CervicalCheck
THE NATIONAL CERVICAL SCREENING PROGRAMME

1 September 2011 to 31 August 2012

Programme Report

CervicalCheck
THE NATIONAL CERVICAL SCREENING PROGRAMME

CervicalCheck Charter

Screening commitment:

- CervicalCheck – The National Cervical Screening Programme offers a free complete quality assured programme of care
- You choose your smeartaker 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 smeartaker 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 smeartaker 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

Contents

The National Screening Service

The National Screening Service (NSS) was part of the Health Service Executive National Cancer Control Programme during the fourth year of the CervicalCheck programme 1 September 2011 to 31 August 2012. The National Screening Service has responsibility for four population-based screening programmes in Ireland:

- BreastCheck – The National Breast Screening Programme which offers women aged 50-64 (over 360,000 women) a free mammogram every two years and commenced screening from February 2000. www.breastcheck.ie
- CervicalCheck – The National Cervical Screening Programme which offers free smear tests to women aged 25 to 60 (over 1.1 million women). Regular smear tests at recommended intervals can prevent cervical cancer. Since CervicalCheck launched in September 2008, almost 1.65 million smear tests have been processed for more than 875,000 women. www.cervicalcheck.ie
- BowelScreen – The National Bowel Screening Programme, for the early detection of bowel cancer in men and women aged 55 to 74 (over one million people). The programme is initially aimed at people aged 60 to 69 years (500,000) and the first round began in late 2012 and may take up to three years to complete, after which each round should be completed in two years. www.bowelscreen.ie
- Diabetic RetinaScreen – The National Diabetic Retinal Screening Programme, for the early detection of diabetic retinopathy is aimed at all people with Type 1 or Type 2 diabetes aged 12 and over (approximately 190,000 people). The programme, which commenced its first round in early 2013, signalled the expansion for NSS into non-cancer related conditions and is a population-based call, re-call screening programme.

When all four population-based screening programmes are fully operational, over two million people in Ireland will be eligible to participate in one or more of the programmes.

The National Screening Service has a commitment to implement special measures to promote participation in its programmes by harder-to-reach individuals and communities within the population.

The National Screening Service is dedicated to continued delivery of screening programmes, sharing expertise and learning across national screening programmes and driving effectiveness through strengthening the single governance model in place for screening.

Background

NSS, formerly the National Cancer Screening Service (NCSS), was established in January 2007 following the launch of 'A Strategy for Cancer Control in Ireland 2006' by the Cancer Control Forum and the Department of Health, which advocated a comprehensive cancer control policy programme in Ireland. The strategy set out recommendations regarding the prevention, screening, detection, treatment and management of cancer in Ireland. It recommended the establishment of the National Cancer Screening Service Board, which was later dissolved when the NCSS joined the Health Service Executive National Cancer Control Programme (NCCP) in 2010.

Overview and introduction to CervicalCheck programme report

This report contains screening statistics for the fourth year of operation (1 September 2011 to 31 August 2012) and an overview of activity and developments within CervicalCheck up to the time of publication.

CervicalCheck is central to cervical cancer prevention in Ireland, working to reduce incidence and mortality from the disease by detecting changes in the cells of the cervix before they become cancerous. The annual average incidence of cervical cancer in Ireland during 2008-2010 was 308 cases with 88 deaths due to the disease in 2010.[1]

With an eligible population of over 1.1 million women aged 25 to 60, CervicalCheck has the potential to reduce mortality from cervical cancer by as much as 80 per cent in the screened population.

Women have a choice of over 4,700 smeartakers in almost 1,450 locations. Results are available quickly, with reduced waiting times for colposcopy.

No screening test is 100 per cent accurate. The value of a population-based screening programme, such as CervicalCheck, is in the repeat nature of screening.

Health professionals including registered GPs, practice nurses and medical practitioners working in primary care and in colposcopy services play a vital role in providing an effective, quality assured environment and experience in all stages of the screening pathway.

It is important to also acknowledge the role that every member of staff and management involved in running the programme has played during the first five years of CervicalCheck.

Through the combined effort of those working on behalf of the programme, eligible women and the wider community, cervical screening at recommended intervals is becoming routine health behaviour.

Majella Byrne
Head, National Screening Service

Dr Gráinne Flannelly
Clinical Director, CervicalCheck

1 Cancer in Ireland 2013: Annual Report of the National Cancer Registry; National Cancer Registry Ireland

2 CIN2+ and adenocarcinoma in situ included

In the first five years of CervicalCheck, more than 1.65 million smear tests provided

Updates

Completion of the first five years of CervicalCheck

CervicalCheck completed its first five-year screening round on 31 August 2013, with over 74 per cent of women age 25-60 having at least one smear test. Over 1.65 million smear tests were provided during the first five years with more than 875,000 eligible women aged 25 to 60 having at least one CervicalCheck smear test.

CervicalCheck has transformed the experience of cervical screening for eligible women, striving to make the programme accessible and as easy as possible for a woman to incorporate a regular smear test into her routine health behaviour.

CervicalCheck uses a multi-layered approach, communicating directly with health professionals and community groups, using media and other communication channels to promote understanding of the value of regular smear tests among its target population.

The programme itself is complex, involving all aspects of delivery from register management, administration, smeartaking in primary care, cytology, colposcopy (diagnosis and treatment) and histology services. Every aspect of the programme is governed by quality assurance standards, based on best international evidence and reviewed by a panel of international experts before publication. The second edition of these guidelines, published in early 2014, builds on the learning of the past five years of the programme and completion of the first round of screening.

CervicalCheck continues to innovate, with recent initiatives including:

- Facilitated referrals to colposcopy
- A more accessible and user-friendly website
- Ability to analyse and evaluate additional performance measures
- Introduction of HPV testing post colposcopy
- Tailored management plans at colposcopy

The programme is adapting within a changing health environment, embracing developments within HPV technology, and making preparations for the inclusion of HPV vaccinated women in the coming years. This discussion is similarly reflected across other countries with a vaccination programme.

Primary care

Women have a great degree of flexibility and a broad choice of locations for their smear test. The vast majority of women chose to have their smear test carried out in a primary care setting. Primary care settings include GP practices, Women's Health, Family Planning and Well Women Clinics.

The remainder of women had their CervicalCheck smear test in a colposcopy clinic, public gynaecology service or STI / GUM (sexually transmitted infection / genito-urinary medicine) clinic.

During the fourth year of the CervicalCheck programme (1 September 2011 to 31 August 2012) over 90 per cent of women had their smear tests in a primary care setting, which is unsurprising with over 4,700 smeartakers registered with CervicalCheck across approximately 1,450 primary care settings.

CervicalCheck national study day

Best Education Project (General Practice/Pharmacy Section) at the Irish Health Care Awards 2012

Smeartaker supports and training

A dedicated Screening Training Unit co-ordinates smeartaker education and training initiatives for those starting out in practice, and clinical updates for experienced smeartakers. The unit provides comprehensive training and resources, developed in collaboration with smeartakers, to ensure provision in a flexible and meaningful way.

CervicalCheck won Best Education Project (General Practice/Pharmacy section) at the Irish Health Care Awards 2012. CervicalCheck also hosted a successful national study day featuring national and international speakers in Autumn 2012. The study day provided a forum for discussing the achievements of the programme as well as the future of cervical screening.

Accredited smeartaker training modules are provided through successful partnerships with the Irish College of General Practitioners (ICGP), Royal College of Surgeons in Ireland (RCSI) and the National University of Ireland, Galway (NUIG).

There has been high level of engagement with GP Training Schemes and a tailored training programme was delivered to 316 GP trainees during 2013. Accredited clinical update sessions have been delivered to Irish Practice Nurse Association (IPNA) practice nurses at regional branch level. Continuing medical education (CME) sessions were provided to clinically responsible doctors.

Over 98 per cent of smear tests were reported as satisfactory during the period of this report, reflecting the skill and professionalism of smeartakers registered with the programme.

An eLearning portal provides a virtual learning environment, facilitating busy health professionals to advance their knowledge and skills in an accessible, flexible format.

The eLearning portal includes CPD accredited 'eUpdates', a cervix image library, resources for GP trainees, and educational modules on other NCSS programmes (available at www.cervicalcheck.ie – health professionals section).

Additional educational resources include the recently revised 'Desktop Guide for Smeartakers'.

Promoting regular smear test as a routine health behaviour

A central principle of the programme is the need for effective communication with eligible women, particularly around raising awareness and driving understanding of the importance of regular smear tests for cervical health. The programme aims to inform, educate and encourage eligible women to participate in the CervicalCheck programme.

