CervicalCheck
AN CLÁR NÁISIÚNTA SCAGTHÁSTÁLA CEIRBHEACS
THE NATIONAL CERVICAL SCREENING PROGRAMME

CervicalCheck Programme Report September 2017-March 2020

An tSeirbhís Náisiúnta Scagthástála
National Screening Service

Contents

Introduction from the Chief Executive, National Screening Service

This report brings to a close the first phase of the Irish population cervical screening programme, CervicalCheck. From March 2020 Ireland moved to be one of the first countries in the world to implement a HPV screening programme. The cytology-based programme used since 2008 has reduced the incidence of cervical cancer in Ireland by 2.8% per year in the 12 years since it started. Because of the programme, more than 1,700 participants have had a cervical cancer detected and treated and more than 120,000 women* have received treatments for cell changes that might have progressed to cancer if left untreated. Cytology screening has been the standard approach used in cervical screening programmes internationally but it is now recognised that the outcomes for the population can be improved by changing to HPV screening. I am delighted to lead the National Screening Service at this very important time for CervicalCheck.

The implementation of a national programme in 2008 came after a successful pilot in the Mid-West region. That pilot was driven by dedicated people committed to reducing the incidence of cervical cancer and improving mortality rates. While it can affect most age groups, cervical cancer often occurs in younger women. Prior to the pilot, there was already a lot of cervical screening being conducted in Ireland but it had not had any significant effect on incidence or mortality. It was ad hoc and non-standardised. It was dependent on doctors offering screening or women requesting it. There was no quality assurance of the process. Since CervicalCheck was implemented, there have been clear standards and guidelines on quality assuring all aspects of the programme. They have regularly been reviewed and adapted according to emerging international evidence.

In 2018, after the news that women with cervical cancer were not given the results of an audit of cytology slides done as part of the quality assurance process, CervicalCheck, guided by the recommendations from the Scally report[1], began to completely review the workings of the programme. That work is now complete. I have heard many of the stories of the women who developed cervical cancer and I acknowledge how it was unacceptable to do the audit without their knowledge. I have heard how traumatic it was for many of them to have the information given to them in a rushed manner, particularly as they had at this point already been through the trauma of diagnosis and treatment. I am sorry that we fell below expected standards in our communication to them and contributed to this being a very difficult experience for them. I am committed to learning the lessons from this and continue to improve the way we communicate with our participants in the future. The NSS has put an emphasis on including the voice of our patients in our work to reform the way we deliver our services and, with your help, we are working towards delivering a truly person-centred service.

Fiona Murphy
Chief Executive, National Screening Service

* Throughout this document when the words ‘woman’ and ‘women’ are used we refer also to other people with a cervix

Message from the CervicalCheck Clinical Director

As a newly-qualified doctor in 2000 I chose the topic of cervical screening for my first ever research project. Encouraged by my mentors, who were strong advocates for cervical cancer screening, the abstract was accepted for presentation at the British Society of Colposcopy and Cervical Pathology (BSCCP). I am delighted now to take on the role of clinical director for this important population health screening programme.

When I joined CervicalCheck as clinical director in August 2020, we were in the midst of a global pandemic which had necessitated a pause in many screening programmes worldwide. CervicalCheck itself had just restarted after a three-month pause. Colposcopy was operating, having continued to work through the pause; our sample takers and laboratories were working hard to increase our capacity to screen; and we were getting the word out to our participants that it was safe for them to come back into a healthcare environment for their routine screening tests.

At the same time, the service was focused on rebuilding people's trust in screening. The news in 2018 that women with cervical cancer were not given the results of an audit of cytology slides done as part of the quality assurance process had triggered a large change process in screening. One of these changes was the implementation of a new test – primary HPV screening – in March 2020. So I joined a service that was both forward-looking, with news to tell about continued improvements and a new test, but one that was also looking back and learning from its past. I am proud to be part of this ongoing work.

The period that this report covers brings us to the end of cytology screening in Ireland. I have therefore taken the opportunity here to document some changes to our cervical screening programme since it began in 2008, in order to observe the impact of some key events, over time.

This report tells the story of the women who took up the offer of screening at a time when the quality of the programme was under great public scrutiny. It shows their lived experience of being offered and coming for an additional screening test, of waiting for their results and possibly for follow-up tests during what was undoubtedly a period of heightened anxiety. It details the continued good work done by all our screening partners at this time – the sample takers in the community, the laboratory scientists, the colposcopists, histologists – and by the screening programme's dedicated staff themselves. We thank them for their valuable contribution to improving the health of the population.

By presenting these annual figures in one combined report, we aim to provide as complete a picture as possible of this important period in the history of cervical screening in Ireland. It is our aim that the further study of this data will aid learning now, and in the future.

Dr Nóirín Russell
Clinical Director CervicalCheck

Abbreviations

AGC	Atypical glandular cells
AIS	Adenocarcinoma in situ. A pre-cancer affecting the cervix, but involving the columnar glandular (endocervical) cells rather than the squamous cells
ASC-H	Atypical squamous cells for which a high-grade lesion cannot be excluded
ASCUS	Atypical squamous cells of undetermined significance
CIN	Cervical intra-epithelial neoplasia, which describes abnormal changes of the squamous cells of the cervix. It has three grades of severity, with grade 3 (CIN 3) being the most severe.
DNA	Did not attend
HPV	Human papillomavirus
HSIL	High-grade squamous intraepithelial (moderate and severe) lesion encompassing moderate (CIN 2) and severe dysplasia (CIN 3/carcinoma in situ)
IARC	International Agency for Research on Cancer
LSIL	Low-grade squamous intraepithelial lesion encompassing HPV infection or mild dysplasia (CIN 1)
NSS	National Screening Service
PPV	Positive predictive value
RV	Referral value

Executive summary

Cervical cancer in Ireland

Each year, around 290 women are diagnosed with cervical cancer and almost 90 women die of cervical cancer.[2] Almost half of women in Ireland diagnosed with cervical cancer are aged 45 years or under.[3] Unfortunately, 40% of these cervical cancers occur in women who have never participated in screening.

Cervical cancer is principally caused by persistent, high-risk human papillomavirus (HPV) infections which cause changes to the cervical cells. If the virus persists in a woman's cervix (neck of uterus), chronic inflammatory changes in the cells lining the cervix may lead to precancerous changes, known as cervical intraepithelial neoplasia (CIN), and may, with time (often years), go on to develop into cancer. Fortunately, early changes in these cells can be detected through screening and lead to investigation and treatment in order to prevent more serious disease. When well women are diagnosed via screening they have an 80% chance that their cancer will be detected at stage 1. By the time women develop symptoms and present to gynaecology clinics, their cancer is usually stage 2 or higher.

Screening for cervical cancer

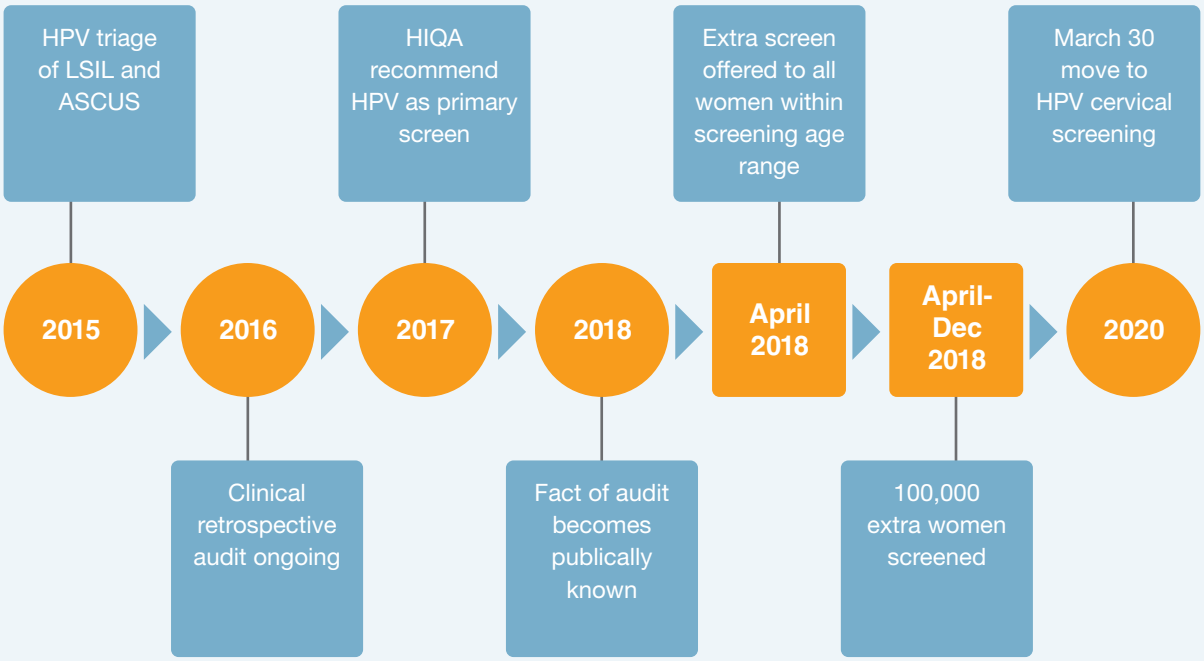
For the time period of this report the Irish cervical screening programme employed cytology (smear) testing offered to the entire population of healthy women in a specific age group (25–60 years). At the end of March 2020, where this report ends, our programme changed to primary HPV testing with follow up smear (cytology) tests for HPV-positive cases. Both the smear test and the HPV test are simple, safe and affordable tests which are easy to administer and acceptable to women.

Neither the cytology test, nor the HPV test are designed to diagnose cervical cancer. The primary purpose of cervical screening is detection of precancerous changes and prevention of cancers, but it also permits the early detection of a cancer when it is most likely to be treatable and curable. The goal of a cervical screening programme is to reduce the incidence of, and mortality from, cervical cancer in an overall population of healthy women at risk.

Number of tests performed

Cervical screening in Ireland came under sustained public focus in 2018. Record numbers of samples were taken during the period 2018-2019, when over 100,000 women took up the government offer of an out-of-cycle (extra) screening test.

Key points timeline 2017-2020



Section 1: Cervical screening overview (Sept 2008-March 2020)

- Almost 3.2 million cervical screening tests provided
- 64,110 cases of high-grade pre-cancerous cells (CIN)
- 60,650 cases of low-grade pre-cancerous cells (CIN)
- 1,786 cancers diagnosed in women who had come for screening.

Section 2: CervicalCheck programme activity 2017-2020

- 78.7% programme coverage (standard is 80% and was reached in 2012/2017)
- Coverage reduced despite an extra 100,000 tests performed in 2017/18
- Coverage varied by county. Counties with the highest coverage were Carlow, Westmeath, Louth, Waterford and Wicklow. Counties with lowest coverage were Kilkenny, Laois, Clare, Dublin, Monaghan and Roscommon
- Coverage varied by age. Participants aged 24-29 had highest coverage; lowest coverage in those aged 55 years and older.

Section 3: Programme response to women

- The Programme aim is that 90% of people receive their results letter within four weeks
- Substantial reduction in number of women getting results within target: in 2018/19 4% women received results within 4 weeks; 92% waited longer than 6 weeks.

Section 4: Laboratory metrics

- Increased number of tests taken: in the time period of this report, 92% of the 659,401 satisfactory tests taken were found to be 'normal'
- Proportion of samples with high-grade result in line with expected international standard
- The proportion of samples with a low-grade result within expected standard in 2017/18 and 2018/19 and above expected standard in 2019/20
- Programme aim is that 95% of results are available from the laboratory within 10 days. From meeting this aim on average 2012-17, only 6% of results were available within 10 days in 2018/2019. this increased to 41% in 2019/2020.

Section 5: Colposcopy

- Referral to colposcopy is either through laboratory notification of cell changes detected or by GP noting a clinical concern
- Majority of women are referred to colposcopy with low-grade abnormal cell changes
- Increased number of referrals to colposcopy for cell changes: 4.6% in 2017/18 and 5.7% in 2018/19
- Increase in GP referrals for clinical concerns: 9,080 (44.6%) in 2017/18 and 10,591 (46.2%) in 2018/19 when compared to an average of 5,459 (32.5%) from 2012-17
- Introduction of HPV triage in 2015 led to an initial reduction in colposcopy referrals as only participants with both cell changes and a positive HPV result were referred to colposcopy
- In 2018/2019, 55% of women with high-grade screening results seen within programme aim (four weeks) and 59% of all referrals seen within eight weeks when compared to an average of 93% and 97% seen within four and eight weeks respectively between 2012-2017.

Section 6: Histology

- Almost half of women attending colposcopy require a biopsy
- High quality of biopsy samples taken by colposcopists with 98% of samples suitable for diagnosis
- Steady increase in number of samples taken yearly reflects increase in colposcopy activity and more conservative approach to managing low-grade disease
- Cytology-histology positive predictive value (PPV) has reduced since 2018 – indicating chance of a high-grade cytology result not being confirmed on histological analysis is increasing
- Referral value (RV) is increasing – indicating more women have to be referred to colposcopy in order to find one woman with high-grade disease.

Section 7: Treatment at colposcopy

- Majority of women (over 98%) who attend colposcopy for treatment were safely treated under local anaesthetic as an outpatient procedure
- Increase in number of women being referred to colposcopy did not lead to increase in treatments. Most women were assessed, reassured and did not require treatment
- Colposcopy PPV decreased – indicating a colposcopy impression of high grade abnormality is less likely to be confirmed on histological analysis.

Section 1
Cervical screening overview

Cervical screening is a preventative strategy and aims to improve the population outcomes for the condition being screened for. This means reducing the incidence of the condition being targeted.

A national, population-based cervical screening programme using cytology tests every three to five years can reduce cervical cancer mortality by up to 80 per cent (IARC 2004)[4]. CervicalCheck has reduced the incidence of cervical cancer significantly since it started in 2008 (National Cancer Registry Ireland, 2021)[2].

Cervical screening divides the target population into two cohorts, those with normal risk, and those at higher risk of developing persistent abnormal cells that could develop into cervical cancer. Screening tests are not diagnostic. Those who have a positive screening test require more testing before a final diagnosis can be established.

Figure 1 below shows the number of cases where abnormal cells (high-grade and low-grade disease) were detected in women participating in the programme. It also shows the numbers of cancers detected each year.

From September 2008 to March 2020, CervicalCheck has provided almost 3.2 million cervical screening tests. Since 2008, 64,110 cases of high-grade pre-cancerous cells (CIN2 and CIN3) and 60,650 cases of low-grade pre-cancerous cells (CIN1) have been identified*. Many of these women could have developed cervical cancer if the abnormalities were not detected and treated via cervical screening. In the absence of screening, cervical cancer would not have been detected in these people until they developed physical signs or symptoms of disease.

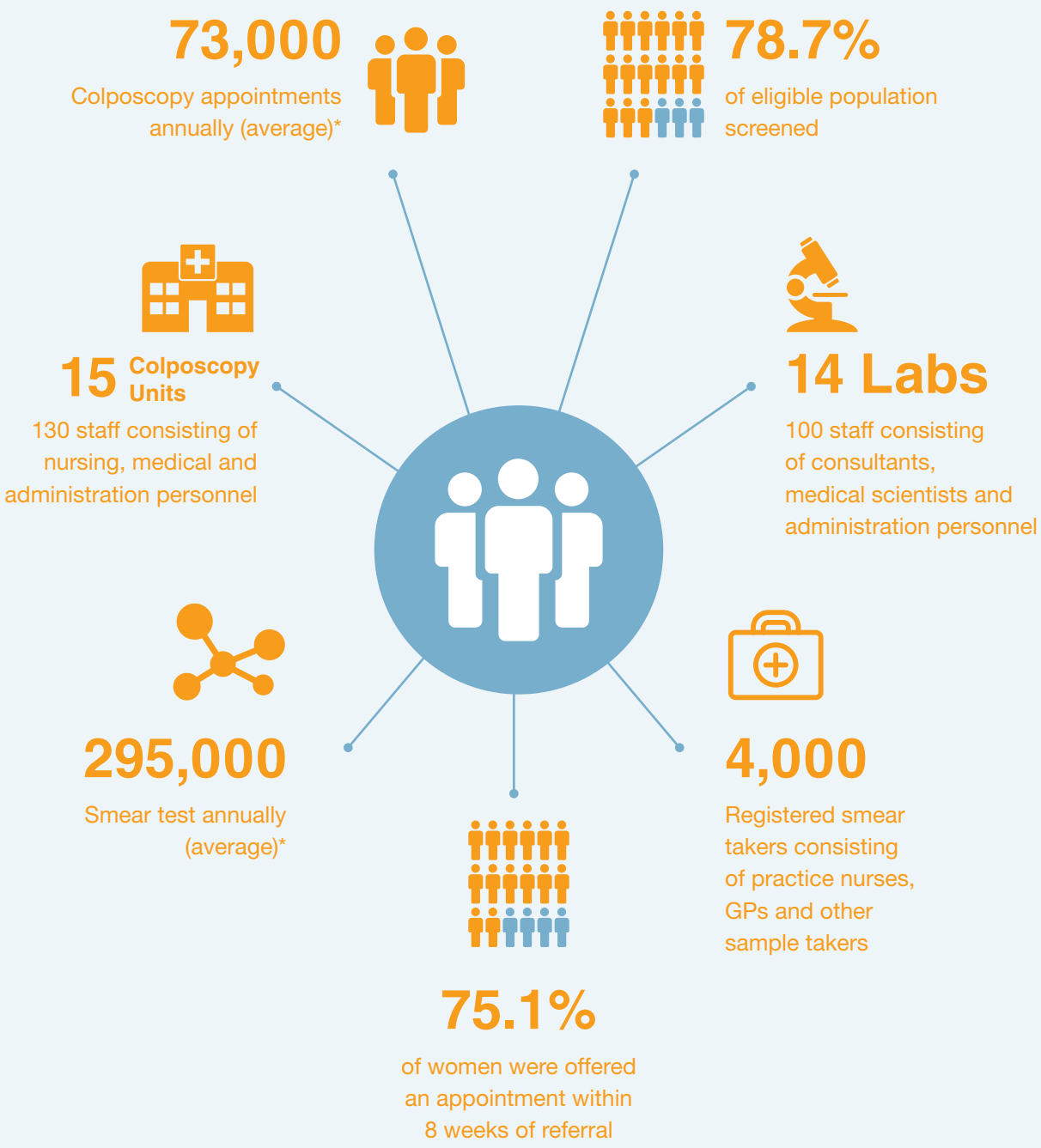
In addition, 1,786* cases of asymptomatic cancer have been detected by the CervicalCheck programme. Since CervicalCheck started in 2008, the number of women who developed cervical cancer decreased by 7% year-on-year from 2010-2015. More recent data shows that the decreasing incidence has been sustained even as the programme matures, with a 2.8% annual percentage decrease from 2010-2018[2].

