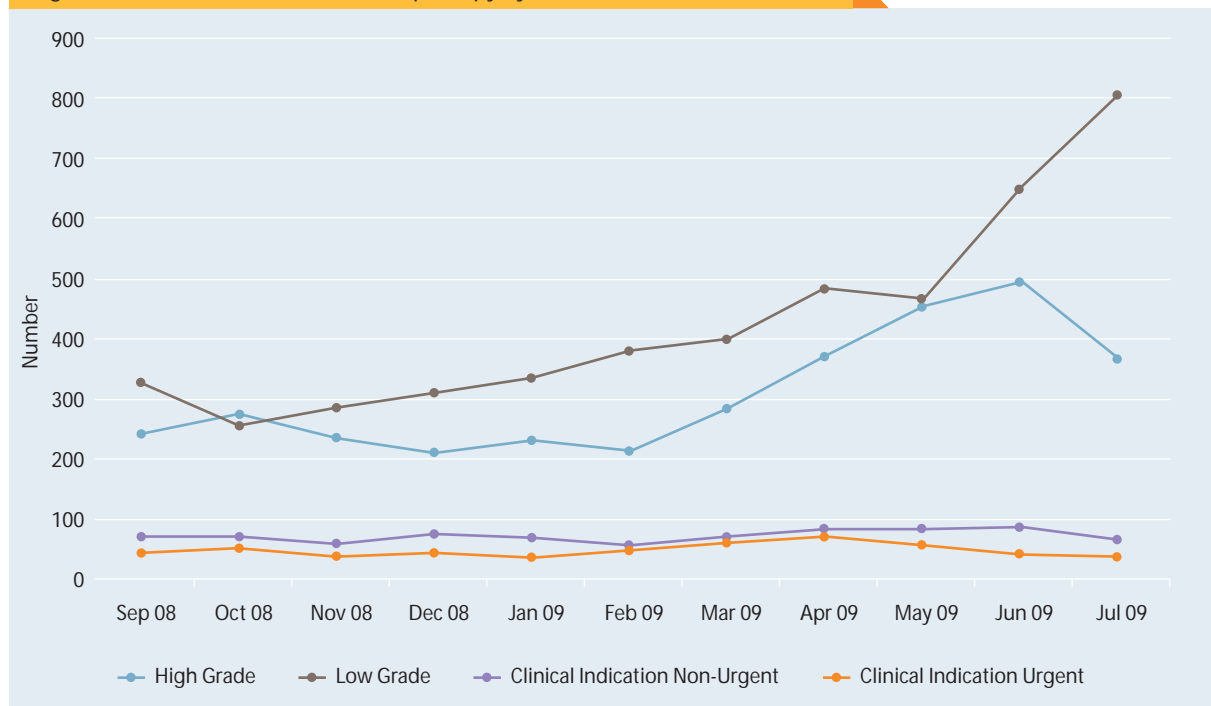


Table 11: Reasons for Referral to Colposcopy Services (consented women only)

| Referral Reason | New Referrals for Whom Consent is Available | |
|----------------------------------|---|-------|
| | N | % |
| Abnormal Smear Test Result | 8,429 | 85.5 |
| Clinical Indication – Non Urgent | 569 | 5.8 |
| Clinical Indication – Urgent | 480 | 4.9 |
| Reason not Recorded | 378 | 3.8 |
| Total | 9,856 | 100.0 |

Table 12: The Presenting Smear Abnormality in Women Referred to Colposcopy Services with an Abnormal Smear Test Result

