CervicalCheck
AN CLÁR NÁISIÚNTA SCAGTHÁSTÁLA CEIRBHEACS
THE NATIONAL CERVICAL SCREENING PROGRAMME

CervicalCheck Programme Report 2020-2022

Contents

Introduction from the CervicalCheck Clinical Director

CervicalCheck is one of the National Screening Service's four national population screening programmes. Cervical screening reduces the risk of cervical cancer developing by identifying high-risk types of the human papillomavirus (HPV) that cause over 90% of cervical cancers. As most cervical cancers are caused by HPV, a screening programme that can detect the virus and enable us to monitor and treat its effect will save many lives. HPV infection leads to the development of abnormal cells (sometimes called pre-cancerous cells) which can lead to cancer if left untreated. In most cases, it takes 15 to 20 years for abnormal cells to develop into cervical cancer. Cervical screening reduces the incidence of cervical cancer in the population by enabling identification and treatment of precancerous abnormalities. It also leads to a reduction in mortality from cervical cancer by detecting and treating cervical cancers at the earliest stage possible. We know that screening doesn't pick up every abnormality; this why having regular screening tests is important. It is also important that women with symptoms have access to clinical evaluation and diagnostic tests.

Change to primary HPV screening

Our CervicalCheck programme moved to primary HPV cervical screening in 2020. It was the biggest change since the programme began in 2008. At the same time, we increased the upper screening age for women and people with a cervix from 60 to 65. We also changed the screening intervals – the time between tests – to every 3 years for women aged 25 to 29 and every 5 years for women aged 30 to 65. In addition, we created an increased surveillance pathway for women who have HPV infection without evidence of abnormal cells. These women are rescreened for HPV after 12 months and are referred for a colposcopic examination if HPV is still present.

We implemented and managed these changes during the most uncertain period of the global COVID-19 pandemic: spring and summer of 2020.

Against this backdrop of change and uncertainty, a sustained public focus on cervical screening since 2018 meant we were also working hard to continue to improve the service and to regain people's trust in screening. Implementing the new HPV screening test was an important part of this work.

Over 1.2 million women and people with a cervix are eligible for cervical screening. In these early years of HPV cervical screening, the factors noted above are affecting how we estimate the numbers of women who are due a screening test each year and are resulting in fluctuations in the numbers actually attending for screening. We share this experience with other countries that have made the switch to HPV screening and, like them, we are monitoring the effects of the change to primary HPV testing with interest. By analysing the data contained in this and subsequent reports it will be possible for us to build up a picture of the impact of HPV cervical screening on many aspects of the programme, including invitation rates, over time.

Screening during the global pandemic

Just as we began to offer HPV cervical screening back in early 2020 all non-essential healthcare was halted as the country responded to the COVID-19 pandemic. Population screening is a non-urgent, preventative service. And so, along with our other population screening programmes, cervical screening was paused during April, May and June 2020 on public health advice. We continued working during the screening pause to keep our non-clinical systems working. Colposcopy clinics continued to see and treat women throughout 2020 and 2021.

Shutting down screening had been a difficult task and restarting screening was also complex. We planned how we would begin inviting participants to attend, to ensure we invited first those women whom we considered to be at higher risk. At the same time, COVID-19 continued to affect how much capacity we had to deliver our screening pathway, our communications and the testing resources available.

After extensive consultation and a pilot for HPV screening, we set a screening restart date of 06 July 2020, three months after we had paused. By the end of 2020 everyone due a screening test that year had been invited. By the end of 2021 we had screened the same number of women in the two-year period of the pandemic as in any other two-year period. This work was accompanied by a comprehensive communications campaign about the new HPV screening test.

Our screening partners and team

I am proud to be part of a dynamic, responsive programme that is continually adapting to new evidence and new technology. This report tells the story of the first two years of primary HPV screening. It tells the story of the women who chose screening at a time when the programme was under public scrutiny and pressure from a global pandemic. It details the continued good work done by all our screening partners at this time – the sample takers in the community, the screening laboratory scientists and cytopathologists, the colposcopists, histology scientists and histopathologists – and by the dedicated CervicalCheck staff and all the National Screening Service teams who support population screening. They are each making a valuable contribution to improving the health of our nation.

By presenting these 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. I look forward to working collaboratively to achieve Ireland's commitment to the WHO cervical cancer elimination goal to make cervical cancer rare by 2040. It is our aim that the further study of this data will contribute to this future goal.

Professor Nóirín Russell

Clinical Director

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
cGIN	Cervical glandular intra-epithelial neoplasia, which describes abnormal pre-cancerous changes of the glandular cells of the cervix
CIN	Cervical intra-epithelial neoplasia, which describes abnormal pre-cancerous changes of the squamous cells of the cervix. It has three grades of severity, with grade 3 (CIN3) being the most severe.
Failsafe	Failsafe processes are an important part of screening, making sure that as far as possible the correct action is taken following a cervical screening test, or that a valid reason for not taking that action is known and recorded
DNA	Did not attend
HPV	Human papillomavirus
HSIL	High-grade squamous intraepithelial (moderate and severe) lesion
IARC	International Agency for Research on Cancer
LSIL	Low-grade squamous intraepithelial lesion
NSS	National Screening Service
PPV	Positive predictive value
RV	Referral value
Women	Women and people with a cervix

Executive summary

Cervical screening overview 2020-2022

526,816 women screened

16,646 women diagnosed with low-grade pre-cancerous cells (CIN1) - most did not require treatment as abnormalities spontaneously return to normal

9,575 women diagnosed with high-grade pre-cancerous cells (CIN 2/3 and cGIN) – majority treated by excision or ablation in colposcopy clinics under local anaesthetic

187 women diagnosed with cervical cancer in colposcopy settings

73% programme coverage

Participants aged 25-29 had highest coverage; lowest coverage in those aged over 60 years

Coverage varied by county with a range of 60-75%

Delivery of results

The programme aims to send 90% of results letters to women within four weeks. During 2020-2022, 61% of women received their results within 4 weeks and 90% of women received their results within 6 weeks. Laboratory turnaround times during this period were impacted by:

- COVID-19 pandemic reducing laboratory capacity due to social distancing policies, access to consumables and COVID-related leave
- New processes associated with the change to HPV primary screening
- Cyber-attacks on the HSE and the Coombe Hospital

Screening results

11.2% overall prevalence of HPV among the screened population

0.9% of the screened population have a HPV positive/high-grade cytology result

3.9% of the screened population have a HPV positive/low-grade cytology result

Of the women that screened HPV positive:

- **57%** had no cytological abnormalities detected
- **35%** had low-grade abnormalities
- **8%** had high-grade abnormalities detected.

All women with a persistent HPV infection are referred to colposcopy for further examination regardless of their cytology result on 12-month follow-up

- **88%** of women who were advised to attend for a repeat HPV test at 1 year attended within 15 months of being invited

Colposcopy performance

Referral to colposcopy is usually due to an abnormal screening test (HPV positive +/- abnormal cytology) but a small number of women are referred by their doctor due to a clinical concern

- Colposcopy referrals for clinical indications have fallen from **37% in 2020 to 20% in 2022** because of an increase in access to ambulatory gynaecology clinics

Changing to primary HPV screening is expected to increase the number of colposcopy referrals and biopsy numbers

- The referral to colposcopy rate from the screened population was **5.7% in 2020/21** and increased to **6.2% in 2021/22**

43,000 women attended for a first visit and more than 60,000 women attended for a follow-up visit at colposcopy clinics. The DNA rate is less than 10% - one of the lowest rates in HSE out-patient services.

- **100%** of patients referred where cancer was suspected were seen within 2 weeks
- **78.3%** of women with HPV positive/ high grade cytology results were seen within 4 weeks
- **69.5%** of all women referred to colposcopy were seen within 8 weeks

The programme referral value (RV) is 3.0: for every 3 women referred to colposcopy, 1 will have CIN2 or higher detected and 2 will have either low-grade abnormalities or no abnormalities

Histology results

44% of women who attended colposcopy had a cervical biopsy taken

>95% of biopsy samples taken by colposcopists samples were suitable for analysis

26,408 cervical biopsies were performed:

- **16,646 (63%)** had evidence of low-grade abnormalities
- **9,575 (36.3%)** had evidence of high-grade abnormalities (including glandular pre-cancerous abnormalities)
- **187 (0.7%)** showed evidence of cervical cancer

The majority of women who have a biopsy taken in colposcopy are found to have low-grade abnormal cells which do not require treatment

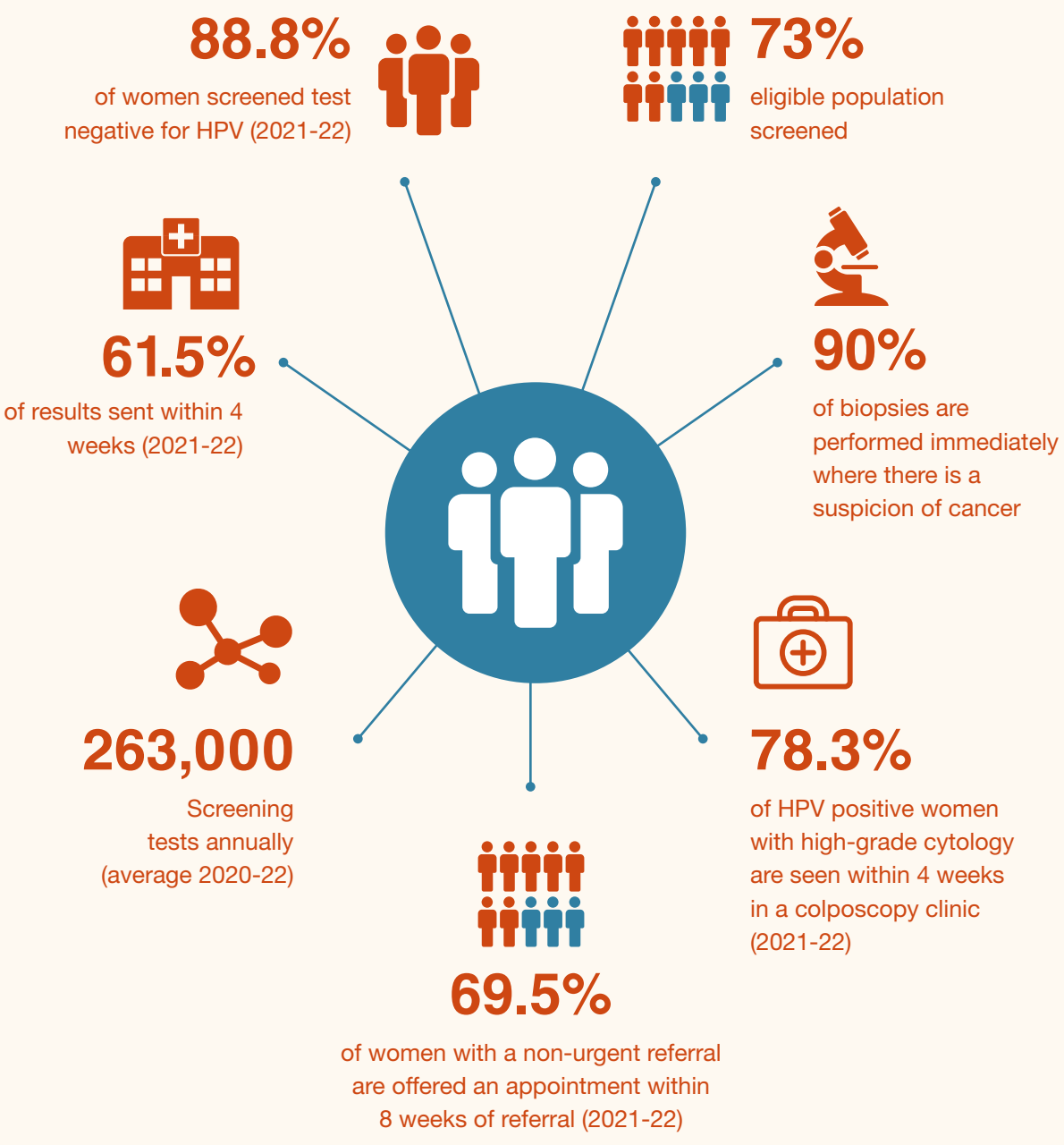
Approx. 7 in 1,000 women who have a biopsy in colposcopy are found to have a cervical cancer

Treatment of pre-cancers and cancers

The majority of treatments at colposcopy are for pre-cancerous changes. These women are followed up through increased surveillance as they have been identified as being at higher risk of developing cervical cancer. Approximately 100 women are diagnosed with cervical cancer in colposcopy clinics each year. Half of these are diagnosed at stage 1A and are treated under local anaesthetic during an outpatient visit in the colposcopy clinic setting.