Maintaining high levels of screening over time is a key challenge internationally for population screening programmes. As the target audience changes, with new women entering the programme and awareness of the programme growing across the wider population, CervicalCheck works to ensure eligible women are aware of the importance of regular smear tests as a routine health behaviour, understanding the value for their health across their lifetime.

Some women in more vulnerable situations can face a number of barriers to participation and are identified as harder-to-reach. Cutting through the impediments to deliver a complex message about the importance of regular smear tests is best achieved using a comprehensive, sensitive screening promotion approach.

A multi-layered approach is devised in partnership by the Screening Promotion and Communications team, which uses traditional mediums such as advertising and public relations alongside specific initiatives to encourage eligible women, particularly those who are harder-to-reach.

The Smeartaker Training Unit likewise has a key role in reinforcing similar messaging amongst the service providers. In addition, CervicalCheck provides:

- A screening promotion team who work on a national basis to increase awareness and understanding.
- A Freephone information and support line.
- Leaflets designed in line with the National Adult Literacy Agency (NALA) Plain English mark.
- An access offer who works to provide equal access to screening for all women, including those with disabilities.
- Resources designed to meet particular needs, such as Braille, audio and different languages.

During 2013 a targeted campaign addressed two key issues:

- Encouraging women aged 50-60 to participate. The international trend for lower participation by women towards the upper end of the age range is reflected in Ireland and a concerted effort was made to raise awareness of the importance of participation across the age range.
- Targeting populations with a low uptake to encourage women across the age range living in those areas to participate.

Dr Gráinne Flannelly promoting the pearl of wisdom, emblem of European Cervical Cancer Prevention Week, January 2014

Cytology services

Cytology services are provided for CervicalCheck by Quest Diagnostics Inc and MedLab Pathology Ltd, two laboratories contracted by the National Screening Service (NSS) following a public procurement process.

A National Cytopathology Training Centre located at the Coombe Cytology Dept began processing CervicalCheck samples from early 2013.

Performance is audited against standards set for cytology as part of the programme to best ensure turn-around times and other performance indicators.

The National Screening Service is currently engaged on a project with Healthlink and the cytology laboratories to provide GPs registered with Healthlink access to electronic cytology results. The project is aiming for completion in 2014.

In order to avoid unnecessary smear tests for women, follow-up of women with low grade abnormalities was modified in April 2012.

During the fourth year of the CervicalCheck programme (1 September 2011 to 31 August 2012)

- **Over 87 per cent of satisfactory smear tests were found to be negative or normal.**
- **11 per cent showed low grade abnormalities.**
- **High grade abnormalities were detected in 1.6 per cent of smear tests.**

Colposcopy services provided at

Colposcopy services

Colposcopy services provided across fifteen locations are vital to ensuring accurate diagnosis and effective treatment of women who have had abnormalities detected in their smear test.

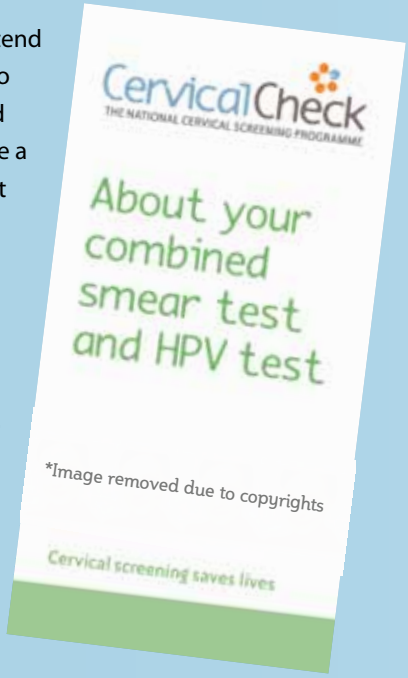
CervicalCheck has greatly improved colposcopy services in Ireland, increasing capacity and ensuring services receive adequate investment and support.

In September 2013 a Colposcopy forum was hosted by the NSS where colleagues from colposcopy services nationally attended to discuss the programme's achievements, new developments and quality assurance at colposcopy services.

Participants at recent colposcopy forum hosted at King's Inns House

CervicalCheck continually works to better identify those women who need treatment and further surveillance. Progress has been made in this area with revised NSS 'Guidelines for Quality Assurance in Cervical Screening' issued recently by the Quality Assurance committee. A clinical guidance document describes the use of HPV testing for the follow-up of treated women. It also updates clinical advice on management and surveillance following colposcopy. Where appropriate a combined smear and HPV test will be provided a year following treatment.

Updated clinical guidance on the management of low grade abnormalities was introduced in early 2014. This tailored approach will identify at an earlier stage those women who need treatment. A number of IT changes and information sources were introduced in order to facilitate this. Women who attend an initial colposcopy where no CIN is identified will be placed under surveillance and receive a combined smear and HPV test in a year's time.



Performance is monitored against standards set for colposcopy as part of the programme and information gathered centrally is analysed to produce the results in this report. Colposcopy services are provided by clinicians certified by the British Society for Colposcopy and Cervical Pathology (BSCCP).

CervicalCheck commits to offering colposcopy appointments:

- Urgent referrals within two weeks of smear test results
- High grade cell changes within four weeks of smear test results
- Low grade cell changes within eight weeks of smear test results.

The programme continues to work towards achieving and surpassing standards to avoid anxiety and maximise efficiency in diagnosis and treatment for the woman.

During the fourth year of the CervicalCheck programme (1 September 2011 to 31 August 2012) the programme exceeded the standard set at 90 per cent for urgent and low grade referrals, with over 93 per cent of women being offered an appointment within eight weeks of the date the letter was received in the clinic.

Facilitated referral process for colposcopy services

The facilitated referral process, recommending a specific colposcopy service for a woman requiring referral, has been of benefit both in terms of capacity management and ensuring appointments are given within programme targets. This ensures that women are referred to colposcopy services with available capacity within agreed targets for offering an appointment.

The facilitated referral process has also seen particular benefit in temporarily diverting referrals from a colposcopy service that becomes unavailable due to unforeseen circumstances. During flooding at Letterkenny General Hospital in August 2013, referrals were quickly diverted to Sligo General Hospital until the hospital reinstated its service areas. This minimised disturbance to women and ensured referrals occurred in a timely fashion.

Histopathology services

Biopsy samples taken at colposcopy are analysed in histopathology laboratories to determine the degree of abnormality found. Treatment decisions are based on histopathology outcomes.

In 2013 NSS extended the scope of its agreements with hospitals providing colposcopy to include histopathology.

Positive predictive value for CervicalCheck programme smear tests

One of the most important quality measures for a screening programme is the positive predictive value (PPV) as it reflects the probability that a positive test has detected the underlying condition being tested.

The positive predictive value is a measure of the likelihood that a woman with a positive smear test actually has a pre-cancerous cervical abnormality or a cancer diagnosis.

Cervical screening programmes aim for early detection of high grade abnormalities while minimising unnecessary investigations, anxiety and possible overtreatment. The value of cytology as a test takes into account both the sensitivity (ability to detect a problem and avoidance of false negatives) and specificity (avoidance of false positives).

During the fourth year of the CervicalCheck programme (1 September 2011 to 31 August 2012) the positive predictive value of Colposcopic impression was 75.3 per cent, above the programme standard of 65 per cent.

328,000+

women screened
from September 2011 -
August 2012

Programme statistics

Introduction to the statistics 2011/2012

CervicalCheck became a national screening programme on 1 September 2008. The figures reported in this section relate to the fourth year of operation (1 September 2011 to 31 August 2012). During this period the programme operated both an invitation entry system whereby eligible women received an invitation letter to screening and 'direct entry' whereby a woman could be screened by a smeartaker who could check her eligibility using an on-line facility.

The response to the programme has been very positive with 328,161 women attending for screening during the reporting period. Quality assurance underpins every aspect of the CervicalCheck programme. The programme's performance is measured against Key Performance Indicators (KPIs) as outlined in Guidelines for Quality Assurance in Cervical Screening First Edition 2009.

Table 1 shows the number of women screened by age group. Women between the ages of 25 and 60 are invited to screening, but a small number of women under 25 may attend under specific criteria. Those women aged 61 or over may have presented for the first time at this age and so were eligible for a first smear test, may have received their invitation to screening at age 60 but delayed some time before presenting for screening, or may reflect women having follow-up smear tests performed.

Table 1: Number of women screened by age group

Age group	Number of women screened	%
<25*	1,812	0.6
25 - 29	55,083	16.8
30 - 34	60,128	18.3
35 - 39	54,378	16.6
40 - 44	47,254	14.4
45 - 49	38,936	11.9
50 - 54	30,840	9.4
55 - 59	23,599	7.2
60	3,659	1.1
≥61	12,472	3.8
Total:	328,161	100

* Based on evidence to date, there is no additional public health benefit in starting population 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.