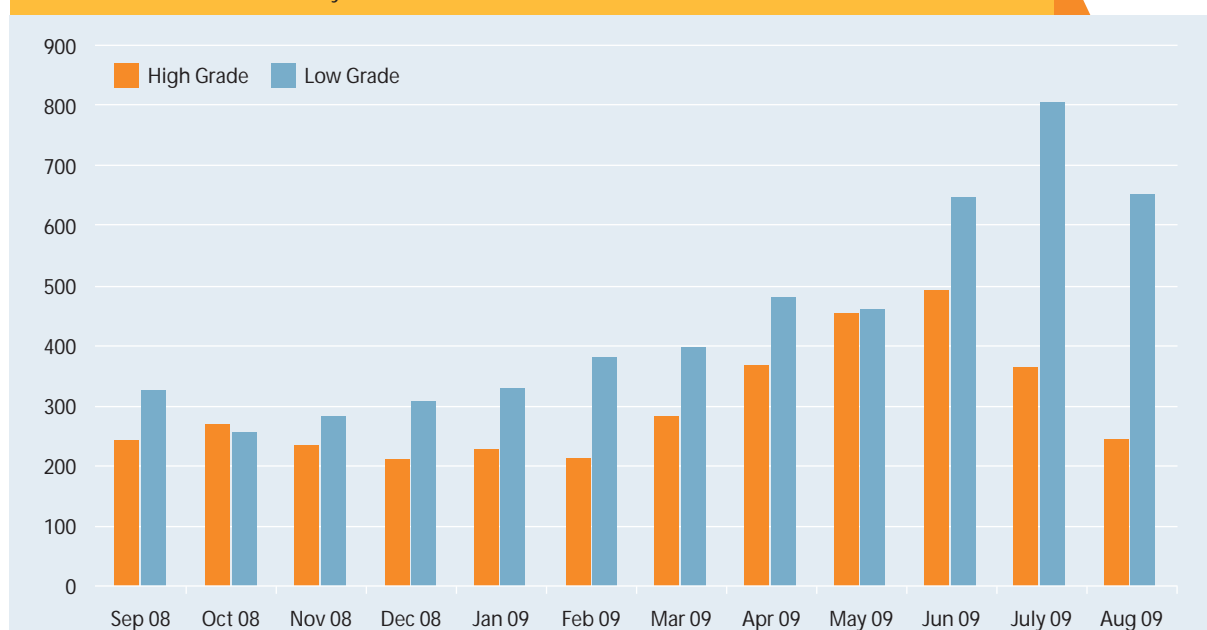
| Referral Smear Abnormality | New Referrals for Whom Consent is Available | |
|----------------------------|---|-------|
| | N | % |
| AGC | 25 | 0.3 |
| AGUS | 297 | 3.5 |
| ASC-US | 1,988 | 23.6 |
| CIN Grade not Specified | 67 | 0.8 |
| HSIL (moderate) | 1,557 | 18.5 |
| HSIL (severe) | 1,541 | 18.3 |
| LSIL | 2,595 | 30.8 |
| Not Recorded | 207 | 2.5 |
| Possible Invasion | 39 | 0.5 |
| Unsatisfactory/Inadequate | 113 | 1.3 |
| Total | 8,429 | 100.0 |

Numbers of New Referrals Attended

Before the introduction of the CervicalCheck programme, a preliminary review of colposcopy services demonstrated the need for change to ensure the delivery of sufficient quality assured capacity. A model of service delivery was developed based on 80 per cent coverage and a referral rate to colposcopy of five per cent which estimated that

the annual capacity for new referrals would have to increase from less than 10,000 before the introduction of the programme to an estimated 16,576 new appointments per year. Changes were implemented to facilitate this expansion and the delivery of the additional capacity can be seen in Figure 4.

Figure 4: Number of New Attendances at Colposcopy Services by Month as a Result of an Abnormal Smear Test Result by Grade of Referral Smear



Waiting Times

Providing access to colposcopy services in a timely manner is one of the key objectives of the CervicalCheck programme. This depends on many factors including demand for colposcopy, capacity and organisational responsiveness. Long waiting times were already a feature at colposcopy services before the introduction of the CervicalCheck programme. The programme set targets of 90 per cent of women with high grade cytological abnormalities waiting less than four weeks and 90 per cent of women with low grade cytological abnormalities waiting less than eight weeks.

For the period 1 September 2008 to 31 August 2009, the date information in the colposcopy extracts was incomplete with valid information available for only 6,376 of the consented new referrals. Overall for women with valid data, 38.4 per cent of women experienced waiting times of longer than eight weeks and in 16.4 per cent of cases the wait was longer than 12 weeks (Tables 13 and 14).

The gradual nature of the delivery of additional colposcopy capacity combined with increased demand due to increased screening activity resulted in slower than anticipated improvements in waiting times. Consequently meeting this standard was not achievable during the first year of operation. Continuing progress is being made to ensure compliance.

Table 13: Waiting Times for Women Referred to a Colposcopy Service whose Appointment was between 1 September 2008 and 31 August 2009 Grouped by Reason for Referral

| Time to First Offered Appointment | Abnormal Smear Test | | Clinical Indication – Urgent | | Clinical Indication | | Total – Non Urgent | |
|-----------------------------------|---------------------|-------|------------------------------|-------|---------------------|-------|--------------------|-------|
| | N | % | N | % | N | % | N | % |
| Up to 2 Weeks | 529 | 6.3 | 42 | 8.8 | 42 | 7.4 | 613 | 6.5 |
| Greater than 2 and Up to 4 Weeks | 945 | 11.2 | 40 | 8.3 | 47 | 8.3 | 1,032 | 10.9 |
| Greater than 4 and Up to 8 Weeks | 2,112 | 25.1 | 43 | 9.0 | 125 | 22.0 | 2,280 | 24.1 |
| Greater than 8 and Up to 12 Weeks | 1,306 | 15.5 | 26 | 5.4 | 75 | 13.2 | 1,407 | 14.8 |
| Greater than 12 Weeks | 942 | 11.2 | 18 | 3.8 | 84 | 14.8 | 1,044 | 11.0 |
| Not Available | 2,595 | 30.8 | 311 | 64.8 | 196 | 34.4 | 3,102 | 32.7 |
| Total | 8,429 | 100.0 | 480 | 100.0 | 569 | 100.0 | 9,478 | 100.0 |