* This is a change to previously reported figures. For information see here.

"Changes to figures of reported cervical intra-epithelial neoplasia (CIN) and cancer cases in cervical screening 2008-2017"
By Dr Laura Heavey

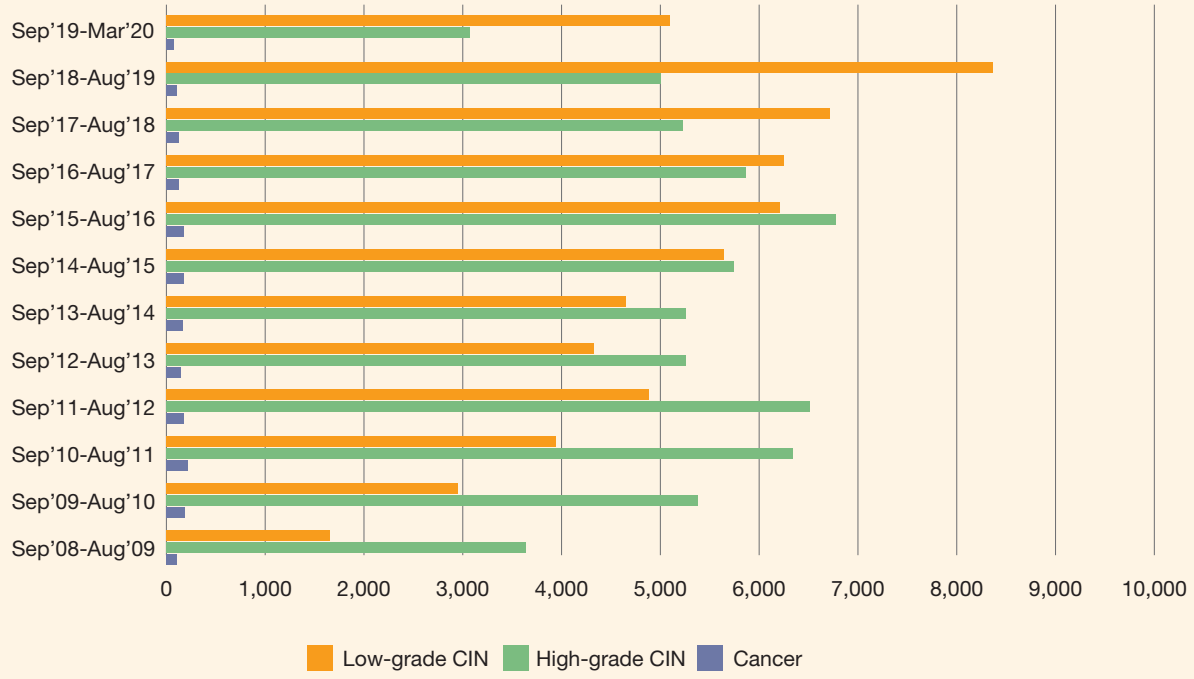
What is involved in the CervicalCheck programme?

CervicalCheck programme 2017-2020



* The colposcopy appointments and smear test averages are only from Sep' 2017 to Sep' 2019 only.

Figure 1: Detection of CIN and cancer in women referred for further investigation following screening from September 2008 to March 2020



* The period 2019 to 2020 runs from September 2019 to end of March 2020 and is only 7 months long instead of the usual 12 months

Table 1: Detection of CIN and cancer in women referred for further investigation following screening from September 2008 to March 2020

	Low-grade	High-grade	Cancer	Totals*
Sep'08-Aug'09	1,652	3,648	99	**5,399**
Sep'09-Aug'10	2,947	5,379	184	**8,510**
Sep'10-Aug'11	3,939	6,343	222	**10,504**
Sep'11-Aug'12	4,885	6,508	185	**11,578**
Sep'12-Aug'13	4,334	5,261	158	**9,753**
Sep'13-Aug'14	4,658	5,265	177	**10,100**
Sep'14-Aug'15	5,618	5,741	170	**11,529**
Sep'15-Aug'16	6,217	6,786	174	**13,177**
Sep'16-Aug'17	6,263	5,853	124	**12,240**
Sep'17-Aug'18	6,702	5,231	119	**12,052**
Sep'18-Aug'19	8,357	5,010	100	**13,467**
Sep'19-Mar'20	5,078	3,085	74	**8,237**
Totals	**60,650**	**64,110**	**1,786**	**126,546**

* Figures recorded by the National Cancer Registry of Ireland (NCRI) for this period also include cancers detected in women diagnosed with cancer who did not come for screening.

Section 2
CervicalCheck programme activity 2017-2020

2.1 Context

The figures in this report relate to data collected from 1st September 2017 until the changeover to primary HPV screening at the end of March 2020. During this period, a combination of 'invitation/re-call' and 'direct entry' was in operation. This means that in addition to the programme sending invitation letters, women and healthcare professionals could check when screening was due, using an online facility on the CervicalCheck website.

All women between the ages of 25 years and 60 years were eligible for participation in the programme. If a person was aged 25 to 45 they were usually offered screening every three years, and those aged from 45 years to 60 years were offered screening every five years.

Not all participants attend exactly when their screen is due. In addition, the number of women on the register has increased year-on-year because of an increasing population in Ireland (demographic changes). For this reason, CervicalCheck does not set an attainable amount (standard) for the number of participants to be screened in a year.

The programme records coverage as one of its key performance indicators (KPIs). Coverage is defined as the proportion of unique women who have had at least one satisfactory screening test taken within the defined screening interval, expressed as a percentage of the total number of eligible women in the population. This is in line with the *European guidelines for quality assurance in cervical cancer screening*[5].

2.2 Number of screening tests performed

Definition: The total number of screening tests performed is a measure of the activity of the CervicalCheck programme. It is a count of the number of screening samples sent to a programme-designated laboratory.

Standard: There is no standard for this metric.

Table 1 shows the total number of screening samples taken over the period of this report according to the screening location in which they were taken.

Table 2: Total number of screening samples taken over the period of this report according to location

Sample taker location	2017/2018	2018/2019	Sept 2019 / Mar 2020
Community	327,970	230,126	105,578
Colposcopy	23,852	23,929	13,970
Other gynaecological services	3,531	3,394	1,721
Total	**355,353**	**257,449**	**121,269**

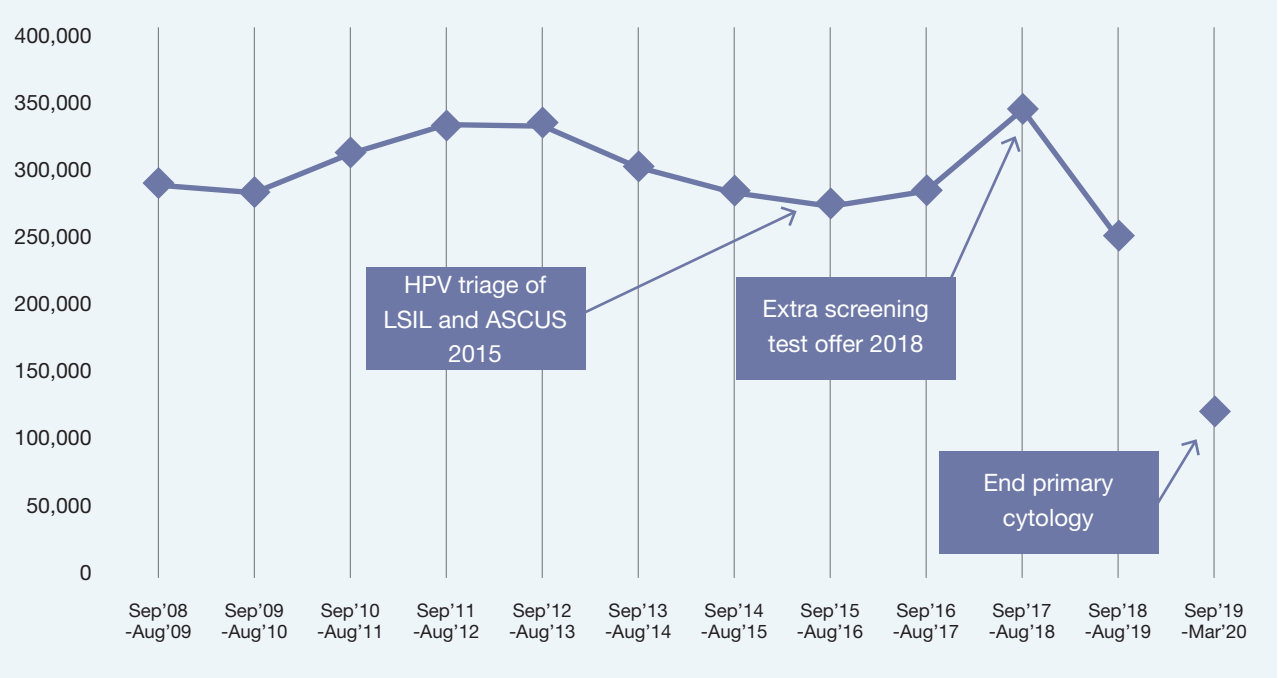
During the time period of this report, the percentage of samples taken in colposcopy increased from 6.7% to 11.5% of programme workload.

2.3 Total number of unique people screened

Definition: The number of people who have had a screening test taken at least once during reporting periods outlined.

Standard: There is no standard for this metric.

Figure 2: Number of unique people who had a CervicalCheck cervical screening test in any location, 1 September 2008 to 31 March 2020



* Participants may have had more than one sample taken in any of the periods so this is not a count of the individual screens taken

Key points

The number of screening tests has varied over the 12-year period in which CervicalCheck has been in operation. In the first five years the numbers increased from 284,833 to 331,790 per annum. It decreased in 2015/2016 to 272,086. The introduction of HPV triage for low-grade cytology findings in 2015 reduced the number of people put on a shorter recall and allowed them to return to the normal recall period for their age, which reduced the total annual number of screens undertaken.

The number of samples processed by CervicalCheck laboratories rose sharply to a peak of 341,908 in the 2017/18 period. The data for 2019/2020 represents 7 months rather than a full 12 months.

2.4 Number of people screened within eligible age cohort

Women aged between 25 and 60 years were eligible for free cervical screening tests at intervals based on their age.

Standard for age cohort eligibility: Women aged 25 to 60.

Table 3 shows the number of unique people who had a CervicalCheck screening test by age September 2017- March 2020.

Table 3: Number of unique people who had a CervicalCheck screening (all locations) test by age September 2017- March 2020

Age group	2017/2018	2018/2019	2019/2020*
	N (%)	N (%)	N (%)
<25*	598 (0.2)	578 (0.2)	**335 (0.3)**
25-29	46,612 (13.6)	37,502 (15.0)	**18,863 (15.7)**
30-34	53,691 (15.7)	40,397 (16.2)	**19,175 (16.0)**
35-39	64,225 (18.8)	46,823 (18.8)	**22,581 (18.8)**
40-44	56,986 (16.7)	40,757 (16.3)	**21,163 (17.6)**
45-49	40,578 (11.9)	30,226 (12.1)	**15,065 (12.5)**
50-54	35,895 (10.5)	24,373 (9.8)	**11,250 (9.4)**
55-59	29,733 (8.7)	19,743 (7.9)	**8,243 (6.9)**
60	4,733 (1.4)	3,046 (1.2)	**1,280 (1.1)**
>=61	8,866 (2.6)	6,281 (2.5)	**2,114 (1.8)**
Total	**341,917 (100)**	**249,726 (100)**	**120,069 (100)**

The period 2019 to 2020 runs from September 2019 to end of March 2020 and is only 7 months long instead of the usual 12 months

Key points

In 2018/2019, 92,191 fewer people participated in the CervicalCheck screening programme compared to 2017/18. Of those who participated over the three-year periods presented, the majority (64.8%; 66.3% and 68.1% respectively) were aged 25 – 44 years. This is an expected finding in the cytology programme where this age group is invited every three years, whereas people over 45 years are invited every five years.

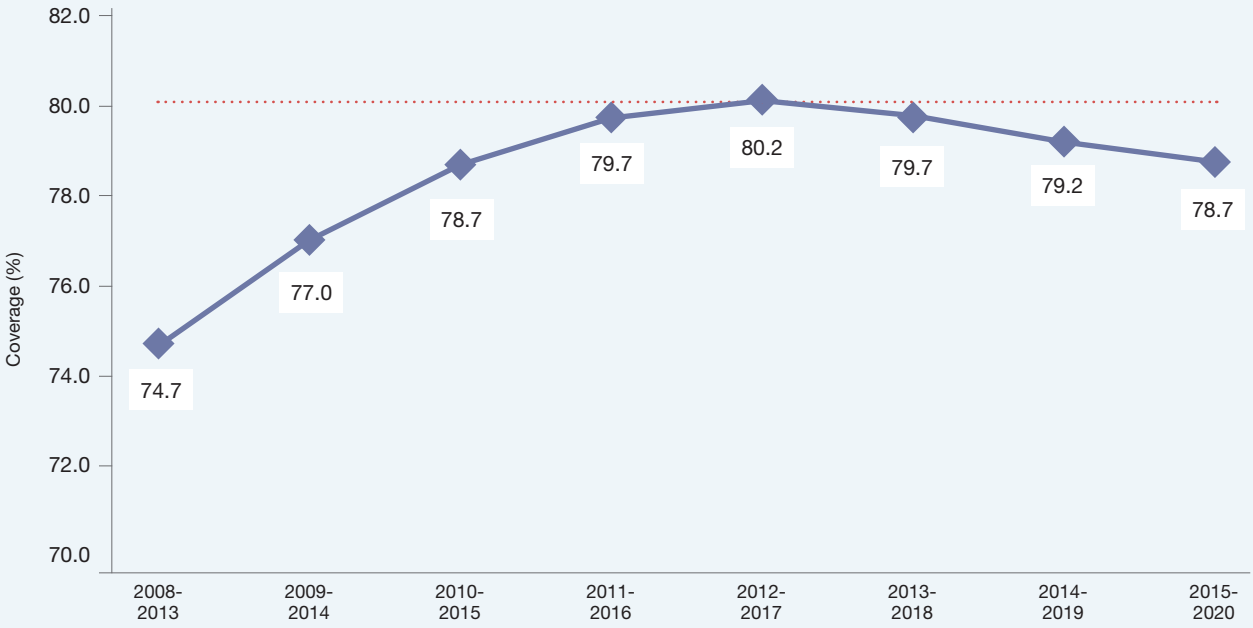
The data is consistent across the three years with more than 97% of screening samples being taken in women who are in the eligible age-range for screening. Note that in specific, defined circumstances, women outside of the age range may be advised to attend screening.

2.5 Programme coverage

Definition: the proportion of unique women who have had at least one satisfactory smear test taken within the defined screening interval, expressed as a percentage of the total number of eligible women in the population.