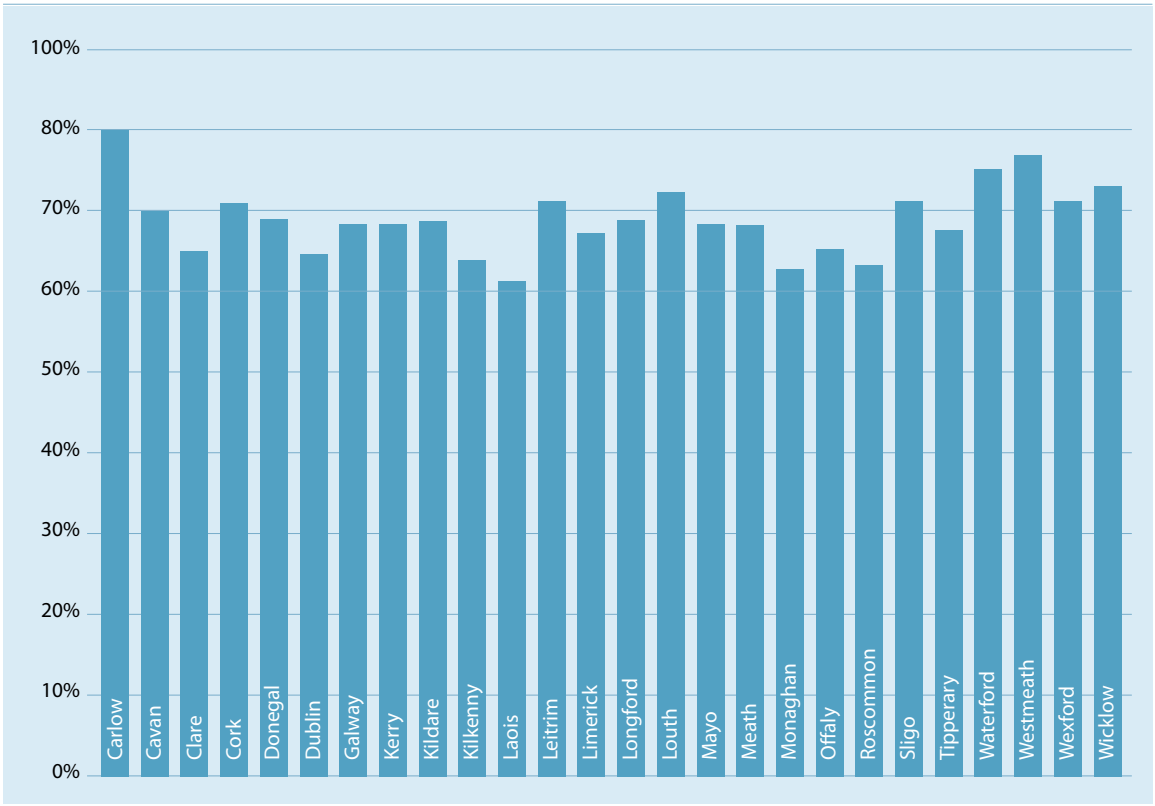
Programme coverage

Coverage is defined as the proportion of unique women who have had at least one satisfactory smear test taken within the defined period, expressed as a percentage of the total number of eligible women in the population. It is a measure of how well the programme is reaching the target population.

The overall percentage of the eligible population screened in the first four years of the national programme was 67.9 per cent nationwide. This demonstrates that CervicalCheck continues to improve coverage, following successful achievement of its target coverage during the first screening round (in years one to three of the national programme coverage was 60.9 per cent).

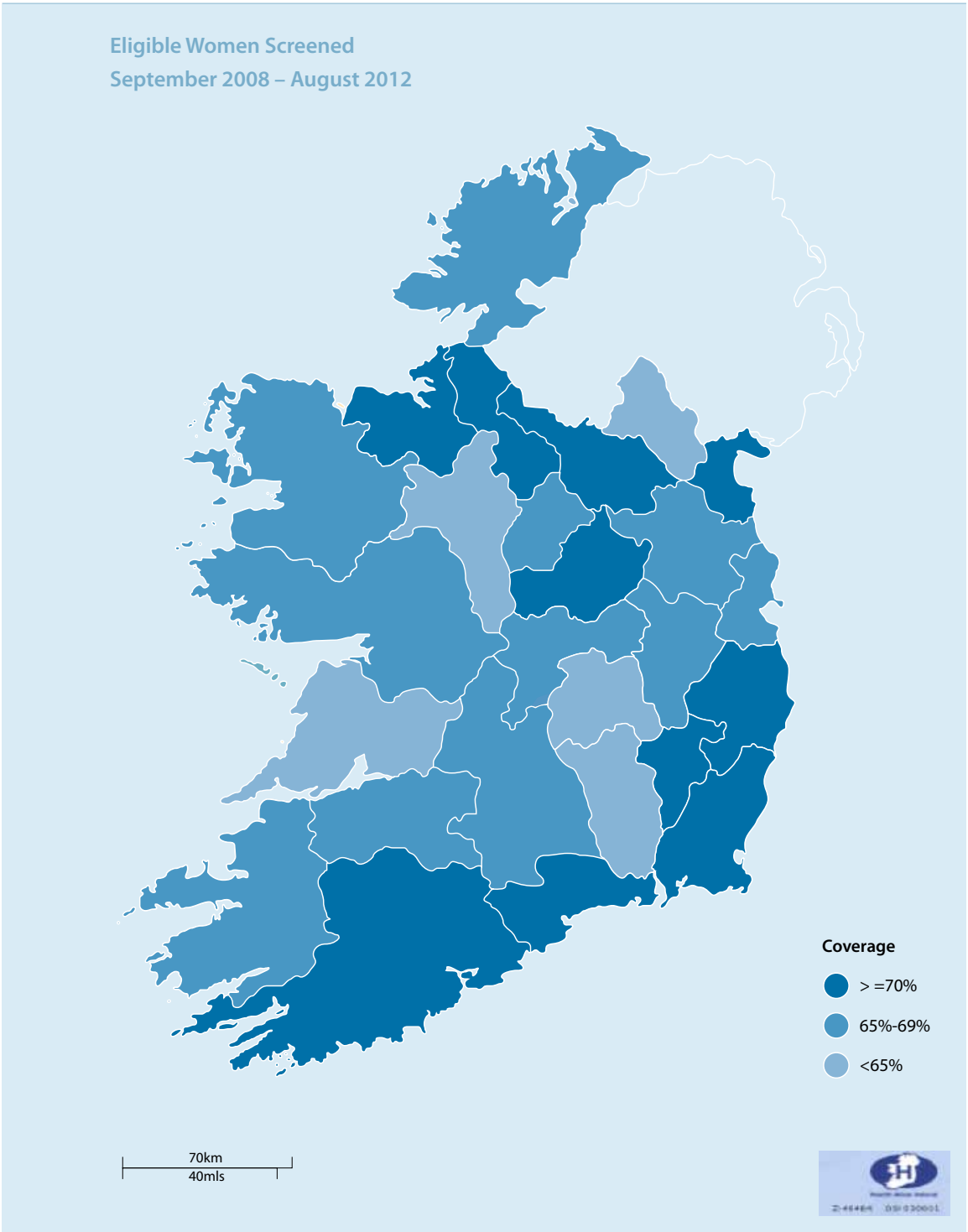
The geographical spread of screening coverage based on the eligible population of each county is shown in Figures 1 and 2.

