

Programme Report

2015-2016

Women's Charter

CervicalCheck aims to reduce the incidence of cervical cancer

Screening commitments

- CervicalCheck offers free cervical screening to all women aged 25 to 60 years
- You can choose which registered doctor or nurse to attend
- You may change your choice of doctor or nurse for subsequent CervicalCheck screening
- If you have special needs and require assistance in accessing the programme, CervicalCheck will support you
- Your screening test sample will be sent to an accredited quality assured laboratory
- CervicalCheck will send you a letter when the result of your test is available from your doctor or nurse, usually within four weeks of your screening test
- If the result is normal, you will be invited again when your next screening test is due
- If you are recommended for follow up tests you will also be offered these free of charge
- If you are recommended for further investigation, you will be offered an appointment free of charge at a programme colposcopy clinic, usually within two months
- All members of CervicalCheck staff will respect your privacy, dignity, religion, race and cultural beliefs
- Your screening records will be treated in the strictest confidence in accordance with data protection legislation

Ways you can help us

- Check that you are registered with CervicalCheck
- Read the information about cervical screening, its benefits and limitations
This is important as you will be asked to sign your informed consent to participate in CervicalCheck
- Make your appointment with a registered doctor or nurse when your smear test is due
- Let us know if you require any specific assistance or have any special needs to help you with your screening appointment
- Having your PPS number with you for your appointment helps to identify your record on the cervical screening register
- Let us know if you change your surname or address, or if you are moving to a different country

You can always tell us what you think

- Your views and opinions are important to us to help us monitor the effectiveness of our services and see if we can improve them

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**An tSeirbhís Náisiúnta Scagthástála
National Screening Service**

Cuid d'Fheidhmeannacht na Seirbhíse Sláinte. Part of the Health Service Executive.

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Introduction from the Head of Screening, National Screening Service

I am delighted to celebrate this report on behalf of the National Screening Service (NSS), which highlights the achievements secured in the eighth year of operation of the CervicalCheck programme.

The NSS, part of the Health Service Executive (HSE), has gained significant expertise, as well as a positive national and international reputation, in the development, implementation and delivery of successful population-based screening programmes in Ireland.

The NSS manages four screening programmes:

BreastCheck -

The National Breast Screening Programme,

CervicalCheck -

The National Cervical Screening Programme,

Diabetic RetinaScreen -

The National Diabetic Retinal Screening Programme and

BowelScreen -

The National Bowel Screening Programme.

Definition of screening

Screening is a means of detecting disease before symptoms appear. Cervical screening aims to prevent cervical cancer through the early detection and treatment of precancerous changes on the cervix. Earlier detection can often increase treatment options, as well as reduce the invasiveness of that treatment. Screening ultimately aims to improve survival rates, reduce morbidity and mortality and improve the quality of life of those who have developed cancer.

The NSS provides screening for both cancer and non-cancer disease. Although screening does not provide a guarantee of diagnosis and cure for all patients, it provides an opportunity for those who have a positive test to receive confirmatory diagnostic testing, before further definitive diagnosis and treatment stages are put in place.

“The programme has coverage levels approaching internationally leading levels, which will maximise its effectiveness on the incidence of cervical cancer.”

Population-based screening

Population-based call and re-call screening programmes provide a consistent, high-quality and standardised approach to identifying the population most at risk from a particular disease, through to diagnosis and referral for treatment. The process begins with developing a register of clients in the identified population, inviting participation in the programme, offering clear referral and treatment pathways within set time limits and developing a mechanism to re-call clients at defined intervals.

Organised screening has many advantages. In particular, the process makes it possible to provide effective early detection and reduced mortality with a test for which consistent repeat participation is necessary, in order to achieve acceptable clinical benefits. This is why adherence to regular screening is an important element of all NSS screening programmes.

CervicalCheck

CervicalCheck began in 2008, with the aim of offering free screening to women aged 25 to 60, at defined intervals. Over the past nine years, the programme has maintained a resolute focus on the provision of a high quality evidence based service to clients. With this report, we present the results from the eighth year of screening and there is much to celebrate. Specifically, the programme has coverage levels approaching internationally leading levels, which will maximise its effectiveness on the incidence of cervical cancer, and has an effective partnership with colposcopy units across the HSE that ensures best practice treatment is provided to appropriate women.

Through our quality assured pathways, the NSS continually evaluates the processes that underpin each screening technology.

As we publish this report, we propose that changes should be made to CervicalCheck, in line with the recommendation of the Health Information and Quality Authority (HIQA), Health Technology Assessment (HTA),¹ which proposes the use of HPV testing as the primary cervical screening tool.

This will be a significant and exciting change as it offers the potential for even fewer women being diagnosed with cervical cancer, fewer women dying each year from the disease and will also enable us to extend the age of screening towards 65. We remain committed to the swift and efficient introduction of this change and remain tightly focused on achieving a coverage level above 80%.

At this juncture, I would like to thank all those involved in the development, implementation and support to the CervicalCheck programme for their dedication, energy and enthusiasm. I would like to particularly thank our colleagues within general practice, colposcopy services, laboratories, histopathology and cytology for their unwavering support. I am delighted that we are now in a position to publish these results, which demonstrate very encouraging outcomes. With the ongoing support of our partners, we will be able to ensure that we can continue to provide cervical screening services of the highest international standard to the women of Ireland.

Charles O'Hanlon,
Head of Screening,
National Screening Service

Message from the Clinical Director, CervicalCheck

CervicalCheck has always strived to provide a cervical screening programme which is comparable to any to be found in other countries. As the programme monitors new research and studies in the field of cervical screening, we have aimed to employ these learnings to benefit the women of Ireland.

The programme has, in recent years, taken advantage of HPV reflex testing to efficiently reduce the number of women who require referral to colposcopy over time. This year's programme report demonstrates the outcome of this change. There was a marked increase in the number of women who attended colposcopy for the first time, resulting in the busiest year on record. Despite this increased workload, the waiting times for colposcopy remained within the recommended target levels. The commitment of the colposcopy services to respond to the additional need should be recognised and commended.

Advances in research show that the introduction of HPV testing as the primary screening tool could further improve the detection of high grade precancerous changes with a resultant decrease in the number of cervical cancers in Ireland. In addition, it is likely that the test would result in a reduction of the frequency of cervical screening appointments and ultimately the number of times a woman will be required to attend for screening in her lifetime.

The outcome of the HIQA "Health technology assessment of human papillomavirus testing as the primary screening method for prevention of cervical cancer"¹ is very welcome and we look forward to examining the feasibility of implementing the recommendations outlined in the report.

Sustained improvements to colposcopy services in Ireland have been achieved through successful collaboration between the programme and colposcopy services nationwide.

As CervicalCheck moves into its tenth year working together with the 15 colposcopy services, it operates within an effective framework supported by established and clearly defined clinical governance and management arrangements. The NSS has worked closely with all 15 colposcopy services, to ensure continuous improvement and adherence to NSS guidelines. The colposcopy service is provided by clinicians who are certified by the British Society for Colposcopy and Cervical Pathology (BSCCP).

Colposcopy services

There are 15 services that provide colposcopy support to the CervicalCheck programme which are based in the following hospitals:

- The Adelaide & Meath National Children's Hospital, Dublin

- St Finbarr's Hospital, Cork

- Coombe Women & Infants University Hospital, Dublin

- Louth County Hospital

- University College Hospital, Galway

- Kerry General Hospital

- Letterkenny General Hospital

- Limerick Regional Maternity Hospital

- Mayo General Hospital

- National Maternity Hospital, Dublin

- Rotunda Hospital, Dublin

- Sligo General Hospital

- South Tipperary General Hospital

- Waterford Regional Hospital

- Wexford General Hospital

In this report, national data is presented against quality key performance parameters for colposcopy, setting a framework for measuring improvement. I wish to acknowledge the support of both the clinical and administration teams at each of the 15 colposcopy services that support CervicalCheck. Their commitment to a high standard of colposcopy service has ensured that women who require a colposcopy are guaranteed timely access to a standardised level of quality assured care. The results presented in this report could not have been achieved without the persistence and dedication of the staff at each of the 15 services.

Professor Gráinne Flannelly,
Clinical Director,
CervicalCheck

“sustained improvements to colposcopy services have been achieved through successful collaboration between the programme and colposcopy services nationwide.”

From 1 September 2015 to 31 August 2016:

263,481

satisfactory smear tests were taken

90.8%

of satisfactory smear tests were found to be negative, or normal

17,907

women attended a colposcopy appointment for the first time, representing an **increase of 1,360 women (8%)** in comparison to the previous year

38,837

women attended a follow-up appointment

7,131

treatments were performed at colposcopy

96.8%

of colposcopy treatments were performed as an outpatient under local anaesthetic

8,885

women had pre-cancerous abnormalities detected

187

women were diagnosed with invasive cancer

Message from the Programme Manager, CervicalCheck

The eighth year of operation of CervicalCheck as the national cervical screening programme saw further progress towards achieving our objective of reducing the incidence and burden of cervical cancer, as well as successful developments in how the programme is implemented.

I am delighted to report that coverage of the target population of almost 1.2 million women aged 25 to 60 years over a five-year period reached 79.7 per cent. More than 50,000 women with high grade CIN have been diagnosed and treated in the eight years, considerably reducing their risk of developing cervical cancer. To date, there are positive indications that the programme is on course to achieve its objective of significantly reducing the incidence of cervical cancer. We are hopeful that data from the National Cancer Registry of Ireland (NCRI) over the coming years will demonstrate this conclusively.