Programme standard		
Coverage of screening population	Women within the defined screening population should have at least one satisfactory smear test within a screening interval	80%

Figure 3: CervicalCheck five-year coverage 2008-2013 to 2015-2020 (population based on mid-point of rolling five-year census data)**



Key points

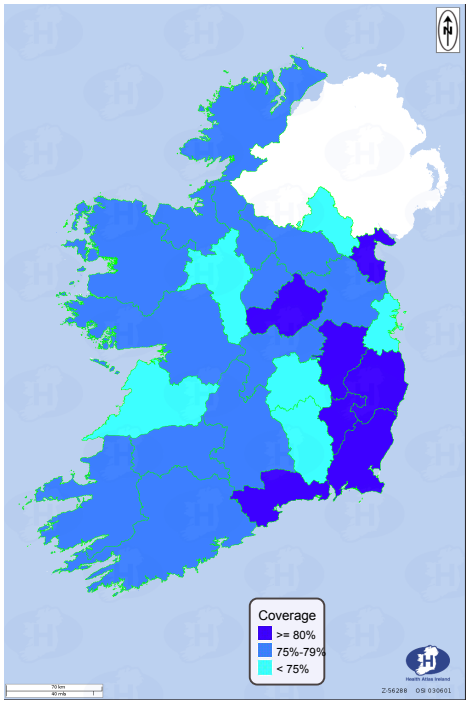
Overall population coverage steadily increased from 74.7% in the initial five years of the programme (2008-2013). It reached the programme standard for the first time (80.2%) in August 2017. It has decreased since then and was slightly below standard at 78.7% in the five-year period ending 31 March 2020.

Coverage based on geographical location

Figure 4 below outlines the five-year coverage by county by the calendar periods specified. The adjacent map shows the geographical variation in coverage using colour grading.

The internationally accepted standard for measuring uptake in cervical screening programmes is coverage over five-year periods. Measuring uptake over a five-year screening 'round' reduces anomalies that can arise, for example, when a person is invited in particular year, but attends the following year.

Figure 4: Five-year screening coverage by county 2012-2020



County	2012-2017 Avg	2017/2018	2018/2019	2019/2020*	Trend
Carlow	87.65%	90.11%	88.41%	87.65%	↑
Cavan	76.22%	79.27%	77.74%	78.02%	→
Clare	70.87%	74.10%	74.89%	74.53%	→
Cork	77.13%	79.46%	78.19%	77.86%	→
Donegal	74.01%	75.18%	76.18%	76.33%	→
Dublin	72.97%	75.94%	75.26%	73.86%	↓
Galway	73.89%	75.87%	77.56%	77.24%	→
Kerry	74.59%	77.84%	75.54%	75.97%	↑
Kildare	76.56%	81.26%	80.87%	80.89%	→
Kilkenny	69.40%	71.59%	69.79%	69.65%	→
Laois	67.49%	70.82%	69.25%	68.98%	→
Leitrim	75.78%	78.92%	78.44%	79.09%	↑
Limerick	74.53%	75.77%	78.83%	78.09%	↓
Longford	75.55%	80.50%	78.43%	77.96%	→
Louth	80.71%	83.81%	82.02%	81.33%	↓
Mayo	73.89%	75.81%	75.63%	76.01%	↑
Meath	75.09%	79.72%	78.59%	78.77%	→
Monaghan	70.54%	74.03%	74.16%	74.26%	→
Offaly	71.73%	75.74%	76.23%	76.12%	→
Roscommon	68.96%	73.87%	73.47%	74.52%	↑
Sligo	76.27%	76.75%	77.87%	78.21%	↑
Tipperary	74.11%	77.25%	78.27%	78.10%	→
Waterford	80.51%	82.65%	82.65%	82.50%	→
Westmeath	83.75%	85.25%	85.46%	84.36%	↓
Wexford	78.33%	82.49%	80.31%	80.15%	→
Wicklow	80.18%	84.43%	82.93%	83.21%	↑

Table Key

> than 80% (above target)
75-79% (approaching or close to target)
70-74% (approaching or close to target)
under 70% (below target)

The tolerance limit for the trend is 0.5% – (i.e. if the difference between 2018 to 2019 and 2019 to 2020 is greater than +0.5% there is a green up arrow. If the difference is between minus 0.5% and plus 0.5% the trend arrow is orange. If the arrow is red, the trend difference is greater than 0.5% on the previous year.

* Sept 2019 - Mar 2020

* The coverage calculations are based on population estimates from census counts rolled forward (as detailed above), and do not take into account estimates of emigration, immigration, hysterectomy or deaths

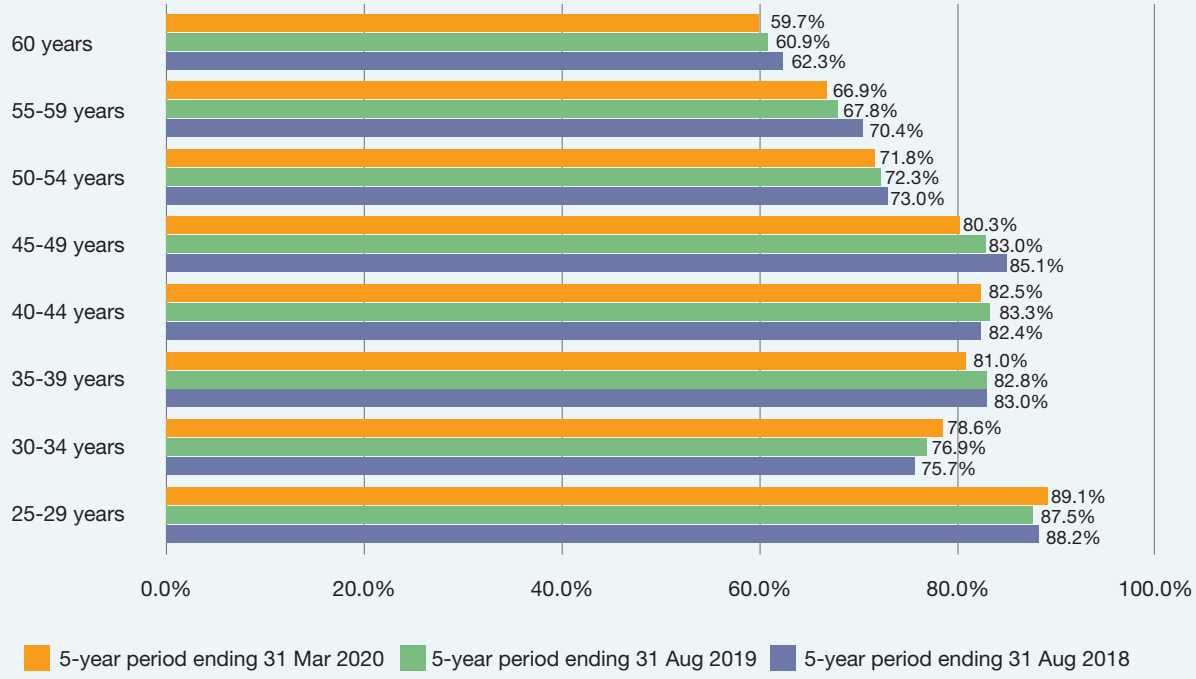
Key points

The five-year screening coverage shows that there is variation by county. Five counties (Carlow, Westmeath, Louth, Waterford and Wicklow) have met the 80% standard consistently. In the 2019/20 period, the majority of the remaining counties (14) have over 75% coverage. Four counties (Clare, Dublin, Monaghan, Roscommon) have a coverage rate between 70-75% whereas two counties (Kilkenny and Laois) have a coverage rate under 70% in 2018/2019 and 2019/2020.

Coverage based on age

Coverage can also vary by age. Figure 5 shows the coverage by age-group.

Figure 5: Five-year coverage of eligible women by age group on the cervical screening register, adjusted for hysterectomy



Key points

The 80% standard for coverage was met in four of the eight, five-year age bands. Consistently over the period of this report, younger participants (aged 25-29 years) have the highest coverage. The lowest coverage is observed in people aged 55 years and over.

2.6 Discussion

The number of people taking part in the CervicalCheck programme per year has increased since it was implemented in 2008, due to increases in the general population and successful communication strategies. Coverage increased to 80% by 2017, but has reduced slightly since then.

Despite the extra screening tests performed during 2018/19, there was a reduction in population coverage (from 80.2% to 78.7%) in the time period of this report. This is the first reported period that coverage has declined over time.

Coverage varies between counties and by participant age. While the coverage has been high and either steady or increasing in the younger age groups, there is a fall-off in coverage in women over 50 years of age.

Section 3
Programme response to women

3.1 Context

This is a patient quality measure for the programme and impacts on the experience women have of the service. It reduces the risk of participants being delayed if they require further actions, such as referral to colposcopy. It does not affect the accuracy of the result.

Definition: The time interval between the woman having her screening test performed and being sent her result.

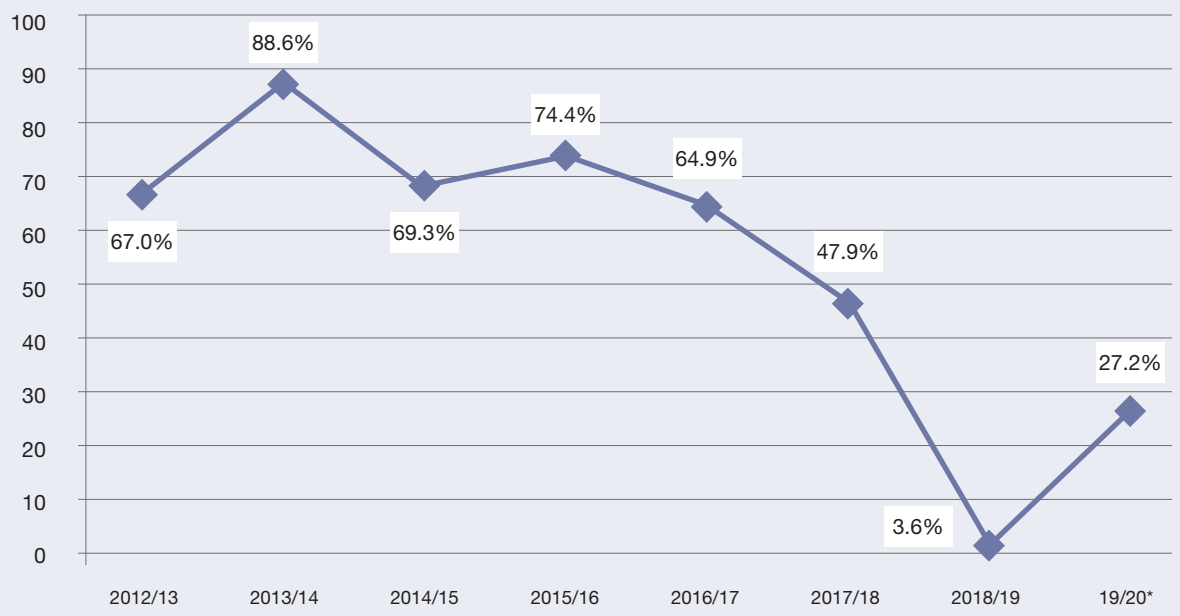
Programme standard		
CervicalCheck letters with the appropriate management recommendations should be received by women within four weeks of their screening test.	% of letters with results and management recommendation sent within four weeks of the woman's attendance	90%

The ability to meet this standard is dependent on each part of the pathway performing optimally.

The pathway starts with the sample being taken. It is dispatched to the laboratory, received and registered in the laboratory, processed, given a result, given a recommendation, and uploaded to the IT system. The result is received in CervicalCheck, quality assurance checks are done on the result and recommendation given, the letter is generated and posted to the participant.

For some samples there was further testing (HPV triage), which added additional time before a recommendation is made. Any delay in any of the steps impacts on the overall turnaround time.

Figure 6: Percentage of women sent results within four weeks of their cervical screening test from 1 September 2017 to 31 March 2020

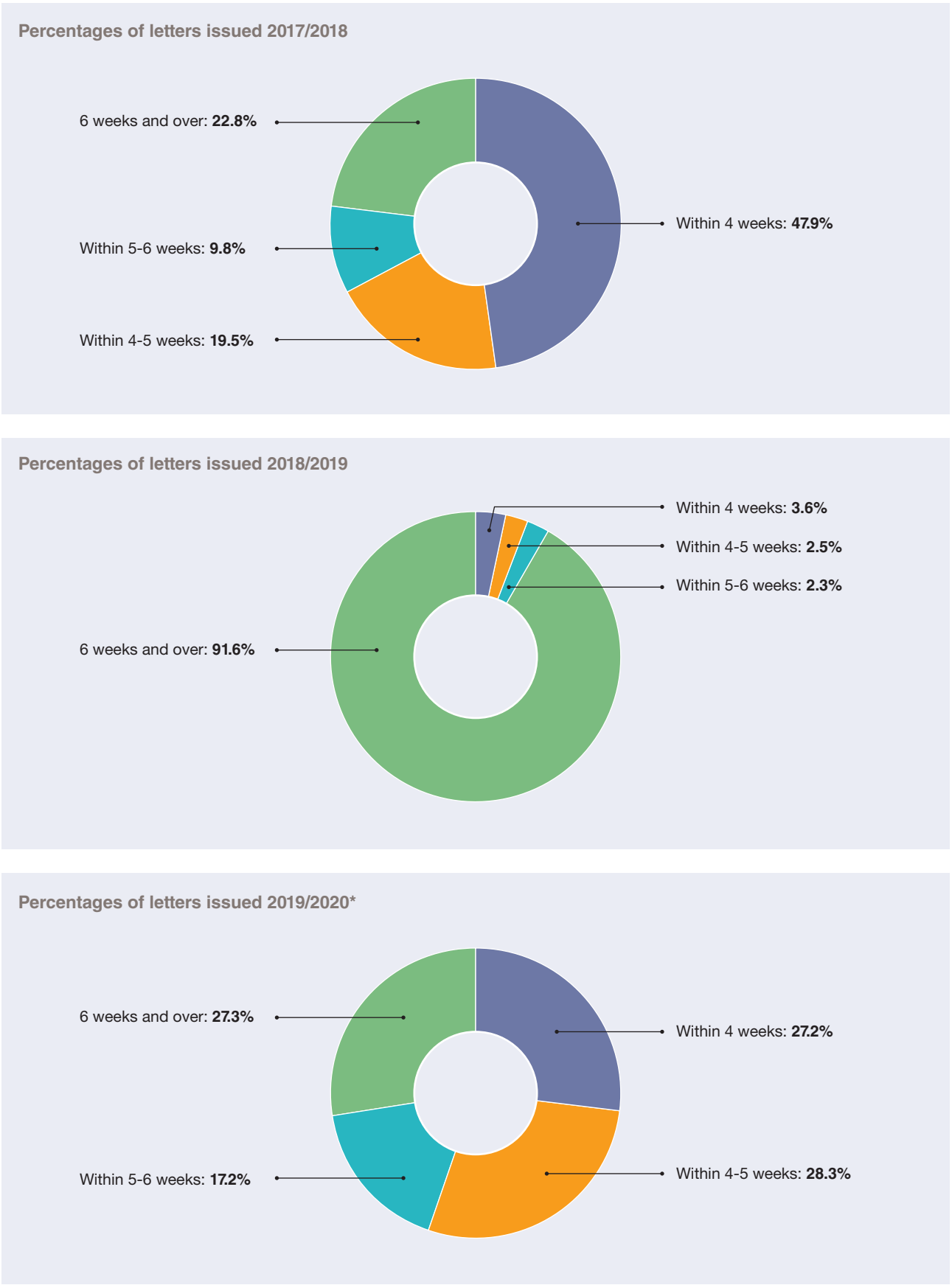


The period 2019 to 2020 runs from September 2019 to end of March 2020 and is only 7 months long instead of the usual 12 months

Table 4: Timelines for women sent results within four weeks of their cervical screening test from 1 September 2017 to 31 March 2020

Time from cervical screening test to result letter printed by programme	2017/2018	2018/2019	2019/2020
Within 4 weeks	47.9%	3.6%	27.2%
Within 5 weeks	67.4%	6.0%	55.5%
Within 6 weeks	77.2%	8.4%	72.7%
Greater than 6 weeks	22.8%	91.6%	27.3%

Figure 7: Time in weeks for the results letter to be issued by the programme (%) from 1 September 2017 to 31 March 2020



* The period 2019 to 2020 runs from September 2019 to end of March 2020, and is only seven months long instead of the usual 12 months

The three charts above demonstrate the time it took for the programme to issue results during the period of this report. There was a reduction in the number of women being sent results within the four-week target across the time periods, with only 4% women receiving results within four weeks and 92% waiting longer than six weeks in 2018/2019.

Key points

Table 3 shows that the CervicalCheck programme has not met the 90% standard for people sent their results letter within four weeks since 2012. In 2017/18 the performance reduced to 49.7% and then fell further in 2018/19 (3.6%) before recovering to nearly 30% in 2019/20. The reduction in performance in 2017/18 and 2018/19 coincided with the large increase in samples taken in 2018.

Discussion

The four-week turnaround time to send results to women has always been challenging. The complexity of the programme means that a delay in any part of the pathway can impact on the ability to meet this target. By 2019/20, over 72.7% of participants were getting their results back within six weeks.