Figure 1: Percentage of eligible women screened based on county of residence* from 1 September 2008 to 31 August 2012



* Population based on CSO 2011 Census extrapolated to 2012

Figure 2: Map showing percentage of eligible women screened by county of residence* from 1 September 2008 to 31 August 2012

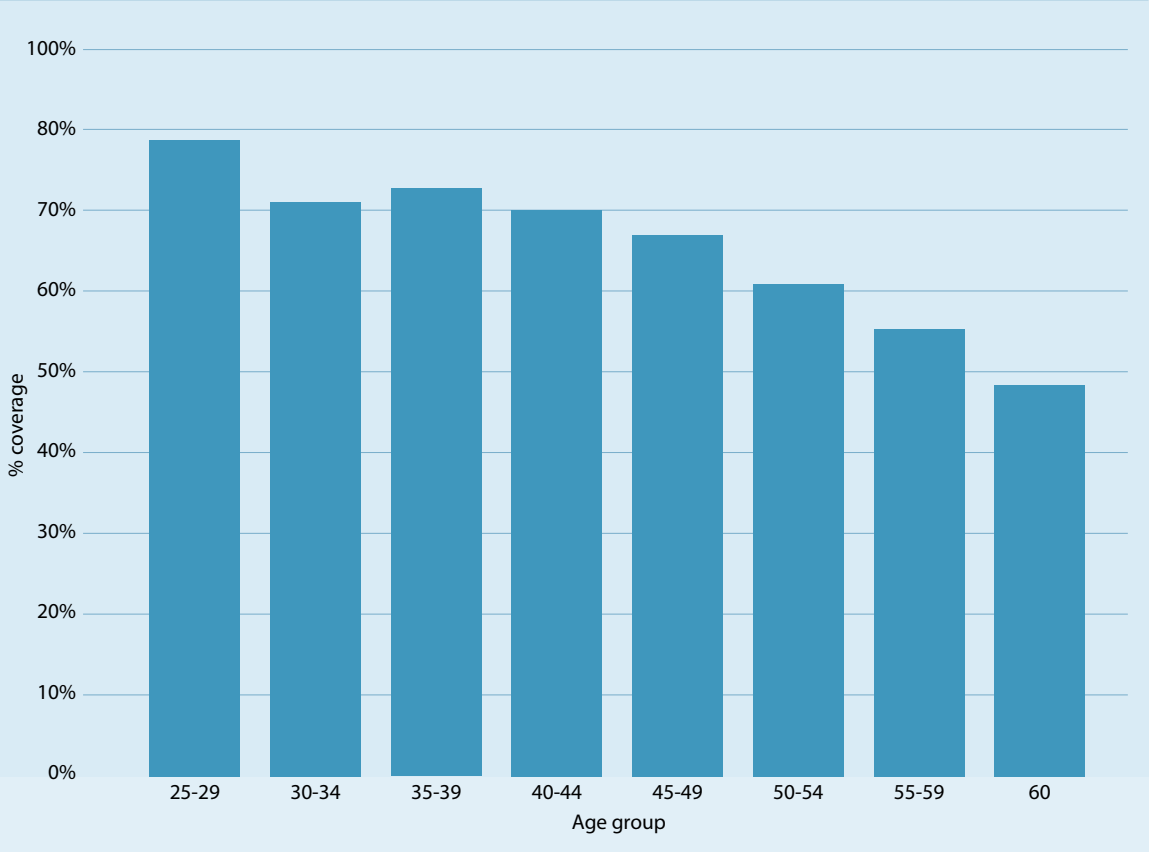


* Data analysed using Health Atlas Ireland.
Population based on CSO 2011 Census extrapolated to 2012

Coverage of the programme by age range for the first four years is shown in Figure 3. These figures represent the number of women screened compared to eligible women as outlined in Census 2011 extrapolated to 2012.

A consistent pattern has been evident since the inception of the programme, with the highest coverage seen in younger age groups and coverage gradually decreasing with increasing age.

Figure 3: Coverage of women by age group



Most women (90.8 per cent) had their smear tests carried out in a primary care setting; 93.2 per cent of these attended a GP practice. For the remainder of women, the first CervicalCheck smear test occurred in a colposcopy clinic, public gynaecology service or STI/GUM clinic.

Laboratory turnaround time

One of the criteria for the selection of laboratories for the provision of cytology services was the capacity and ability to process smear tests within 10 days to facilitate the provision of results to women within four weeks from the date of the smear test. Table 2 shows how the laboratories performed over the fourth year of the programme. Overall for the reporting period 88.2 per cent of test results were received by the programme within two weeks, slightly below the target set.

The laboratories' performance metrics are audited and monitored on an ongoing basis to ensure adherence to the guidelines for quality assurance in cervical screening.

Table 2: Laboratory turnaround time - time from receipt of sample at laboratory to results returned to the programme

Performance parameter	2011/12	Target
% results returned within two weeks of receipt of sample at laboratory.	88.2%	>90%

CervicalCheck women's charter

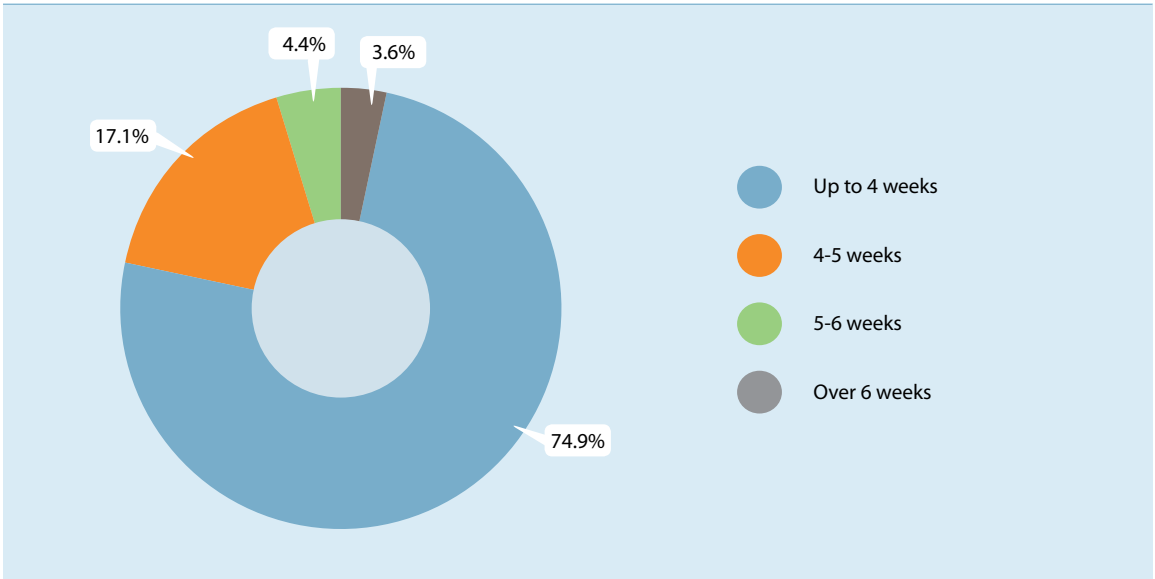
The CervicalCheck women's charter includes the commitment that "your result and any treatment recommendation will be provided to you and your nominated smeartaker by the programme within four weeks". Laboratories typically provide written results to doctors within three weeks of receipt of samples. The programme is notified that the result is available, and women are issued a letter from the programme outlining the next step and any recommendation following their smear test.

By the end of August 2012 almost 75 per cent of women received a results letter from the programme within four weeks (over 91 per cent within five weeks) of their smear test date (Table 3 & Figure 4). Over the first four years of the national programme there has been sustained improvement. The number of women sent results letters within four weeks increased from 40.5 per cent in 2008-2009 to 74.8 per cent in 2011-2012. Ongoing monitoring and actions are taken to progressively improve this response time, working with smeartakers on sample submission as well as process improvements.

Table 3: Percentage of women sent results letter within four weeks of smear test date

Time from smear test to results letter printed date	2011/12	Target
Within 4 weeks	74.8%	>90%

Figure 4: Time in weeks for results letter sent to women (%)



Cytology

Cytology findings reported in Tables 4 and 5 are based on smear test results received by the programme in the period 1 September 2011 to 31 August 2012, rather than the smear test date. Of the 364,213 smear tests taken, a small number were unsatisfactory (Table 4). The outcomes of the remaining 359,659 satisfactory smears are reported in Table 5.

Table 4: 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	%
364,213	4,554	1.3	359,659	98.7

Over 87 per cent of satisfactory smear test results in the period were found to be negative or normal. Of the remainder, 11 per cent showed low grade abnormalities and 1.6 per cent showed high grade abnormalities (HSIL (moderate or severe), ASC-H, query invasive squamous carcinoma or query glandular neoplasia).

The high rate of low grade abnormalities remained an interesting feature of the programme during this year. This is because some were repeat smears that were recommended following a previous low grade smear test result.

Table 5: Cytology results excluding unsatisfactory smear tests

Cytology results	**N**	**%**
NAD (no abnormality detected)	314,476	87.4
Low Grade		
ASCUS	25,497	7.1
AGC (Atypical Glandular Cells)	1,211	0.3
LSIL	12,860	3.6
High Grade		
ASC-H	2,026	0.6
HSIL (Moderate)	1,683	0.5
HSIL (Severe)	1,870	0.5
Query Squamous Cell Carcinoma	10	0.0
Query Glandular Neoplasia or AIS	26	0.0
Total	359,659	100

Of smear tests performed outside of colposcopy clinics 14,194 (4.2%) resulted in a referral to colposcopy.