The original screening strategy utilised liquid-based cytology (LBC) screening. In May 2015, the screening strategy changed to include reflex HPV testing of samples with low grade cytological abnormalities. The eighth year provided evidence from a full year of operation following the introduction of this new strategy and demonstrated its effectiveness in providing earlier detection of abnormalities for some women, while avoiding unnecessary tests for other women.

The successful change in strategy was effected through the planning and collaboration of key service providers: GP and practice nurses, laboratories, colposcopy services and the programme office.

Some of the key factors in the achievements of the screening programme to date include:

- Consistent messaging and support for women, with a continual emphasis upon quality.
- The recognition of the CervicalCheck name and logo.
- The information content, linkages and functionality of the Cervical Screening Register.
- The active engagement of doctors, nurses and associated staff in primary care.
- The active engagement of colposcopy services to provide adequate capacity and appropriate resources, timely appointments and the management and follow up of women.
- The coordination, support and resources for key service providers – GPs and practice nurses, laboratories and colposcopy services.
- The provision of women's screening history to key stakeholders, to support the management of women within the screening programme.

Over 4,500 GPs, doctors and nurses in more than 1,400 primary care locations are registered with CervicalCheck for cervical screening. They provide access to CervicalCheck for most women, promoting cervical screening to eligible women, assessing cervical screening needs, taking the screening tests and following up test results. The NSS Screening Training Unit is developing significantly enhanced online resources for these health professionals to complement the existing online facilities, training programmes and e-learning modules.

As the programme moves to its tenth year and beyond, we are resolutely focused on our objective of reducing the incidence of cervical cancer in women in Ireland and to further progress developments to ensure effective implementation.

John Gleeson,
Programme Manager,
CervicalCheck

Highlights

Impact of HPV reflex testing

The eighth year of the programme witnessed the full implementation of a change in screening strategy whereby the screening tests of women with low grade changes underwent a reflex HPV test to better select those women who should be investigated for high grade CIN, while avoiding unnecessary repeat tests for other women.

Highest number of high grade CINs detected

One of the aims of CervicalCheck is to detect abnormal cell changes in the cervix at an early stage, when treatment is more effective. This report highlights that the programme has detected the highest number of high grade CINs since the start of the programme.

Highest coverage

At 79.7 per cent, this is the highest coverage ever achieved by CervicalCheck. The programme is close to meeting its target of 80 per cent of women screened within five years. Achieving and maintaining this target is important if CervicalCheck is to perform at its most effective in terms of reducing mortality and morbidity from cervical cancer in Ireland.

Highest number of colposcopy referrals

More women were referred to colposcopy than in any previous year. Despite this increase, waiting times were maintained.

Outstanding colposcopy performance

There was sustained improvement in colposcopy clinics nationwide, with most targets for colposcopy being exceeded for all services.

Introduction to the statistics 2015/2016

CervicalCheck - The National Cervical Screening Programme has been in operation since 1 September 2008. The figures reported in this section relate to the eighth year of the programme (1 September 2015 to 31 August 2016). During the reporting period, a combination of “invitation / re-call” and “direct entry” was in operation. This means that in addition to the programme sending letters to women to remind them that their next cervical screening test is due, women whose details were on the Cervical Screening Register could check their next cervical screening test due date using an on-line facility on the CervicalCheck website. A separate facility is also available to health professionals for this purpose.

Quality assurance underpins every aspect of the CervicalCheck programme and programme performance is measured against key performance indicators (KPIs) as outlined in the Guidelines for Quality Assurance in Cervical Screening (2013).²

PART 1

Cervical screening activity

The data in this section of the programme report is obtained from the Cervical Screening Register. The response to the Programme was very positive in year eight with 272,086 women attending for a cervical screening test in all locations (primary and secondary care including colposcopy services).

Women between the ages of 25 and 60 are invited for screening, but a small number of women under the age of 25 may attend under specific circumstances. Those women aged 61 or over include women presenting for the first time at this

age, as well as those who first attended for a cervical screening test before the age of 61 but who did not have a second successive normal result; this second normal result is required to exit the programme.

Table 1 shows the number of women who had a cervical screening test by age group.

There were 248,963 women screened in the period in non-colposcopy settings, 98.9 per cent of which were screened in primary care (GP or family planning clinic).

Table 1: Number of women who had a CervicalCheck cervical screening test (all locations including colposcopy) by age group between September 2015 and August 2016

Age group	Number of women who had a cervical screening test	% of women who had a cervical screening test
<25*	666	0.2
25-29	44,555	16.4
30-34	48,380	17.8
35-39	51,369	18.9
40-44	46,923	17.2
45-49	33,323	12.2
50-54	19,545	7.2
55-59	15,273	5.6
60	2,550	0.9
≥61	9,502	3.5
Total	272,086	100.0

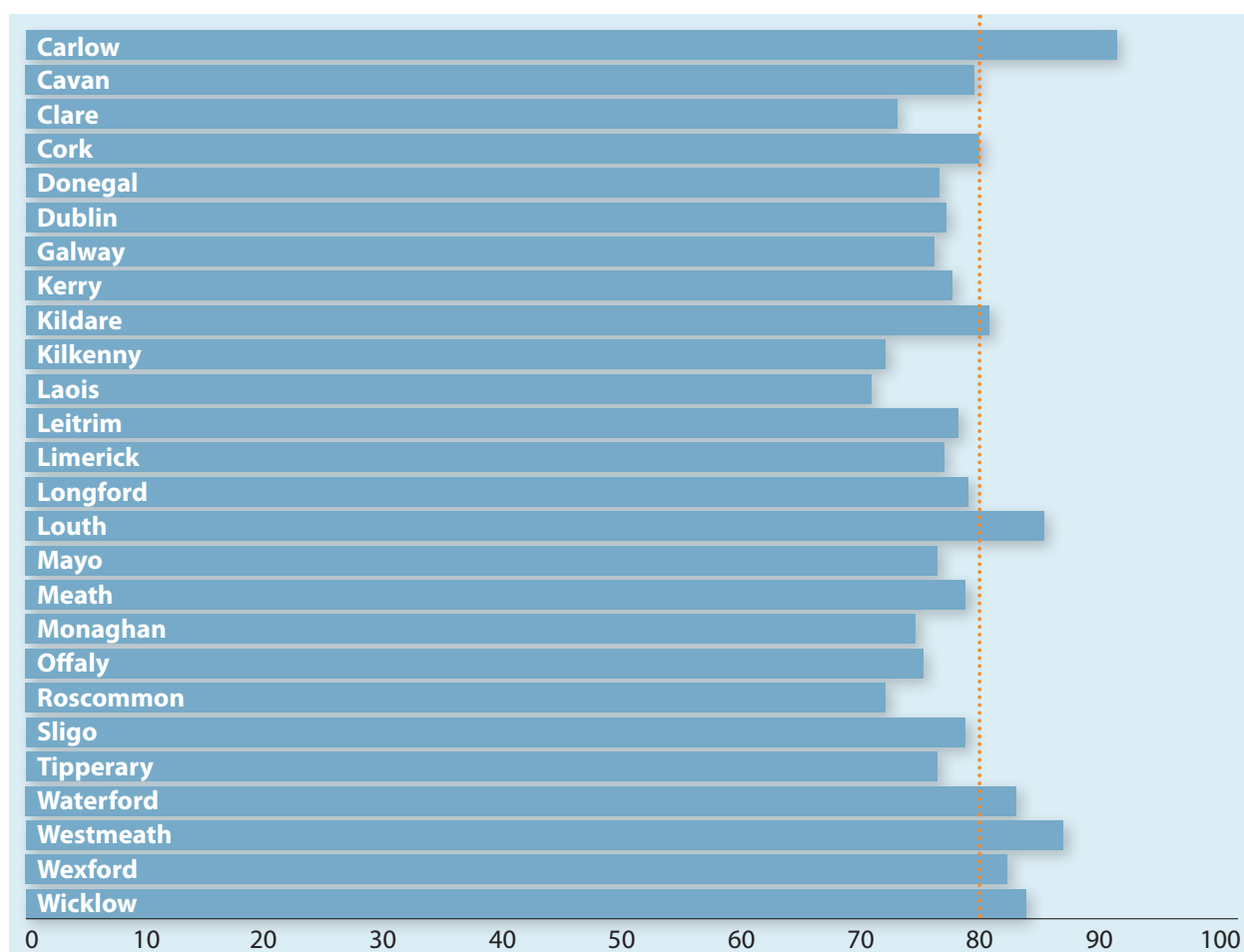
* Based on international evidence to date, there is no additional public health benefit in starting population screening below the age of 25. Screening in women under the age of 25 may lead to many women receiving unnecessary treatment for lesions that would never have developed into invasive cancer. 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 cervical screening 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 cervical screening test result and are within the recommended follow-up period.

Programme coverage

Coverage, a key performance indicator for the programme, is a measure of the proportion of the target population based on national census figures 2011 projected to 2013 (which is the mid-point year of the five-year screening round) screened within a period and indicates the effectiveness of the screening programme in reaching the target population. Coverage is measured by five-year screening round. The five-year coverage at the end of the reporting period (31 August 2016) was 79.7 per cent. This national figure is adjusted for those women who have had a total hysterectomy with complete removal of the cervix and therefore do not form part of the target population for cervical screening. The programme's goal is 80 per cent coverage over a five-year period.