Table 14: Waiting Times for Women Referred to a Colposcopy Service whose Appointment was between 1 September 2008 and 31 August 2009 Grouped by Referral Smear Test Grade

| Time to First Offered Appointment | High Grade | | Low Grade | | Total | |
|-----------------------------------|------------|-------|-----------|-------|-------|-------|
| | N | % | N | % | N | % |
| Up to 2 weeks | 322 | 9.1 | 198 | 4.2 | 520 | 6.3 |
| Greater than 2 and Up to 4 weeks | 605 | 17.2 | 320 | 6.8 | 925 | 11.3 |
| Greater than 4 and Up to 8 weeks | 1,124 | 31.9 | 934 | 19.9 | 2,058 | 25.0 |
| Greater than 8 and Up to 12 weeks | 360 | 10.2 | 898 | 19.1 | 1,258 | 15.3 |
| Greater than 12 weeks | 183 | 5.2 | 736 | 15.7 | 919 | 11.2 |
| Not Available | 932 | 26.4 | 1,610 | 34.3 | 2,542 | 30.9 |
| Total | 3,526 | 100.0 | 4,696 | 100.0 | 8,222 | 100.0 |

Biopsy Rate

The role of colposcopy is to facilitate diagnosis and treatment of women with abnormal smear test results. Where an abnormality is suspected at colposcopy it is good practice to perform a biopsy where possible to confirm the diagnosis. Two main types of biopsy are possible – a diagnostic biopsy, which involves sampling a portion of the abnormal area only, and an excisional biopsy which removes the abnormal area in its entirety. In addition other biopsies can be performed including the removal of polyps as well as endometrial biopsies.

At appointments attended by consented women during the reporting period 3,956 diagnostic biopsies and 3,399 excisional biopsies were performed. Miscellaneous other biopsies were recorded in 496 cases. The numbers of biopsies per month increased as the year progressed, reflecting the increased number of appointments due to increased uptake of screenings and referrals.

The initial colposcopy visit determines the presence or absence of an atypical Transformation Zone. The biopsy rates according to the grade of the referral smear test and reasons for referral are presented in Tables 15 and 16. Eighty one per cent of women presenting with a high grade cytological abnormality had a biopsy performed at the first visit compared with 59 per cent of women presenting with a low grade cytological abnormality. Of interest is the relatively high rate of excisional biopsies in women presenting with borderline glandular cells (AGUS). This reflects the difficulty of managing this relatively new group of women particularly if the colposcopic appearance is normal or unsatisfactory.

Figure 5: Number of Women Undergoing Biopsy at Colposcopy Services

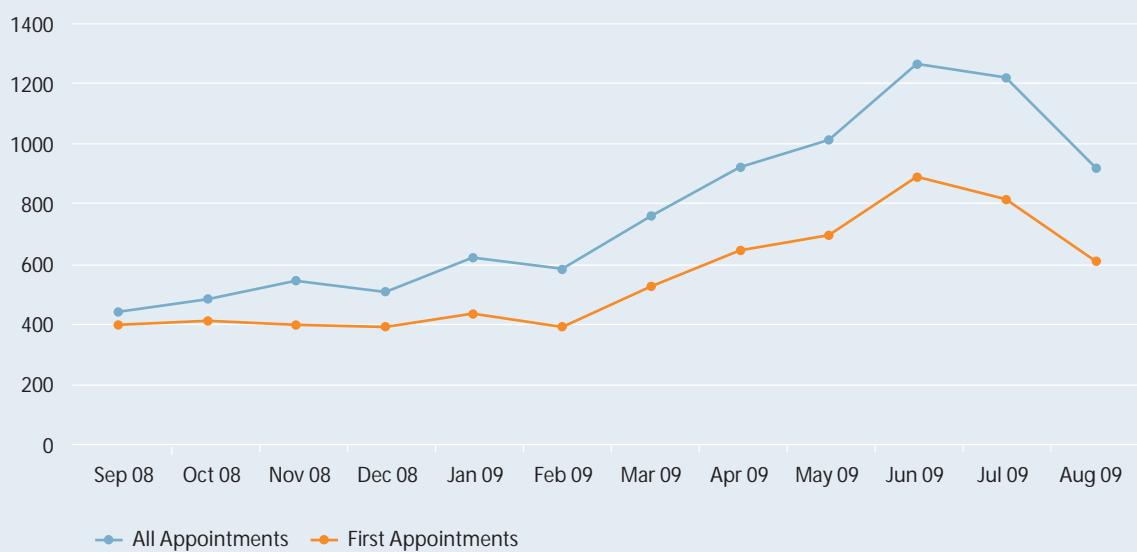


Table 15: Biopsies Performed during the First Visit to Colposcopy (consented women only)