Highlights of 2020-2022

CervicalCheck programme 2020-2022



Introduction

CervicalCheck - Ireland's national cervical screening programme – has been in operation since 1 September 2008. This publication reports on the performance of the programme against published programme standards[1]. The figures presented in this report relate to data from the first two years of the primary HPV screening programme, from 1 April 2020 to 31 March 2022.

Every year approximately 250 women are diagnosed with cervical cancer in Ireland.[2] Some women have a screen-detected cancer when a diagnosis of cancer is made after a screening test result recommends referral to a colposcopy clinic. Approximately 40% of cervical cancers are diagnosed in women who have never had a screening test.[3]

The incidence of cervical cancer in Ireland is 10.4 per 100,000 women per year.[2] Before the programme began in 2008 the incidence was 15 per 100,000 (Figure 1). The National Cancer Report[4] shows a steep decline in cervical cancer incidence in Ireland – an average 2.8% reduction annually between 2009 and 2019. While total numbers of cervical cancer deaths per year have shown an increasing trend from 1994 to 2019, the age-standardised mortality rates, taking into account changes in the size and age-profile of the underlying population (Figure 2), have shown a significant decreasing trend (by on average 1.1% per year)[4].

Cervical cancer is principally caused by persistent, high-risk human papillomavirus (HPV) infections which cause changes to the cervical cells. HPV is a common virus – around 80% of us will pick it up through sexual contact at some point in our lives. The majority of people will clear the virus without any symptoms but for some people, the virus persists. If it 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). It usually takes 15-20 years for these abnormal cells to develop into cancer. Fortunately, early changes in these cells can be detected through screening and this leads to investigation and timely treatment.

Cervical screening is not just a single test taken in a community care setting. It is a pathway that traverses many other areas of healthcare, from primary care clinics to screening laboratories and onwards to hospital outpatient clinics and laboratories. Unlike many cervical screening programmes internationally, CervicalCheck provides the full pathway of care from maintaining the population register, and calling and recalling women for screening, through to providing examination, diagnosis and treatment in hospital colposcopy clinics.

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. Cervical screening achieves this goal by detecting and treating pre-cancerous changes. It also leads to the detection of early-stage cancer when it is most likely to be treatable by less invasive treatments.

Women who have a cervical cancer detected via screening are more likely to be at stage 1 when compared to women who present with symptoms outside of screening (Figure 3).[4] By the time women develop symptoms and present to gynaecology clinics, their cancer is usually stage 2 or higher. Detection at an earlier stage leads to a reduction in mortality from cervical cancer in the population.

Figure 4 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 number of women who had a cervical cancer detected each year since the programme began. Since the introduction of primary HPV screening, there has been a relative increase in low-grade disease.

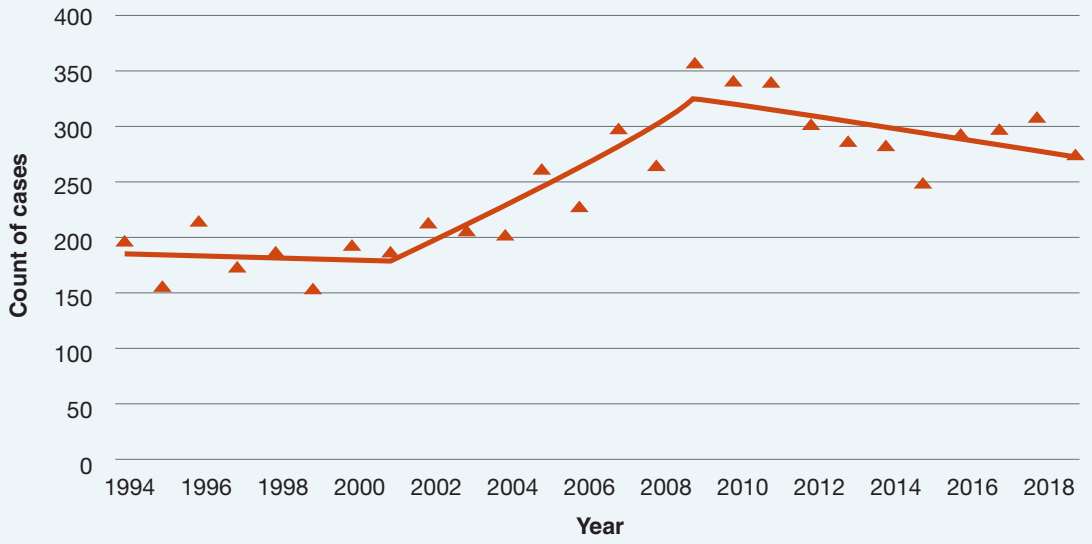
The majority of treatments performed at colposcopy are for high-grade pre-cancerous cell changes. Women with low-grade pre-cancerous cells are usually managed conservatively as these tend to regress spontaneously without treatment. Between 6,000 and 7,000 women receive treatment for high-grade pre-cancerous cell changes every year at 15 quality-assured colposcopy clinics around Ireland. Because of these treatments, most will not develop cervical cancer. This explains why the incidence of cervical cancer has fallen in Ireland since the introduction of the cervical screening programme.[2,4]

On 30 March 2020 CervicalCheck moved to primary HPV screening with associated cytology triage for HPV positive tests. Women who have HPV detected and have abnormal cells found on follow-up cytology testing are referred to colposcopy for further examination. Those who have HPV detected without evidence of cytological abnormalities are invited for a further HPV test after 12 months. If this test shows persistent HPV infection the women are referred to colposcopy. With the introduction of primary HPV screening, the upper age limit for eligibility for the programme increased from 60 to 65 years.

If abnormal cells are found through primary HPV testing, women are referred for a colposcopy. If it is confirmed that they have abnormal cells, they may have treatment to remove the cells. Not all women who attend colposcopy require treatment as many can be reassured after clinical assessment that treatment is not required.

Figure 1. Trends in cervical cancer case counts and age-standardised rates (ASR), 1994-2019

C53 Cervix Uteri: Females: Incidence trend during 1994-2019
Case Count



from-to	apc	ci	trend
1994-2001	-0.4	(-4.9, 4.2)	⟷
2001-2009	7.6	(3.4, 12.0)	↑
2009-2019	-1.7	(-3.7, 0.4)	⟷

Incidence rate per 100,000 (1976 ESP age weights)

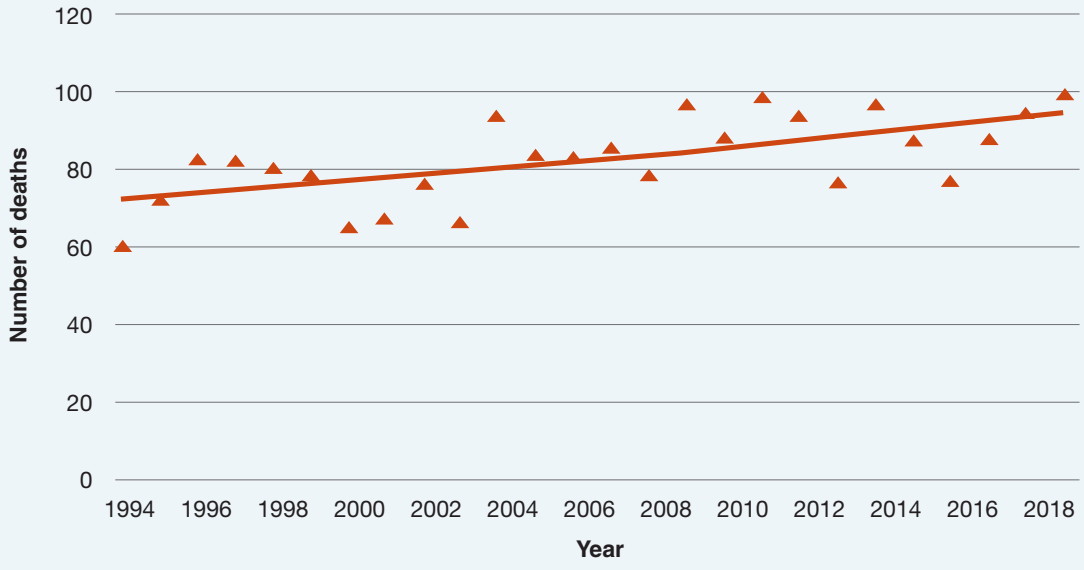
from-to	apc	ci	trend
1994-2001	-4.7	(-11.3, 2.5)	⟷
2001-2009	4.1	(1.4, 6.9)	↑
2009-2019	-2.8	(-4.7, -0.9)	↓

from-to = range of years; **apc** = annual percentage of change over range (%); **ci** = 95% confidence intervals of apc for each distinct range; **trend:** ↑ = significant increase, ↓ = significant decrease, ⟷ = no change, at the 95% level.

Source: *Cancer Trends 38 - Breast, cervical and colorectal cancer 1994-2019: National trends for cancers with population-based screening programmes in Ireland. National Cancer Registry, 2022*

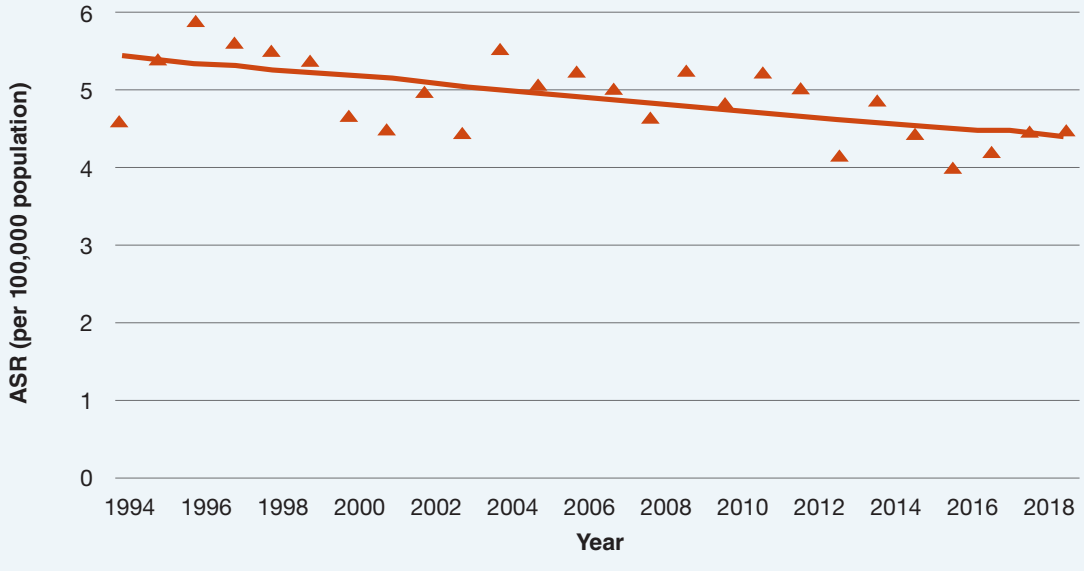
Figure 2. Cervical cancer deaths and age-standardised mortality rates, 1994-2019