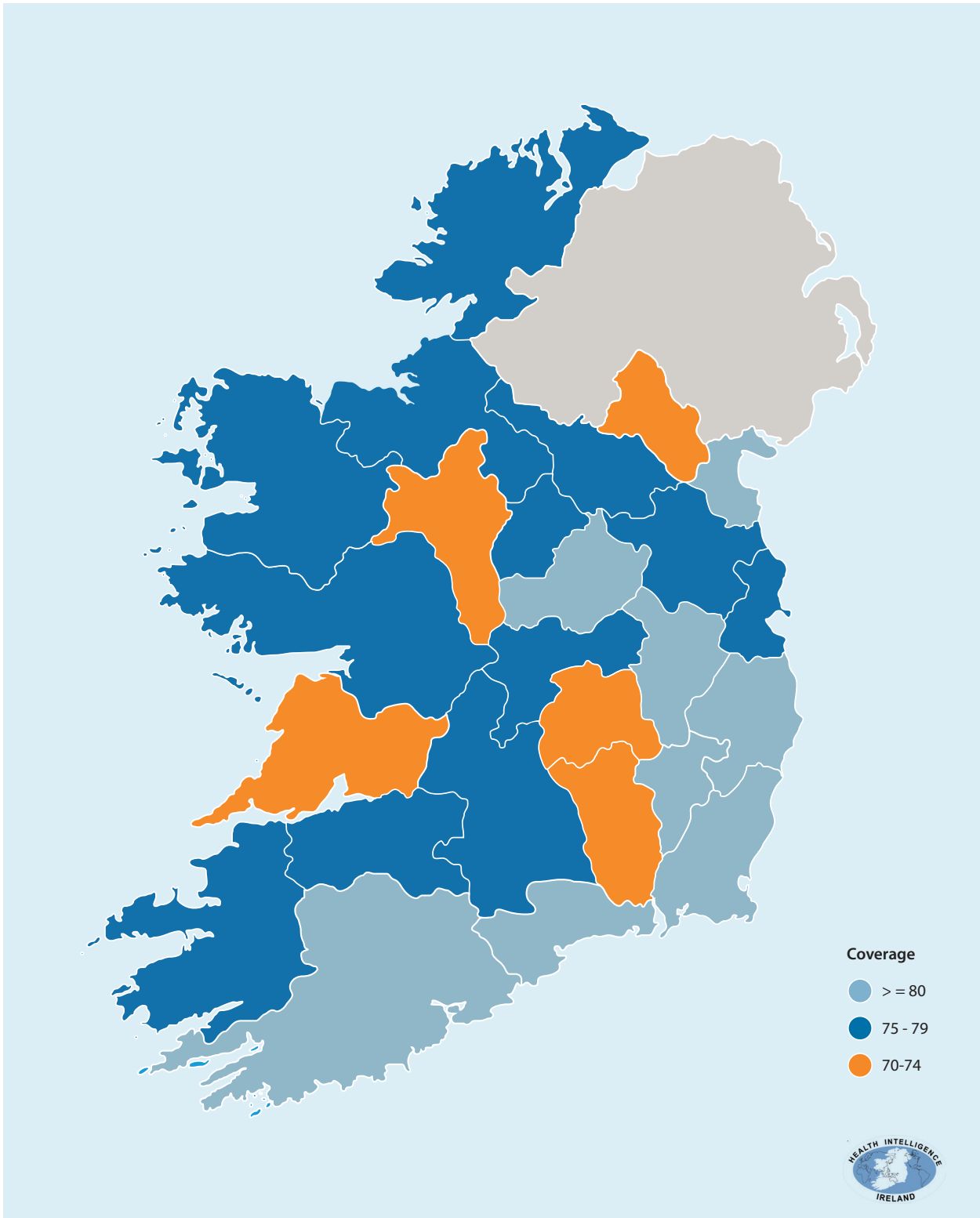
An indicative geographical spread of screening coverage by county is shown in Figures 1 and 2. The coverage calculations are based on population estimates from census 2011 counts rolled forward to 2013, and do not take into account estimates of emigration, immigration, hysterectomy or deaths. Eight counties achieved the target of 80 per cent coverage over the five-year period and one of those counties achieved higher than 90 per cent during this time. Five counties had coverage between 70 and 75 per cent.

Figure 1: Five-year coverage (%) based on county of residence on the cervical screening register* for period ending 31 August 2016



* Population based on CSO 2011³ figures projected to 2013, not adjusted for hysterectomy (hysterectomy data is not available by geographic location)

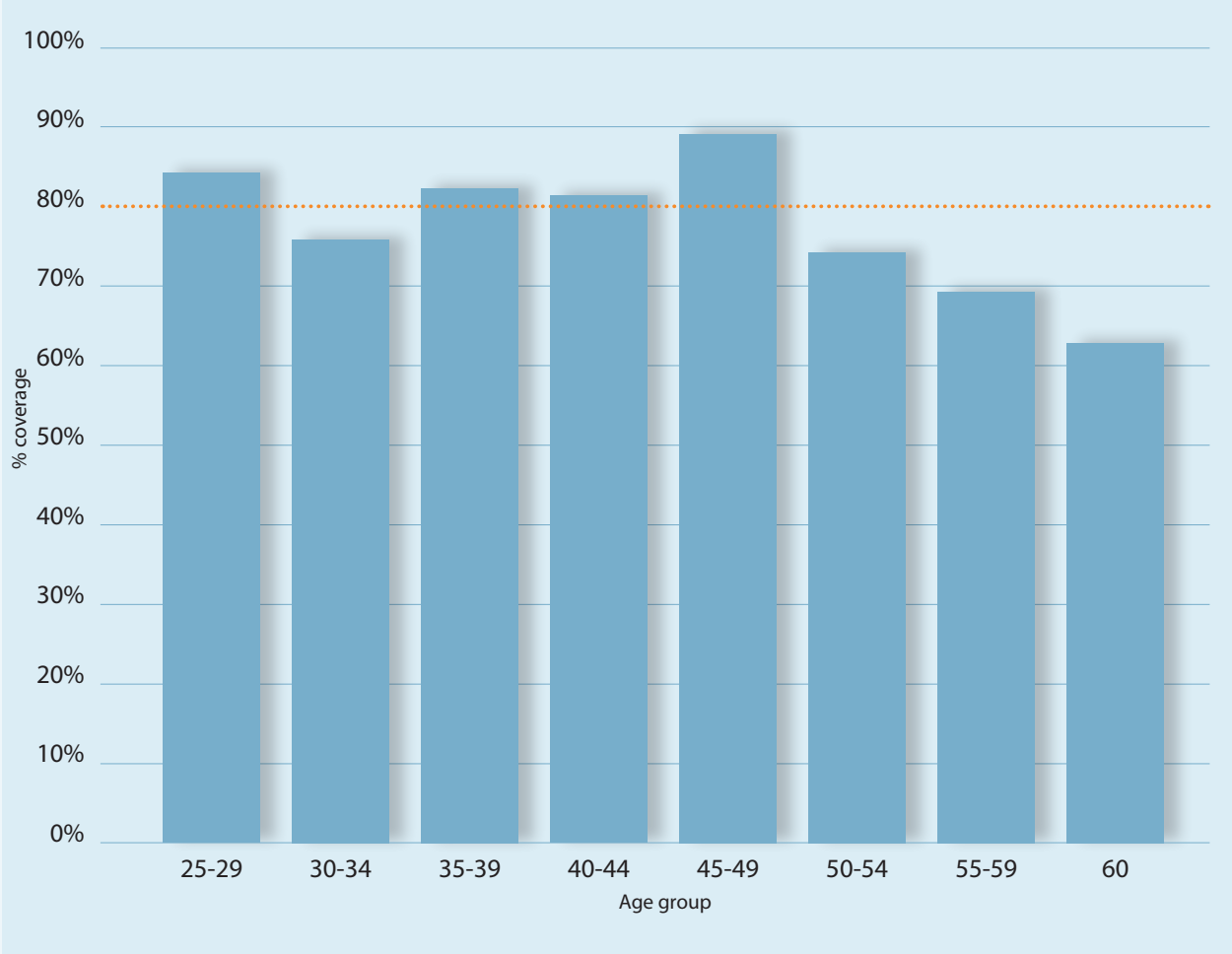
Figure 2: Five-year coverage (%) based on county of residence on the cervical screening register * for period ending 31 August 2016



Data analysed using Health Atlas Ireland.

* Population based on CSO 2011³ figures projected to 2013, not adjusted for hysterectomy (hysterectomy data is not available for geographic location)

Figure 3: Five-year coverage of eligible women by age group* for period ending 31 August 2016



* Population based on CSO 2011³ projected to 2013, adjusted for hysterectomy

Figure 3 demonstrates five-year coverage by age group for the period 1 September 2011 to 31 August 2016. A consistent pattern has been evident since the beginning of the programme with younger women more likely to have participated in cervical screening (82.4 per cent of women aged 25 to 49 years screened compared to 71.4 per cent of women in the 50 to 60 year old group), although coverage in the older age cohorts continues to improve (70.4 per cent in year seven). Women who are known to have had a total hysterectomy are excluded from the target population.