Section 4
Laboratory metrics

4.1 Context

A number of laboratories have processed CervicalCheck samples since 2008. All of the laboratories were contracted to work to the standards set by the programme. These standards are based on those of the NHS Public Health England[7-9].

Laboratory performance was monitored by the programme's laboratory team, the quality assurance committee and the executive management team.

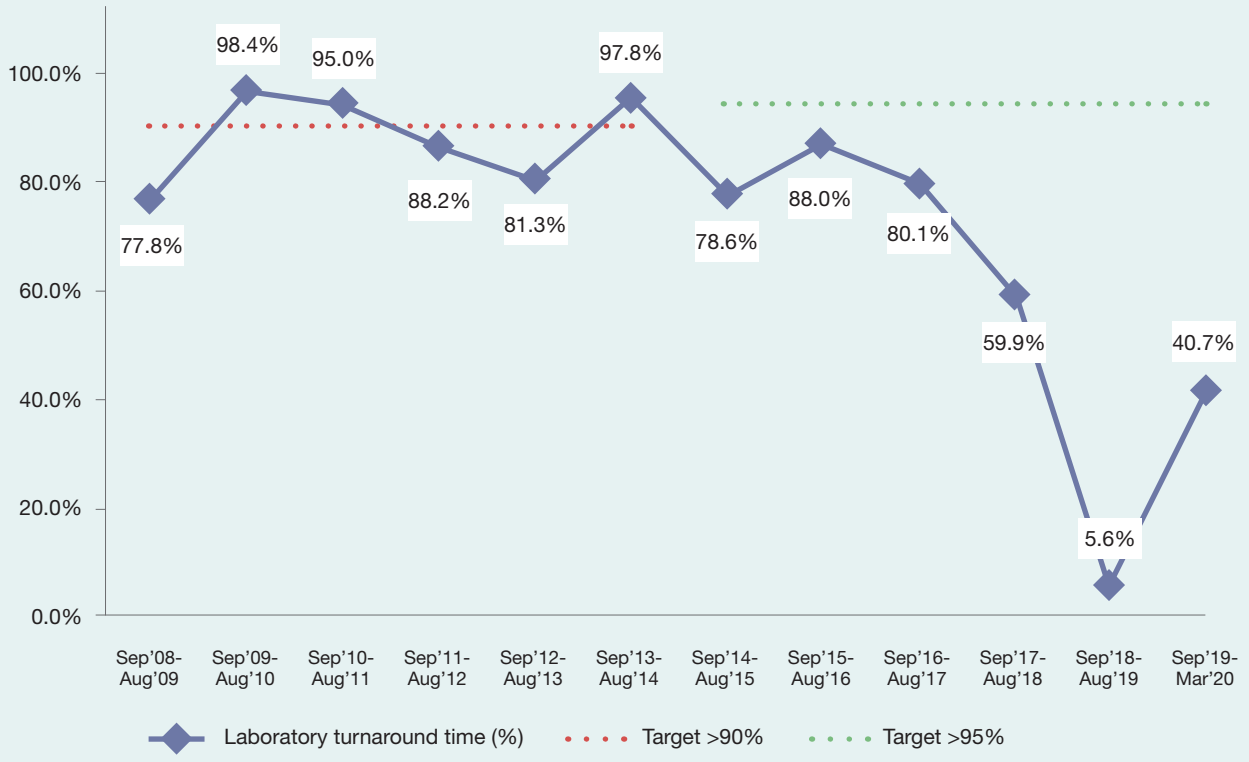
4.2 Laboratory turnaround time

Laboratory turnaround time is an important metric to ensure that the programme turnaround time for returning results to participants within four weeks is achieved (outlined in section 3 above). The laboratory services standard is to process cervical screening tests within 10 working days of receipt of the sample. This is a patient quality measure for the programme and impacts on the experience women have of the service. It does not affect the accuracy of the result.

Definition: The laboratory turnaround time is defined as the time taken between the arrival of the specimen at the laboratory and the result being authorised. The programme standard is that 95% of results should be authorised, released and transmitted to CervicalCheck within 10 working days.

Programme standard	2012-2017 Avg	2017/2018	2018/2019	2019/2020	Target
% results returned within 10 working days of receipt of sample at laboratory	85.2%	59.9%	5.6%	40.7%	>95%

Figure 8: Percentage of results finalised within 10 working days of receipt of sample at laboratory, 1 September 2008 to 31 March 2020



Key points

The target for achieving the ten-day turnaround time was increased from 90% to 95% in 2014. Prior to this change, the programme had comfortably achieved the target in three out of the six years of operation.

Turnaround times for 2018/2019 were significantly impacted with only 6% of samples being finalised within 10 days. This was beginning to improve by 2019/2020 when 41% were finalised within 10 days. This compares to the 2016/2017 report when 80% of samples were processed within the standard of 10 working days.

4.3 Satisfactory screening samples

Satisfactory sample

A satisfactory sample is one that has been taken, processed and read appropriately and to approved procedures which have produced a valid screening result. An unsatisfactory test is not an abnormal test but it is a quality measure. Having a low number of unsatisfactory tests reduces the number of participants who have to return for a repeat test. A sample can be 'unsatisfactory' for a number of reasons and these will vary between laboratories.

Standard: The proportion of unsatisfactory samples is monitored against the ranges as specified annually by the NHS Cervical Screening Programme Statistical Returns.

Table 5: CervicalCheck laboratory metrics (measured against NHS cervical screening programme Statistical Returns)

	2017/2018	2018/2019	2019/2020
Unsatisfactory Rate	1.8% (1.0 – 4.8%)	3.7% (1.0 – 4.2%)	2.7% (0.3- 4.7%)

Table 6: Percentages of cytology outcomes of satisfactory cytology tests compared to NHS cervical screening programme Statistical Returns (colposcopy samples excluded)

Laboratory	2017/2018	2018/2019	2019/2020
	N (%)	N (%)	N (%)
Quest Diagnostics	137,061 (99.3)	146,344 (96.7)	121,501 (97.6)
Med Lab Pathology	103,780 (97.2)	104,852 (96.0)	2,239 (99.9)
Coombe Women and Infants University Hospital	17,073 (95.5)	18,860 (94.6)	7,691 (92.5)
Total	**257,914 (98.2)**	**270,056 (96.3)**	**131,431 (97.3)**

* The period 2019 to 2020 runs from September 2019 to end of March 2020 and is only 7 months long instead of the usual 12 months

Table 5 shows that only a small percentage of samples are declared unsatisfactory (1.8%; 3.7% and 2.7% respectively for the three time periods).

4.4 Outcomes of satisfactory cytology tests

Context

The majority of screening samples have a normal result. The majority of women are not referred onwards for a diagnostic test or further investigation and are instead recommended to continue with routine screening.

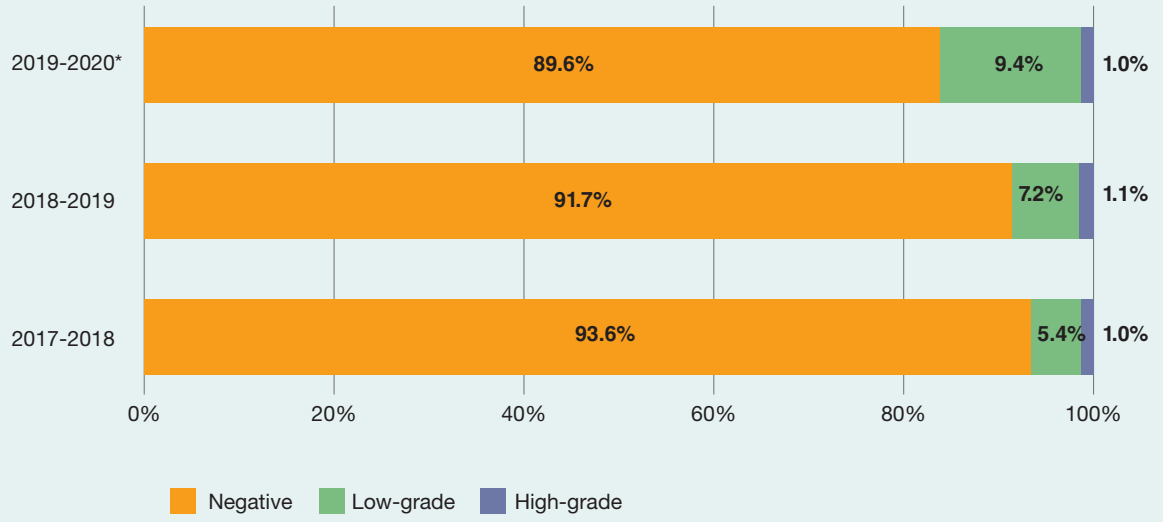
Definition: The outcome of a test is the result obtained. The programme is monitored against the ranges as specified annually by the NHS Cervical Screening Programme Statistical Returns (see table below). In a cervical screening programme, the expected proportion of low-grade and high-grade abnormalities in the populations is 3-8% and 0.7-1.3% respectively.

Standard:

Annual CervicalCheck Laboratory Metrics (NHS Cervical Screening Programme Statistical returns).

Programme standard	2017/2018	2018/2019	2019/2020	Target
Low-grade results	5.4%	7.2%	9.4%	3-8%
High-grade results	1.0%	1.1%	1.0%	0.7-1.3%

Figure 9: Percentage of negative, high-grade and low-grade abnormalities on cytology samples



* The period 2019 to 2020 runs from September 2019 to end of March 2020 and is only 7 months long instead of the usual 12 months

Key findings

Over the period covered by this report, the majority of participants received a negative result on their samples. The number of samples where high-grade abnormalities were found was within the NHS expected range (0.7- 1.3%) during the period of this report. The proportion of samples with a low-grade result in 2017/18 (5.4%) and 2018/19 (7.2%) were within the expected range (3-8%). In the seven-month period of 2019/20 this proportion was more than slightly increased at 9.4%.

4.5 Cytology results reported by laboratory

CervicalCheck has worked with a number of laboratory providers since the start of the programme. From 2017-2020, it commissioned services from three laboratories – Quest Diagnostics, MedLab Pathology and the Coombe Women and Infants University Hospital (CWIUH). Its contract with MedLab ceased in 2019.

Table 7: Cytology outcomes for satisfactory tests, taken outside colposcopy, by reporting laboratory from 1 September 2017 to 31 March 2020

Cytology results	Quest Diagnostics			MedLab Pathology			CWIUH			Total
	2017/2018	2018/2019	2019/2020	2017/2018	2018/2019	2019/2020	2017/2018	2018/2019	2019/2020	2017-2020
	N (%)	N (%)	N (%)	N (%)	N (%)	N (%)	N (%)	N (%)	N (%)	N (%)
Negative normal	128,017 (93.4)	133,484 (91.2)	108,704 (89.5)	98,082 (94.5)	97,512 (93.0)	2,225 (99.4)	15,359 (90.0)	16,667 (88.4)	6,812 (88.6)	606,862 (92.0)
Low-grade (3-8%)										
ASCUS	5,313 (3.9)	8,576 (5.9)	8,644 (7.1)	2,414 (2.3)	3,272 (3.1)	9 (0.4)	407 (2.4)	720 (3.8)	306 (4.0)	29,661 (4.5)
AGC (borderline granular)	143 (0.1)	154 (0.1)	67 (0.1)	100 (0.1)	104 (0.1)	0 (0)	16 (0.1)	20 (0.1)	14 (0.2)	618 (0.1)
LSIL	2,610 (1.9)	2,927 (2.0)	2,972 (2.4)	2,008 (1.9)	2,593 (2.5)	4 (0.2)	924 (5.4)	1,119 (5.9)	405 (5.3)	15,562 (2.4)
Low-grade Totals	**8,066 (5.9)**	**11,657 (8.0)**	**11,683 (9.6)**	**4,522 (4.4)**	**5,969 (5.7)**	**13 (0.6)**	**1,347 (7.9)**	**1,859 (9.9)**	**725 (9.4)**	**45,841 (7.0)**
High-grade (0.7-1.3%)										
ASC-H	340 (0.2)	418 (0.3)	378 (0.3)	370 (0.4)	361 (0.3)	0 (0)	21 (0.1)	23 (0.1)	18 (0.2)	1,929 (0.3)
HSIL (moderate)	348 (0.3)	448 (0.3)	432 (0.4)	222 (0.2)	356 (0.3)	0 (0)	249 (1.5)	223 (1.2)	81 (1.1)	2,359 (0.4)
HSIL (severe)	258 (0.2)	301 (0.2)	276 (0.2)	534 (0.5)	570 (0.5)	1 (0.0)	87 (0.5)	78 (0.4)	44 (0.6)	2,149 (0.3)
Query invasive squamous carcinoma	6 (0.004)	13 (0.01)	5 (0.004)	14 (0.01)	17 (0.02)	0 (0)	1 (0.01)	3 (0.02)	5 (0.1)	64 (0.0)
AGC favour neoplasia	14 (0.01)	12 (0.01)	13 (0.01)	15 (0.01)	37 (0.04)	0 (0)	0 (0)	5 (0.03)	2 (0.03)	98 (0.0)
Query glandular neoplasia / (AIS) / adenocarcinoma	12 (0.01)	11 (0.01)	10 (0.01)	21 (0.02)	30 (0.03)	0 (0)	9 (0.1)	2 (0.01)	4 (0.1)	99 (0.0)
High-grade totals	**978 (0.7)**	**1,203 (0.8)**	**1,114 (0.9)**	**1,176 (1.1)**	**1,371 (1.3)**	**1 (0.0)**	**367 (2.1)**	**334 (1.8)**	**154 (2.0)**	**6,698 (1.0)**
Total (100%)	**137,061**	**146,344**	**121,501**	**103,780**	**104,852**	**2,239**	**17,073**	**18,860**	**7,691**	**659,401**

* The period 2019 to 2020 runs from September 2019 to end of March 2020 and is only 7 months long instead of the usual 12 months

Key findings

Table 7 shows the result rates between laboratories and their percentage of the total number of slides processed.

The outcomes of the 659,401 satisfactory screening tests taken during the time period of this report are displayed. Over the time period, 92% of screening test results were found to be normal.

Of the remainder, 45,841 (6.9%) showed low-grade abnormalities and 6,698 (1%) showed high-grade abnormalities. Low-grade abnormalities include ASCUS, LSIL, AGC (borderline glandular). High-grade abnormalities include ASC-H, HSIL (moderate or severe), query invasive squamous carcinoma, AGC favour neoplasia and query glandular neoplasia. The overall programme results are in line with the expected population rates of 3-8 % low-grade and 0.7-1.3% high-grade disease (NHS CSP statistical returns).

Some variation in result rates is expected to arise between laboratories due to the demographic variations in the populations from which the laboratories are receiving samples. Variation in laboratory workload is another factor in differing result rates. The laboratories represented in the table have widely varying workloads. Small detection rates, for example, are more dramatically affected in a laboratory processing smaller numbers and are not alone a measure of laboratory performance.

4.6 HPV testing (triage) outcomes

In 2015 the CervicalCheck programme introduced HPV testing when the initial screen identified low-grade abnormalities. This secondary test was introduced to triage these samples and inform the recommendations. Those where HPV was detected were referred to colposcopy whereas those where HPV was not detected were returned to routine screening.

Standard: There is no standard for this metric. This is measured to assess the impact on colposcopy capacity.

Table 8: HPV triage results in low-grade cytology samples from 1 September 2017 to 31 March 2020 (all screening locations and excluding colposcopy)

HPV test results	ASCUS			LSIL			Recommended outcome
	2017/2018	2018/2019	2019/2020	2017/2018	2018/2019	2019/2020	
	N (%)	N (%)	N (%)	N (%)	N (%)	N (%)	
HPV detected	3,362 (34.2)	3,754 (33.4)	1,941 (26.2)	4,390 (66.4)	3,751 (68.0)	1,809 (68.3)	Refer to colposcopy
Equivocal / Indeterminate / Unknown / Not processed	115 (1.2)	144 (1.3)	4 (0.1)	58 (0.9)	67 (1.2)	10 (0.4)	Refer to colposcopy
HPV not detected	6,346 (64.6)	7,341 (65.3)	5,460 (73.7)	2,163 (32.7)	1,699 (30.8)	829 (31.3)	Routine screening
Total	**9,823**	**11,239**	**7,405**	**6,611**	**5,517**	**2,648**	

* The period 2019 to 2020 runs from September 2019 to end of March 2020 and is only 7 months long instead of the usual 12 months

Table 8 shows that approximately one-third of women with an ASCUS cytology result and two-thirds of women with an LSIL cytology result were found to have HPV detected on triage. This enabled more rapid referral to colposcopy for these women.