C53 Cervix Uteri: Females: Mortality trend during 1994-2019
Deaths



from-to	apc	ci	trend
1994-2019	1.1	(0.5, 1.7)	↑

Mortality rate per 100,000 (1976 ESP age weights)



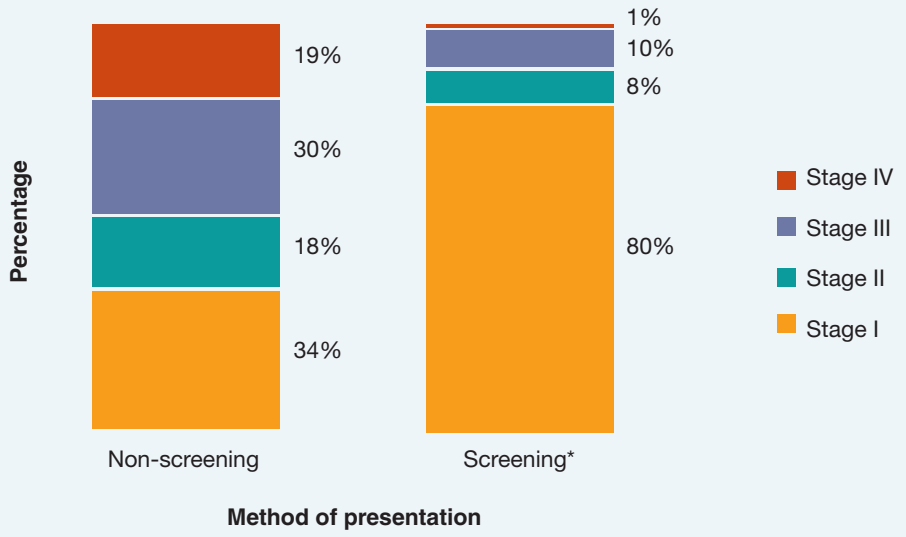
from-to	apc	ci	trend
1994-2019	-1.1	(-1.6, -0.5)	↓

from-to = range of years; **apc** = annual percentage of change over range (%); **ci** = 95% confidence intervals of apc for each distinct range; **trend:** ↑ = significant increase, ↓ = significant decrease, ⟷ = no change, at the 95% level.

Source: *Cancer Trends 38 - Breast, cervical and colorectal cancer 1994-2019: National trends for cancers with population-based screening programmes in Ireland. National Cancer Registry, 2022*

Figure 3. Stage of cervical cancers in screened and non-screened cohorts diagnosed 2014-2018

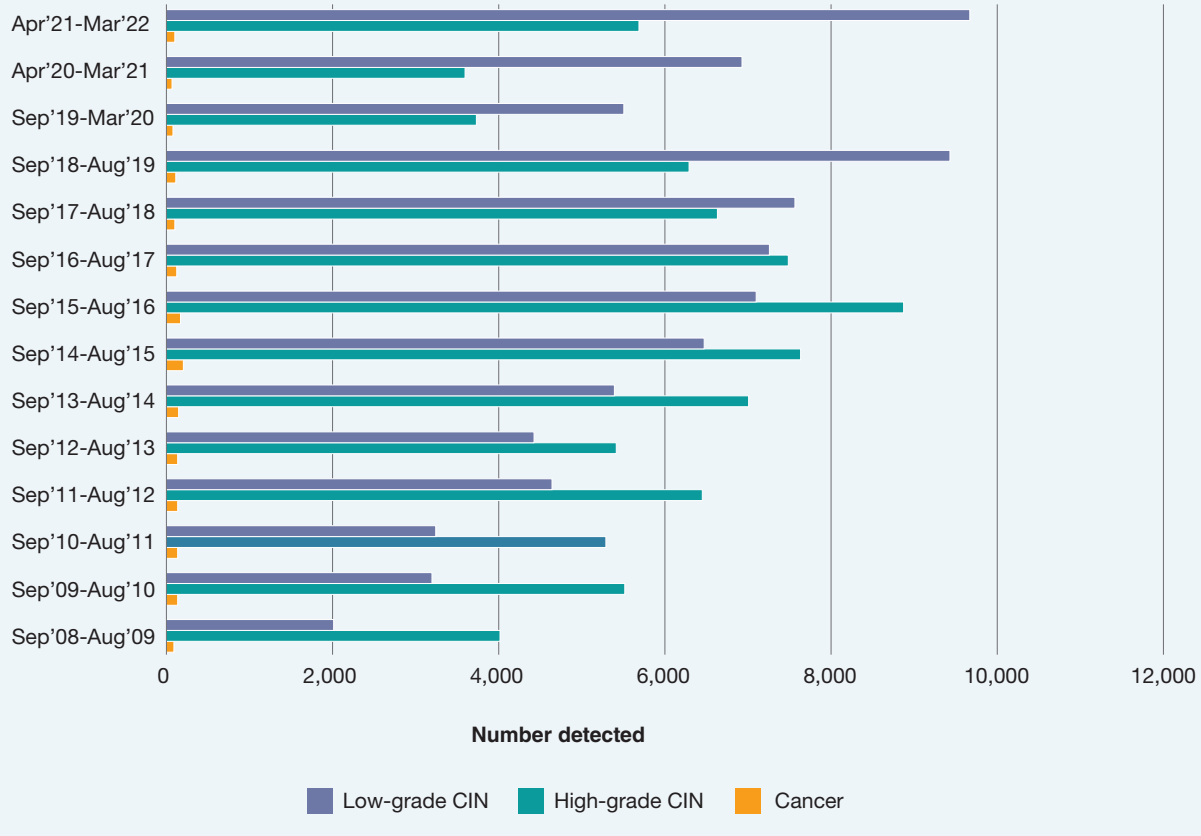
C53 Cervix Uteri: Females: Stage and Method of presentation of screening age group 2014-2018



* Includes opportunistic & unspecified screening

Source: *Cancer Trends 38 - Breast, cervical and colorectal cancer 1994-2019: National trends for cancers with population-based screening programmes in Ireland. National Cancer Registry, 2022*

Figure 4. Detection of low-grade CIN, high-grade CIN and invasive cancers



Screening activity overall

The figures reported relate to the women screened by CervicalCheck between 1 April 2020 and 31 March 2022. The women screened were either advised to return to routine screening or increased frequency screening, or referred onwards for colposcopy during this period. Quality assurance underpins every aspect of the CervicalCheck programme and programme performance is measured against programme standards as outlined in the Guidelines for Quality Assurance in Cervical Screening)[1]. This report describes programme performance against these standards.

Table 1 shows the number of women screened in each year by age group. This includes tests taken in the community, in secondary care clinics, and in colposcopy. In total 526,816 screening tests were carried out in the period of this report. Women between the ages of 25 and 65 are invited for screening, but a small number of those under the age of 25 may attend under specific circumstances. Women aged 66 or above include women presenting for the first time at this age as well as those who are attending for post-colposcopy surveillance.

Table 1. Number of unique women who had a CervicalCheck screening (all locations) test by age cohort from 1 April 2020 to 31 March 2022

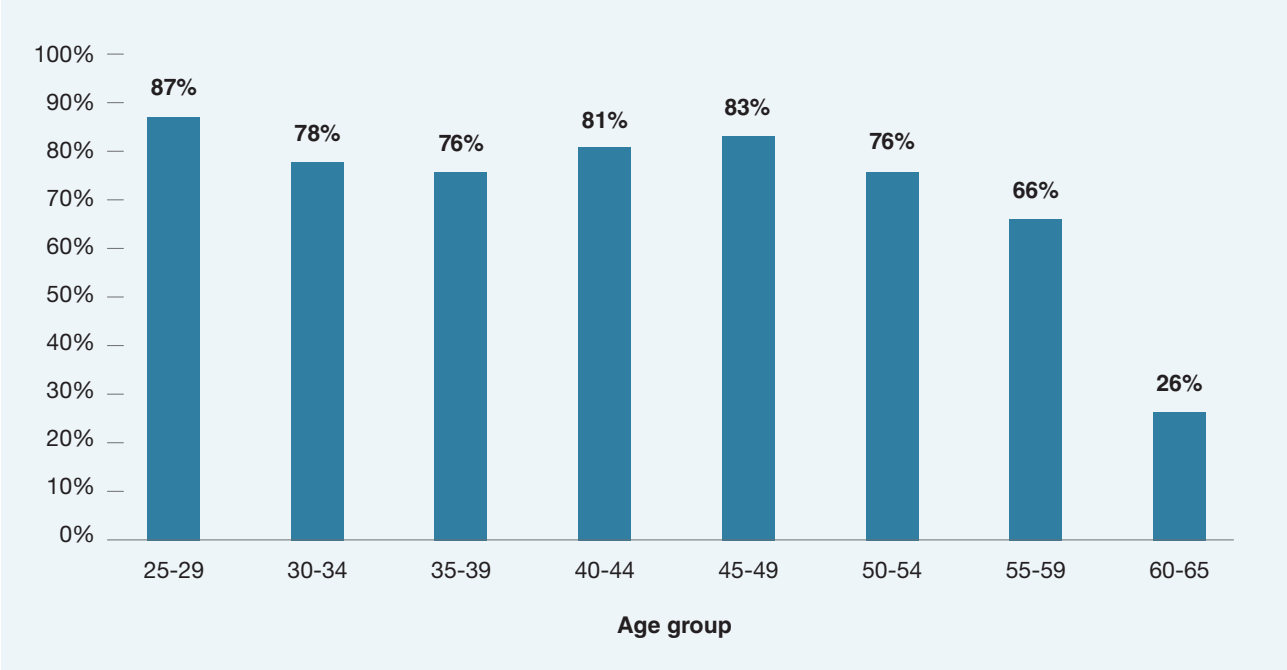
Age group	2020/21		2021/22	
	N	%	N	%
<25*	590	0.3	**455**	**0.1**
25 - 29	37,352	17.3	**40,159**	**12.9**
30 - 34	34,774	16.1	**47,511**	**15.3**
35 - 39	40,236	18.6	**57,604**	**18.6**
40 - 44	40,378	18.7	**60,872**	**19.6**
45 - 49	28,087	13.0	**41,888**	**13.5**
50 - 54	19,405	9.0	**30,474**	**9.8**
55 - 59	12,168	5.6	**23,512**	**7.6**
60	1,914	0.9	**3,903**	**1.3**
61-65	1,050	0.5	**3,540**	**1.1**
>65*	517	0.2	**427**	**0.1**
Total	**216,471**	**100.0**	**310,345**	**100.0**

* *Based on international evidence to date, the risk / benefit analysis does not favour starting population screening below the age of 25 or continuing after the age of 65. Cervical screening under the age of 25 may lead to women receiving unnecessary treatment for lesions that would never have developed into invasive cancer. Exceptions may include women who are post-colposcopy, women who are on renal dialysis or post-organ transplant, women living with HIV, or who have had a previous abnormal test result and are within the recommended follow-up period.*

Programme coverage 2017-2022

Coverage, a key performance indicator for the programme, represents the proportion of the target population* screened within a five-year period and indicates the effectiveness of the screening programme in reaching the target population. The programme target is 80 per cent coverage over a five-year period. The five-year coverage at the end of the previous reporting period (31 March 2020) was 78.7%[5]. For the current period this has dropped to 73%. A factor in this drop is the extension of the age range for screening from 60 to 65 years, without the required time elapsing for all eligible women within this new age range to attend.

Figure 5. Five-year coverage of eligible women by age group on the cervical screening register* (as of 31 March 2022)



*Population based on CSO 2016 projected to 2019, 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.