82.4%
of women aged 25-49
were screened
compared to 71.4% of
women aged 50-60

Notification of results

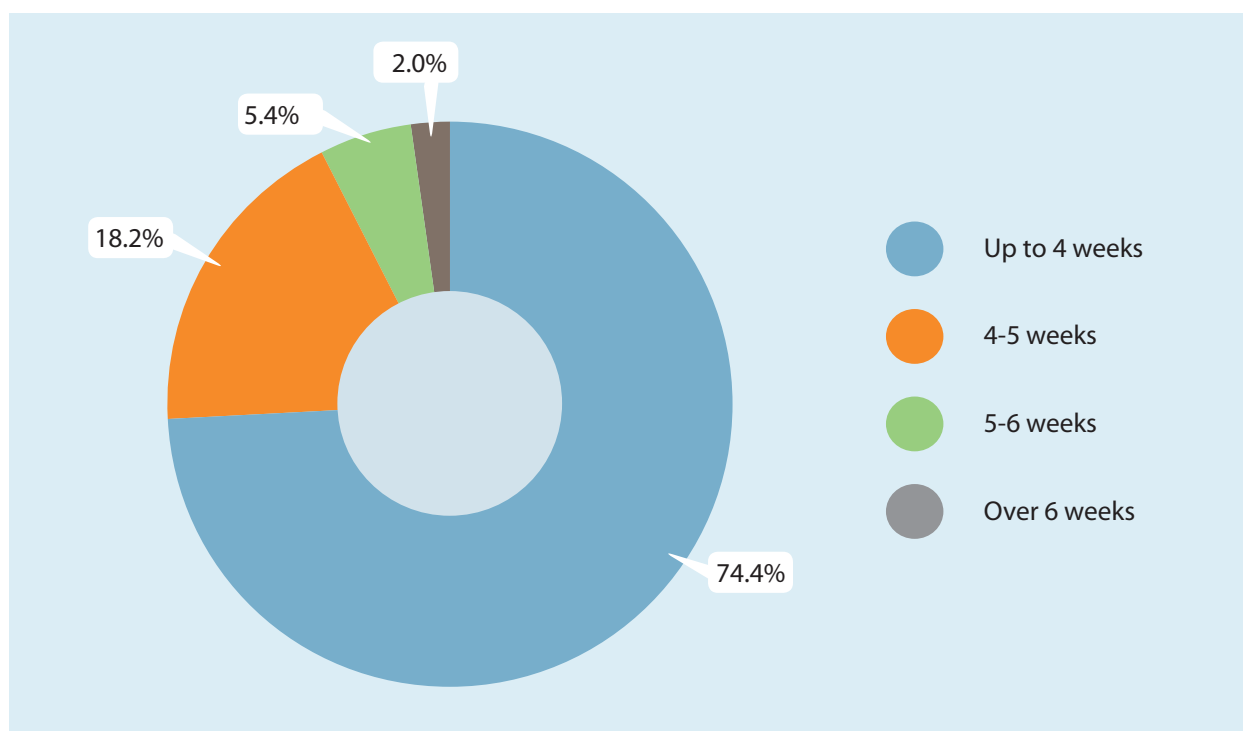
The CervicalCheck Women’s Charter includes the commitment that “CervicalCheck will send you a letter when the result of your test is available from your doctor or nurse, usually within four weeks of your screening test”. Table 2 illustrates the performance of the programme in issuing letters advising of the availability of test results, with a steady improvement from 40 per cent in the first year to 74.4 per cent in the eighth year of the programme. The letter was issued within five weeks in 92.6 per cent of cases (Table 2 & Figure 4).



Table 2: Percentage of letters advising results available sent within four to five weeks of cervical screening test date from 1 September 2015 to 31 August 2016

Time from cervical screening test to letter printed date	2015/2016	Target
Within 4 weeks	74.4%	>90%
Within 5 weeks	92.6%	

Figure 4: Time in weeks for the letter to be issued by the programme (%) from 1 September 2015 to 31 August 2016



Cytology and HPV testing

Laboratory turnaround time

It is important that cytology services process cervical screening tests within 10 working days of receipt of the sample in the laboratory to facilitate the timely provision of results to doctors and women following their cervical screening test.

A laboratory turnaround time of less than 10 working days in 95 per cent of cases is a programme standard. In this reporting year, 88 per cent of results were received by the programme within 10 working days of the receipt of the sample being notified by the laboratory, which falls below the programme standard (Table 3). The proportion of results returned within 15 working days of receipt of the sample at the laboratory in the year was 99 per cent.

Cytology findings

Cytology findings reported in Tables 4 and 5 are based on test results received by the programme in the period 1 September 2015 to 31 August 2016, rather than the date on which the test was taken. Of the 267,704 tests examined, a small number were unsatisfactory (4,223; 1.6 per cent) (Table 4).

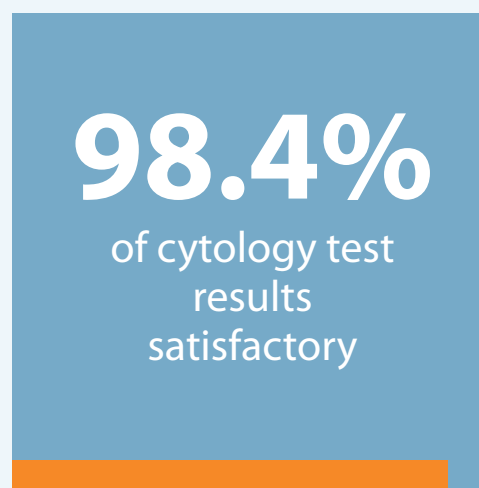


Table 3: Laboratory turnaround time - time from notification of receipt of sample to the programme to results returned to the programme

Performance parameter	2015/2016	Target
% results returned within ten working days of receipt of sample at laboratory.	88.0%	>95%

Table 4: Cytology findings for test results (all locations including tests taken in colposcopy) received by the Programme from 1 September 2015 to 31 August 2016

Total number of tests reported in Year 8	Cytology findings			
	Unsatisfactory inadequate tests		Satisfactory/adequate tests	
	N	%	N	%
267,704	4,223	1.6	263,481	98.4

The outcomes of the 263,481 satisfactory tests are reported in Table 5. Over 90 per cent of satisfactory test results were found to be negative (normal).

Of the remainder, 7.6 per cent showed low-grade abnormalities (ASCUS, LSIL, AGC (borderline glandular)) and 1.6 per cent showed high-grade abnormalities (ASC-H, HSIL (moderate or severe), query invasive squamous carcinoma, AGC favour neoplasia or query glandular neoplasia).



HPV testing (triage) outcomes

HPV testing has been used in colposcopy services since 2012 as a risk assessment tool for women who are post-treatment as well as women with persistent low-grade abnormalities. In May 2015, CervicalCheck introduced HPV reflex testing (triage) in order to identify women with low-grade cytological abnormalities who have a higher risk of precancerous change and who would benefit from immediate referral to colposcopy. The aim was to enhance the early detection and treatment of these abnormalities while reducing unnecessary interventions, especially for younger women.

The cervical screening test was performed in the usual manner. Programme laboratories carried out a HPV test on samples with a low grade result (reflex test). Women who were HPV positive for one or more of the 14 high-risk types were referred to colposcopy, while women with negative HPV test results were routinely recalled (Table 6).

Table 5: Cytology outcomes for satisfactory tests (all locations including tests taken in colposcopy) from 1 September 2015 to 31 August 2016

Cytology results	N	%
Negative/normal	239,328	90.8
Low grade		
ASCUS	9,705	3.7
AGC (borderline glandular)	351	0.1
LSIL	9,916	3.8
High grade		
ASC-H	1,006	0.4
HSIL (moderate)	1,458	0.6
HSIL (severe)	1,567	0.6
Query invasive squamous carcinoma	31	0.01
AGC favour neoplasia	44	0.02
Query glandular neoplasia / (AIS) / adenocarcinoma	75	0.03
Total	263,481	100.0

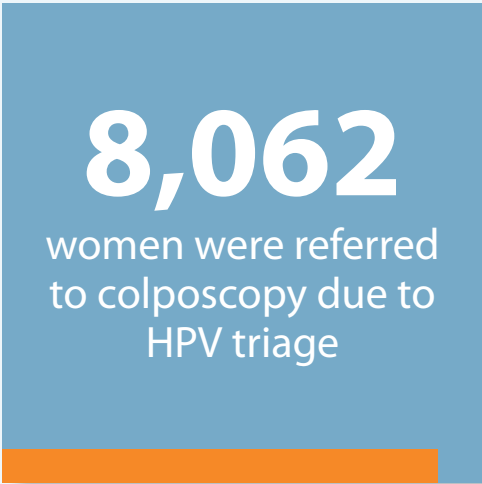
Table 6: HPV test results of reflex tests for low-grade cytology (all locations excluding colposcopy) from 1 September 2015 to 31 August 2016

HPV test results	ASCUS	%	LSIL	%	Routine screening recommended	Refer to colposcopy recommended
HPV detected	3,175	38.5	4,865	71.7	N/A	8,040
HPV not detected	5,073	61.4	1,911	28.1	6,984	N/A
Unknown	8	0.1	14	0.2	N/A	22
Total	8,256	100.0	6,790	100.0	6,984	8,062

In the current reporting year, the number of women who were referred to colposcopy due to HPV triage was 8,062. The number of women who were recommended routine screening due to HPV triage was 6,984.