4.7 Discussion point

In the period of this report, 257,914 samples were processed in 2017/18; 270,056 in 2018/19; and 131,431 in the seven month period of 2019/20. Of these, 93.6%, 91.7% and 89.6% respectively were normal. The proportion of high-grade lesions reported on cytology stayed constant and within standard across all three years at 1-1.1% (standard 0.7-1.3%). The low-grade cytology results were also within standard (3-8%) for 2017/18 and 2018/19 (5.4% and 7.2% respectively) but increased to 9.4% in 2019/20. After HPV triage, the percentage of the low-grade cytology results that were HPV positive and referred to colposcopy each year was 48.2%; 45.7% and 37.4% respectively.

This report is the last year of primary cytology with HPV triage within the CervicalCheck programme.

Section 5
Colposcopy

5.1 Referral to colposcopy

Context

The colposcopy service is the diagnostic and treatment arm of the CervicalCheck programme. Women with abnormal screening test results are assessed at clinics to determine if further treatment is required. The people referred to colposcopy during this period include those with a positive screening result (the true screening cohort) and also those referred by their GP because of a clinical concern noted at the time of the screening test. The data is presented to show the proportions in each group.

Definition:

Abnormal screening test referrals

Positive screening tests that lead to colposcopy referral include (a) high-grade cytological abnormalities (b) low-grade cytological abnormalities with HPV detected and (c) persistent unsatisfactory results.

Clinical referrals

Clinical indications that lead to colposcopy referrals are outlined in the table below. Clinical indications are classified as either urgent or non-urgent. People referred for this reason may or may not have a positive cytology result.

Table 9: Programme definition of urgent and non-urgent clinical referrals

Clinical indication – urgent	Clinical indication – non urgent
Clinically suspicious cervix	Inflammation
Contact bleeding	Polyps
Post coital bleeding > 4 weeks (age > 35)	Vaginal changes – No abnormal cytology
Suspicious symptoms*	

* Women referred for this reason may or may not have a positive cytology. they may have a negative smear; smear not done; or smear done and result not back yet.

Standard: There is no agreed standard for the proportion of clinical referrals to colposcopy that should occur. We measure this to monitor the colposcopy capacity available for assessment of people with positive screening tests.

Table 10: Reason for all new referrals to colposcopy from 1 September 2017 to 31 March 2020

Reason for referral to colposcopy	New referrals			
	2012/2017 Average	2017/2018	2018/2019	2019/2020*
	N (%)	N (%)	N (%)	N (%)
Abnormal screening test	11,175 (67.2)	11,277 (55.4)	12,324 (53.8)	8,702 (64.9)
Clinical indication – non-urgent	3,307 (19.9)	5,504 (27.0)	6,100 (26.6)	2,620 (19.5)
Clinical indication – urgent	2,150 (12.9)	3,576 (17.6)	4,491 (19.6)	2,087 (15.6)
Total	**16,632 (100)**	**20,357 (100)**	**22,915 (100)**	**13,409 (100)**

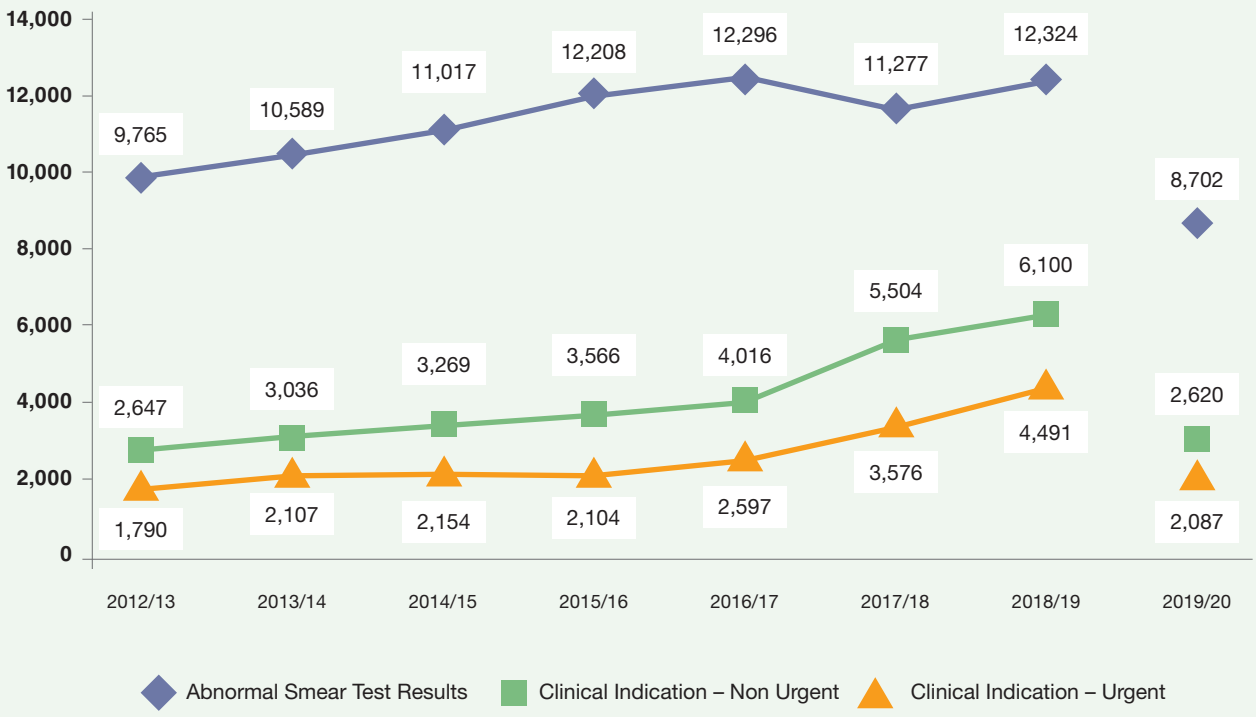
* The period 2019 to 2020 runs from September 2019 to end of March 2020 and is only 7 months long instead of the usual 12 months

The table above shows that the proportion of colposcopy capacity used to see people with clinical indications has increased substantially in 2017/18 (44.6%) and 2018/19 (46.2%) compared to the average for the programme from 2012-2017 (32.5%).

The table also shows that the overall number of referrals for clinical indications increased from aapproximately 5,500 per annum in 2012-2017 to approximately 10,500 per annum (6,100+4,491) in 2018/2019.

The trend over the lifetime of the programme is shown in more detail in the graph below.

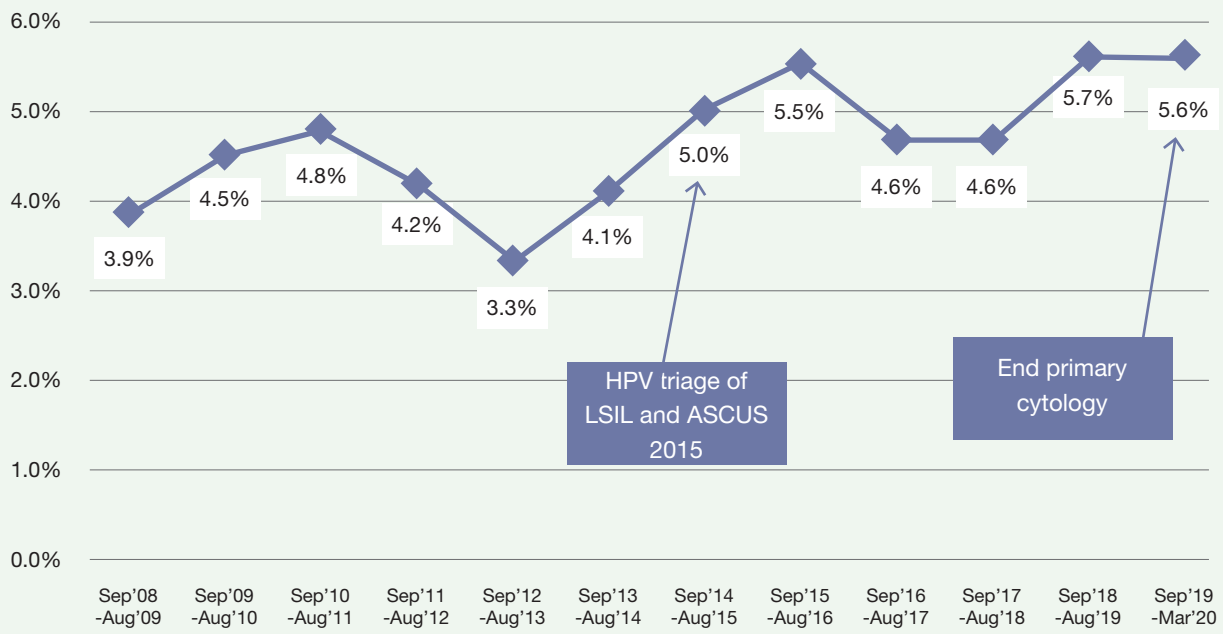
Figure 10: Number of new referrals for all reasons from programme to colposcopy 2012-2020



Referral to colposcopy for screening indications

Figure 11 below details the rate of referral to colposcopy due to a positive screening result since the start of the programme. The data includes those women who have a cytology test performed in primary screening locations and excludes samples taken at colposcopy clinics as part of follow-up.

Figure 11: Referral to colposcopy from screening tests from 1 September 2008 to 31 March 2020



* The period 2019 to 2020 runs from September 2019 to end of March 2020 and is only 7 months long instead of the usual 12 months

Key points

The introduction of HPV triage for low-grade disease in 2015 led to a reduction in referral to colposcopy because the presence of both abnormal cells and HPV infection were required before colposcopy referral was instigated. Colposcopy referral increased again in 2018/19 and 2019/20.

Abnormal screening tests that prompt colposcopy referral

The table below describes the reasons that women are referred to colposcopy after an abnormal screening test result is obtained. The majority of women are referred to colposcopy with low-grade abnormalities.

Table 11: Reason for referral to colposcopy with an abnormal screening test result 2012-2020

Referral screening abnormality	New referrals			
	2012/2017 Average	2017/2018	2018/2019	2019/2020*
	N (%)	N (%)	N (%)	N (%)
Unsatisfactory/ inadequate	77 (0.7)	101 (0.9)	138 (1.1)	101 (1.2)
Low-grade				
ASCUS	3,030 (26.8)	3,308 (29.3)	4,026 (32.7)	3,278 (37.7)
AGC	385 (3.4)	306 (2.7)	365 (3.0)	156 (1.8)
LSIL	4,215 (47.3)	4,576 (40.6)	4,738 (38.4)	3,249 (37.3)
Total low-grade referrals	**7,631 (67.5)**	**8,190 (72.6)**	**9,129 (74.1)**	**6,683 (76.8)**
High-grade				
ASC-H	1005 (8.9)	925 (8.2)	850 (6.9)	638 (7.3)
HSIL (moderate)	1161 (10.3)	947 (8.4)	1,043 (8.5)	667 (7.7)
HSIL (severe)	1357 (12.0)	1,062 (9.4)	1,099 (8.9)	590 (6.8)
Query invasive squamous carcinoma	19 (0.2)	17 (0.2)	17 (0.1)	10 (0.1)
Query glandular neoplasia / AIS / adenocarcinoma	51 (0.4)	35 (0.3)	48 (0.4)	13 (0.1)
Total high-grade referrals	**3,593 (31.8)**	**2,986 (26.5)**	**3,057 (24.8)**	**1,918 (22.0)**
Total referrals	**11,301 (100)**	**11,277 (100)**	**12,324 (100)**	**8,702 (100)**

* The period 2019 to 2020 runs from September 2019 to end of March 2020 and is only 7 months long instead of the usual 12 months

The table reflects the spread of results from the screening programme and, as discussed in Table 5 (Cytology outcomes for satisfactory tests, taken outside colposcopy), are within accepted standards for screening programmes.

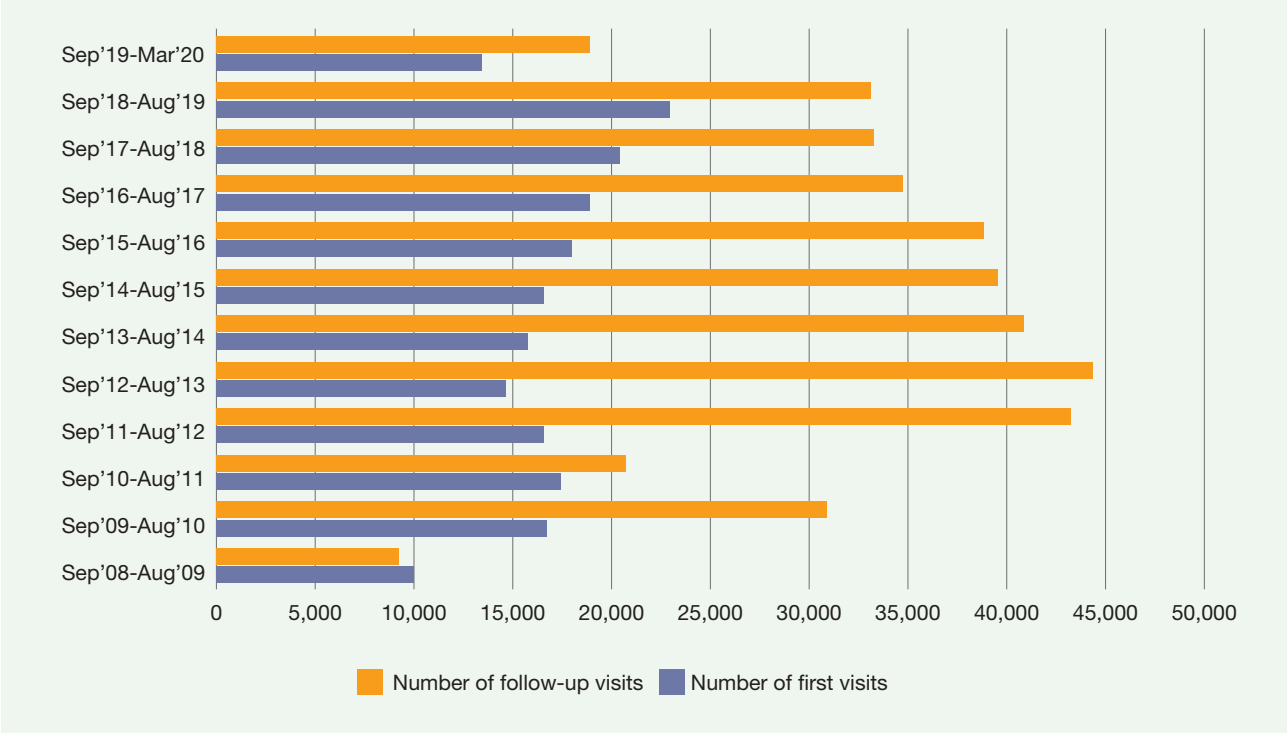
Discussion

Colposcopy capacity has increased over the period of the CervicalCheck programme. The rate of referral to colposcopy for abnormal screening results has also increased. However, over the period of 2017-2020, the large increase was driven by the number of referrals for clinical indications.

5.2 Colposcopy activity

Standard: There is no standard for colposcopy activity. It reflects the activity in the rest of the programme and the population prevalence of cervical abnormalities. We monitor it to manage capacity to ensure people are seen in a timely manner.

Figure 12: Number of new referrals and follow up visits at colposcopy service September 2008 - March 2020



* The period 2019 to 2020 runs from September 2019 to end of March 2020 and is only 7 months long instead of the usual 12 months

The figure above shows the trends in activity for both new and follow-up appointments since the start of the programme. From 2012/13 there has been a steady increase in new appointments and a gradual reduction in the number of follow-up visits (2019/20 is not representative as it only included 7 months of data). This data can be read in conjunction with the colposcopy clinical protocol changes which have taken place at intervals since the programme started in 2008.

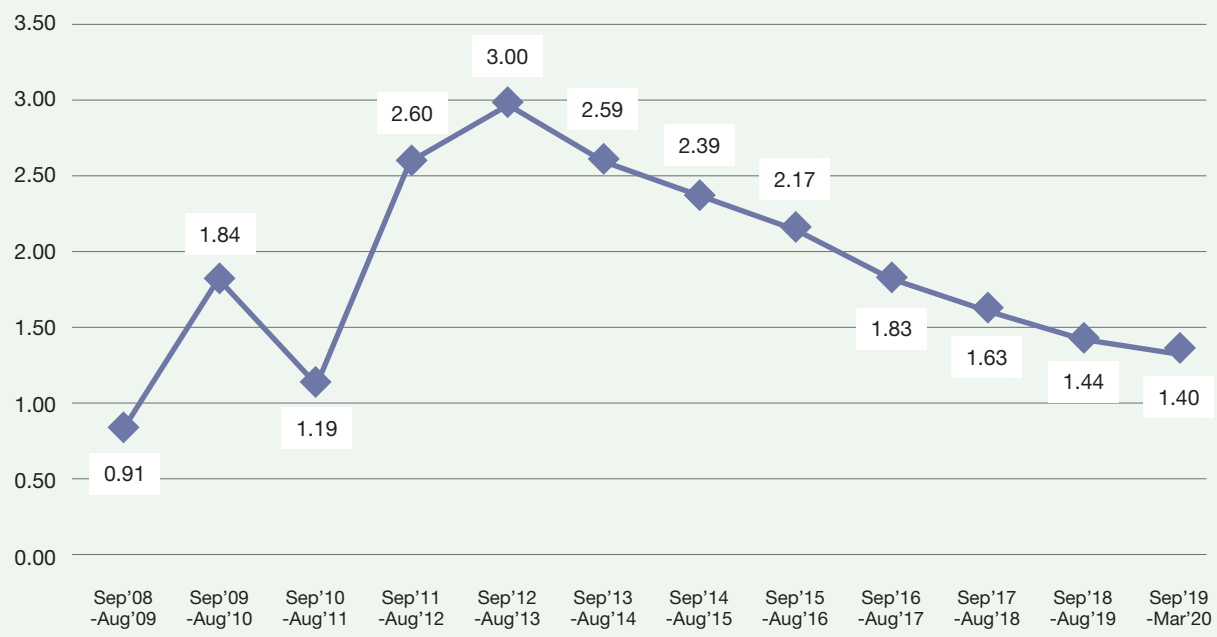
The new: review ratio

The graph below details the number of follow-up visits generated by each new referral to colposcopy services.