Figure 5 shows coverage by age group. Screening coverage is high in women up to age 54 but decreases in older cohorts. Coverage in women aged 60-65 is lower than other groups as they only became eligible for screening from 30 March 2020 and there has not been sufficient time (5 years) for the full cohort to avail of screening. The programme will continue to monitor coverage in this age group over time.

Geographical coverage

The geographical spread of screening coverage by county is shown in Figures 6 and 7. The coverage calculations are based on population estimates from census 2016 counts rolled forward to 2019 (as detailed below figure 7), and do not take into account estimates of emigration, immigration, hysterectomy or deaths. There is variation in coverage across counties ranging from 60% to 75%.

Figure 6. Five-year screening coverage by county 2017-2022

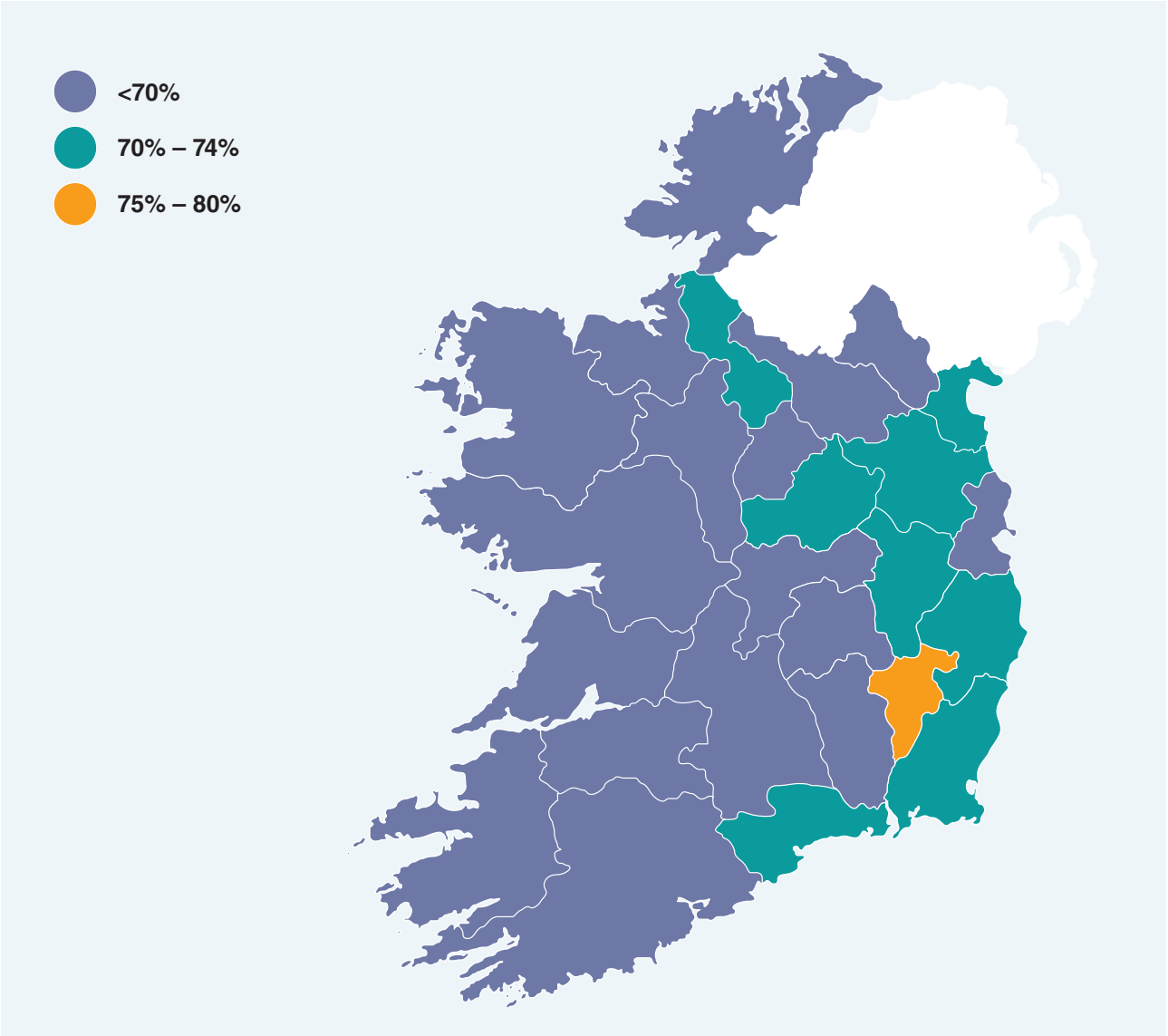
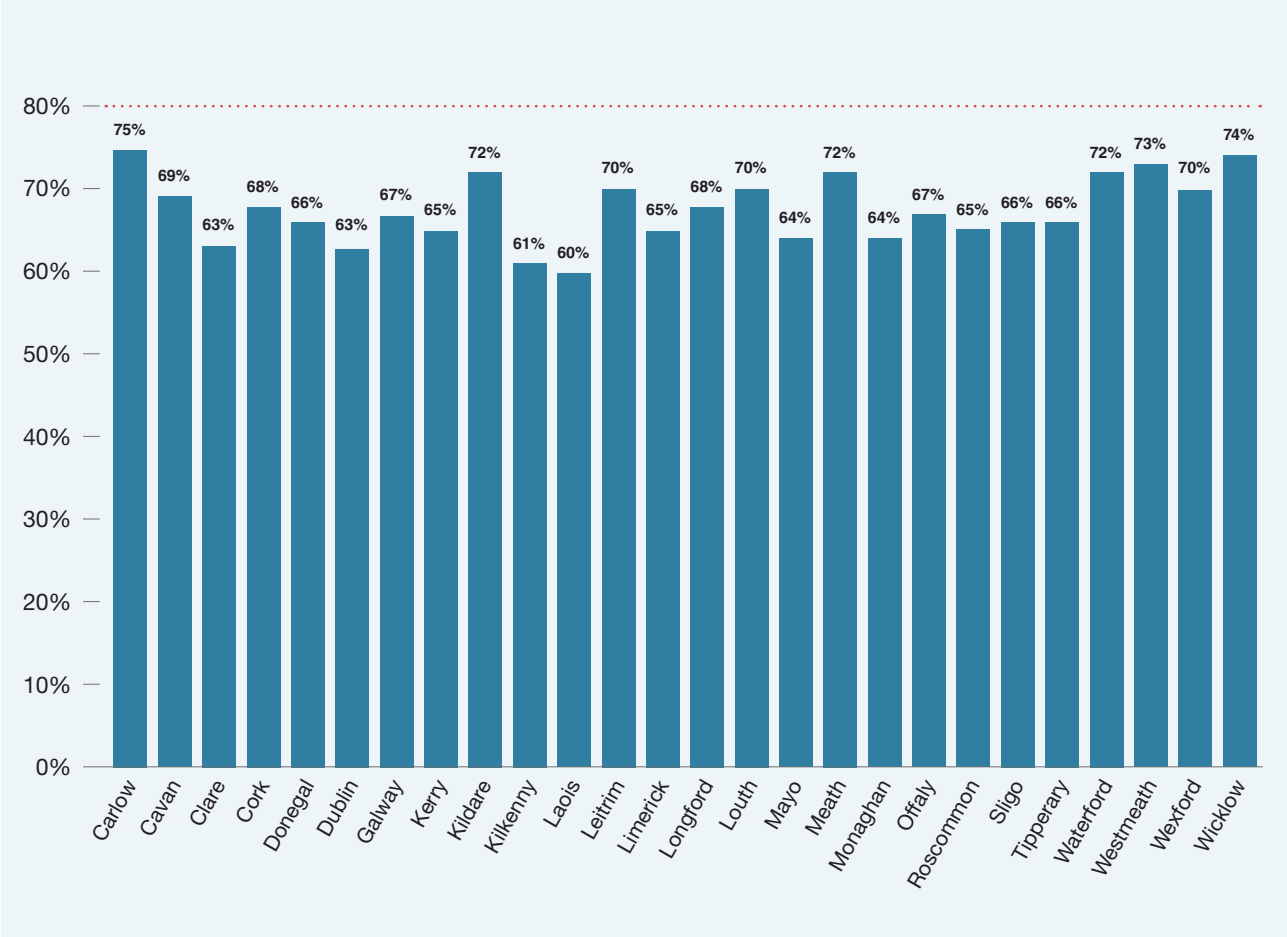


Figure 7. Five-year coverage (%) based on county of residence* for period ending 31 March 2022



*Population based on CSO 2016 figures projected to 2019, not adjusted for hysterectomy (hysterectomy data not available by geographical location). Unique women 25-65 years screened in period.

Laboratory turnaround time

CervicalCheck quality assurance standards require that screening results are authorised, released, and transmitted to CervicalCheck within 10 working days of test samples being received by the laboratory. This facilitates the timely provision of results to women and their doctors. This is a quality measure for the programme and impacts on the experience of women who choose screening. It does not affect the accuracy of the result.

Several factors had an impact on laboratory turnaround times during the time period of this report. In 2018, the government offered an extra screening test to all eligible women at the same time as laboratory services were withdrawn by one major provider. Turnaround times at the remaining principal laboratory provider were extended to 15 days to assist in processing the large volume of tests which had resulted. A second laboratory continued to process around 10% of all programme samples during this time. The percentages of results returned to the programme within 10 working days, and within 15 days, respectively, of receipt of sample at laboratories for 2020/21 and 2021/22 are shown in Table 2 and Figure 8.

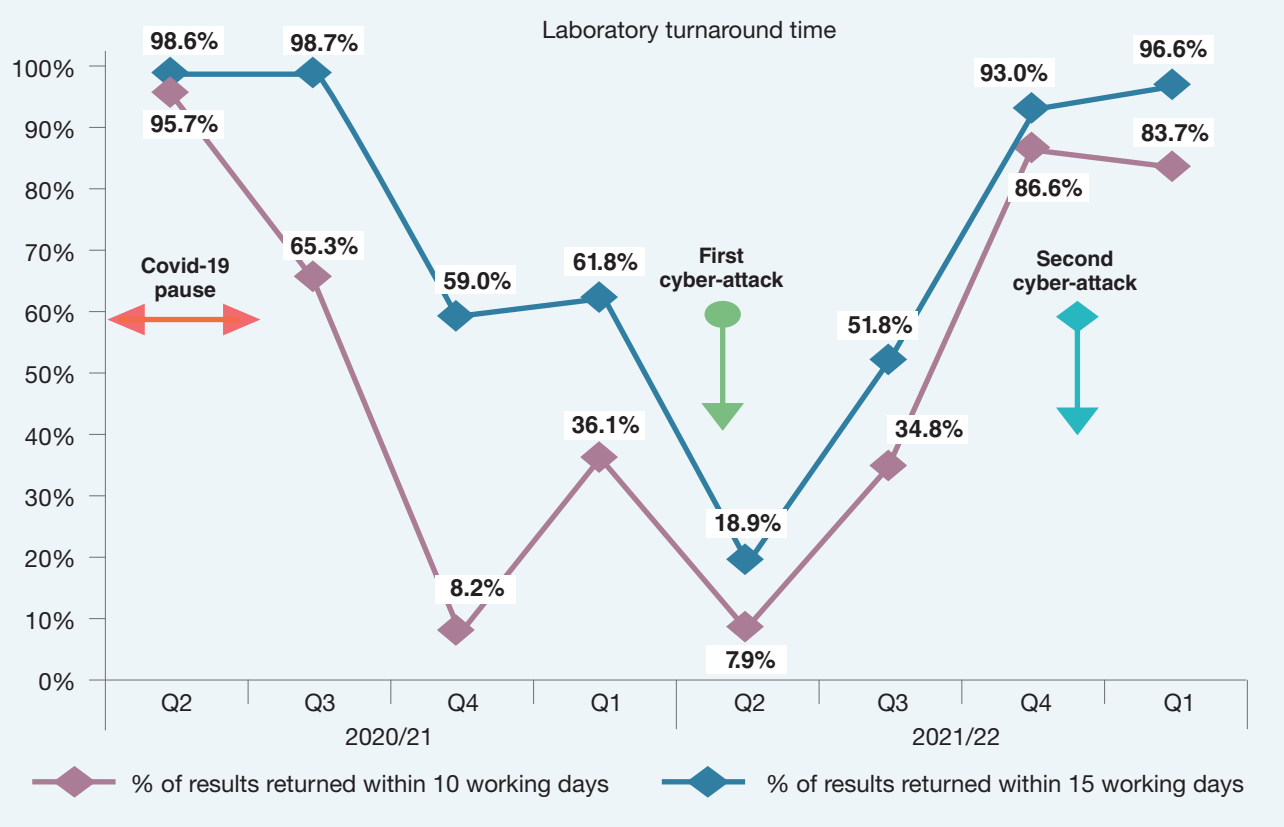
Laboratory turnaround times were also impacted by the significant changes in laboratory processes that resulted from the move from cytology screening to primary HPV screening. Times were further affected by the COVID-19 pandemic and the pause in screening from April 2020. When cervical screening resumed in July 2020, laboratory capacity was restricted by social distancing rerquirements and COVID-related leave.