Referral to colposcopy

Cytology results of cervical screening tests performed on women outside colposcopy services are accompanied by a recommendation of referral to colposcopy for a) high-grade cytological abnormalities, b) low-grade cytological abnormalities with HPV detected, and c) persistent unsatisfactory results. During the year under review, of the cervical screening tests performed on women outside colposcopy clinics, 13,741 (5.5 per cent) resulted in a referral to colposcopy.



“In May 2015, CervicalCheck introduced HPV reflex testing (triage) in order to identify women with low-grade cytological abnormalities who have a higher risk of precancerous change and who would benefit from immediate referral to colposcopy.”

PART 2

Diagnosis and treatment

Quality assured colposcopy services with timely diagnosis and treatment are an important component of successful cervical screening programmes. Fifteen colposcopy services nationwide work effectively with the programme. Each has agreed a service plan 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.

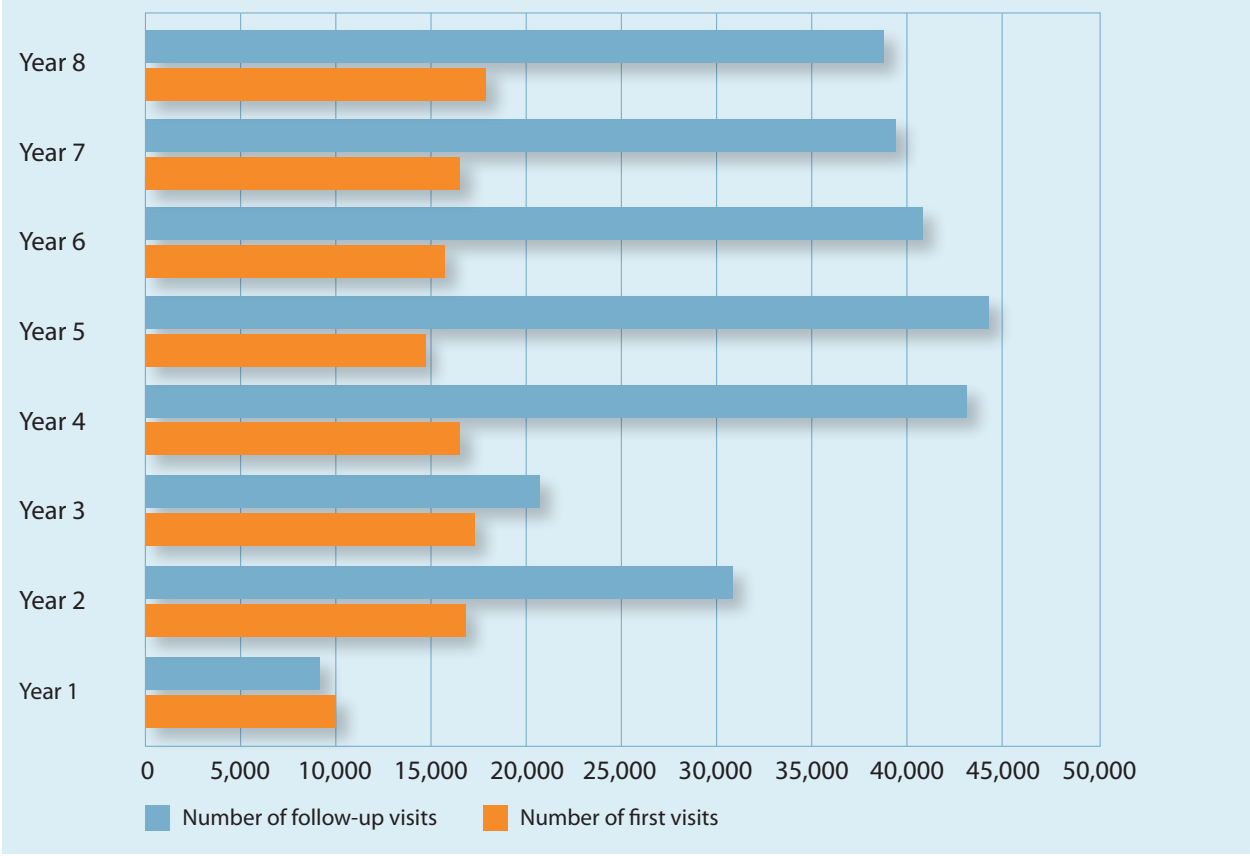
Table 7: Outcome of appointments at colposcopy clinics from 1 September 2015 to 31 August 2016

	First visits		Follow-up visits		Total	
	N	%	N	%	N	%
Attended	17,907	72.5	38,837	58.1	56,744	62.0
Cancelled	4,879	19.8	19,404	29.0	24,283	26.5
DNA	1,877	7.6	8,589	12.8	10,466	11.4
Missing	25	0.1	59	0.1	84	0.1
Total	24,688	100.0	66,889	100.0	91,577	100.0

During the year, 17,907 women attended colposcopy for the first time representing an increase when compared to the previous year and the largest number since the start of the programme (Table 7 and Figure 5). This reflects a change in practice whereby women with low grade abnormalities have a reflex HPV test and if positive, are referred directly to colposcopy. By contrast, the number of follow-up visits continues to reduce through increased use of HPV testing in combination with cytology to identify women in colposcopy who are at low risk of high-grade CIN and who are suitable for discharge.

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 2016



Of the 17,907 new attendances at colposcopy, information on the age of the woman was available for 17,870 (99.8 per cent). The mean age at referral was 35.3 years. The majority of women (87.5 per cent) were aged between 25 to 49 years with 3 per cent under 25 years of age and 9.6 per cent aged 50 or over.

The Guidelines for Quality Assurance in Cervical Screening states that the rate of defaulted appointments, where no prior notice was given

(DNA), should be kept to a minimum. This target was amended from below 15 per cent to below 10 per cent in 2013.² The recorded rate for the eighth year of the programme was 11.4 per cent (Table 8). While this met the previous target, it will be a focus of continued efforts to achieve the new target of less than 10 per cent with continued improvements to appointment reminder systems in colposcopy services.

Table 8: Attendance at colposcopy services

Performance parameter	2015/2016	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	11.4%	<10%

The rate of DNA appointments is presented in Table 9 according to type of visit and age-group. The DNA rate is higher for return visits than for first visits, possibly reflecting the fact that these appointments are made up to one year in advance of the attendance date. Text reminders for appointments are currently used by a number of colposcopy services, though not yet by all. Where they are in use, they have generally been judged effective as one measure to address DNA rates. As in previous programme reports, younger women were more likely to default than older women.

“DNA rate is higher for return visits 12.8% than for first visits 7.5%”

Table 9: DNA rates for colposcopy 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	761	9.9	2,519	16.3
25 – 29	8,090	8.2	22,350	14.0
30 – 34	5,204	8.6	15,285	13.8
35 – 39	3,872	6.9	9,887	11.9
40 – 44	2,727	5.7	6,882	11.5
45 – 49	1,765	6.6	4,360	10.4
50 – 54	982	6.3	2,665	9.8
55 – 59	677	5.2	1,646	8.6
60	113	6.2	233	5.6
61+	523	5.5	945	8.1
Total	24,714	7.5	66,772	12.8

Reasons for referral

Women were referred to colposcopy either on the basis of an abnormal screening test result or for clinical reasons, such as abnormal vaginal bleeding or suspicion of an anatomical abnormality of the cervix (Table 10). This table excludes 27 women (0.2 per cent) for whom no consent information was recorded.

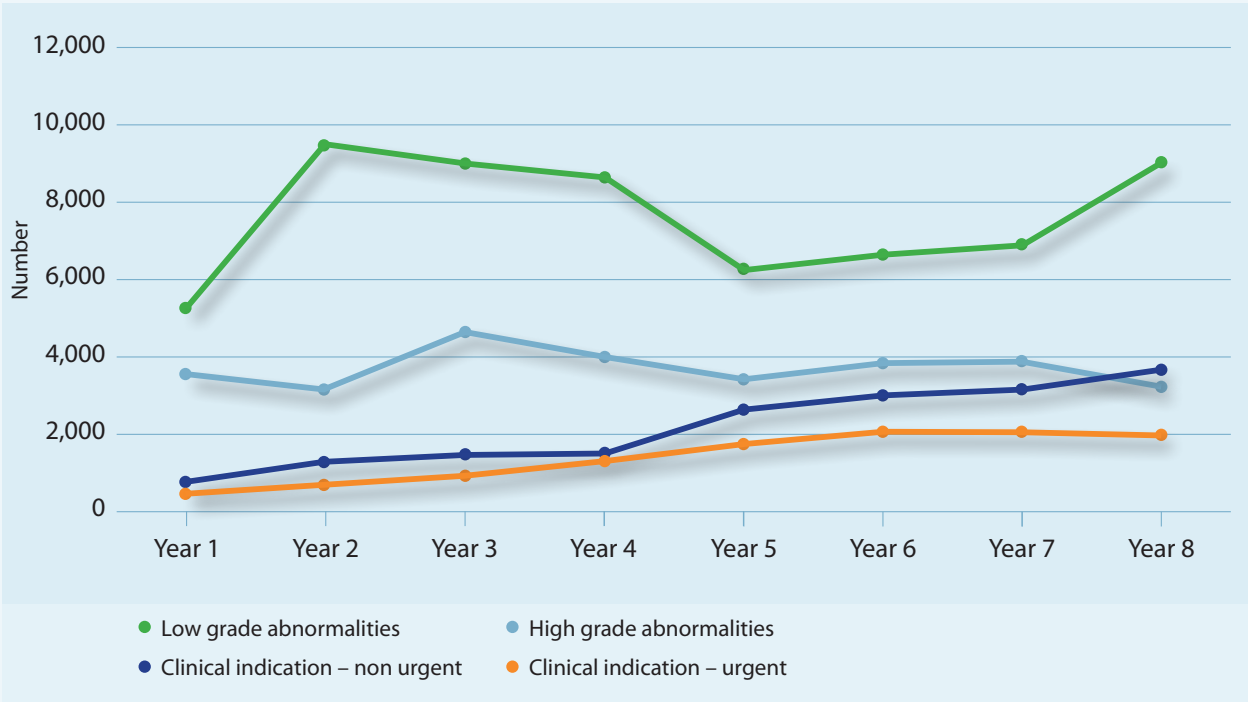
The reasons for referral to colposcopy for 17,876 of the 17,907 new referrals are presented in Table 10. Over two thirds of women were referred on the basis of an abnormal cervical screening test result and 31.8 per cent were referred for clinical reasons. This relative increase in clinical referrals (women with anatomical abnormalities of the cervix or those with intermenstrual or post coital bleeding) represents the utilisation of capacity in colposcopy services to facilitate the inclusion of some women who previously would have been seen in outpatient gynaecology services (Figure 6).