| Grade of Cytology Result of Referral Smear | Biopsy Performed | | | | | | | | | |
|--|-------------------|------|-------------------|------|-----------------|------|----------------------------|-----|-------|-------|
| | Diagnostic Biopsy | | Excisional Biopsy | | No Biopsy Taken | | Other – Type Not Specified | | Total | |
| | N | % | N | % | N | % | N | % | N | % |
| AGUS | 117 | 44.8 | 48 | 18.4 | 91 | 34.9 | 5 | 1.9 | 261 | 100.0 |
| High Grade | 995 | 35.6 | 1,224 | 43.8 | 546 | 19.5 | 32 | 1.1 | 2,797 | 100.0 |
| Low Grade | 1,910 | 48.7 | 324 | 8.3 | 1,615 | 41.2 | 75 | 1.9 | 3,924 | 100.0 |
| Result Not Available | 40 | 27.8 | 14 | 9.7 | 86 | 59.7 | 4 | 2.8 | 144 | 100.0 |
| Unsatisfactory/ Inadequate | 28 | 26.9 | 5 | 4.8 | 66 | 63.5 | 5 | 4.8 | 104 | 100.0 |
| Total | 3,090 | 42.7 | 1,615 | 22.3 | 2,404 | 33.3 | 121 | 1.7 | 7,230 | 100.0 |

Table 16: Biopsies Performed during the First Visit to Colposcopy Services Grouped by Reason for Referral (consented women only)

| Reason for Referral to Colposcopy Service | Biopsy Performed | | | | | | | | | |
|---|-------------------|------|-------------------|------|-----------------|------|----------------------------|-----|-------|-------|
| | Diagnostic Biopsy | | Excisional Biopsy | | No Biopsy Taken | | Other – Type Not Specified | | Total | |
| | N | % | N | % | N | % | N | % | N | % |
| Abnormal Smear Test Result | 3,090 | 42.7 | 1,615 | 22.3 | 2,404 | 33.3 | 121 | 1.7 | 7,230 | 100.0 |
| Clinical Indication – Non Urgent | 120 | 24.2 | 31 | 6.3 | 296 | 59.8 | 48 | 9.7 | 495 | 100.0 |
| Clinical Indication – Urgent | 154 | 37.9 | 23 | 5.7 | 202 | 49.8 | 27 | 6.7 | 406 | 100.0 |
| Reason Not Recorded | 26 | 13.7 | 25 | 13.2 | 137 | 72.1 | 2 | 1.1 | 190 | 100.0 |
| Total | 3,390 | 40.7 | 1,694 | 20.4 | 3,039 | 36.5 | 198 | 2.4 | 8,321 | 100.0 |

Treatment at Colposcopy

Treatment at colposcopy is often required to eradicate high grade CIN and reduce the risk of cervical cancer. The standards for the CervicalCheck programme state that this be performed as an outpatient procedure under local anaesthetic more than 80 per cent of the time.

During the reporting period, 4,714 treatments were recorded at colposcopy (consented women only). Of these 4,347 were performed following an abnormal smear test. The increased capacity of colposcopy services meant that the number of treatments per month increased as the year progressed (Figure 6).

Large Loop Excision of the Transformation Zone (LLETZ) was performed in 4,326 cases, ablative treatment was used in 353 cases and 27 knife cone biopsies were recorded. Information was available on the type of anaesthetic used in 4,582 cases. Local anaesthetic was used in over 95 per cent of cases while 3.8 per cent of women required a general anaesthetic, clearly meeting the standard set by the programme (Table 17). Treatment was performed at the first visit in 1,730 cases (20%); this included 44 per cent of women who presented with a high grade smear test result and eight per cent of women who presented with a low grade smear test result (Table 18).