Diagnosis and treatment

The provision of high quality colposcopy services with timely diagnosis and treatment is a crucial component of successful cervical screening programmes and remains a key priority for the CervicalCheck programme. Fifteen colposcopy services nationwide work with the Programme, each with agreed individualised service plans delivered by dedicated multidisciplinary teams. Information is collected electronically and a central data extraction performed. These data form the basis for this section of the report.

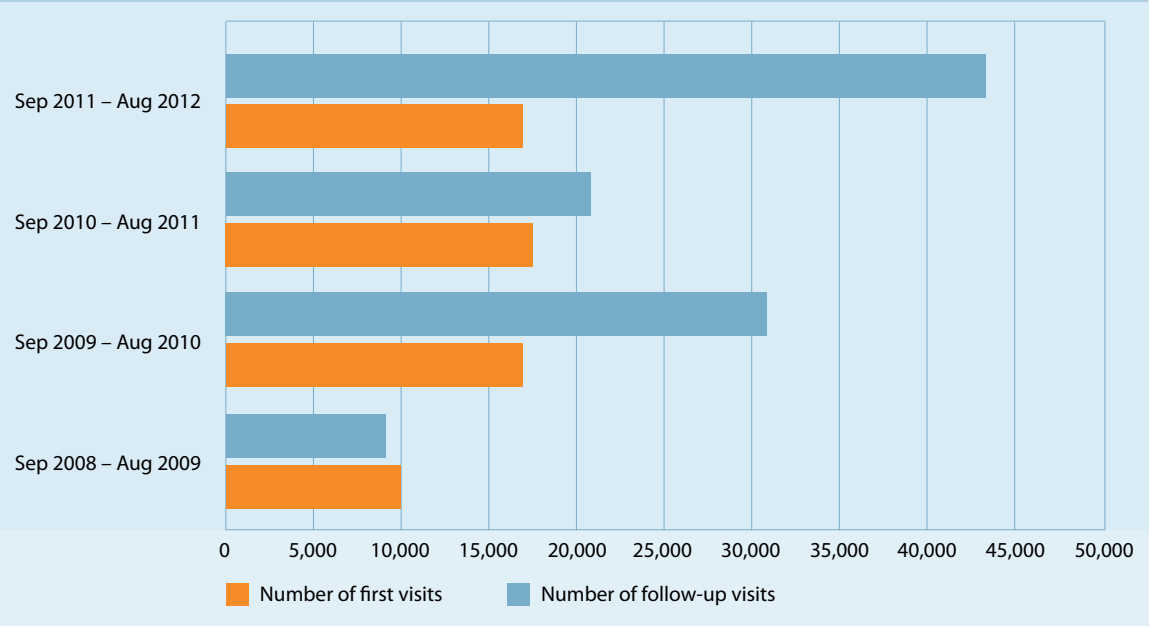
Table 6: Outcome of appointments at colposcopy clinics

	First visits		Follow-ups		Total	
	N	%	N	%	N	%
Attended	16,621	72.6	43,202	53.7	59,823	57.9
Cancelled	5,056	22.1	28,609	35.6	33,665	32.6
Did not attend (DNA)	1,172	5.1	8,531	10.6	9,703	9.4
Not recorded	54	0.2	60	0.1	114	0.2
Total	22,903	100	80,402	100	103,305	100

During the year 16,621 women attended colposcopy for the first time. This represents a slight drop on the previous year. The sustained increase in referrals seen in previous years is reflected in a doubling of the numbers of women attending for follow up appointments (43,202 in 2012 compared to 20,769 in 2011).

It is important to note the number of women referred and the number of new referrals attended will not be the same in any given time period. This is because of the lead time between the colposcopy referral and the date of the first colposcopy visit as well as additional referrals for clinical reasons.

Figure 5: Attendance at colposcopy services from 1 September 2008 – 31 August 2012



Of the 16,621 new attendances at colposcopy, information on the age of the woman was available for 16,488 (99.2%). The mean age at referral was 36 years. The majority of women were aged between 25-45 years with 3.8 per cent aged under 25 years and 11.3 per cent over 50 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.

Women who default from attendance at colposcopy services according to CervicalCheck standards

Performance parameter	2011/12	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.	9.4%	<15%

The rate of DNA appointments is presented according to the type of visit and the age of the woman (Table 7). The DNA rate is higher for return visits than for first visits. As reflected in last year's report, younger women were more likely to default than older women. This may reflect higher levels of mobility within this population of women.

Table 7: DNA rates for appointments offered to women by age group

Age in years at first offered appointments	Number of first appointments	First visit DNA rate (%)	Number of follow-up appointments	Follow-up visit DNA rate (%)
<25	946	12.6	5,798	15.5
25 – 29	6,224	5.5	23,412	12.0
30 – 34	5,011	5.5	17,952	11.2
35 – 39	3,420	5.1	11,470	9.7
40 – 44	2,596	4.0	8,381	8.5
45 – 49	1,927	2.9	5,897	7.5
50 – 54	1,310	2.7	3,592	6.7
55 – 59	684	3.1	1,893	6.1
60	77	2.6	248	3.6
≥61	355	1.7	654	5.2
Not recorded	353	9.3	1,105	12.8

Reasons for referral

Of the 16,621 new referrals who attended colposcopy services, consent information was available for the CervicalCheck programme for 16,590 women (99 per cent). For the remaining one per cent the consent information was not recorded. The reasons for referral to colposcopy for these women were:

- 83 per cent were referred on the basis of an abnormal smear
- 17 per cent for clinical reasons

A number of women were referred to colposcopy from outside of the programme for clinical reasons such as 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 (Table 8).

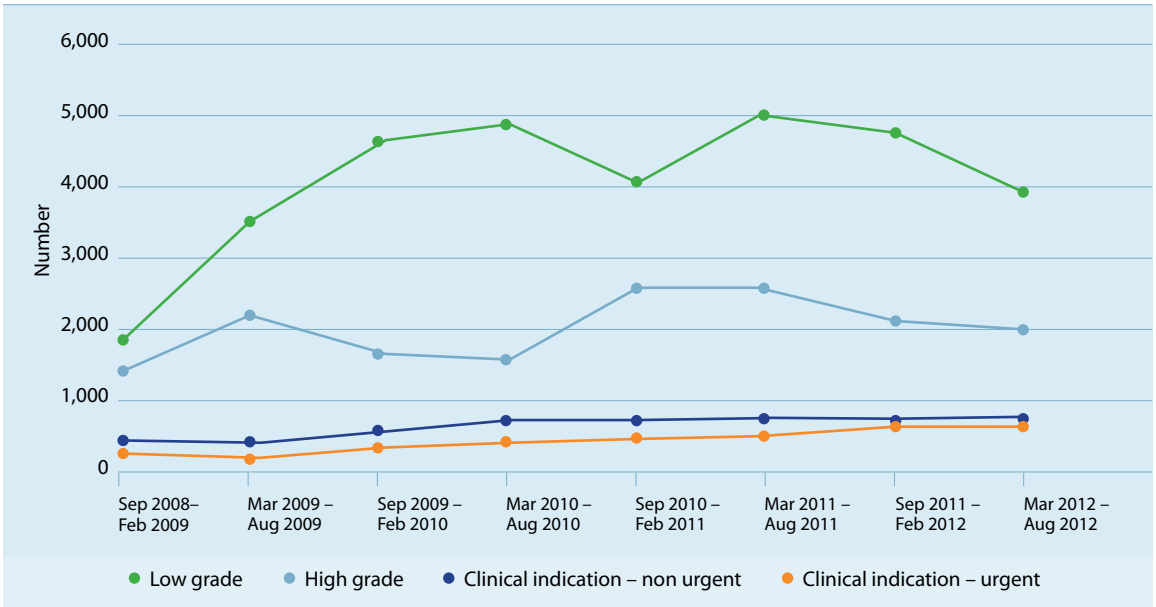
The relative increase in clinical referrals is facilitated by an increase in capacity for these referrals at colposcopy which previously would have been seen in outpatient gynaecology services (Figure 6).

Table 8: Reason for referral to colposcopy

	New referrals for whom consent is available	
Reason for referral to colposcopy	**N**	**%**
Abnormal smear test result	13,728	82.8
Clinical indication – non urgent	1,531	9.2
Clinical indication – urgent	1,316	7.9
Total*	16,575	100

* 15 women had no reason entered

Figure 6: Reason for referral for women attending colposcopy services from 1 September 2008 – 31 August 2012



Of the 13,728 women who presented with an abnormal smear, 4,092 (30%) were referred following detection of a high-grade abnormality (Table 9). The detection of a low-grade smear test result (LSIL or ASCUS) was the reason for referral in 8,690 (63%) women and a smear test showing AGC (borderline glandular cells) was the reason for referral in 883 cases (6.4%). The numbers of women referred with persistently unsatisfactory or inadequate results (63; 0.5%) remained consistently low.