Table 10: Reason for referral to colposcopy from 1 September 2015 to 31 August 2016

Reason for referral to colposcopy	New referrals	
	N	%
Abnormal Screening Test	12,206	68.3
Clinical Indication - non urgent	3,566	19.9
Clinical Indication - urgent	2,104	11.8
Total*	17,876	100.0

* the reason for referral was not recorded in four cases

Figure 6: Reason for referral for women attending colposcopy services from 1 September 2008 – 31 August 2016



Of the 12,206 women who attended for the first time with an abnormal screening test result, 3,259 (26.7 per cent) were referred following detection of a high-grade abnormality (Table 11). The detection of a low grade abnormality (LSIL or ASCUS) was the reason for referral of 8,583 (70.3 per cent) women and cytology tests showing AGC (atypical

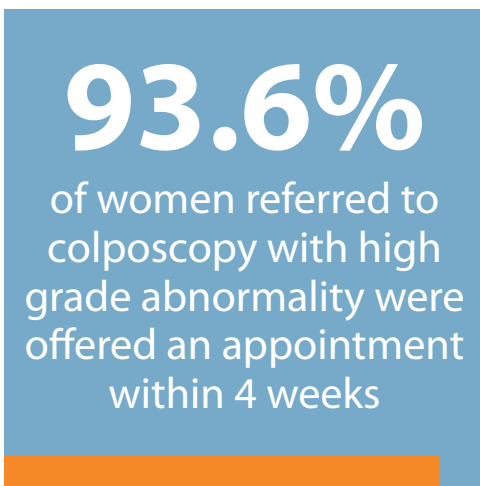
glandular cells) was the reason for referral in 289 cases (2.4 per cent). The relative increase in referral for women with a low grade abnormality reflects the introduction of HPV testing to triage women for colposcopy. The number of women referred with persistently unsatisfactory or inadequate results (0.6 per cent) remained consistently low.

Table 11: Reason for referral to colposcopy as a result of an abnormal screening test result from 1 September 2015 to 31 August 2016

Referral screening abnormality	New referrals	
	N	%
Unsatisfactory/inadequate	75	0.6
Low Grade		
ASCUS	3,324	27.2
AGC	289	2.4
LSIL	5,259	43.1
High Grade		
ASC-H	833	6.8
HSIL (moderate)	1,084	8.9
HSIL (severe)	1,277	10.5
Query invasive squamous carcinoma	13	0.1
Query glandular neoplasia / AIS / adenocarcinoma	52	0.4
Total	12,206	100.0

Waiting times for appointments

One of the key challenges faced by the CervicalCheck programme has been the provision of access to colposcopy in a timely fashion for women. For the period 1 September 2015 to 31 August 2016, information on waiting times was available for 17,867 of the 17,907 new attendances. For women referred to colposcopy with a high grade abnormality, 93.6 per cent were offered an appointment within four weeks (Table 12). Overall, 2.5 per cent of women experienced waiting times of longer than eight weeks (Table 13).



“Overall, 2.5 per cent of women experienced waiting times of longer than eight weeks.”

Table 12: Waiting times for colposcopy services 2015 to 2016

Performance parameter	2015/2016	Target
All women referred to colposcopy should be offered an appointment within 8 weeks of the date the letter was received at the clinic	96.9%	> 90%
Women referred to colposcopy with a screening test result suggestive of CIN 2 or CIN 3 should be offered an appointment within 4 weeks of receipt of referral at the clinic	93.6%	> 90%
Women referred to colposcopy with clinical suspicion of invasive cancer should be offered an appointment within 2 weeks of receipt of referral at the clinic	92.3%	> 90%
All women referred to colposcopy with a screening test result suggestive of glandular neoplasia or AIS should be offered an appointment within 4 weeks of the date the letter was received at the clinic	98.1%	> 90%

Table 13: Waiting times for women referred to colposcopy grouped by grade of referral cytological abnormality

	High grade*		Low grade**		Total	
	N	%	N	%	N	%
2 weeks or less	1,596	49.0	2,111	23.6	3,707	30.4
Between 2 and 4 weeks	1,453	44.6	1,991	22.3	3,444	28.2
Between 4 and 8 weeks	189	5.8	4,550	50.9	4,739	38.8
Between 8 and 12 weeks	9	0.3	246	2.8	255	2.1
Greater than 12 weeks	11	0.3	42	0.5	53	0.4
Total	3,258	100.0	8,940	100.0	12,198	100.0

* Includes ASC-H, Adenocarcinoma *in situ* (AIS), HSIL, and Query invasive carcinoma

** Includes ASCUS, LSIL and AGC (Borderline glandular)

Biopsy rate

Colposcopy plays a key role in the diagnosis and treatment of women with abnormal screening 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, 17,027 diagnostic biopsies and 5,414 excisional biopsies were performed (Figure 7). The initial colposcopy visit determines the presence or absence of an atypical Transformation Zone (TZ) for women referred with an abnormal screening test result. This is the area of the cervix which is most prone to abnormal cell changes. A biopsy was performed in 97 per cent of cases where the TZ was documented as atypical or abnormal. A biopsy was performed in all cases where an invasive cancer was suspected (Table 14).

Figure 7: Number of women undergoing biopsy at colposcopy services

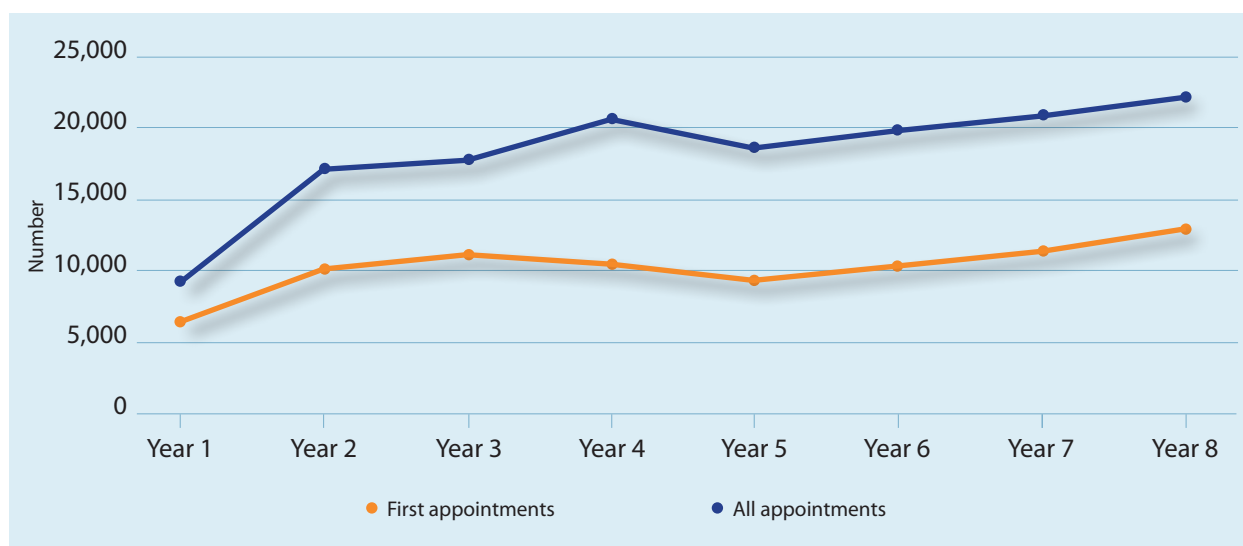


Table 14: Biopsy rates measured against colposcopy standards

Performance parameter	2015/2016	Target
A biopsy should be performed in the presence of an atypical Transformation Zone	97.0%	>90%
If there is a suspicion of invasive disease a biopsy must be performed immediately	100.0%	>90%

The rate of biopsy at the first visit varied with the grade of cytological abnormality. Just under 90 per cent of women presenting with a high grade cytological abnormality had a biopsy performed at the first visit compared with 83.6 per cent of women presenting with a low grade cytological abnormality. Just under 80 per cent of women presenting with AGC (borderline glandular cells) had a biopsy at the first visit which included an excisional biopsy in 10.4 per cent of cases.

The biopsy rates according to the grade of the referral cytological abnormality and reasons for referral are presented in Table 15.