Figure 6: Number of Women Undergoing Treatment at Colposcopy Services

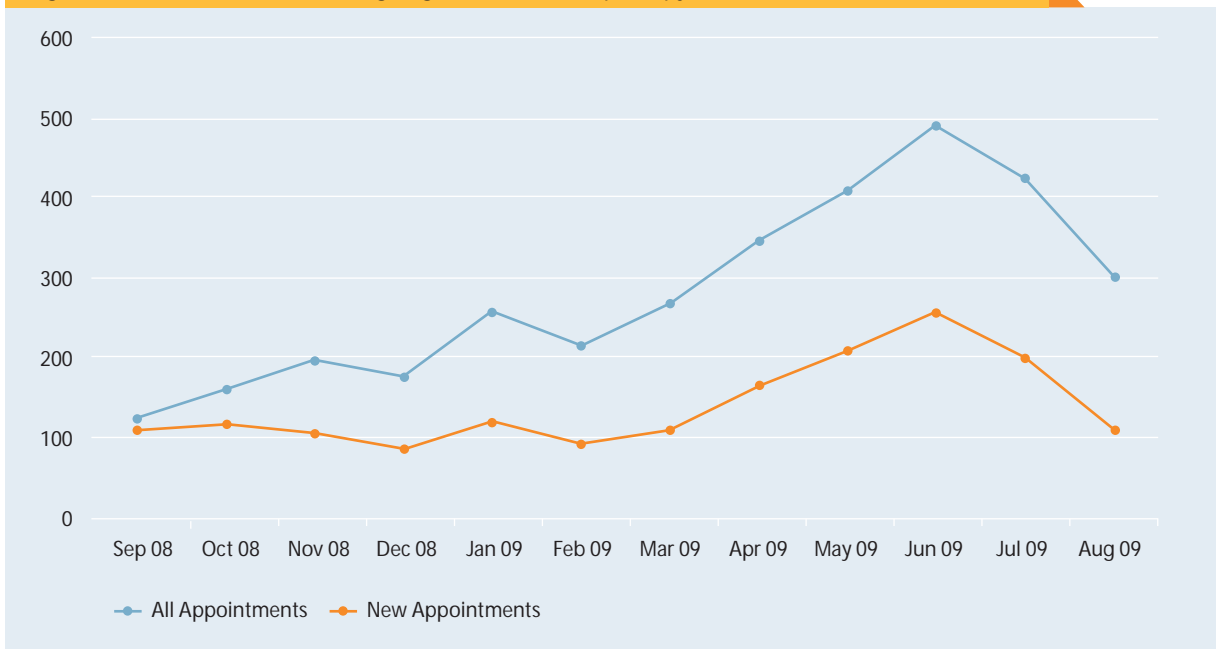


Table 17: Outcome of Use of Local Anaesthetic Measured Against Colposcopy Standards

| Performance Indicator | Achieved | Target |
|--|----------|--------|
| The majority of women should have treatment performed as an outpatient under local anaesthesia | 95.2% | >80% |