Table 9: Reason for referral to colposcopy as a result of an abnormal smear test result

	New referrals for whom consent is available	
Referral smear abnormality	**N**	**%**
Unsatisfactory / inadequate	63	0.5
Low Grade		
ASCUS	4,334	31.6
AGC (borderline glandular)	883	6.4
LSIL	4,356	31.7
High Grade		
ASC-H	1,410	10.3
HSIL (moderate)	1,272	9.3
HSIL (severe)	1,377	10.0
Query invasive squamous carcinoma	11	0.01
Query glandular neoplasia AIS / adenocarcinoma	22	0.2
Total	13,728	100

Waiting times

One of the key challenges faced by the CervicalCheck programme in the first four years was the provision of access to colposcopy in a timely fashion for women. Since the start of the programme, services have been actively engaged in a process to increase capacity and this has resulted in sustained improvements year on year.

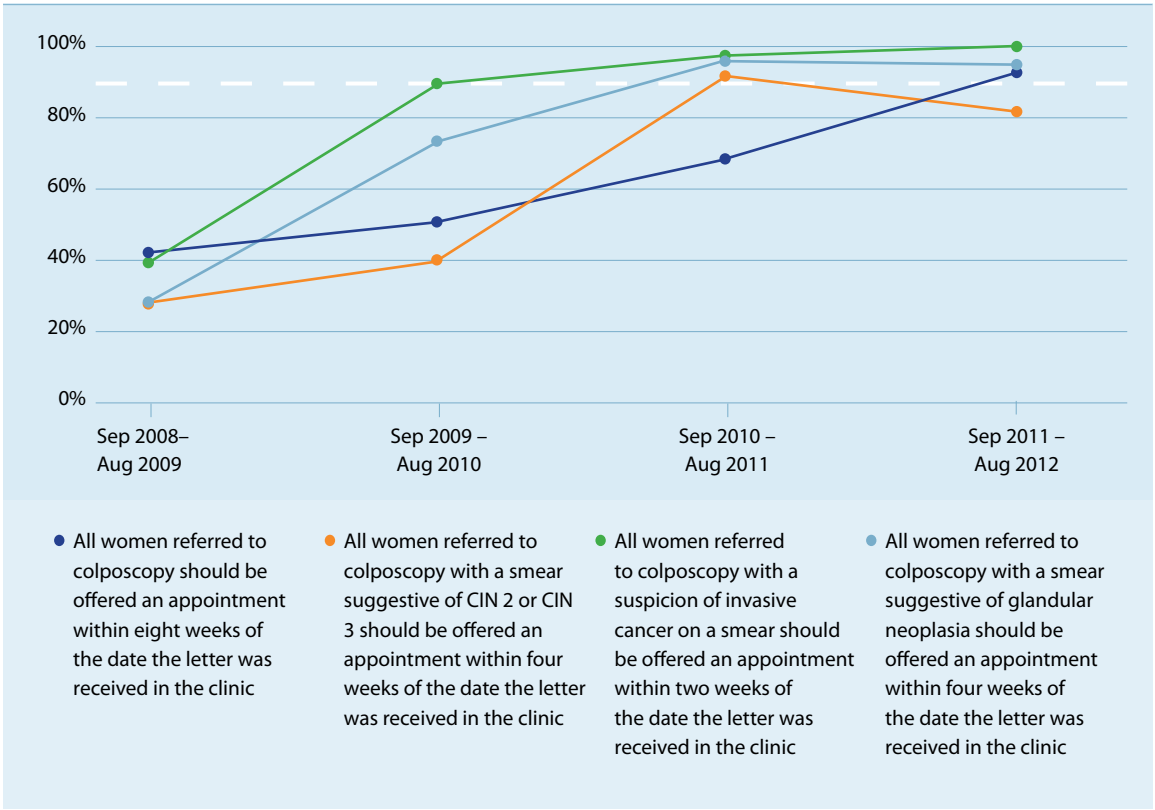
Standards for the programme state that 90 per cent of women with high grade cytological abnormalities should wait less than four weeks and 90 per cent of all women should wait less than eight weeks for an appointment.

For the period 1 September 2011 to 31 August 2012 information on waiting times was available for 15,115 of the 16,590 new attendances (Table 10, Figure 7).

For women referred to colposcopy with a smear test suggestive of CIN2/CIN3, 81.6 per cent were seen within four weeks.

Overall however, only seven per cent of women experienced waiting times of longer than eight weeks and in only one per cent of cases the wait was longer than 12 weeks. This represents a considerable improvement in the fourth year of the programme (during the previous year the wait was longer than 12 weeks in 15.8 per cent of cases).

Figure 7: Waiting time for colposcopy services over first four years of the programme – measured against CervicalCheck standards over time



Waiting times for colposcopy measured against colposcopy standards

Performance parameter	2011/12	Target
All women referred to colposcopy should be offered an appointment within eight weeks of date the letter was received in the clinic.	93.4%	> 90%
All women referred to colposcopy with a smear suggestive of CIN 2 or CIN 3 should be offered an appointment within four weeks of date the letter was received in the clinic.	81.6%	> 90%
All women referred to colposcopy with a suspicion of invasive cancer on a smear should be offered an appointment within two weeks of date the letter was received in the clinic.	100%	> 90%
All women referred to colposcopy with a smear suggestive of glandular neoplasia should be offered an appointment within four weeks of the date the letter was received in the clinic	95.5%	> 90%

Table 10: Waiting times for women referred to colposcopy grouped by grade of referral smear test

	High grade		Low grade		Total	
	N	%	N	%	N	%
Less than 2 weeks	1,411	35.1	1,639	17.4	3,050	22.7
Between 2 and 4 weeks	1,848	45.9	2,274	24.1	4,122	30.6
Between 4 and 8 weeks	689	17.1	4,695	49.7	5,384	40.0
Between 8 and 12 weeks	42	1.0	703	7.4	745	5.5
Greater than 12 weeks	12	0.3	129	1.4	141	1.0

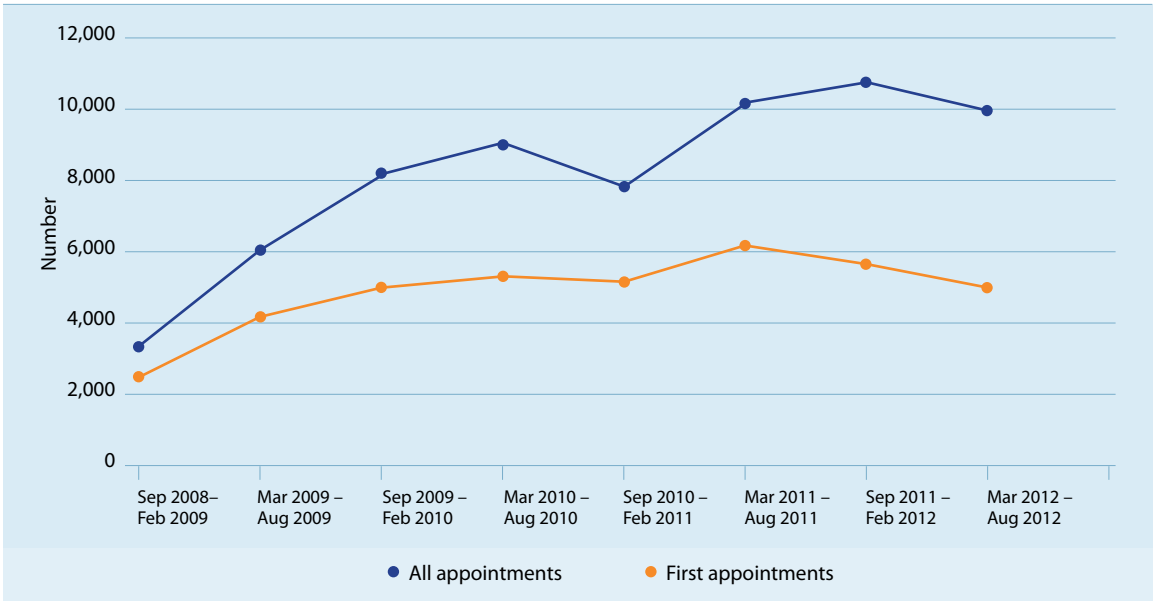
Biopsy rates measured against colposcopy standards

Performance parameter	2011/12	Target
A biopsy should be performed in the presence of an atypical Transformation Zone and a smear test which suggests underlying CIN.	88.0%	>95%
If there is a suspicion of invasive disease a biopsy must be performed immediately.	93.9%	>90%

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 to confirm the diagnosis. There are two main types of biopsy performed – 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.