Table 15: Biopsies performed during the first visit to colposcopy according to referral screening test result grade from 1 September 2015 to 31 August 2016

	Type of biopsy performed							
	Excisional biopsy		Diagnostic biopsy		No biopsy taken		Total	
Grade of cytology result of referral screening test	N	%	N	%	N	%	N	%
AGC	30	10.4	201	69.5	58	20.1	289	100.0
High Grade	709	21.8	2,208	67.7	342	10.5	3,259	100.0
Low Grade	168	2.0	7,010	81.6	1,405	16.4	8,583	100.0
Unsatisfactory / inadequate	0	0.0	17	22.7	58	77.3	75	100.0
Total	907	7.4	9,436	77.3	1,863	15.3	12,206	100.0

“Where an abnormality is suspected at colposcopy, it is good practice to perform a biopsy to confirm diagnosis.”

Treatment at colposcopy

Effective treatment of high grade CIN and Adenocarcinoma in situ (AIS) with subsequent reduction of the risk of invasive cancer is vital to the success of any cervical screening programme. Treatments should be performed safely and be acceptable to women and should aim to eradicate all CIN from the cervix.

CervicalCheck programme standards state that treatments are performed as outpatient procedures under local anaesthetic at least 90 per cent of the time. During the eighth year of the programme, outpatient treatments occurred using local anaesthetic in almost 97 per cent of the time, surpassing this target (Table 16).

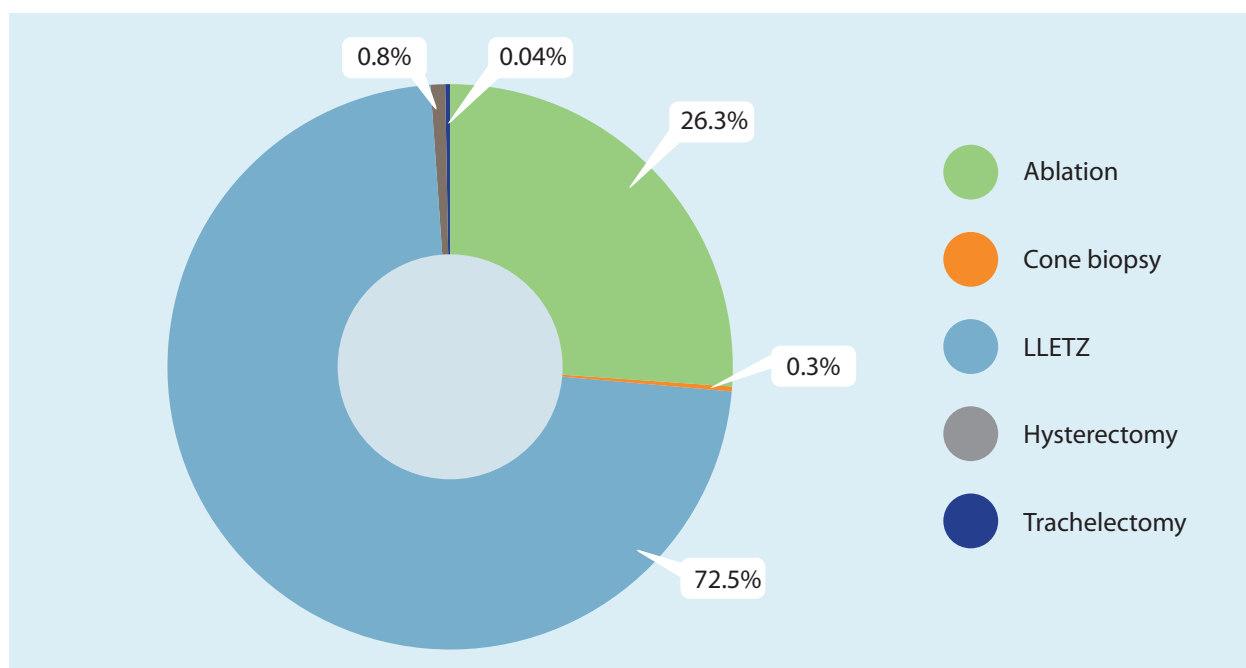
During the reporting period, 7,131 treatments were recorded at colposcopy. Large Loop Excision of the Transformation Zone (LLETZ) was performed in 5,173 (72.5 per cent) cases and ablative treatment was used in 1,879 (26.3 per cent) cases (Figure 8). Nineteen cone biopsies (0.3 per cent), 57 hysterectomies (0.8 per cent) and 3 trachelectomies (0.04 per cent) were also performed.

The number of treatments performed annually has grown markedly since the start of the CervicalCheck programme due to increased capacity at colposcopy as well as the prioritisation of women with high grade cytological changes (Figure 9).

Table 16: The use of local anaesthetic

Performance parameter	2015/2016	Target
The majority of women should have treatment performed as an outpatient under local anaesthetic	96.8%	≥90%

Figure 8: Treatments at colposcopy services from 1 September 2015 to 31 August 2016



One of the guiding principles of screening is the avoidance of overtreatment. This is of particular relevance to cervical screening because of the potential adverse effect of some treatments on future fertility. The treatments performed at the first visit according to the reasons for referral to colposcopy are shown in Table 17.

“Colposcopy treatments have grown markedly since start of CervicalCheck.”

Figure 9: Number of women undergoing treatment at colposcopy services

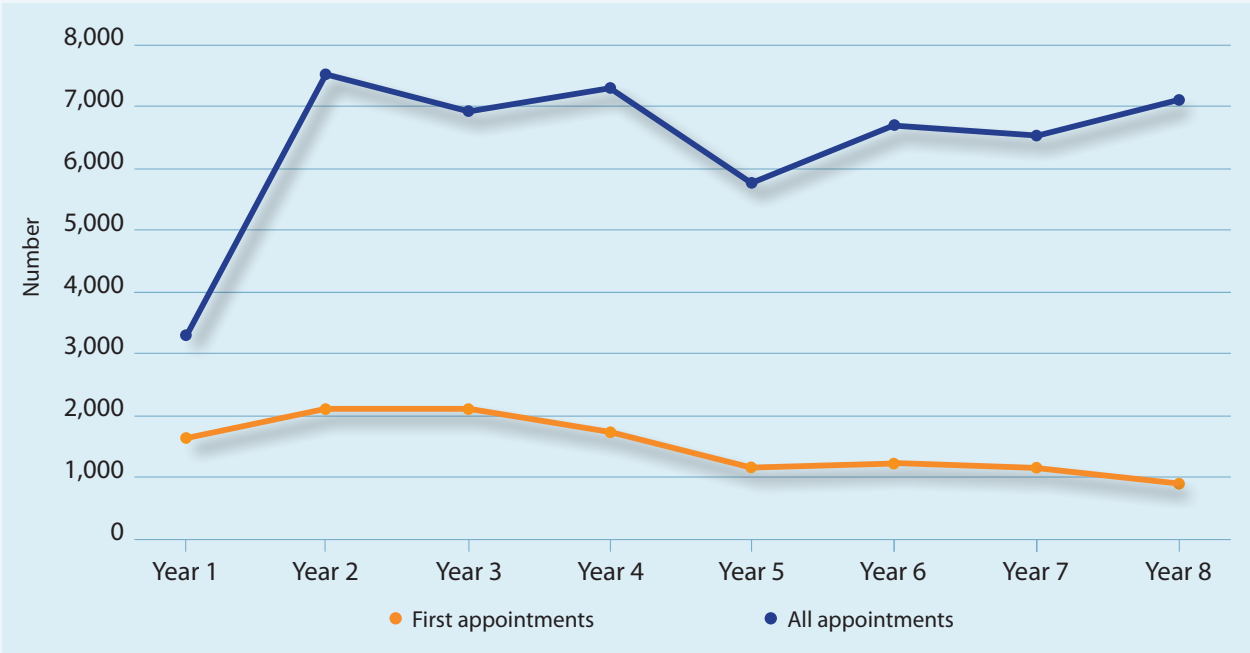


Table 17: Treatment at first visit to colposcopy from 1 September 2015 to 31 August 2016

Reason for referral to colposcopy	No treatment on first visit		Treatment on first visit		Total number of women attending	
	N	%	N	%	N	%
Clinical indication – non urgent	3,447	96.7	118	3.3	3,565	100.0
Clinical indication – urgent	2,051	97.5	53	2.5	2,104	100.0
AGC (borderline glandular)	260	90.0	29	10.0	289	100.0
High Grade	2,565	78.7	694	21.3	3,259	100.0
Low Grade	8,425	98.1	158	1.9	8,583	100.0
Unsatisfactory / Inadequate	75	100.0	0	0.0	75	100.0
Total	16,823	94.4	1,052	5.9	17,875	100.0

Treatment at the first visit for women who present with low grade abnormalities should be avoided and kept below 10 per cent. During the eighth year of the programme, this figure was within the target at 1.9 per cent (Table 18).

More than 90 per cent of women who undergo excisional procedures should have histologically-proven CIN detected on the excised specimen

if the procedure is performed at the first visit to colposcopy. During the eighth year of the programme, 91.5 per cent of women treated at the first visit had CIN detected which met this target (Table 19). In addition, 91.2 per cent of women who had an excisional treatment at any visit had CIN histology, meeting the target of greater than 85 per cent (Table 19).