Figure 7: Treatments at Colposcopy Services

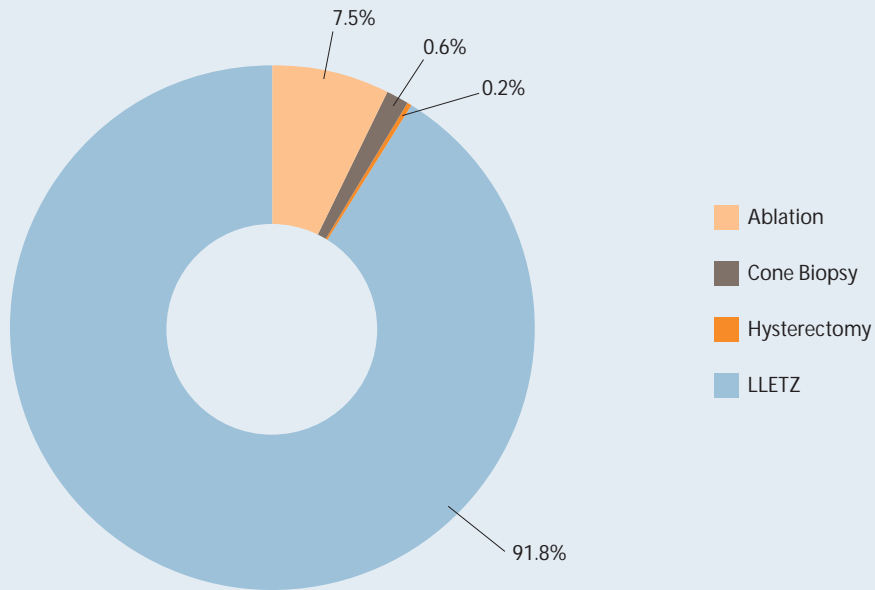


Table 18: Treatment at First Visit to Colposcopy

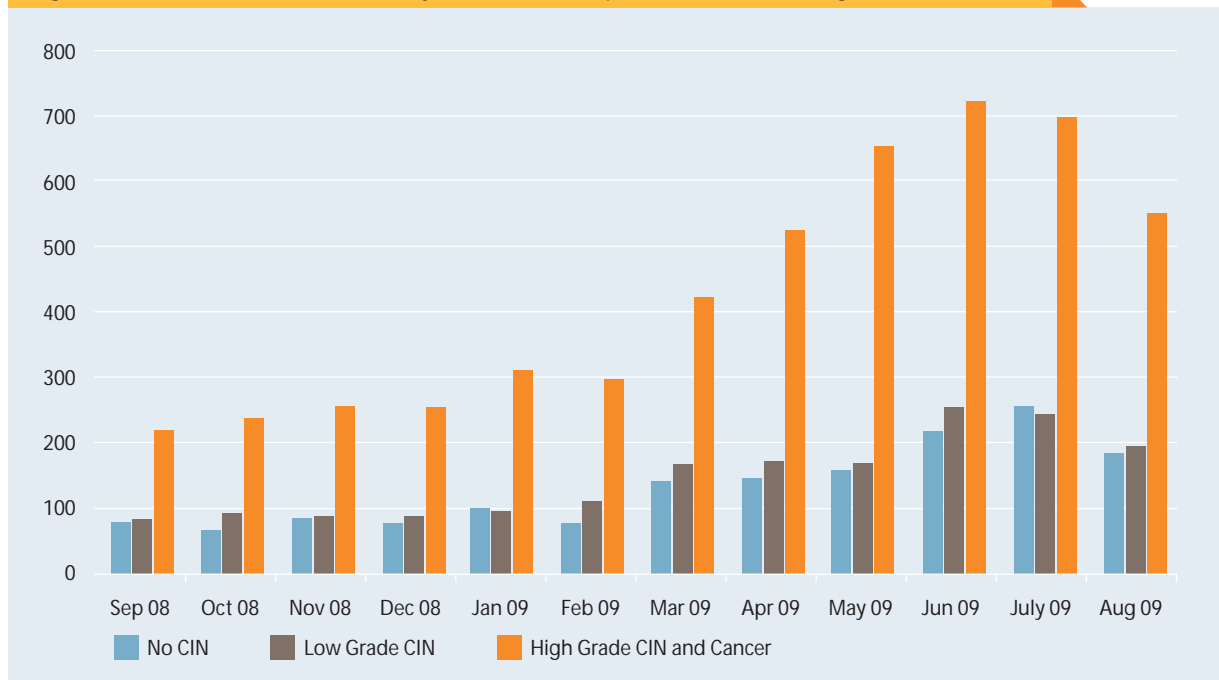
| Reason for Referral to Colposcopy Service | No Treatment on First Visit | | Treatment on First Visit | | Total Number of Women Attending | |
|---|-----------------------------|-------------|--------------------------|-------------|---------------------------------|--------------|
| | N | % | N | % | N | % |
| AGUS | 215 | 82.4 | 46 | 17.6 | 261 | 100.0 |
| Clinical Indication – Non Urgent | 464 | 93.7 | 31 | 6.3 | 495 | 100.0 |
| Clinical Indication – Urgent | 371 | 91.4 | 35 | 8.6 | 406 | 100.0 |
| High Grade | 1,563 | 55.9 | 1,234 | 44.1 | 2,797 | 100.0 |
| Low Grade | 3,588 | 91.4 | 336 | 8.6 | 3,924 | 100.0 |
| Reason Not Recorded | 162 | 85.3 | 28 | 14.7 | 190 | 100.0 |
| Result Not Available | 129 | 89.6 | 15 | 10.4 | 144 | 100.0 |
| Unsatisfactory/Inadequate | 99 | 95.2 | 5 | 4.8 | 104 | 100.0 |
| Total | 6,591 | 79.2 | 1,730 | 20.8 | 8,321 | 100.0 |

Histology

Cervical screening programmes aim to reduce the incidence and mortality of cervical cancer through the detection and treatment of high grade CIN (CIN2/3). One of the key hallmarks of a successful programme therefore is the level of detection of these abnormalities. The histology is presented by month in Figure 8. The yield of high grade abnormalities increased as the year progressed, again reflecting increased capacity in the clinics.

The histology results for consented women attending colposcopy during the first year of the programme according to the referral smear test result is shown in Table 20. Invasive cancer was diagnosed in 100 women. Three thousand nine hundred and eighty women (52%) had CIN 2/3 and 57 women had adenocarcinoma in situ. No CIN was detected in 1,512 women (19%). This figure decreased with increasing levels of cytological abnormality.

Figure 8: Detection of CIN and Cancer by Month from 1 September 2008 to 31 August 2009



Positive Predictive Values for CervicalCheck Programme Smear Tests

The positive predictive value (PPV) represents the proportion of test-positive women who are truly positive. It can be considered a measure of the likelihood that a woman with a positive test truly has a precancerous cervical abnormality. It is one of the most important diagnostic measures of a screening programme as it reflects the probability that a positive test has detected the underlying condition being tested.

If the smear test showed a high grade abnormality, a histological result showed CIN2 or higher in 86.4 per cent of cases. If the smear test demonstrated a low grade abnormality (LSIL) the histology result demonstrated CIN1 or higher in 95 per cent of cases (Table 19).