Definition: The number of new patients that attend a service compared to the number of review patients that attend a service. The New: Return ratio is expressed by setting out how many review patient attendances occur for each new patient attendance.

Standard: There is no agreed standard for this metric. We monitor this mainly to ensure that people who are referred to colposcopy are managed according to the programme's quality assurance standards and discharged when clinically appropriate and in line with programme policy. This is a quality measure and also helps ensure that colposcopy capacity is sufficient to meet the needs of the people referred.

Figure 13: Number of return visits generated by each new referral for colposcopy clinics 2008-2020



* The period 2019 to 2020 runs from September 2019 to end of March 2020 and is only 7 months long instead of the usual 12 months

Key points

The ratio has been dropping since a peak of three return visits for every new referral in 2012-13. This decrease reflects a combination of programme standardisation of colposcopy policies and protocols for care and improved monitoring arrangements.

'Did not attend' (DNA) rates for colposcopy services

Context

The rate of non-attendance ('DNA') where no prior notice was given should be kept to a minimum to ensure best use of publicly-funded services. This programme target was amended from <15% in 2008 to <10% in 2013. The target for outpatient DNA rates in HSE clinics is set to 5% - 8% in line with international best practice. The programme target was <10% during the time period of this report. The DNA rate at colposcopy clinics is one of the lowest in the HSE for out-patient services. It compares favourably to other services where DNA rates above 20% are common[6].

Definition: A DNA is a defaulted appointment where no prior notice was given.

Programme standard	2017/2018	2018/2019	2019/2020	Target
The DNA rate should be maintained at a low level to maximise the efficiency of the colposcopy service and to avoid the loss of women to follow-up.	9.8%	8.7%	8.2%	<10%

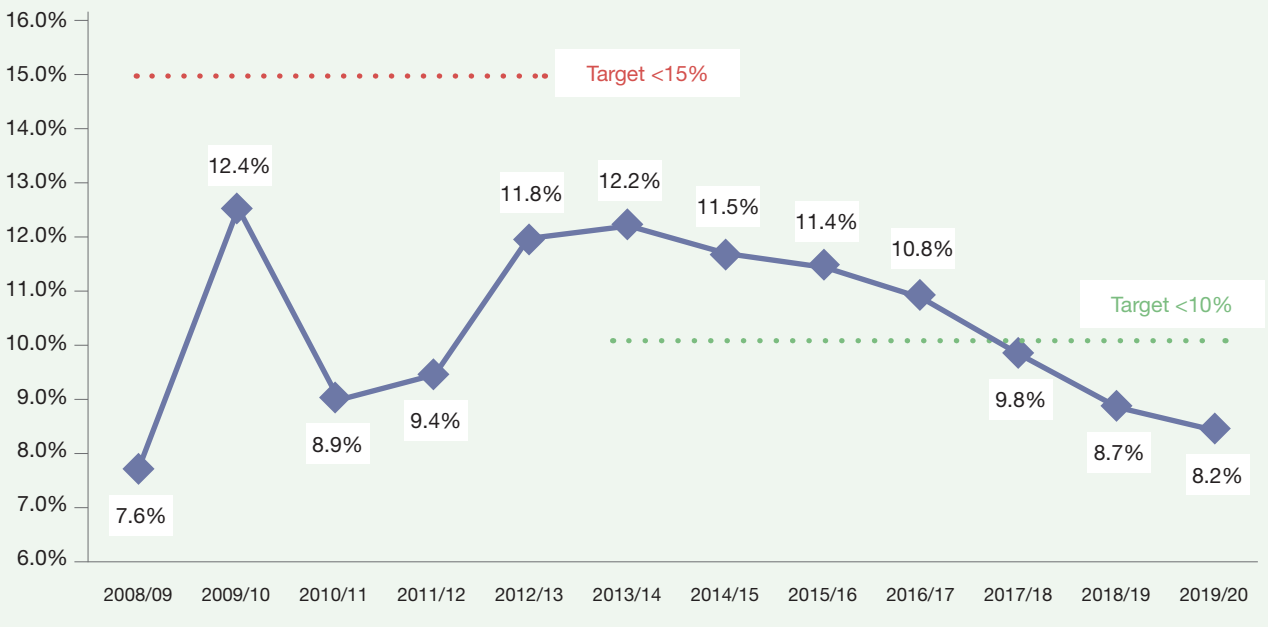
Key points

The DNA rate was within programme standard for the duration of this reported period. There were 53,619; 56,055; and 32,323 people seen in colposcopy respectively in each of the three time periods of this report. The percentage of new people seen in Colposcopy Clinics increased from 38% (20,394) in 2017/18; to 41% (22,937) in 2018/19 and 42% (13,475) in 2019/20.

DNA rate since start of programme

The graph below details the DNA rate since the start of the CervicalCheck programme.

Figure 14: The percentage of DNAs to colposcopy 2008-2020



* The period 2019 to 2020 runs from September 2019 to end of March 2020 and is only 7 months long instead of the usual 12 months

5.3 Waiting times for colposcopy

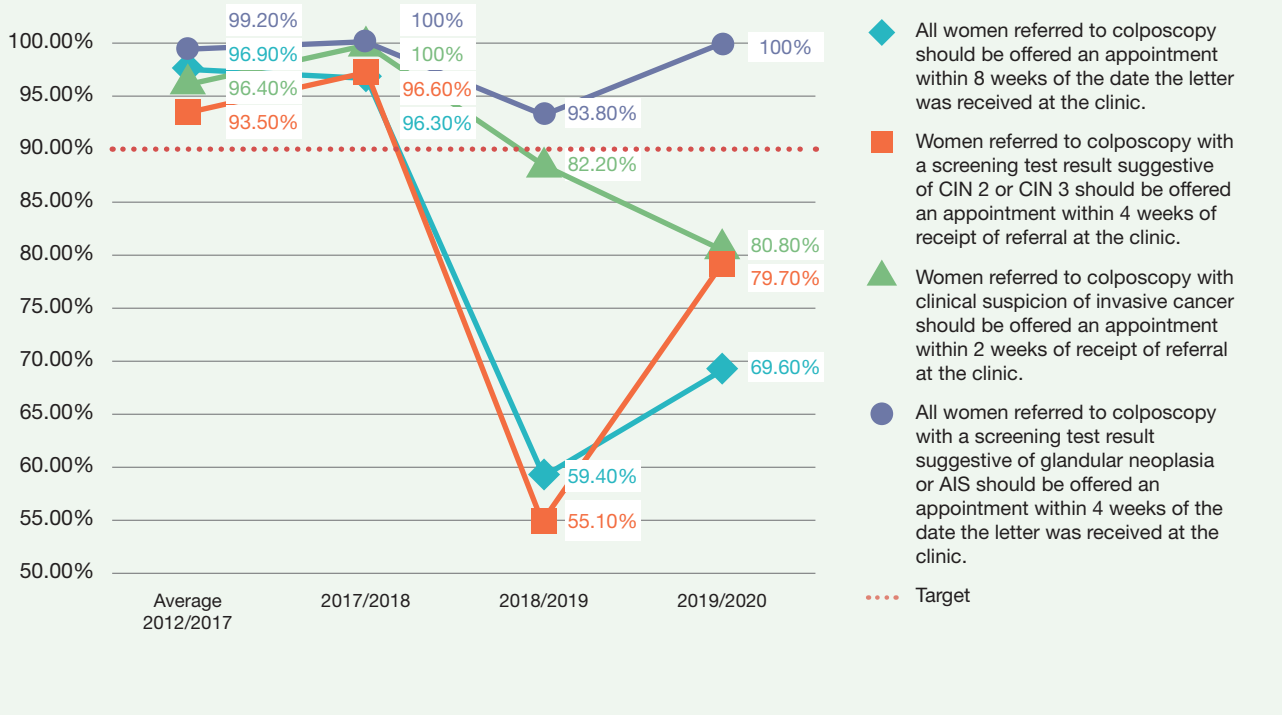
Context

The figure below details the percentage of women seen within the programme standard waiting times since 2012.

Definition: Colposcopy waiting time is the interval between the referral letter being received by the clinic and the woman attending colposcopy.

Standard: Standard waiting times for colposcopy services 2012 to 2020.

Figure 15: Waiting times for colposcopy services 2012 to 2020



Discussion

The programme processed an additional 100,000 tests and noted an increase in women being referred to colposcopy due to ‘clinical indications’ over this period. In 2018/2019, only 55% of women with high grade screening results were seen within 4 weeks, and only 59% of all referrals were seen within 8 weeks.

5.4 Diagnostic biopsies at colposcopy

Where an abnormality is suspected at colposcopy, a biopsy is performed to confirm the diagnosis. Biopsies can be diagnostic, which involves sampling a portion of the abnormal area only, or therapeutic which involves excising the abnormal area in its entirety.

The table below details the adherence to the programme standards regarding biopsy rates if an atypical Transformation Zone is present. It also details the biopsy rates when invasive disease is suspected.

Table 12: Biopsy rates measured against colposcopy standards

Performance parameter	2012-2017 Average	2017/2018	2018/2019	2019/2020*	Target
A biopsy should be performed in the presence of an atypical Transformation Zone	92.9%	95.0%	95.1%	94.1%	>90%
If there is a suspicion of invasive disease a biopsy must be performed immediately	98.8%	90.5%	85.6%	89.7%	>90%

* The period 2019 to 2020 runs from September 2019 to end of March 2020 and is only 7 months long instead of the usual 12 months

Key points

Since 2018, the biopsy rate when invasion is suspected is lower than 90%. In cases of frank malignancy, a decision may be made to perform the diagnostic biopsy in a theatre setting under general anaesthetic rather than in the colposcopy clinic.

Section 6
Histology

6.1 Number of biopsies

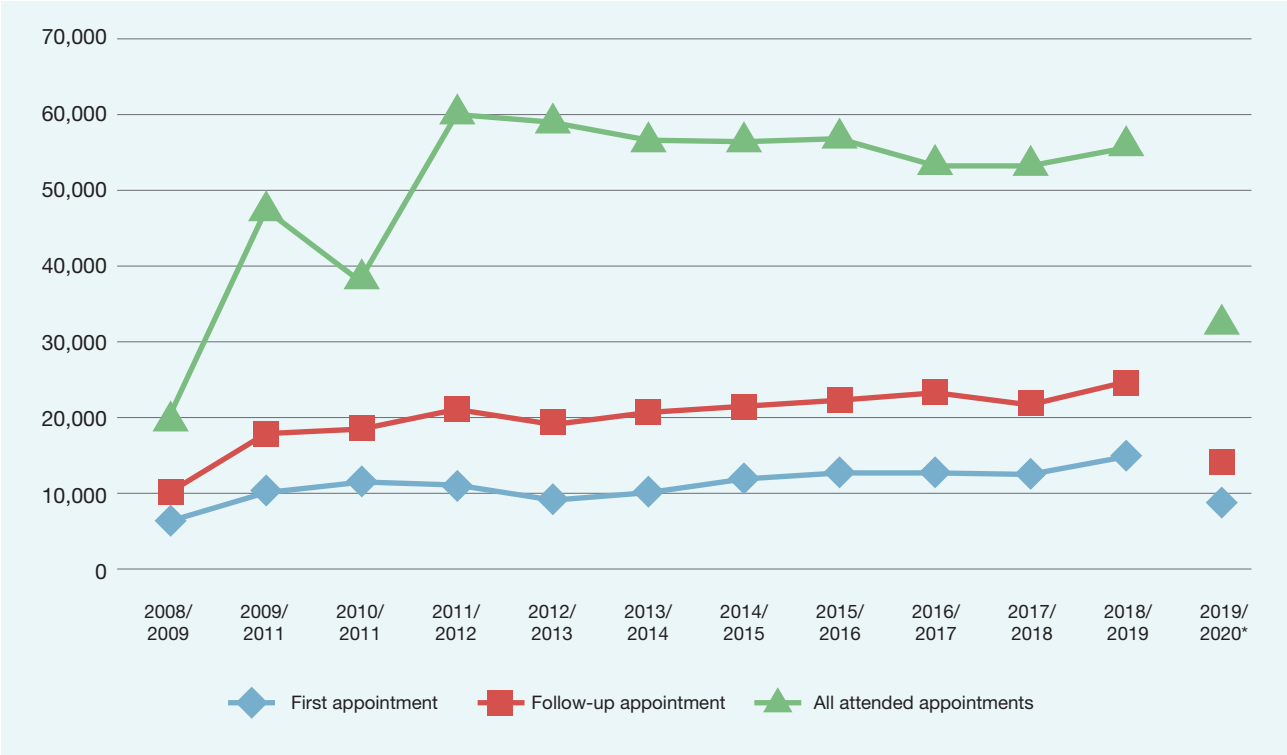
The graph below details the numbers of biopsies performed at colposcopy clinics since the start of the programme. The histology workload is increasing year on year as the number of biopsies in both new referrals and return patients is increasing over time.

The green line is total number of attendances at colposcopy since the start of the programme and demonstrates that almost half of women attending colposcopy require a biopsy.

The blue line represents the number of biopsies in patients on their first visit to colposcopy.

The red line is number of patients who have a biopsy taken at any visit (first or follow-up).

Figure 16: Number of women undergoing biopsy at colposcopy services from 1 September 2008 to 31 March 2020, with overall attendance at colposcopy indicated



* The period 2019 to 2020 runs from September 2019 to end of March 2020 and is only 7 months long instead of the usual 12 months

Table 13: Biopsies performed for new and follow up visits at colposcopy

Period	First Appointment	Follow Up Appointment	All Appointments	All Attendances
2008/2009	6,654	2,724	9,378	19,294
2009/2011	10,191	7,058	17,249	47,695
2010/2011	11,244	6,656	17,900	38,206
2011/2012	10,585	10,184	20,769	59,823
2012/2013	9,436	9,348	18,784	59,137
2013/2014	10,451	9,525	19,976	56,655
2014/2015	11,579	9,410	20,989	56,106
2015/2016	12,810	9,223	22,033	56,744
2016/2017	12,575	10,098	22,673	53,679
2017/2018	12,805	8,541	21,346	53,619
2018-2019	14,415	9,109	23,524	56,055
2019-2020*	8,376	4,854	13,230	32,323

* The period 2019 to 2020 runs from September 2019 to end of March 2020 and is only 7 months long instead of the usual 12

All colposcopists working in CervicalCheck clinics are accredited by the British Society of Colposcopy and Cervical Pathology (BSCCP) as per the programme quality assurance standards. The standard below shows the high level of quality specimens taken at colposcopy clinic and sent for histological analysis.

Performance parameter	2017/2018	2018/2019	2019/2020*	Target
Biopsy specimens should be suitable for histological diagnosis	98.2%	98.4%	98.5%	>95%

* The period 2019 to 2020 runs from September 2019 to end of March 2020 and is only 7 months long instead of the usual 12 months

Discussion

There is a steady increase in the total number of cervical biopsy samples taken yearly. This reflects the increase in colposcopy activity and also the change in the proportion of low-grade referrals and an increased tendency to manage patients with low-grade disease conservatively. Additional biopsies are frequently taken to be reassured of the diagnosis and underpin this clinical management. It is reassuring that the quality standard for these biopsies has been consistently met.

6.2 Correlation between cytology and histology

Context

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. These include the positive predictive value (PPV) and the referral value (RV) of referral cytology.

Definition

Positive predictive value of high-grade cytology

The cytology-histology PPV is reported as the percentage of women referred with high-grade cytological abnormality who subsequently have a histological diagnosis of CIN2 or higher.