Other significant factors affecting turnaround times included an increased attendance of women in 2021 when COVID restrictions lifted, and two significant cyber-attacks on the Irish health service's IT systems which left the programme dependent on one laboratory contractor for some of the time period.

Table 2. Turnaround times between receipt of sample at laboratory to results being returned to programme

Performance parameter	2020/21	2021/22	Target
Overall			
% results returned within 10 working days of receipt of sample at laboratory	35.2%	47.8%	>95%
% results returned within 15 working days of receipt of sample at laboratory	67.7%	59.7%	>95%
Quarterly			
Q2(01 April -30 June)			
% within 10 working days	95.7%	7.9%	
% within 15 working days	98.6%	18.9%	
Q3 (01 July – 30 Sept)			
% within 10 working days	65.3%	34.8%	
% within 15 working days	98.7%	51.8%	
Q4 (01 Oct – 31 Dec)			
% within 10 working days	8.2%	86.6%	
% within 15 working days	59.0%	93.0%	
Q1 (01 Jan – 31 March)			
% within 10 working days	36.1%	83.7%	
% within 15 working days	61.8%	96.6%	

Figure 8. Laboratory turnaround times*

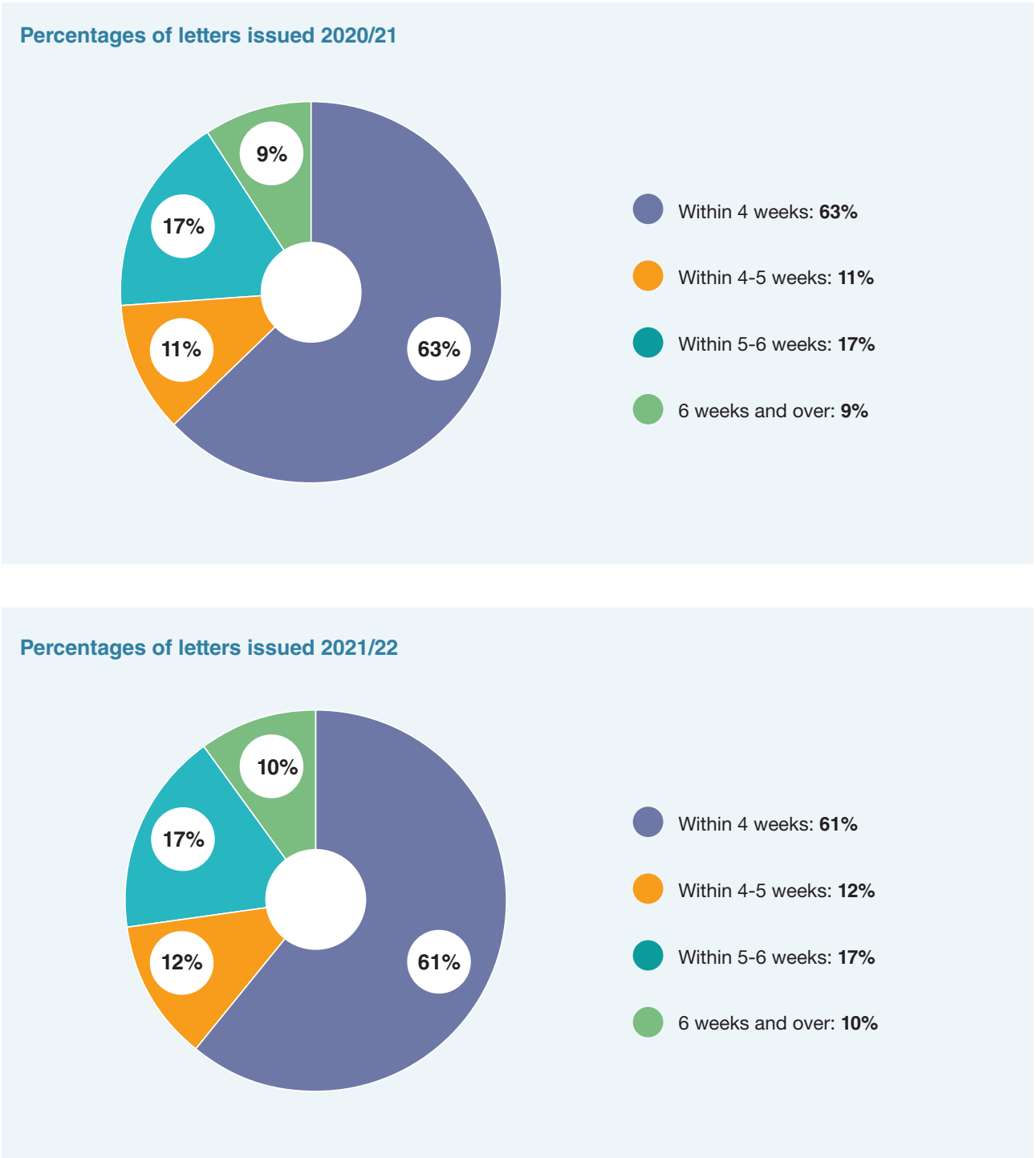


*Quarters for each reporting year in this figure reflect calendar quarters

Programme response to women

Figure 9 outlines the percentages of women sent results within four, five and six weeks respectively from 1 April 2020 to 31 March 2022. The programme aims to dispatch results and recommendations to women within four weeks of their screening test. The slower laboratory turnaround times in 2020 and 2021 had a knock-on effect on timing of women receiving their results.

Figure 9. Percentage of women sent results letter within specified timeframes from 1 April 2020 to 31 March 2022



Screening results

Screening outcomes for tests in 2020 to 2022 are shown in Table 3 and Figure 10. The overall prevalence of HPV among the screened population is 11.2%. Overall 0.9% of the screened population have a HPV positive/ high-grade cytology result and 3.9% of the population have a HPV positive/low-grade cytology result. This is in line with internationally published reference ranges.[6]

Approximately 57% of women with a HPV positive test outcome had no cytological abnormalities detected; 35% had low-grade abnormalities detected; and 7.6% had high-grade abnormalities detected (Table 3). Women with cytological abnormalities are referred to colposcopy for further examination while those without cytological abnormalities are recalled for a follow-up HPV screening test 12 months later.

Table 3. Primary screening results* (HPV & cytology) for women aged 25-65 years

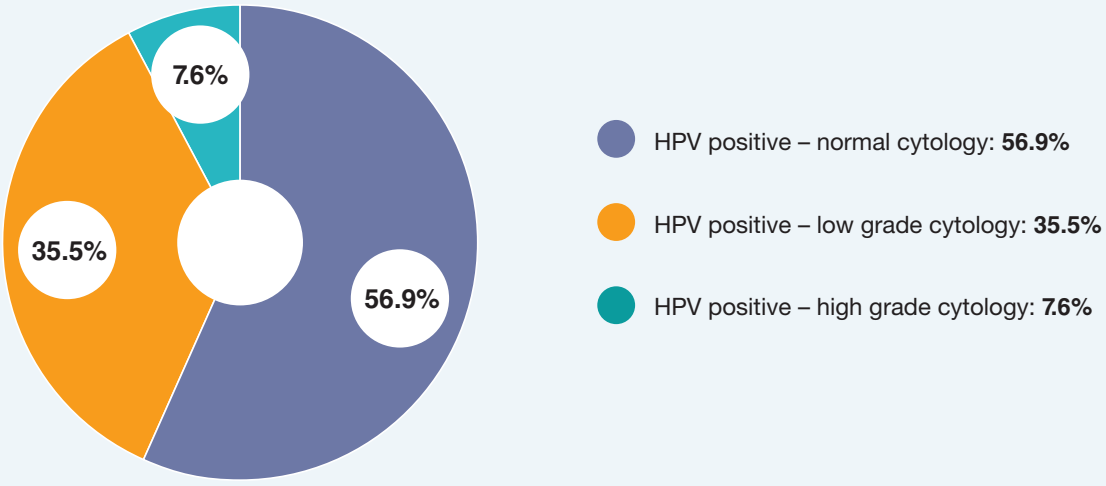
	2020/21		2021/22	
	Number	**%**	**Number**	**%**
HPV screening result				
HPV negative**	167,476	87.7	256,319	89.5
HPV positive	23,514	12.3	30,095	10.5
Total	**190,990**	**100.0**	**286,414**	**100.0**
Cytology result in HPV positive women				
HPV positive with normal cytology	13,379	56.9	17,329	57.6
HPV positive with low grade cytological abnormality	8,341	35.5	10,437	34.7
HPV positive with high grade cytological abnormality	1,794	7.6	2,329	7.7
Total of HPV positive women	**23,514**	**100.0**	**30,095**	**100.0**

*excluding unsatisfactory/inadequate screening tests, non-colposcopy setting only

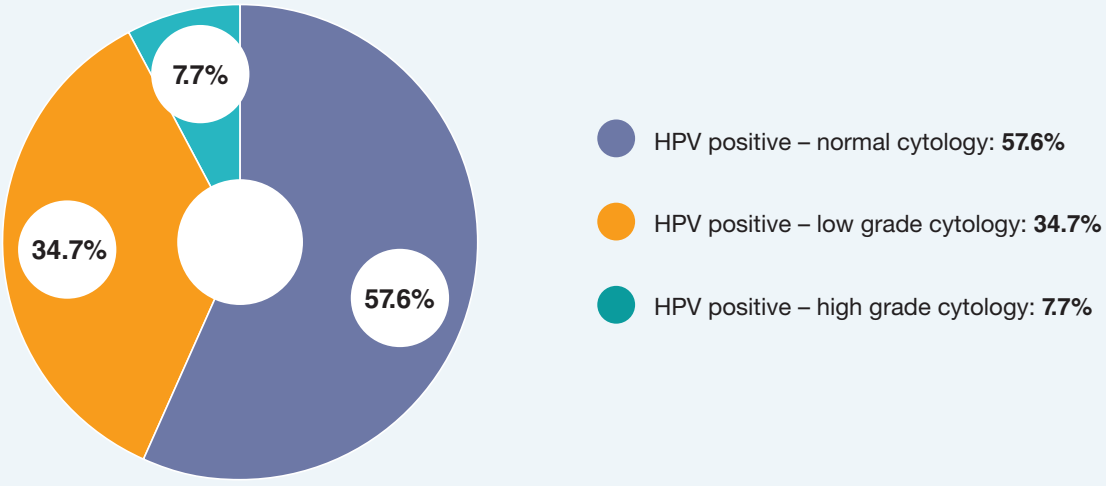
**HPV negative/no cytology performed (primary HPV screening result)

Figure 10. Primary screening results* (HPV & cytology) for women aged 25-65 years

HPV positivity & referral cytology 2020/21



HPV positivity & referral cytology 2021/22



*excluding unsatisfactory/inadequate screening tests, non-colposcopy setting only

Table 4 shows the outcomes for women who had attended for their 12-month follow-up of previous HPV positive / normal cytology test result. No follow-up HPV tests were performed in the first year of the move to HPV screening. In 2021/22, 42.3% of the repeat HPV tests were negative, which indicated that these women had spontaneously cleared their HPV infection and therefore they were advised to return to routine screening. All women with a persistent HPV infection were referred to colposcopy for further examination. Of the 57.7% with persistent HPV infection, 64.7% had no evidence of a cytological abnormality, 31.2% had low-grade cytological abnormalities and 4.2% had high-grade cytological abnormalities.