Table 18: Treatment at first visit for low grade screening test result

Performance parameter	2015/2016	Target
Treatment at the first visit to colposcopy should not be performed on women who present with low grade cytological change	1.9%	<10%

Table 19: Outcome of treatment by excision technique

Performance parameter	2015/2016	Target
Women treated by excisional technique at first visit should have CIN on histology	91.5%	>90%
Women treated by excisional technique at any visit should have CIN on histology	91.2%	>85%

“One of the guiding principles of screening is the avoidance of overtreatment.”

Colposcopy correlation measure

The correlation between the colposcopic impression and histological diagnosis is a useful marker of the quality of colposcopy. During the reporting year, the positive predictive value (PPV) of a colposcopic impression of high grade disease was almost 73 per cent which is in excess of the programme's target of greater than 65 per cent (Table 20).

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 success. The use of HPV testing to triage women with low grade abnormalities was designed to enhance the early diagnosis and treatment of high grade CIN.

Overall, for all women who attended colposcopy in the eighth year of the programme (both new and follow up appointments), there were 187 cancers detected, 8,885 high grade CIN (CIN2, CIN3 or AIS) and 7,114 low grade CIN (Figure 10). This was the highest number of high grade abnormalities recorded since the start of the CervicalCheck programme (Figure 10) which is almost certainly as a result of the HPV triage strategy. The specimen was suitable for histological analysis in 98.6 per cent of women biopsied (target >95%) (Table 21).

In the first eight years of CervicalCheck, there have been 50,302 cases of high grade CIN, 36,619 cases of low grade CIN and 1,269 cancers detected.

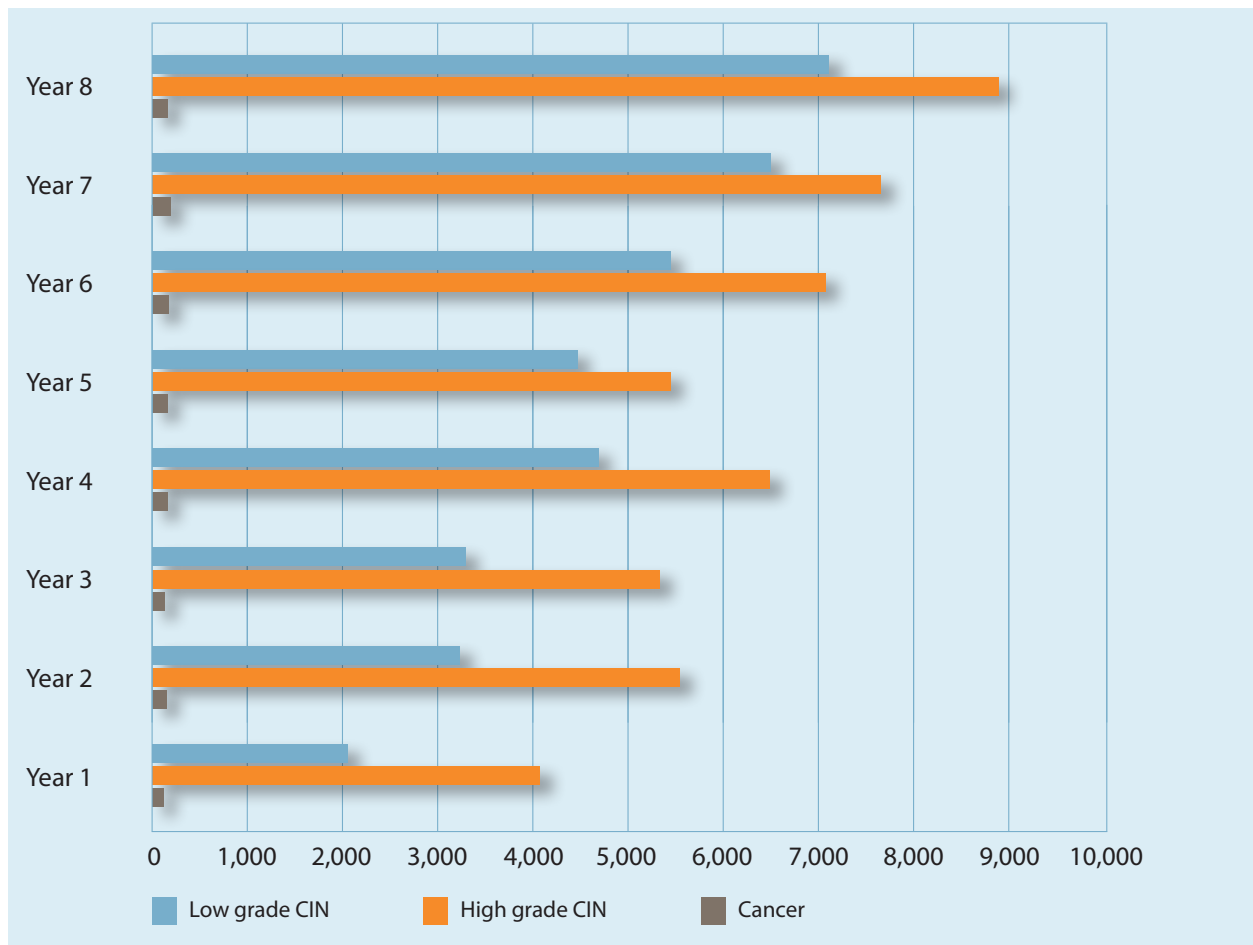
Table 20: The positive predictive value of colposcopy

Performance parameter	2015/2016	Target
Compliance between colposcopic impression of high grade disease and histologically proven high grade CIN	72.6%	>65%

Table 21: Biopsy specimen suitable for histological diagnosis

Performance parameter	2015/2016	Target
Biopsy specimens should be suitable for histological diagnosis	98.6%	>95%

Figure 10: Detection of CIN and cancer for the eight-year period ending 31 August 2016



“In the first eight years of Cervical Check there have been 50,302 cases of high grade CIN, 36,619 cases of low grade CIN and 1,269 cancers detected.”

Correlation between cytology and histology

Cervical screening programmes have to balance the early detection of high grade abnormalities with the avoidance of unnecessary investigations and possible overtreatment. Internationally accepted performance measures have been developed to correlate referral cytology results with histological outcomes in organised, population-based screening programmes.⁴ These include the positive predictive value (PPV) and the referral value (RV).

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 82.2 per cent (Table 22). This represents an increase from year seven (81.6 per cent) and is an improvement as higher PPV values indicate better quality programmes.

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 higher. During the current reporting year, the RV was 2.13 (Table 22), this means for every 213 women referred to colposcopy, 100 had CIN2 or higher detected. This is an improvement on the year seven value of 2.18.

“Cervical screening programmes have to balance the early detection of high grade abnormalities with the avoidance of unnecessary investigations and possible overtreatment.”

Table 22: Correlation measures between cytology and histology

Cytology-histology correlation	
Positive Predictive value (PPV)	82.2%
Referral Value (RV)	2.13

Table 23: Histology results for women who had a satisfactory biopsy at first visit to colposcopy from 1 September 2015 to 31 August 2016

Grade of cytology result of referral screening test	No CIN/No HPV (normal)		HPV/Cervicitis only		CIN 1		CIN 2		CIN 3		Adenocarcinoma in situ/CGIN		Cancer (including micro invasive)		Total	
	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
ASCUS	428	16.3	203	7.7	1,037	39.4	587	22.3	359	13.7	9	0.3	6	0.2	2,629	
AGC (borderline glandular)	61	27.9	23	10.5	62	28.3	17	7.8	28	12.8	23	10.5	5	2.3	219	
LSIL	582	13.3	323	7.4	1,964	44.9	1,014	23.2	476	10.9	10	0.2	1	0	4,370	
ASC-H	66	9.8	46	6.8	173	25.7	167	24.8	213	31.6	3	0.4	6	0.9	674	
HSIL (moderate or severe)	71	3.3	72	3.4	240	11.2	448	20.9	1,251	58.4	16	0.7	44	2.1	2,142	
Query invasive squamous carcinoma	0	0.0	0	0.0	0	0.0	0	0.0	4	40.0	0	0.0	6	60.0	10	
Query glandular neoplasia / AIS / adenocarcinoma	3	6.5	2	4.3	4	8.7	0	0.0	2	4.3	30	65.2	5	10.9	46	
Unsatisfactory/ Inadequate	11	64.7	1	5.9	5	29.4	0	0.0	0	0.0	0	0.0	0	0.0	17	
Total	1,222	12.1	670	6.6	3,485	34.5	2,233	22.1	2,333	23.1	91	0.9	73	0.7	10,107	

REFERENCES:

1. Health Information and Quality Authority. Health Technology Assessment of Human Papillomavirus Testing as the Primary Screening Method for Prevention of Cervical Cancer. Dublin; Health Information and Quality Authority: 2017.

2. National Cancer Screening Service. Guidelines for Quality Assurance in Cervical Screening Second Edition 2013. NCSS/PUB/Q-1 Rev 2, ISBN 978-1-907487-13-2. Dublin; National Cancer Screening Service: 2013.

3. Central Statistics Office. Census 2011 Profile 2 - Older and Younger [Internet] [cited 2015 Oct 5]. Available from <http://www.cso.ie/en/census/census2011reports/census2011profile2-olderandyounger/>

4. NHS Cervical Screening Programme. Achievable standards, Benchmarks for reporting, and Criteria for evaluating cervical cytopathology (3rd Edition) ISBN 978 1 84463 081 3. UK; NHS Cervical Screening Programme; 2013.



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