Table 19: Positive Predictive Values (PPV) for CervicalCheck Programme Smear Tests

| | |
|------------------------------|-------|
| PPV of High Grade Smear Test | 86.4% |
| PPV of Low Grade Smear Test | 95.1% |

Table 20: Histology Results for Women Presenting to Colposcopy with a CervicalCheck Smear Test

| Cytology Result | Histology Result | | | | | | | | | | | |
|----------------------------|--------------------------|------|-------|------|-------|------|-------|------|-------------------------------|-----|-----------------------------------|------|
| | No CIN / No HPV (normal) | | CIN 1 | | CIN 2 | | CIN 3 | | Adenocarcinoma in Situ / CGIN | | Cancer (including micro-invasive) | |
| | N | % | N | % | N | % | N | % | N | % | N | % |
| Unsatisfactory /Inadequate | 12 | 50.0 | 7 | 29.2 | 3 | 12.5 | 1 | 4.2 | 0 | 0.0 | 1 | 4.2 |
| NAD | 293 | 37.6 | 362 | 46.4 | 89 | 11.4 | 32 | 4.1 | 2 | 0.3 | 2 | 0.3 |
| ASC-US | 602 | 26.7 | 645 | 28.6 | 493 | 21.9 | 488 | 21.7 | 11 | 0.5 | 14 | 0.6 |
| BNA (Glandular) | 115 | 34.5 | 83 | 24.9 | 47 | 14.1 | 67 | 20.1 | 14 | 4.2 | 7 | 2.1 |
| LSIL | 366 | 20.8 | 719 | 40.9 | 377 | 21.4 | 291 | 16.5 | 4 | 0.2 | 2 | 0.1 |
| HSIL | 122 | 4.9 | 220 | 8.8 | 501 | 20.0 | 1,576 | 62.9 | 25 | 1.0 | 62 | 2.5 |
| Glandular Neoplasia | 2 | 12.5 | 0 | 0.0 | 2 | 12.5 | 4 | 25.0 | 1 | 6.3 | 7 | 43.8 |
| Query Invasive | 0 | 0.0 | 0 | 0.0 | 2 | 14.3 | 7 | 50.0 | 0 | 0.0 | 5 | 35.7 |
| Total | 1,512 | 19.7 | 2,036 | 26.5 | 1,514 | 19.7 | 2,466 | 32.1 | 57 | 0.7 | 100 | 1.3 |

Cervical screening programmes aim to reduce the negative effects of screening and the risk of overtreatment. One way of ensuring this is the requirement that most of the women who undergo excisional procedures should have CIN on the excised specimen. This is particularly

important when the procedure is done at the first visit to colposcopy (select and treat). Table 21 shows that the targets for these standards were met in the first year of the programme.

Table 21: Outcome of Excisional Treatments Measured against Colposcopy Standards

| Performance Indicator | Achieved | Target |
|---|----------|--------|
| Women treated by excisional technique at first visit should have CIN on Histology | 93.1% | >90% |
| Women treated by excisional techniques at any visit should have CIN on Histology | 92.4% | >80% |

Glossary



Ablative Treatment

Treatment which involves the destruction of the cervical abnormalities using a variety of techniques. It does not allow for histological examination of the whole abnormal area and strict criteria must be followed therefore to minimise the risk of inadvertent treatment of hidden microinvasive cancer.

Abnormal/Not Normal Smear Test

A smear test which shows cells which are not typically normal or where precancerous or cancerous cells are identified.

Adenocarcinoma

A cancer affecting the cervix, but involving the columnar (endocervical) cells rather than the squamous cells. The columnar cells are involved in glandular activity.

Adenocarcinoma in Situ

A pre-cancer affecting the cervix, but involving the columnar (endocervical) cells rather than the squamous cells.

Adequate Smear Test Result

A smear test which is deemed satisfactory for evaluation by the laboratory.

AGC

Atypical Glandular Cells.

AGUS

Atypical Glandular Cells of Undetermined Significance.

ASC-H

Atypical Squamous Cells for which a high-grade lesion cannot be excluded.

ASC-US

Atypical Squamous Cells of Undetermined Significance.

Atypical Transformation Zone

The term used when changes are detected by colposcopy in the Transformation Zone.

Biopsy

The removal of a sample of tissue from the body for examination using a microscope.

Cervical Cancer

Cancer of the cervix. Cancer cells have spread beyond the natural basement membrane boundary of the cervical skin. Cervical cancer can be of squamous origin (approximately 85%) or glandular origin (approximately 15%).

Cervical Cytology

A microscopic examination of a single layer of cells sampled from the surface of the cervix.

Cervical Intraepithelial Neoplasia (CIN)

CIN is not cancer but is the histological term referring to the abnormal growth of pre-cancerous cells in the surface layers of the cervix. It describes varying degrees of abnormality of the cells within and confined to the epithelium. There are three grades of CIN: CIN 1, CIN 2 and CIN 3.

Cervical Screening

A process which involves the application of a screening test at regular intervals to a defined population of women to detect precancerous changes.

Colposcopy

An examination of the cervix using a specialised optic instrument (colposcope) that provides magnification to allow direct observation and study of vaginal and cervical epithelium. It identifies lesions on the cervix which can be biopsied and treated.

Cone Biopsy

A surgical removal of a cone-shaped section of the cervix to remove abnormal cells.