In 2021/22, 88% of women who were advised to attend for a repeat HPV test at 1 year had attended within 15 months of being invited. It is important to communicate with women that choosing to attend at the time they are invited is the best way to reduce their risk of developing cervical cancer. The programme has several failsafe mechanisms in place to remind women that they are due a screening test.

Table 4. Follow up screening result* after initial HPV positive result recommended repeat

	2021/22	
	Number	**%**
HPV negative	4,078	42.3
HPV positive	5,560	57.7
Cytology result in HPV positive women		
HPV positive with high-grade cytology	232	4.2
HPV positive with low-grade cytology	1,732	31.2
HPV positive with negative cytology	3,596	64.7
Total of HPV positive women	**5,560**	

*excluding unsatisfactory screening tests

Table 5 details the rates of referral to colposcopy from screening tests from 2020 to 2022. As primary HPV screening continues it is expected that referrals to colposcopy will increase. The referral to colposcopy rate was 5.7% in 2020/21 and increased to 6.2% in 2021/22. The programme management team measure and monitor this referral rate so that they can work to ensure there is colposcopy capacity available to provide assessment for HPV positive women.

Table 5. Referral to colposcopy from screening tests

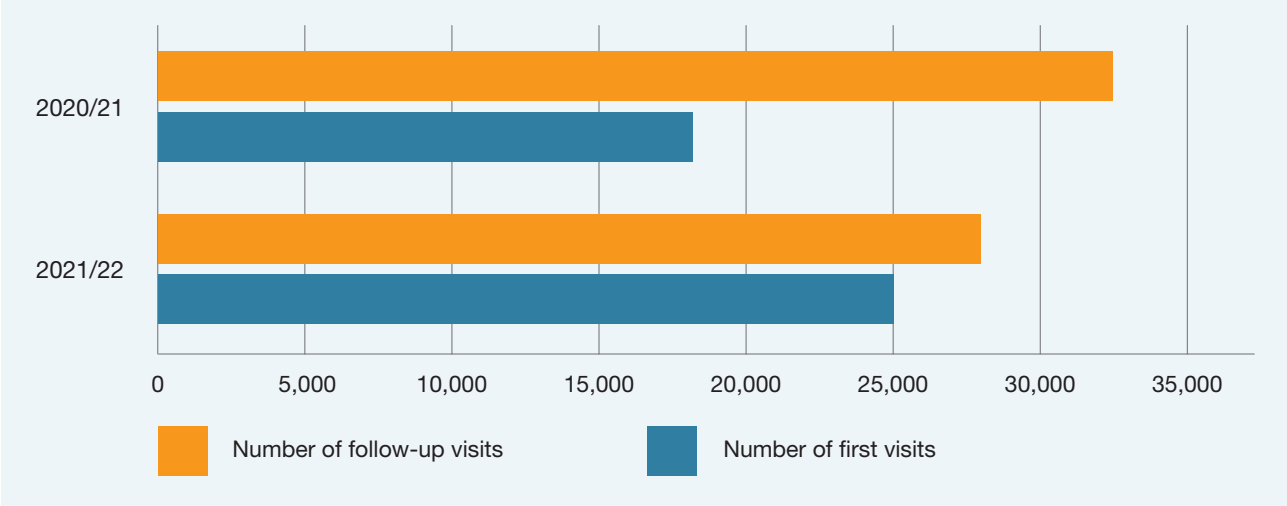
Time period	Number of screening tests performed in primary screening locations resulting in a referral to colposcopy
2020/21	11,119 (5.7%)
2021/22	18,772 (6.2%)

Colposcopy activity and outcomes

In 2020/21 and 2021/22 over 43,000 new women were referred to colposcopy clinics for further examination (Figure 11). The majority were referred with a positive HPV test (either a first test associated with abnormal cytology or follow-up test showing persistent HPV after 12 months). The number of women referred for clinical reasons is reducing due to increased availability of gynaecological assessment for women attending their GP with symptoms suggestive of cervical cancer. The programme continues to work with the National Women and Infants Health Programme to ensure women get access to the right person at the right time in the right clinical setting. A small number of women who had a cytology screening test prior to 30 March 2020 were referred on the basis of an abnormal cytology test.

In addition, over 60,000 women attended colposcopy as return patients during the time period of this report. These included surveillance for low-grade disease and follow-up post-treatment of abnormal pre-cancerous cells.

Figure 11. Number of first and follow-up visits at colposcopy from 1 April 2020 to 31 March 2022



	Number of first visits	Number of follow-up visits	Total
2020/21	18,053	32,393	50,446
2021/22	25,008	27,951	52,959

Table 6 shows the histology results from histological biopsies taken in colposcopy clinics. Low-grade CIN is usually treated conservatively as it has a high rate of regression (returning to normal with no treatment). High-grade CIN is less likely to regress and is usually treated by excision or ablation. The number of women screened in 2020 was lower than usual due to the impact of COVID-19. This impacted on numbers attending colposcopy clinics and therefore the number of biopsies taken.

Table 6. Histology results from diagnostic and therapeutic biopsies taken in colposcopy

Histology results in colposcopy patients	2020/21	%	2021/22	%
Low-grade CIN	6,954	**64.8%**	9,692	**61.8%**
High-grade CIN/CIN uncertain grade	3,602	**33.6%**	5,693	**36.3%**
Adenocarcinoma in-situ / CGIN	98	**0.9%**	182	**1.2%**
Cancer	79	**0.7%**	108	**0.7%**
Total	**10,733**		**15,675**	

New to return ratio

The table below (**Table 7**) details the new to return ratio. This is a measure of the number of follow-up visits generated by each new referral to colposcopy services.

Definition: The number of new patients who attend a service compared to the number of review patients who attend a service. The new to 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. This is a quality measure that helps ensure that colposcopy capacity is sufficient to meet the needs of the women referred. This is monitored to ensure that women 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.

Table 7. New to return ratio 2020-2022

	New to return ratio
2020/21	**1:1.7**
2021/22	**1:1.1**

Table 8 outlines the reasons that women were referred to colposcopy for the first time. In 2021/22, over 80% were referred due an abnormal screening test result and the remainder were referred due to a clinical reason.

Table 8. Reason for new referrals to colposcopy from 1 April 2020 to 31 March 2022

Referral Reason	2020/21	%	2021/22	%
Abnormal screening test (HPV positive +/- cytological abnormality)	8,670	**48.0%**	20,042	**80.1%**
Abnormal screening (cytological abnormality)	2,750	**15.2%**	28	**0.1%**
Clinical indication - nonurgent	2,949	**16.3%**	2,867	**11.5%**
Clinical indication - urgent	3,684	**20.4%**	2,071	**8.3%**
Total	**18,053**	**100.0%**	**25,008**	**100.0%**

Table 9 displays the screening results in patients referred to colposcopy for the first time in 2020/21 and 2021/22. The most common screening result in newly referred patients is HPV positive/ low-grade cytology.

Table 9. HPV and cytology results in patients newly referred to colposcopy

Screening results	2020/21	% of total new referrals	2021/22	% of total new referrals
Clinical Referrals/ screening not done	6,633	**36.8%**	4,938	**19.7%**
HPV positive – High-Grade Cytology	1,640	**9.1%**	3,202	**12.8%**
HPV positive – Low-Grade Cytology	8,882	**49.1%**	14,088	**56.3%**
Persistent HPV – Normal Cytology	846	**4.7%**	2,730	**10.9%**
Unsatisfactory/Inadequate Sample	52	**0.3%**	50	**0.2%**
Total	**18,053**	**100%**	**25,008**	**100%**

DNA rate

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

Table 10 shows the rate of women who did not attend (DNA) their appointment at colposcopy services. The rate of DNA where no prior notice was given should be kept to a minimum to ensure optimal benefits for the highest possible number of the population in publicly-funded services. 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.[7]

Table 10. The rate of DNA for colposcopy services from 1 April 2020 to 31 March 2022

Programme standard	2020/21	2021/22	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.	9.2%	8.4%	<10%

Key points

The DNA rate was within programme standard for the duration of this reported period.

Waiting times

Table 11 below details the percentage of women seen within the programme standard for waiting times. The programme standards recommend that over 90% of all women referred should be offered an appointment within eight weeks. The standards recommend that those referred with high-grade cytology should be offered an appointment within four weeks.

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

Table 11. The percentage of women seen within the programme standard for waiting times 2020 - 2022

Referral reason	Waiting Time Standard	2020/21 - % women seen within standard	2021/22 - % women seen within standard
Suspicion of cancer	**2 weeks**	**100.0%**	**100.0%**
HPV positive/ high-grade cytology	**4 weeks**	**79.6%**	**78.3%**
HPV positive/ low-grade cytology	**8 weeks**	**63.1%**	**63.3%**
HPV positive / normal cytology	**8 weeks**	**71.3%**	**59.8%**
Cytology not recorded/ cytology unsatisfactory	**8 weeks**	**70.5%**	**76.0%**
All referrals to colposcopy	**8 weeks**	**69.6%**	**69.5%**

Histological biopsies

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.

Table 12 shows the high quality of biopsy specimens taken at colposcopy clinic and sent for histological analysis. The programme standard is that >90 per cent of biopsies should be suitable for diagnosis and this standard is being consistently met.

Table 12. Percentage of biopsy specimens that are suitable for histological examination

Performance parameter	2020/21	2021/22	Target
Biopsy specimens should be suitable for histological diagnosis	98.50%	98.60%	>90%

Table 13 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 13. Biopsy rates measured against colposcopy standards for 2020-2022

Performance parameter	2020/21	2021/22	Target
A biopsy should be performed in the presence of an atypical transformation zone	95.40%	96.30%	>90%
If there is a suspicion of invasive disease a biopsy must be performed.	90.40%	90.80%	>90%

Number of biopsies performed at colposcopy

Table 14 details the numbers of biopsies performed at colposcopy clinics. The number of biopsies has increased in line with the increase in numbers referred to colposcopy.

Table 14. Numbers of biopsies performed at colposcopy clinics

Period	Biopsies at new appointment	Biopsies at follow-up appointment	Total biopsies	Total attendances at colposcopy
2020/21	10,563	8,443	19,006	50,446
2021/22	17,499	8,908	26,407	52,959

The total number of cervical biopsy samples being performed has increased. This reflects the increase in colposcopy activity and also the change in the proportion of low-grade referrals. Additional biopsies are taken to be reassured of the diagnosis and underpin clinical management. It is reassuring that the quality standard for these biopsies has been consistently met. It is important to ensure adequate histopathology staffing to meet this additional workload.