During the reporting period 13,373 diagnostic biopsies, 7,375 excisional biopsies and 40 other biopsies were performed. The initial colposcopy visit determines the presence or absence of an atypical Transformation Zone. A biopsy was performed in 88 per cent of cases where the transformation zone was documented as atypical and over 93 per cent of cases where an invasive cancer was suspected.

Figure 8: Number of women undergoing biopsy at colposcopy services



The biopsy rates according to the grade of the referral smear test and reasons for referral are presented in Table 11. Eighty five per cent of women presenting with a high grade cytological abnormality had a biopsy performed at the first visit compared with 60 per cent of women presenting with a low grade cytological abnormality. Over 69 per cent of women presenting with AGC (borderline glandular cells) had a biopsy at the first visit which included an excisional biopsy in 16.4 per cent. This reflects the continued difficulty of managing this relatively new group of women particularly if the colposcopic appearance is normal or unsatisfactory.

Table 11: Biopsies performed during the first visit to colposcopy according to referral smear grade

	Biopsy performed							
	Excisional		Diagnostic biopsy		No biopsy biopsy		Total taken	
Grade of cytology result of referral smear	**N**	**%**	**N**	**%**	**N**	**%**	**N**	**%**
AGC (borderline glandular)	145	16.4	468	53.0	270	30.6	883	100
High Grade	1,193	29.2	2,283	55.8	616	15.1	4,092	100
Low Grade	360	4.1	4,821	55.5	3,509	40.4	8,690	100
Unsatisfactory / inadequate	2	3.2	19	30.2	42	66.7	63	100
Total	1,700	12.4	7,591	55.3	4,437	32.3	13,728	100

Treatment at colposcopy

Effective treatment of high grade CIN and adenocarcinoma in situ with subsequent reduction of the risk of invasive cancer is vital to the success of any cervical screening programme. This treatment should be effective, safe and acceptable. It should aim to eradicate all CIN from the cervix and should be tailored to the circumstances of the individual woman.

The standards for the CervicalCheck programme state that treatments be performed as an outpatient procedure under local anaesthetic more than 80 per cent of the time. During the fourth year of the programme treatment was performed as an outpatient using local anaesthetic 94 per cent of the time, surpassing this target.

The outcome of use of local anaesthetic measured against colposcopy standards

Performance parameter	2011/12	Target
The majority of women should have treatment performed as an outpatient under local anaesthetic.	94.0	>80%

During the reporting period, 8,109 treatments were recorded at colposcopy. Large loop excision of the Transformation Zone (LLETZ) was performed in 7,236 (89.2%) and ablative treatment was used in 758 (9.3%) cases. Forty cone biopsies (0.5%), 74 hysterectomies (0.9%) and one trachalectomy (0.01%) were performed (Figures 9 and 10). Of the total treatments, 7,545 were performed following an abnormal smear test.

Figure 9: Treatment at colposcopy

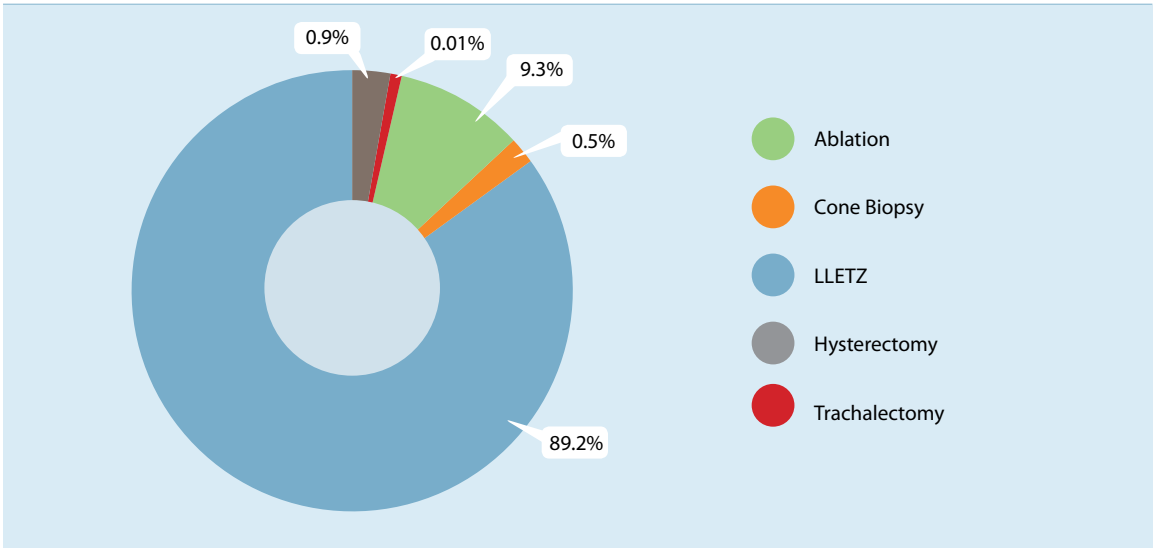


Figure 10: Number of women undergoing treatment at colposcopy

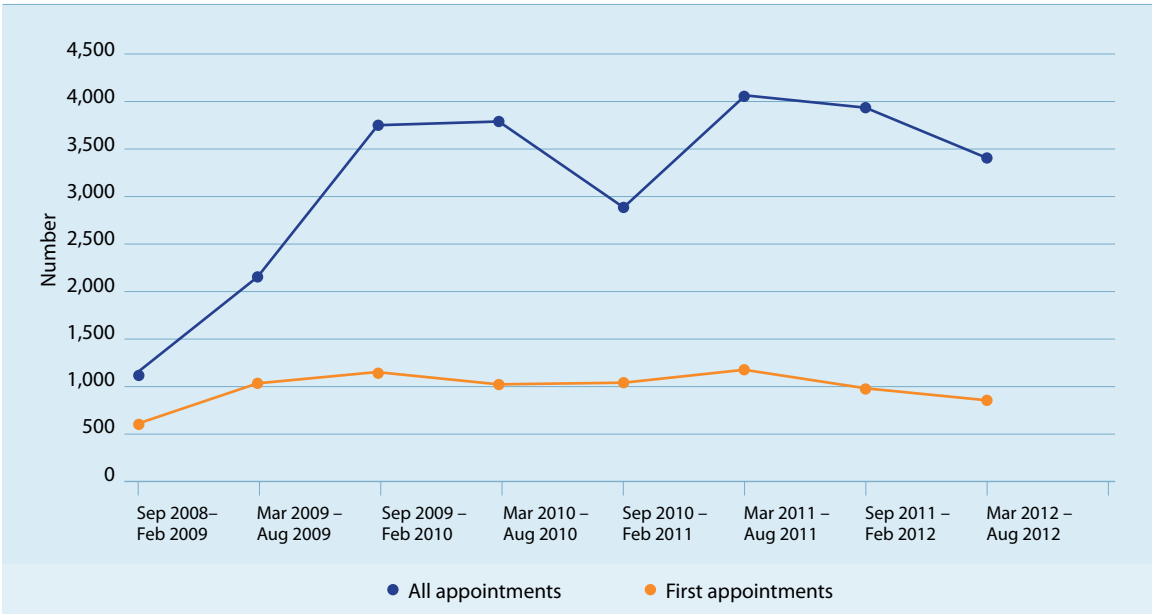


Table 12: Treatment at first visit to colposcopy

Reason for referral to colposcopy	No treatment on first visit		Treatment on first visit		Total number of women attended	
	N	%	N	%	N	%
Clinical indication – non urgent	1,472	96.1	59	3.9	1,531	100
Clinical indication – urgent	1,282	97.4	34	2.6	1,316	100
AGC (borderline glandular)	737	83.5	146	16.5	883	100
High grade	2,901	70.9	1,191	29.1	4,092	100
Low grade	8,330	95.9	360	4.1	8,690	100
Unsatisfactory /inadequate	61	96.8	2	3.2	63	100
Total	14,783	89.2	1,792	10.8	16,575	100

One of the key challenges of screening is the avoidance of overtreatment. This is of particular relevance to cervical screening because treatment has the potential to have an adverse effect on future fertility. In this regard treatment at the first visit for women who present with low grade abnormalities should be avoided and kept below 10 per cent. During the fourth year of the programme this figure was within the target at 4.1 per cent.

It is generally accepted that most of the women who undergo excisional procedures should have CIN on histology on the excised specimen. This is particularly true if the procedure is performed at the first visit to colposcopy. During the fourth year of the CervicalCheck programme this target was reached with nearly 92 per cent of women treated at the first visit having CIN on histology.