Standard for cytology-histology PPV

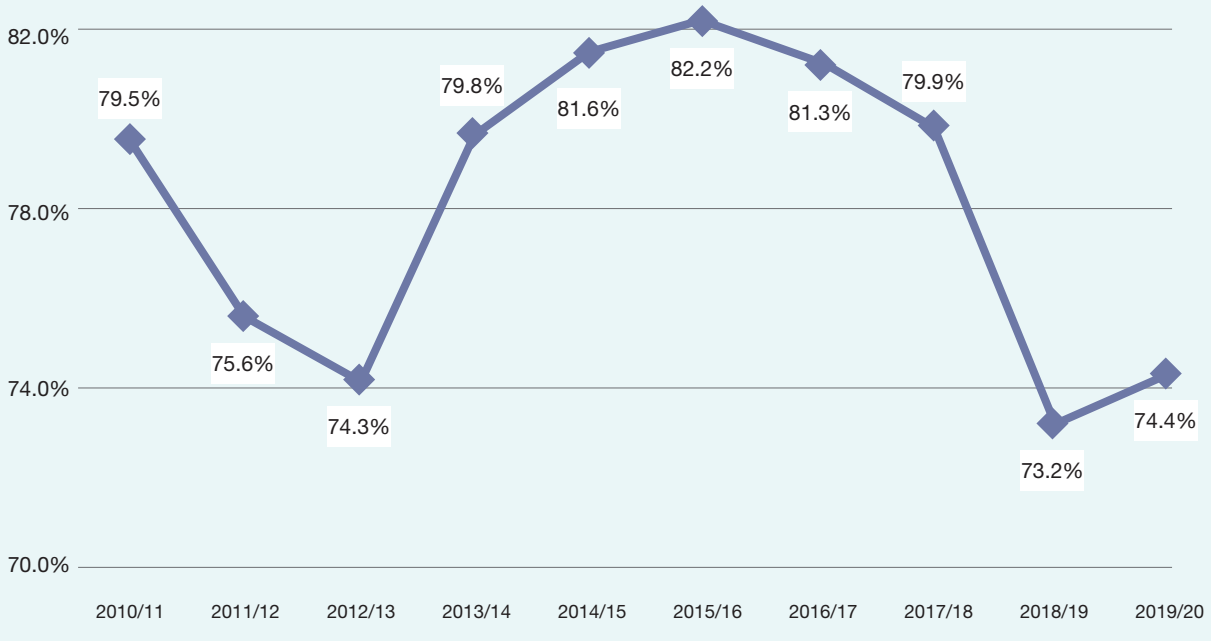
The programme is monitored against the ranges as specified annually by the NHS Cervical Screening Programme statistical returns (see table below).

Annual CervicalCheck laboratory metrics (NHS Cervical Screening Programme statistical returns)[7-9].

	2012-2017 avg	2017-2018	2018-2019	2019-2020
PPV	79.8%	79.9% (76.2 -92.3%)	73.2% (76.2 - 92.5%)	74.4% (76.6 – 91.6%)

This graph demonstrates the changes in PPV over time since 2010. When the PPV is 79.9% per cent, this means that for every 100 women who are referred with a high-grade abnormal screening result, approximately 80 will have a histological abnormality found that confirms high-grade CIN lesion or an invasive cancer. The other 20 women will either not have a biopsy taken, or will have a normal or low-grade CIN (which might return to normal without intervention). These 20 women represent the overdiagnosis rate of the programme.

Figure 17: The positive predictive value of cytology-histology correlation, 1 September 2010 to 31 March 2020*



* The period 2019 to 2020 runs from September 2019 to end of March 2020 and is only 7 months long instead of the usual 12 months

Referral value

The referral value (RV) correlates referral cytology results with histological outcomes. This measure examines the number of women that need to be referred to colposcopy to enable the detection of one case of high-grade CIN or invasive cervical cancer (excluding inadequate referrals).

Standard for RV

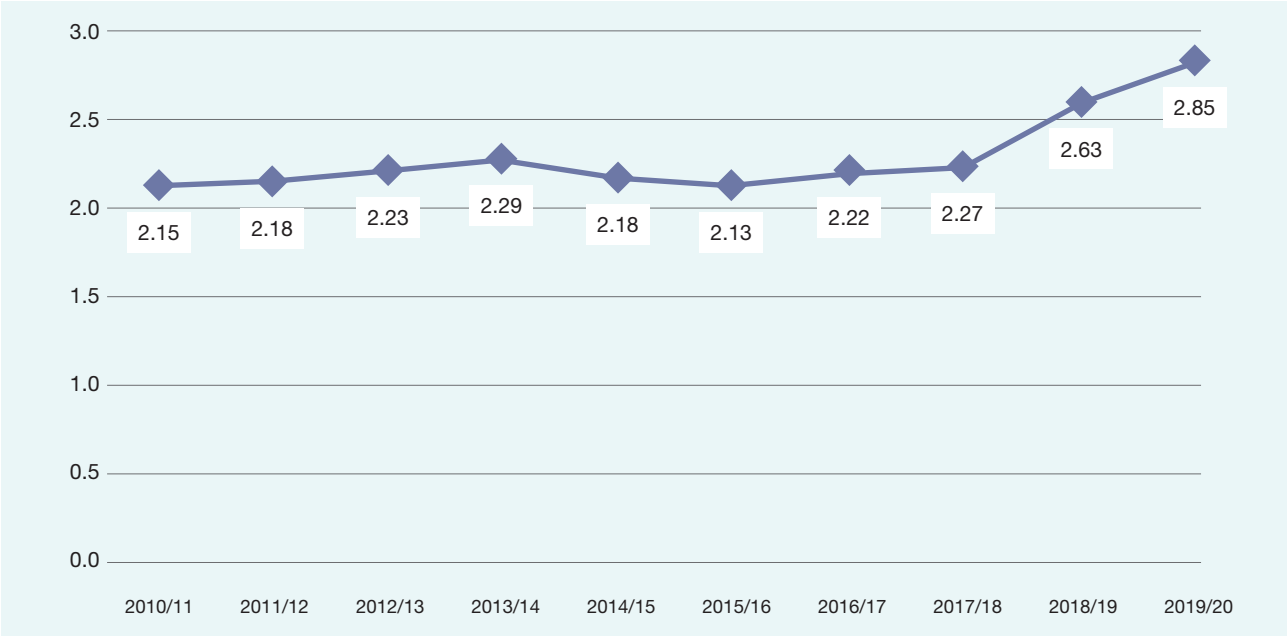
The referral value (RV) is used when reviewing laboratory performance, but it is not a programme standard. The Referral Value accepted range is 2.1 - 4.4 based on NHS Cervical Screening Programme Statistical returns.

Cytology-histology correlation				
	2012-2017 Average	**2017/2018**	**2018/2019**	**2019/2020***
Referral value (RV)	2.21	2.27	2.63	2.85

* The period 2019 to 2020 runs from September 2019 to end of March 2020 and is only 7 months long instead of the usual 12 months

This graph demonstrates the programme RV, since 2010. When the RV is 2.27, this means that for every 227 women referred to colposcopy, 100 had CIN2 or higher detected; whereas 127 had either low-grade abnormalities or no abnormalities. These 127 women represent the possible overdiagnosis rate of the programme.

Figure 18: The referral value of cytology-histology correlation, 1 September 2010 to 31 March 2020*



6.3 Discussion

The correlation between the cytology referral result and the histological diagnosis is a useful marker of the quality of the cytology laboratories and of the overall programme. The cytology-histology PPV has reduced since 2018. This means that a high-grade cytology referral is less likely to be confirmed as high-grade on histological analysis. The decrease in cytology-histology PPV since 2018 is concerning and is likely multifactorial.

The RV has risen during the period of this report which indicates that a higher number of women are referred to colposcopy to find one woman with high-grade disease.

Section 7
Treatment at colposcopy

7.1 Context

Effective treatment of high-grade CIN and adenocarcinoma in situ (AIS) leads to a reduction of the risk of invasive cancer in the future and underpins the success of any cervical screening programme. The majority of women can be safely treated under local anaesthetic in the outpatient setting at colposcopy clinics. This table details adherence to the programme standard regarding treatment under local anaesthetic.

Definition: Outpatient treatment: the number of women treated for CIN under local anaesthetic in an outpatient setting.

Standard:

Cervical treatments performed under local anaesthetic

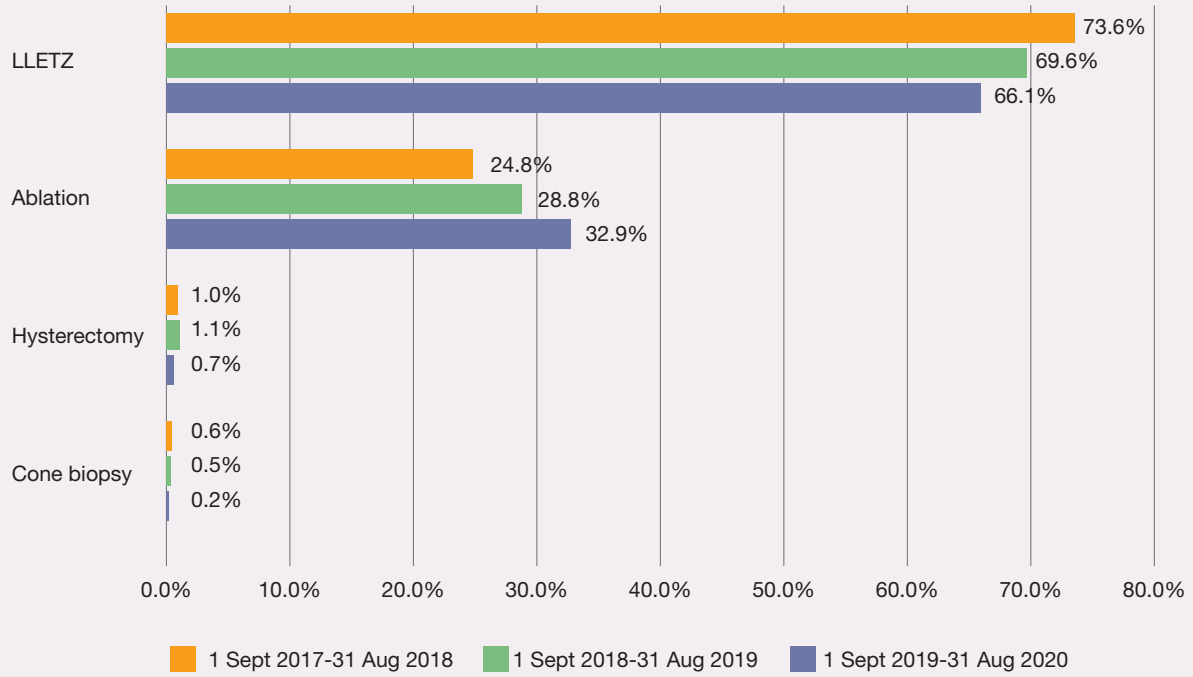
Performance parameter	2017/2018	2018/2019	2019/2020*	Target
The majority of women should have treatment performed as an outpatient under local anaesthetic	98.4%	98.3%	99.0%	≥90%

* The period 2019 to 2020 runs from September 2019 to end of March 2020 and is only 7 months long instead of the usual 12 months

Whereas the majority of women who attend colposcopy can safely be treated under local anaesthetic as an outpatient procedure, some women will require a large loop excision of the transformation (LLETZ) under general anaesthetic. If there is evidence of persistent disease, a small number of women are referred to the gynae-oncology team for a cone biopsy (wider excision of cervical tissue), trachelectomy (removal of entire cervix) or hysterectomy (removal of the entire uterus and cervix). These treatments are performed in theatre under general anaesthetic.

Figure 19 below shows the treatments received by women who attended colposcopy clinics between September 2017 and March 2020. During the reporting period, 16,505 treatments were recorded. LLETZ was performed in 11,589 cases (70.2%) cases and ablative treatment was used in 4,672 cases (28.3%). In addition, 81 cone biopsies and 162 hysterectomies were also performed when patients were referred onwards for persistent disease. These represent 0.5% and 1% respectively of treatments performed for women attending the colposcopy services.

Figure 19: Treatments performed for women attending colposcopy services September 2017 to March 2020*



* The period 2019 to 2020 runs from September 2019 to end of March 2020 and is only 7 months long instead of the usual 12 months

7.2 Treatments at colposcopy

Context

Between 6,000 and 7,000 women receive treatment for precancerous cell changes every year at colposcopy clinics.

Every year approximately 290 women are diagnosed with cervical cancer in Ireland[2]. Approximately 120 women are diagnosed with cervical cancer in colposcopy clinics each year after screening referral meaning over 100 women are diagnosed outside of the programme when they present with symptoms. These women may be overage, may not have taken up screening, may not have attended screening at the recommended interval or be false-negatives.

The number of patients treated by ablation as opposed to excision is showing a slight upward trend. It is too early to say if this is significant; however, it reflects the earlier finding of increasing use of biopsy. This is in line with an increasing body of international literature recommending conservative management of mild (CIN1) and moderate (CIN2) abnormalities.

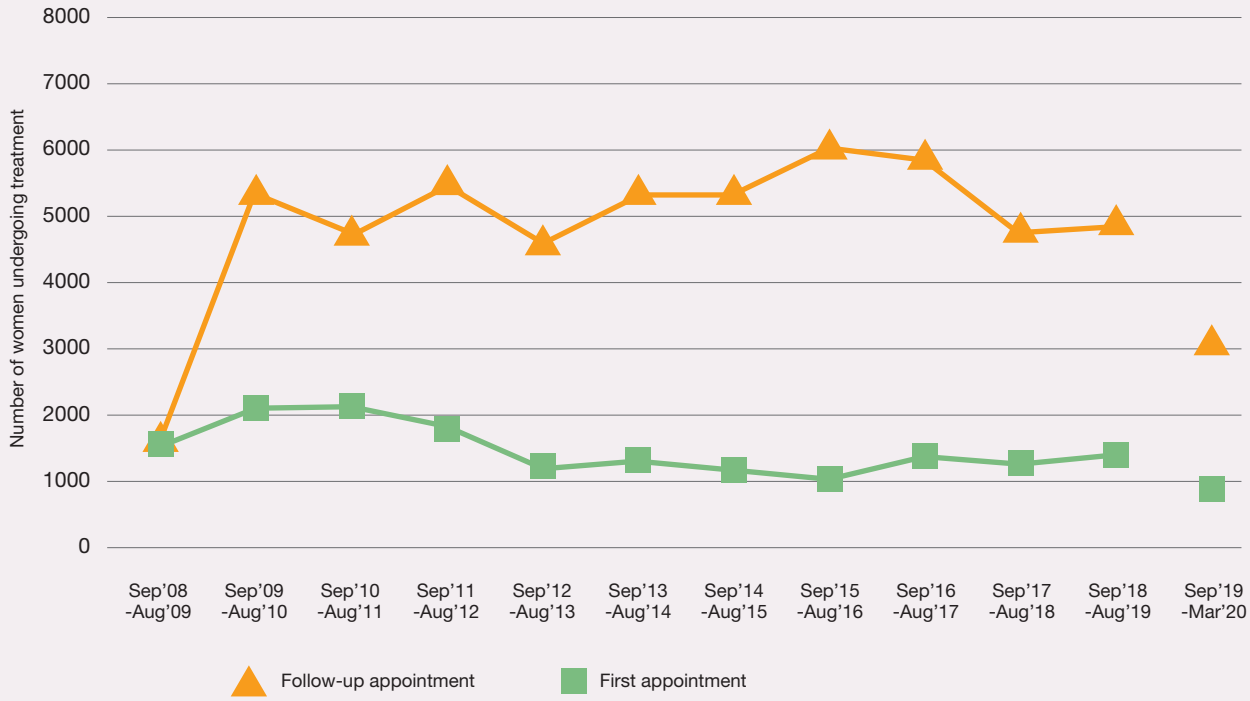
Table 14: Number of treatments at colposcopy services

Treatment at	Average 2012/2017	2017/2018	2018/2019	2019/2020*
First appointment	1,235	1,342	1,400	909
Follow-up appointment	5,475	4,813	4,922	3,109
All appointments	6,710	6,155	6,322	4,018

The period 2019 to 2020 runs from September 2019 to end of March 2020 and is only 7 months long instead of the usual 12 months

The graph below shows the number of treatments performed at colposcopy clinics since the programme began in 2008. There appears to be a slight reduction in the number of treatments performed. This is despite the marked increase in referrals to colposcopy noted above. These combined figures merit further study to determine the effect, if any, that increased referrals have in increasing detection of disease.

Figure 20: Number of women undergoing treatment at first and follow up visits to colposcopy



* The period 2019 to 2020 runs from September 2019 to end of March 2020 and is 7 months long instead of the usual 12 months

7.3 Treatment at first visit to colposcopy

Context

The majority of women referred to colposcopy clinics have no evidence of cancer or significant abnormal cells. Treatment at the first visit is rare for women – whether referred with clinical indications (either urgent or non-urgent) or with low-grade cytology.

For those referred with high-grade disease, only one in four will have a treatment performed at the first visit. In order to avoid overtreatment, most women will first have a diagnostic biopsy performed to clarify diagnosis.