Treatment at colposcopy

Context

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.[8]

The majority of treatments performed at colposcopy are for pre-cancerous changes. Between 6,000 and 7,000 women receive treatment for precancerous cell changes every year at colposcopy clinics. These women are followed up on increased surveillance pathways as they have been identified as being at high-risk of developing cervical cancer. The vast majority will not develop cervical cancer. Approximately 10% will require a repeat treatment within 10 years.[9]

Approximately 100 women are diagnosed with cervical cancer in colposcopy clinics each year. Half are diagnosed at stage 1A and are treated under local anaesthetic during an outpatient visit in the colposcopy clinic setting. The remainder are diagnosed at a higher stage and are referred to gynae oncology services for treatment.

Table 15 shows the rates of women who had treatment performed as outpatients under local anaesthetic in 2020/21 and 2021/22. Whereas most women who attend colposcopy are treated under local anaesthetic as an outpatient procedure, approximately 1% of women will require a procedure under general anaesthetic for treatment of their pre-cancer or cancer.

Some women are recommended to have a simple hysterectomy for persistent precancerous abnormalities. If there is evidence of cancer or persistent high-grade disease, some 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.

Table 15. Treatment under local anaesthetic

Performance parameter	2020/21	2021/22	Target
The majority of women should have treatment performed as an outpatient under local anaesthetic	97.30%	97.80%	≥90%

The programme continually monitors patients treated by ablation as well as those treated by cervical excision. There is a body of international literature recommending conservative management of moderate CIN (CIN2). It is important to balance the risks of overtreatment with the risk of missing a cancer.[1, 10]

Figure 12. Types of treatments performed during or after initial colposcopy assessment

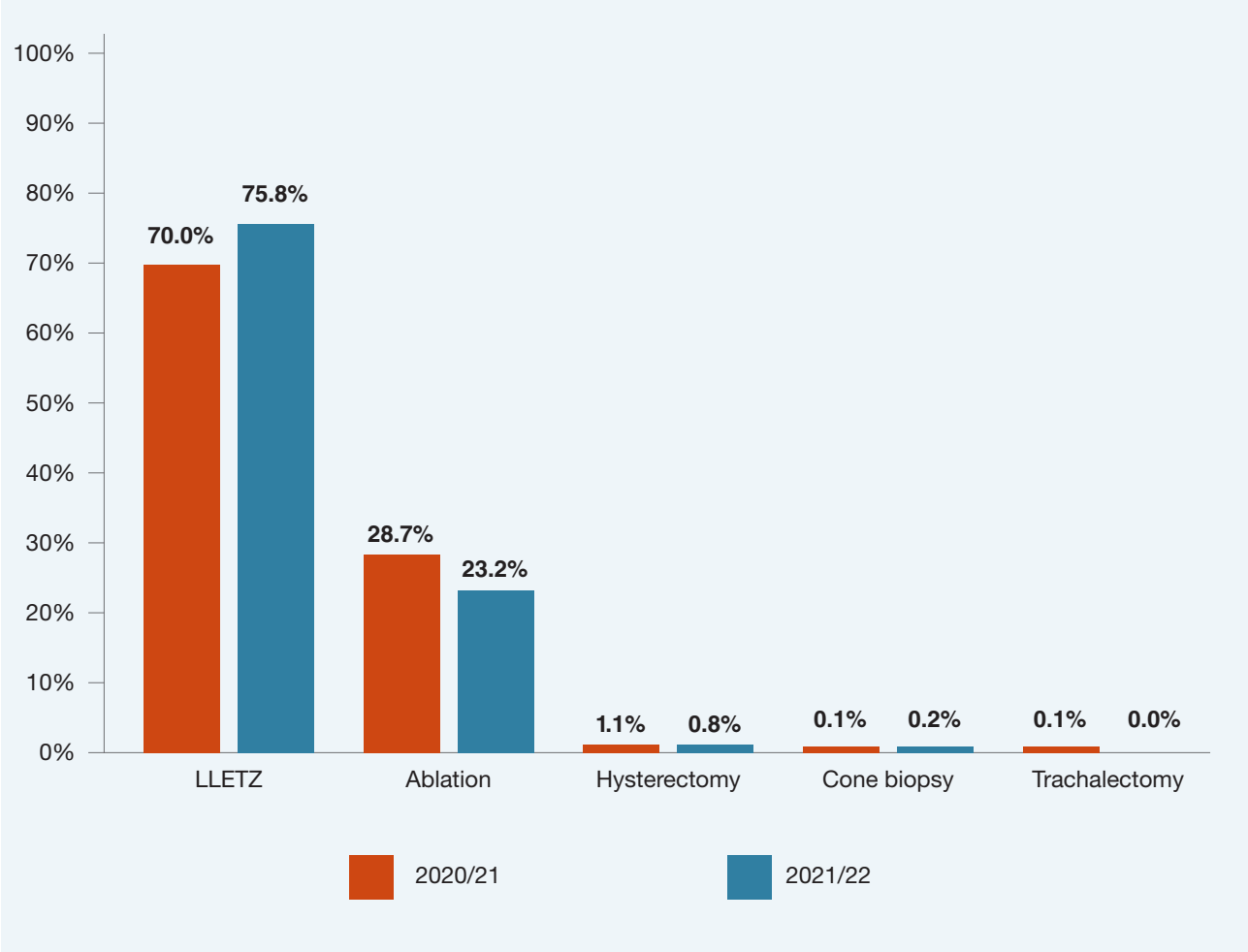


Figure 12 and **Table 16** show the percentages and numbers of treatments performed for patients who attended colposcopy services. Most treatments are performed under local anaesthetic in colposcopy outpatient settings.

Table 16. Numbers of treatments for patients attending colposcopy

Treatments performed	2020/21	2021/22	Total
LLETZ	3,752	5,405	**9,157**
Ablation	1,535	1,651	**3,186**
Referred for onward treatment under GA			
Hysterectomy	60	56	**116**
Cone	7	15	**22**
Trachelectomy	3	0	**3**
Total	**5,357**	**7,127**	**12,484**

Table 17 shows the number of women undergoing treatment at first and follow-up visits to colposcopy. The majority of treatments are performed at follow-up colposcopy appointments but some women are selected for treatment at first visit. Most appointments are diagnostic visits where a colposcopy +/- diagnostic biopsy are performed. Treatment is required at 10.6-13.5% of visits and the majority of women who attend colposcopy do not require treatment. It is important to continue to document this rate of treatment as the HPV programme becomes more established.

Table 17. Number of treatments performed at first and follow-up visits to colposcopy

Treatments at colposcopy	2020/21	2021/22
Total number of colposcopy appointments	50,446	52,959
Treatments at first appointment	1,011	1,644
Treatments at follow-up appointment	4,346	5,483
Total number of treatments performed	5,357	7,127
% of appointments where a treatment was performed	10.60%	13.50%

Treatment by excisional biopsies

Context

Cervical screening involves a balance of risks and benefits. Excisional treatments of the cervix can lead to an increased risk of late miscarriage and preterm birth. In order to avoid overtreatment, all excisional biopsies are histologically examined to confirm the presence of CIN. An excisional biopsy is the removal of abnormal cervical tissue which usually involves the transformation zone. The programme standard states that >90% of women treated for CIN on the first visit should have evidence of CIN on histological examination of the specimen.

Table 18 shows the rate of CIN in women treated by excisional technique.

Table 18. The rate of CIN in women treated by excisional technique

Performance parameter	2020/21	2021/22	Target
Women treated by excisional technique at **first visit** should have at least CIN1 on histology	83.8%	90.0%	>90%
Women treated by excisional technique at **any visit** should have at least CIN1 on histology	86.6%	89.4%	>85%

Reason for referral – treatment on first visit

Context

The majority of women referred to colposcopy clinics have no evidence of high-grade cervical abnormality or cancer. Treatment at the first visit is rare – whether they are referred with clinical indications (either urgent or non-urgent) or with an abnormal screening test (HPV positivity +/- abnormal cytology).

Table 19 shows the referral reasons for women treated at their first colposcopy visit for 2020 to 2022. In 2020/21 5.5% of women were treated at their first visit to colposcopy. In 2021/22, 6.5% of women were treated at their first visit. To avoid overtreatment, most women will first have a diagnostic biopsy performed to clarify diagnosis.

Table 19. Referral indications for patients treated at first visit

Referral reasons for patients treated at first visit	2020/21	% contribution to treatment rate	2021/22	% contribution to treatment rate
Total number of first visits to colposcopy	**18,053**		**25,008**	
Non-urgent clinical indication - treated at first visit	**117**	0.65%	**139**	0.56%
Urgent clinical indication - Treated at first visit	**167**	0.93%	**100**	0.40%
Positive HPV test	**707**	**3.92%**	**1,375**	**5.50%**
Atypical glandular cells	**7**	0.04%	**27**	0.11%
HPV positive – high-grade cytology	**534**	2.96%	**1,051**	4.20%
HPV positive – low-grade cytology	**163**	0.90%	**260**	1.04%
Persistent HPV – normal cytology	**3**	0.02%	**35**	0.14%
Inadequate cytology	**0**	0.00%	**2**	0.01%
Total number of treatments at first visit	**991**	**5.49%**	**1,614**	**6.45%**

Table 20 shows the referral reasons for women treated at any colposcopy visit, as well as the numbers of women treated by referral reason. In 2020/21, 10.6% of women referred to colposcopy required a treatment at any visit and in 2021/22, this increased to 13.5%.

Table 20. Referral indications for patients treated at any visit

Referral reasons for patients treated at any visit	2020/21	% contribution to treatment rate	2021/22	% contribution to treatment rate
Total number of visits to colposcopy	**50,446**		**52,959**	
Non-urgent clinical indication – treated at any visit	**524**	1.04%	**639**	1.21%
Urgent clinical indication – treated at any visit	**442**	0.88%	**276**	0.52%
Positive HPV test	**4,391**	**8.70%**	**6,212**	**11.73%**
Atypical glandular cells	**34**	0.07%	**76**	0.14%
HPV positive – high-grade cytology	**2,846**	5.64%	**4,335**	8.19%
HPV positive – low-grade cytology	**1,492**	2.96%	**1,667**	3.15%
Persistent HPV – normal cytology	**9**	0.02%	**126**	0.24%
Inadequate cytology	**10**	0.02%	**8**	0.02%
Treatments at any visit	**5,357**	**10.62%**	**7,127**	**13.46%**

Table 21 shows the likelihood of a treatment being performed based on the referral cytology in HPV positive women. The most common reason for treatment at first visit was a referral cytology suggesting high-grade abnormalities. Although the number of referrals for atypical glandular cells was low, the rate of treatment at the first visit was similar to other high-grade cytology referrals.

Table 21. Likelihood of treatment at first visit based on referral cytology in HPV positive women

Referral cytology for women treated on first visit	2020/21			2021/22		
	Total treated	Total new referrals	Percentage treated who were new referrals	Total treated	Total new referrals	Percentage treated who were new referrals
Atypical glandular cells	7	17	**41.2%**	27	84	**32.1%**
High-grade	534	1,300	**41.1%**	1,051	3,171	**33.1%**
Low-grade	163	6,705	**2.4%**	260	13,912	**1.9%**
Normal	3	112	**2.7%**	35	1,243	**2.8%**
Inadequate	0	39	**0.0%**	2	49	**4.1%**
Totals	**707**	**8,173**		**1,375**	**18,459**	

Positive predictive value of high-grade cytology

Definition

The positive predictive value (PPV) is reported as the percentage of women referred with high-grade cytological abnormality who subsequently have a histological diagnosis of CIN2 or higher.

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.

For example, when the PPV is 77%, this means that for every 100 women who are referred with a HPV positive/ high-grade cytology screening result, approximately 77 will have a histological abnormality found that confirms high grade CIN lesion or an invasive cancer. The other 23 women will either not have a biopsy taken or will have a normal or low-grade CIN which is expected to spontaneously regress and return to normal without intervention.