Coverage

The proportion of women aged 25-60 years who have had a screening result recorded on the screening register over a complete screening round.

Diagnosis

A process aimed at the clarification of cervical abnormalities to inform decision making regarding treatment.

Dyskaryosis

Term used in cytology to describe nuclear abnormalities in cervical cells.

Eligible for Screening

Women aged 25-60 years for whom CervicalCheck recommends and funds screening according to national policy.

Endocervix

The portion of the cervix located within the canal of the cervix.

Excisional Treatment

Treatment which involves the removal of the abnormality in its entirety thereby allowing histological examination of the entire Transformation Zone.

HSIL

High Grade Squamous Intraepithelial (moderate and severe) Lesion encompassing moderate (CIN 2) and severe dysplasia (CIN 3/Carcinoma in Situ).

Histology

The microscopic study of the structure and composition of body tissue.

Human Papilloma Virus (HPV)

A group of viruses of which a high proportion are sexually transmitted. Over 100 different types of HPV have been identified and each is known by number. Types 6 and 11 are associated with genital warts and types 16 and 18 are associated with high grade lesions.

Hysterectomy

The surgical removal of the uterus (womb) – called total if it includes the cervix or subtotal/partial if the cervix is not entirely removed.

Incidence

The number of new cases of a disease or happening that occurs in a given period in a specified population.

Informed Consent

The giving of all the necessary information by the smearer to the woman in order that she fully understands the smear test procedure and possible results so that she can make an educated decision to participate in the programme. For the CervicalCheck informed consent process, the necessary information covers participation in the programme, the transfer of data to third parties, limitations of screening, results, associated tests and treatment.

Invasive Cancer

Abnormal cells, not limited to the outer layer of the epithelial but which breach the basement membrane to invade the underlying stroma (layer of tissue).

Key Performance Indicators (KPIs)

A metric used to help an organisation define and measure progress toward organisational goals or standards.

LLETZ

Large Loop Excision of the Transformation Zone is a diagnostic and/or treatment method to remove the cervical areas of abnormality. The procedure involves removal of the entire Transformation Zone using a thin wire electrode charged with electric current to provide a sample for examination by the pathologist.

Lesions

A zone of tissue with impaired function as a result of damage by disease or injury.

Liquid Based Cytology (LBC)

The placement of harvested cells into a special transport solution for sending to the laboratory, where the slide is made ready for examination.

LSIL

Low Grade Squamous Intraepithelial Lesion encompassing HPV infection or mild dysplasia (CIN 1).

Microinvasive Cancer

This represents early stage cervical cancer where the abnormal cells breach the basement membrane and invade to not greater than 5mm in depth and not more than 7mm in width.

Mortality

The number of deaths from a specified disease during a defined period of time in a given population.

NAD

No abnormality detected (normal).

Polyp

A benign swelling on the surface of the cervical canal.

Positive Predictive Value (PPV)

The proportion of test-positive women who are truly positive. It can be considered a measure of the likelihood that a woman with a positive test truly has a precancerous cervical abnormality.

Primary Care Setting

First contact care that is not hospital or specialist care - General Practice, Family Planning, Women's Health and Well Woman Centres and Clinics.

Quality Assurance

A programme for the systematic monitoring and evaluation of the various aspects of the National Cervical Screening Programme to ensure that standards of quality are being met.

Screening Programme

An organised approach to screening a defined population to determine the likelihood of a specific disease within the population with the aim of reducing the risk of the disease and improving the quality of life through early diagnosis.

Select and Treat

A process whereby women with suspected high grade disease are selectively treated at the first visit to colposcopy.

Smear Test

A screening test where cells from the surface of the cervix are sampled, preserved immediately and sent to the laboratory for cytological analysis.

Smear taker

A doctor or nurse who takes smear tests.

Specimen

A sample of tissue removed from the body for microscopic examination.

Squamous

A type of multi-layered cells, which line the vagina and outer layer of the cervix.

Squamous Cell Carcinoma/Cancer

The most common form of cervical cancer involving the squamous cells.

Standard

A minimum requirement against which performance can be measured.

Transformation Zone (TZ)

The region of the cervix where the columnar cells of the inner cervix have or are changing to outer squamous cells. The process of change is called metaplasia. It is the area most at risk of abnormal change.

Treatment

A process aimed at the eradication of cervical abnormalities thus restoring normal cytology and reducing the chance of subsequent cancer by 90%.

Unsatisfactory Colposcopy

A term used to describe the inability to visualise the whole of the Transformation Zone colposcopically.

Unsatisfactory/Inadequate Smear Test Result

An 'inadequate' or 'unsatisfactory' smear test that cannot be assessed by the cytology laboratory.



The National Cancer Screening Service is part of the Health Service Executive National Cancer Control Programme. It encompasses BreastCheck – The National Breast Screening Programme and CervicalCheck – The National Cervical Screening Programme.