Table 15: Treatment at first visit to colposcopy from 1 September 2017 to 31 March 2020

Reason for referral to colposcopy	2012-2017 average	Treatment on first visit		
		2017/2018	2018/2019	2019/2020*
	N (%)	N (%)	N (%)	N (%)
Clinical indication – non urgent	102 (3.1)	146 (2.7)	186 (3.0)	78 (3.0)
Clinical indication – urgent	66 (2.9)	105 (2.9)	147 (3.3)	61 (2.9)
AGC (borderline glandular)	30 (8.1)	21 (13.0)	26 (14.7)	10 (10.0)
High-grade	850 (23.5)	750 (25.1)	684 (22.3)	486 (25.3)
Low-grade	186 (2.6)	319 (4.0)	356 (4.0)	274 (4.2)
Unsatisfactory / Inadequate	1 (1.0)	1 (1.0)	1 (0.7)	0 (0.0)
Total	**1235 (7.4)**	**1342 (6.6)**	**1400 (6.1)**	**909 (6.8)**

* The period 2019 to 2020 runs from September 2019 to end of March 2020 and is only 7 months long instead of the usual 12 months

Women referred to colposcopy with low-grade disease

Women referred to colposcopy with low-grade disease are unlikely to require treatment at the first visit. Treatment at the first visit for women who present with low-grade abnormalities should be below 10 per cent due to the risk of overtreatment.

Definition: Number of women referred with low-grade cytology who are treated at the first visit to colposcopy.

Performance Parameter	2012-2017 Avg	2017/2018	2018/2019	2019/2020*	Target
Treatment at the first visit to colposcopy should not be routinely performed on women who are referred with low-grade cytological changes	2.6%	4%	4%	4.2%	<10%

* The period 2019 to 2020 runs from September 2019 to end of March 2020 and is only 7 months long instead of the usual 12 months

7.4 Excisional biopsies

Context

In order to avoid overtreatment, all excisional biopsies are histologically examined to confirm the presence of CIN.

Definition: An excisional biopsy is the removal of abnormal cervical tissue which usually involves the Transformation Zone.

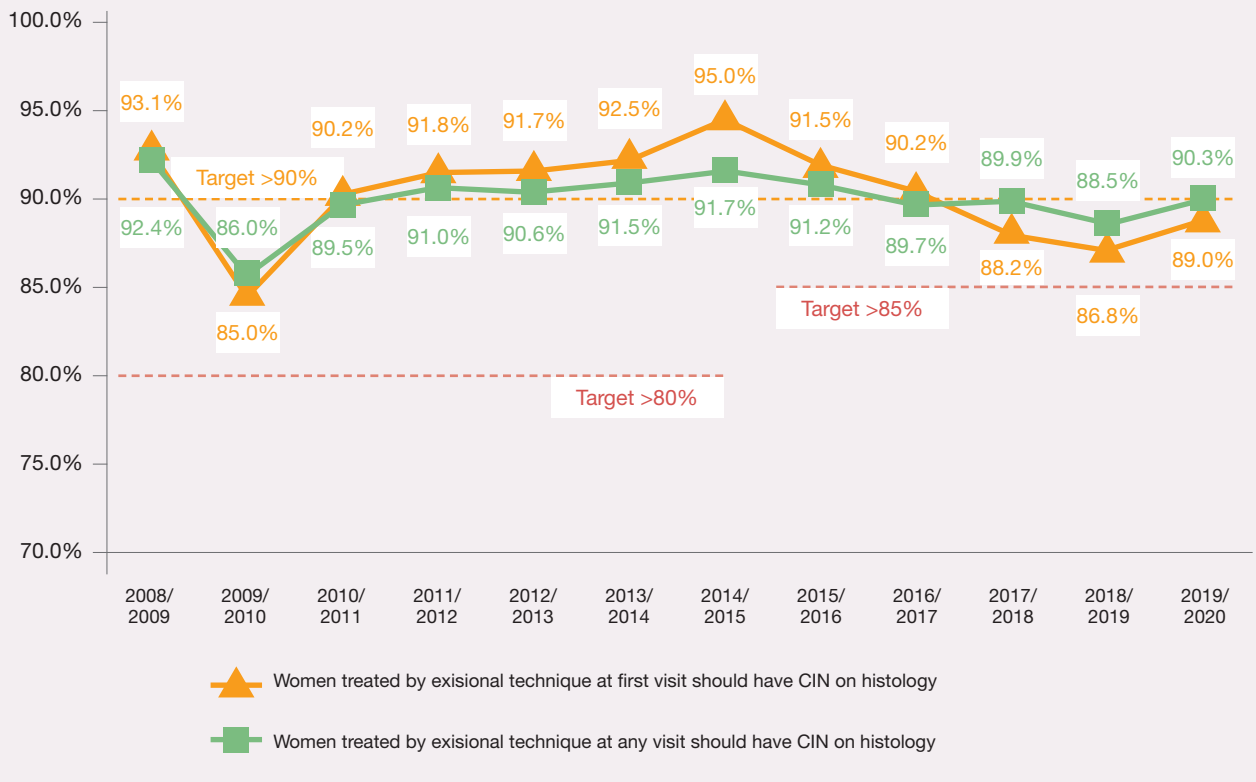
Performance Parameter	2012-2017 Avg	2017/2018	2018/2019	2019/2020*	Target
Women treated by excisional technique at first visit should have CIN on histology	92.2%	88.2%	86.8%	89.0%	>90%
Women treated by excisional technique at any visit should have CIN on histology	90.9%	89.9%	88.5%	90.3%	>85%

* The period 2019 to 2020 runs from September 2019 to end of March 2020 and is only 7 months long instead of the usual 12 months

Initially the programme standard was that 80% of women treated with an excisional biopsy at any visit should have histological confirmation of CIN. As the programme became more established the target standard was increased from 80% to 85%. This standard was changed as a quality improvement measure to reduce the risk of overtreatment for women participating in the programme.

The figure below shows the confirmation of CIN in excisional biopsies since the start of the programme. the presence of CIN on excisional biopsies has reduced below 90% in the time period of this report. it is likely that this is multifactorial, and merits further study.

Figure 21: Presence of CIN after treatment by excision technique 2008-2020



* The period 2019 to 2020 runs from September 2019 to end of March 2020 and is 7 months long instead of the usual 12 months

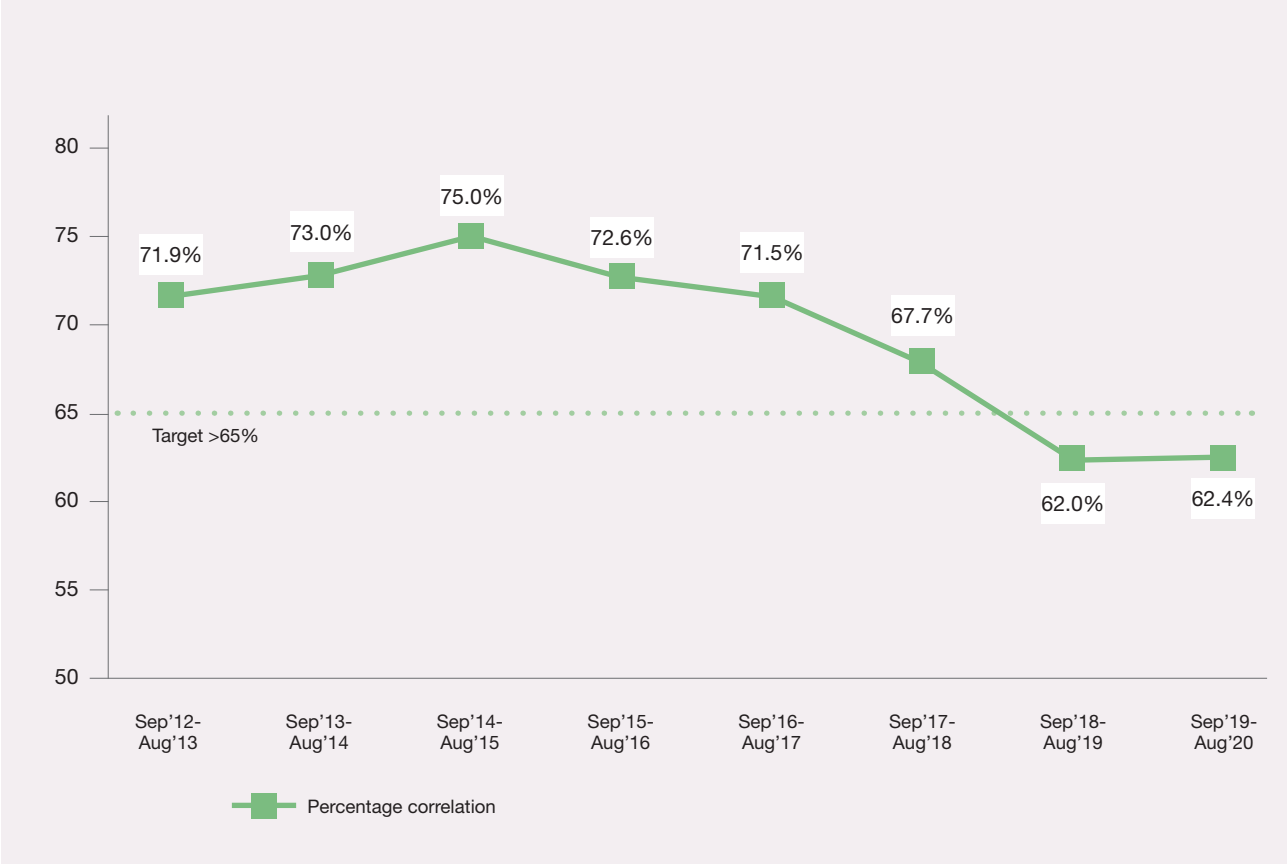
Colposcopy correlation measure

Context

The correlation between the colposcopic impression and histological diagnosis is a useful marker of the quality of colposcopy. It indicates the likelihood that a colposcopic impression of high-grade disease will be confirmed by histological analysis.

Defintion: the colposcopy-histology PPV is the likelihood that a colposcopic impression of high-grade disease will be confirmed on histological biopsy.

Figure 22: The positive predictive value of colposcopy



* The period 2019 to 2020 runs from September 2019 to end of March 2020 and is 7 months long instead of the usual 12 months

Performance Parameter	Average 2012 - 2017	2017/2018	2018/2019	2019/2020*	Target
Correlation between colposcopic impression of high-grade disease and histologically proven high-grade CIN	72.8%	67.7%	62.0%	62.4%	>65%

* The period 2019 to 2020 runs from September 2019 to end of March 2020 and is only 7 months long instead of the usual 12 months

Discussion

The rate of CIN in excisional biopsies performed at any visit remains above the 85% standard for the time period of this report. Interestingly the percentage of CIN in excisional biopsies for women treated at the first visit has dropped marginally below the 90% target. It is important to monitor this standard on a regular basis to determine if any trends exist.

The current programme standard is that women treated with excisional technique at first visit should have CIN on histology in >90% of biopsies and for all treatments > 85% should have evidence of CIN. The performance against this standard is detailed in figure 21, which shows that colposcopist prediction of which women require treatment appears to be very good. A slight reduction below standard is noted for treatments at first visit.

The PPV for colposcopy has decreased below the programme standard since 2017/2018. Between 2016/17 and 2017/18 there is evidence of a significant decrease in PPV of colposcopy ($p=0.0002$). This decrease in PPV of colposcopy remained significant between 2017/18 and 2018/19 ($p<.0001$). This data requires further research.

Conclusion

The report offers a data-led picture of the screening programme's operation from September 2017 until March 2020. It details the programme's coverage and response times to women – indicating how many eligible women used the service, and how quickly we interacted with them. Metrics concerning the numbers of cell changes and cancers detected through screening, and the functioning of the cervical screening system, are similarly detailed and measured against key performance indicators where relevant.

Some of the actions informed by the data to date are listed below.

Screening uptake

Over 100 women each year are diagnosed outside of the programme when they present with symptoms of cervical cancer. While there are many reasons for this, it is important to continue to explore ways to encourage screening uptake in women who do not come for screening, and in those who do not come regularly. We will continue to emphasise the importance of regular cervical screening as one of the best ways to protect against cervical cancer developing, and give women the opportunity to make an informed choice, considering both the benefits and limitations of cervical screening.

Result turnaround times

It is important to continue to strive to achieve a target of 90% of women receiving results within 4 weeks. The programme has developed a series of quality improvement projects to understand and address areas of the pathway where improvements can be made.

Women with clinical symptoms

It is important that women and their doctors can easily differentiate between the services aimed at well women who have a positive screening test, and those aimed at women who present with symptoms and need access to diagnostic services. Since the start of the programme, women have been referred with clinical symptoms to colposcopy services. This report shows the impact that this workload has on screened women's access to their follow-up services. It is essential that timely access to gynaecology services is available for women with clinical symptoms to ensure they get an appropriate, holistic assessment of their symptoms. This also ensures colposcopy capacity is available for people with a positive screening result.

The National Women and Infants Health Programme (NWIHP) leads the management, organisation and delivery of maternity, gynaecology and neonatal services. During 2021 we began working closely with NWIHP to ensure that women with symptoms can access gynaecological care in a timely manner, and to enable women with an abnormal screening result to access rapid colposcopy review. This action is ongoing and requires monitoring over time.

Histology

As biopsy workload is increasing for both colposcopists and histologists, it is important that hospitals and the programme work collaboratively to ensure workforce planning and resourcing of both services. We know that during the period of this data that a higher number of women were referred to colposcopy to find one woman with high-grade disease. It is important that the programme monitors this to avoid unnecessary colposcopy referrals and potential increased patient anxiety and unnecessary treatment.

Positive predictive value (PPV)

It is important that the programme continues to monitor the PPV of high-grade cytology results. Changes in cytology-histology PPV and referral value (RV) are important as they indicate laboratory performance. Screening is a balance between the risks of overtreatment and the benefits of risk reduction for cervical cancer.

The move to HPV-based cervical screening combined with HPV vaccination programmes is predicted to lead to cervical cancer becoming a rare disease in the future. We are currently working with Australian modelling experts to determine the future of screening in Ireland. Recent publications are suggesting that HPV negative women may need less frequent screening in the future. Work done in this area will give indications as to the amount of screening and required changes in criteria for referral to colposcopy, especially for people who are vaccinated.

The colposcopy PPV is declining which indicates the likelihood that a colposcopic impression of high-grade disease will be confirmed on histological biopsy. This is important to monitor as we move into a primary HPV programme.

Equity

We are committed to providing an equitable cervical screening service. This report illustrates that women over 50 are less likely to attend for screening. We are actively investigating this area with the aim of increasing attendance among older women. There are geographical variations in screening attendance which also merit further investigation. In addition, we know that half of all cervical cancers are diagnosed in women who have never had a screening test. A focus for the programme is working on what barriers these women face and how we can help address them. Our NSS Equity Strategy, in conjunction with our communications team, is taking an equity-based approach to communicating about cervical screening in Ireland during 2022 and beyond.

HPV cervical screening programme

In order to capture the significance of the new HPV screening test in operation in Ireland, which is expected to increase referrals to colposcopy in year two of the programme, we will consider covering the period March 2020 to March 2022 in our next report.

Glossary

Cervix	Neck of the uterus.
Coverage	The proportion of unique women who have had at least one satisfactory screening test taken within the defined screening interval, expressed as a percentage of the total number of eligible women in the population. The internationally accepted standard for measuring uptake in cervical screening programmes is coverage over five-year periods. Measuring uptake over a five-year screening 'round' reduces anomalies that can arise, for example, when a person is invited in particular year, but attends the following year.
Eligible women	Women and people with a cervix living in Ireland who are within the age range for cervical screening.
Glandular neoplasia	Cervical glandular intra-epithelial neoplasia (CGIN) – pre-cancerous abnormality of glandular cells.
Hysterectomy	A total hysterectomy involves removal of the uterus and the cervix. A subtotal (partial) hysterectomy involves removal of the uterus but the cervix remains in situ.
Metric	A system or standard of measurement.
Out-of-cycle screen	A free CervicalCheck screening test that occurs in between the times women were eligible for routine screening; eg every three years for women aged 25-44 and every five years for women aged 44-60.
Overdiagnosis	Where an abnormality is suspected on the screening test but not confirmed on further assessment.
Overtreatment	Where women receive treatment they don't need due to a false positive test result.
Standard	A measure, norm, or model in comparative evaluations.
Target	An objective or result towards which our efforts are directed.

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This data was prepared by the National Screening Service's Programme Evaluation Unit. The unit produces accurate data for the epidemiological evaluation of the National Screening Service's population screening programmes, BreastCheck, CervicalCheck, BowelScreen and Diabetic RetinaScreen.

An tSeirbhís Náisiúnta Scagthástála
National Screening Service

CervicalCheck
AN CLÁR NÁISIÚNTA SCAGTHÁSTÁLA CEIRBHEACS
THE NATIONAL CERVICAL SCREENING PROGRAMME

CS/PR/PM-23