The performance of colposcopy treatment parameters measured against colposcopy standards

Performance parameter	2011/12	Target
Treatment at first visit should not be performed on women who present with low grade cytological change even if there is a Colposcopic suspicion of high grade disease (except in special circumstances).	4.1%	<10%
Women treated by excisional treatments at first visit should have CIN on histology.	91.8%	>90%
Women treated by excisional treatments at any visit should have CIN on histology.	91.0%	>80%

Colposcopy plays an important role in the evaluation of women with suspected cervical abnormalities. It allows the identification of the site of the abnormality as well as an estimation of the grade of abnormality including the presence or absence of features suggestive of invasive cancer. The correlation between the colposcopic impression and histological diagnosis is a useful marker of the quality of colposcopy. During the year the positive predictive value of a colposcopic impression of high grade disease was 75 per cent which exceeds the CervicalCheck standard (>65%).

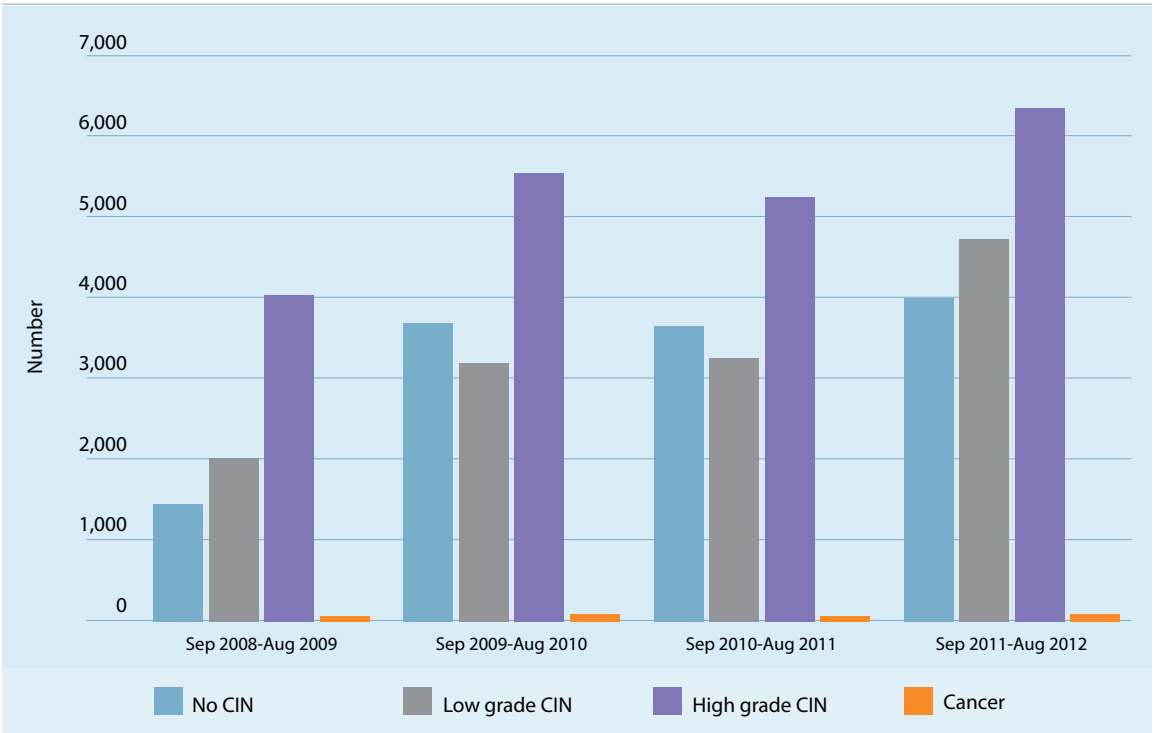
The positive predictive value of colposcopy measured against colposcopy standards

Performance parameter	2011/12	Target
Compliance between Colposcopic impression of high grade disease and histologically proven high grade CIN.	75.3%	>65%

Histology

The objective of a cervical screening programme is the detection and treatment of high grade CIN and the yield of these abnormalities is one of the hallmarks of a successful programme. The histology is presented by year in Figure 11. The yield of high grade abnormalities remained consistently high and illustrates the programme is achieving its objective of detection and treatment of high grade CIN. This reflects the sustained high levels of activity in the colposcopy services.

Figure 11: Detection of CIN and cancer



Performance parameter	2011/12	Target
Biopsy specimens should be suitable for histological diagnosis	98.7%	>95%

Table 13: Histology results for women who had a satisfactory biopsy in colposcopy from 1 September 2011 to 31 August 2012

	No CIN/No HPV (normal)		HPV / Cervitis only		CIN 1		CIN 2		CIN 3		Adenocarcinoma in situ / CGIN		Cancer (including micro invasive)	
Grade of cytology result of referral smear	**N**	**%**	**N**	**%**	**N**	**%**	**N**	**%**	**N**	**%**	**N**	**%**	**N**	**%**
ASCUS	723	20.9	448	12.9	1,431	41.3	517	14.9	331	9.6	10	0.3	4	0.1
AGC (borderline glandular)	249	29.2	85	10.0	244	28.6	88	10.3	124	14.5	52	6.1	12	1.4
LSIL	654	15.0	435	10.0	1,732	39.7	925	21.2	603	13.8	14	0.3	1	0.02
ASC-H	144	9.7	103	7.0	324	21.9	272	18.4	610	41.2	12	0.8	16	1.1
HSIL (moderate or severe)	211	6.0	147	4.2	501	14.2	560	15.9	2,007	56.9	29	0.8	71	2.0
Query invasive squamous carcinoma	1	10.0	0	0.0	0	0.0	0	0.0	1	10.0	1	10.0	7	70.0
Query glandular neoplasia AIS / adenocarcinoma	6	20.7	1	3.4	3	10.3	1	3.4	9	31.0	5	17.2	4	13.8
Unsatisfactory / Inadequate	11	40.7	5	18.5	8	29.6	0	0.0	3	11.1	0	0.0	0	0.0
Total	1,999	14.5	1,224	8.9	4,243	30.8	2,363	17.2	3,688	26.8	123	0.9	115	0.8

Performance measures for CervicalCheck programme smear tests

Cervical screening programmes have to balance the early detection of high grade abnormalities with avoiding unnecessary investigations and possible overtreatment. Performance measures have been developed which look at how valid the screening tests are within organised programmes. These include the positive predictive value (PPV), abnormal predictive value (APV), total predictive value (TPV) and referral value (RV).

Measures of the performance of cytology	
PPV	75.6%
APV	28.7%
TPV	45.8%
RV	2.18

The positive predictive value (PPV) is reported as the percentage of women referred with high-grade cytological abnormality who have a histological diagnosis of CIN2 or higher. During the current reporting year the PPV was 75.6 per cent.

The abnormal predictive value (APV) calculates the percentage of samples reported as borderline or low-grade that led to referral to colposcopy and subsequent histological diagnosis of CIN2 or higher. During the current reporting year the APV was 28.7 per cent.

The total predictive value (TPV) examines the percentage of all women referred to colposcopy on the basis of an abnormal smear who have a histological outcome of CIN2 or worse. During the reporting year 45.8 per cent of women referred to colposcopy had CIN2 or higher demonstrated on histology.

The referral value (RV) looks at this in another way and examines the number of women referred to colposcopy for the detection of one case of CIN2 or worse. During the current reporting year, for every 2.18 women referred to colposcopy one had CIN2 or higher detected (for every 218 women referred to colposcopy 100 had CIN2 or higher detected).

Glossary

Ablation

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 pre-cancerous 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. These changes can include a variety of patterns including: leukoplakia, acetowhite epithelium and abnormal vascular patterns.

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 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 or 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 pre-cancerous changes.

Cervical cytology

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

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

Woman aged 25 to 60 who live in Ireland are eligible to have a free smear test.

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/CIS).

Histology

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

Human papillomavirus (HPV)

A group of wart 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 smeartaker 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.

Large loop excision of the Transformation Zone (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 wounding.

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).

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 pre-cancerous cervical abnormality.

Primary care setting

First contact care that is not hospital or specialist care - general practice, Well Woman and Family Planning 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.

Smeartakers

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-layers 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 per cent.

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.

National
Cancer Screening
Service

The National Cancer Screening Service is part of the Health Service Executive. It encompasses BreastCheck – The National Breast Screening Programme, CervicalCheck – The National Cervical Screening Programme, BowelScreen – The National Bowel Screening Programme and Diabetic RetinaScreen – The National Diabetic Retinal Screening Programme

QA - CS/PR/PM-17 Rev 1
ISBN number: 978-1-907487-14-9