The positive predictive values of high-grade cytology in HPV positive women for 2020/21 and 2021/22 are shown in **Table 22**.

Table 22. The positive predictive value of a high-grade cytology in HPV positive women

Performance parameter	2020/21	2021/22
Correlation between high-grade cytology and histologically proven high-grade CIN	76.6%	76.9%

Positive predictive value of colposcopy

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

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. **Table 23** displays the PPV values of colposcopy for 2020/21 and 2021/22.

Table 23. The positive predictive value of colposcopy

Performance parameter	2020/21	2021/22	Quality standard
Correlation between colposcopic impression of high-grade disease and histologically proven high-grade CIN	58.7%	62.4%	>65%

Negative predictive value of colposcopy

The international evidence on the negative predictive value of colposcopy demonstrates that the likelihood that a patient with a negative (normal) colposcopy does not have high-grade CIN is 71%. In one large study, 6 per 1,000 patients with a negative colposcopy were subsequently diagnosed with a cervical cancer.[11] False negative colposcopy is a known potential harm of screening.

Referral value

The referral value (RV) correlates referral cytology results with histological outcome and is an important indicator of screening programme performance. It is also useful when planning colposcopy resources. 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 referrals for inadequate cytology). **Table 24** shows the referral values for 2020/21 and 2021/22.

Table 24. Referral value for 2020/21 and 2021/22

Performance parameter	2020/21	2021/22
Referral value	3.3	3.0

For example, when the RV is 3.0, this means that for every 3 women referred to colposcopy, 1 will have CIN2 or higher detected, whereas 2 had either low-grade abnormalities or no abnormalities.

Quality improvement

The CervicalCheck programme is committed to continuous quality improvement. Quality improvement is a systematic approach, guided by data to improve the quality and safety of healthcare. It is particularly important to seek to assure and improve the quality of services if screening is to achieve the intended benefits for population health, while minimising unintended harms to those taking part. Following the publication of external reports in 2019 and the planned move to primary HPV screening in 2020, the programme developed a three-year quality improvement portfolio.

There are several different approaches to quality improvement. Due to the service needs at this time, a project management approach was utilised which included the development of charters, project plans and close out reports incorporating lessons learned when projects were completed. The quality improvement initiatives within the portfolio are the responsibility of clinical and operational managers. A detailed summary of the CervicalCheck Quality Improvement portfolio is found in the appendix.

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Appendices

Development of the CervicalCheck Quality Improvement Portfolio

First steps towards quality improvement

Strategic planning workshops were held between September 2020 and January 2021, from which the following initiatives were proposed:

- Develop a cohesive understanding of the programme at all levels. This was important as the programme had several changes of key leadership levels in 2020.
- Identify and agree how the programme's operating model can be strengthened. This included a review of the governance structures.
- Consider all aspects of the participant pathway – what is working well / what needs to be improved / possible solutions.
- Actively call out the negatives and biggest risks to the programme.
- Develop a united clinical vision for CervicalCheck.
- Translate the vision into a strategic plan for next 3 years.
- Develop a roadmap to operationalise the strategic plan – considering priorities, risks, timelines, resource requirements.
- Build sustainable, integrated working relationships between the CervicalCheck Senior Management Team & operational team.

Benefits to the programme

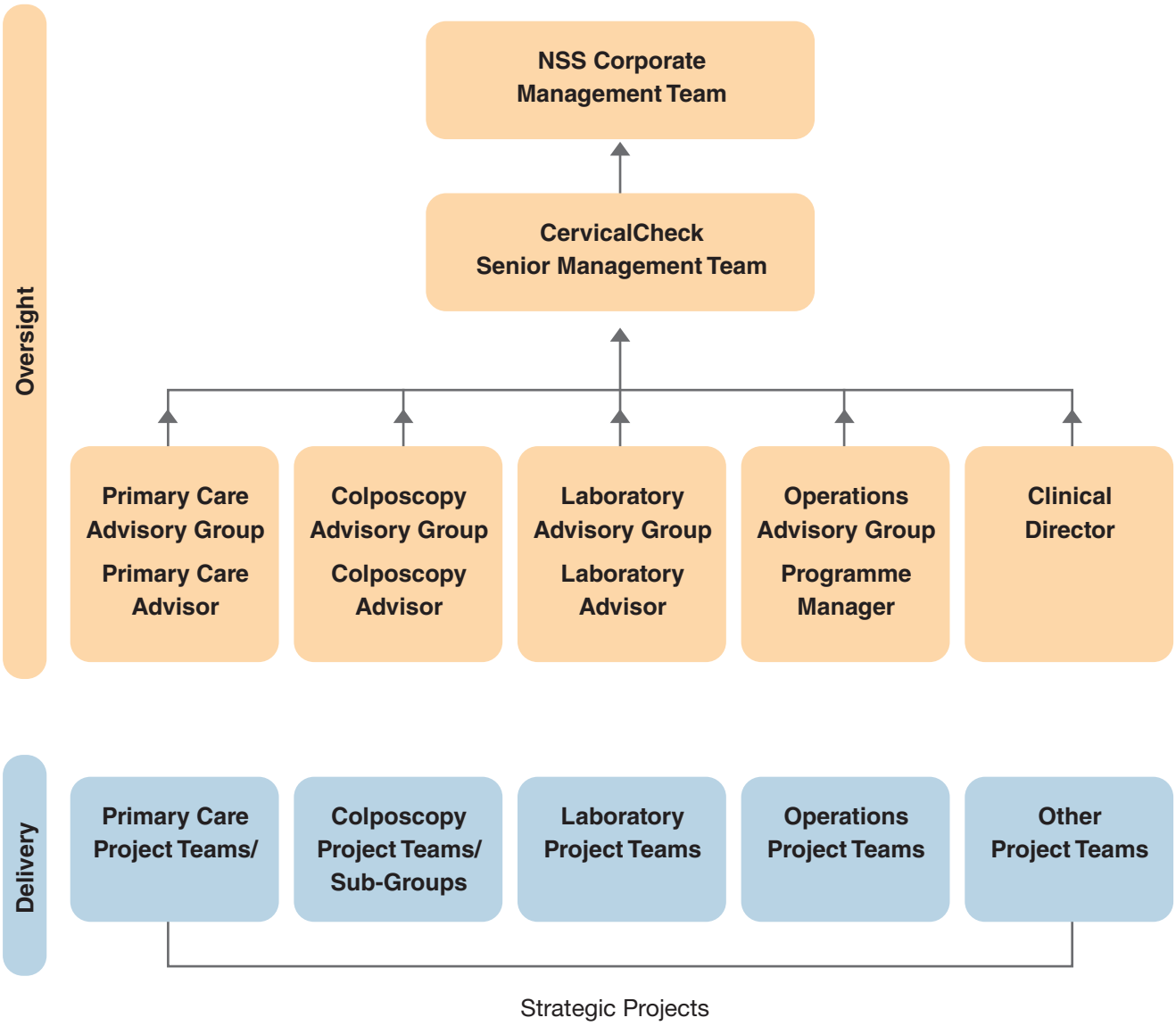
Quality improvement initiatives can enhance not only the service that is being provided but the engagement with and productivity of staff. A single organisation vision, system-wide collaboration, and clear processes were required. By using a systematic and coordinated approach to plan and implement changes, and an open and collaborative approach, projects were delivered on time and in scope. Fundamental to success was the fact that subject matter experts were given the time, resources and support to lead improvements. The leadership team at NSS and CervicalCheck recognise the importance of creating a workplace culture that is conducive to improvement. Clear leadership and good governance supported the planning and implementation of projects.

Quality improvement portfolio governance

The CervicalCheck Strategic Improvement Portfolio includes cross-organisational stakeholders and multiple internal and external dependencies. It is essential that the appropriate governance structure is in place at all levels.

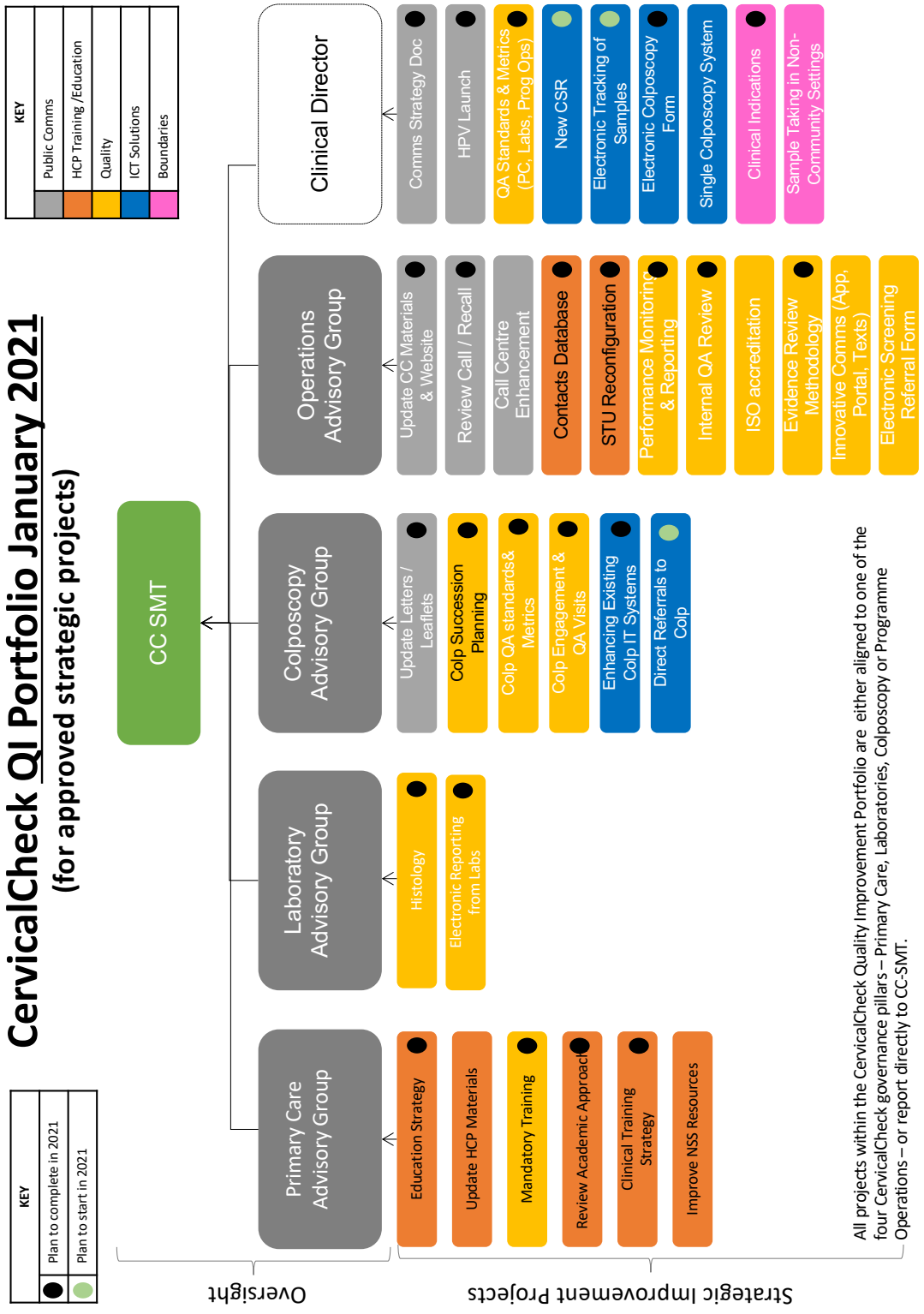
The portfolio governance structure includes the following:

- Portfolio Sponsor
- CervicalCheck Senior Management Team
- Chairs of the four CervicalCheck Advisory Groups
- Project Managers
- Programme Management Office (PMO)

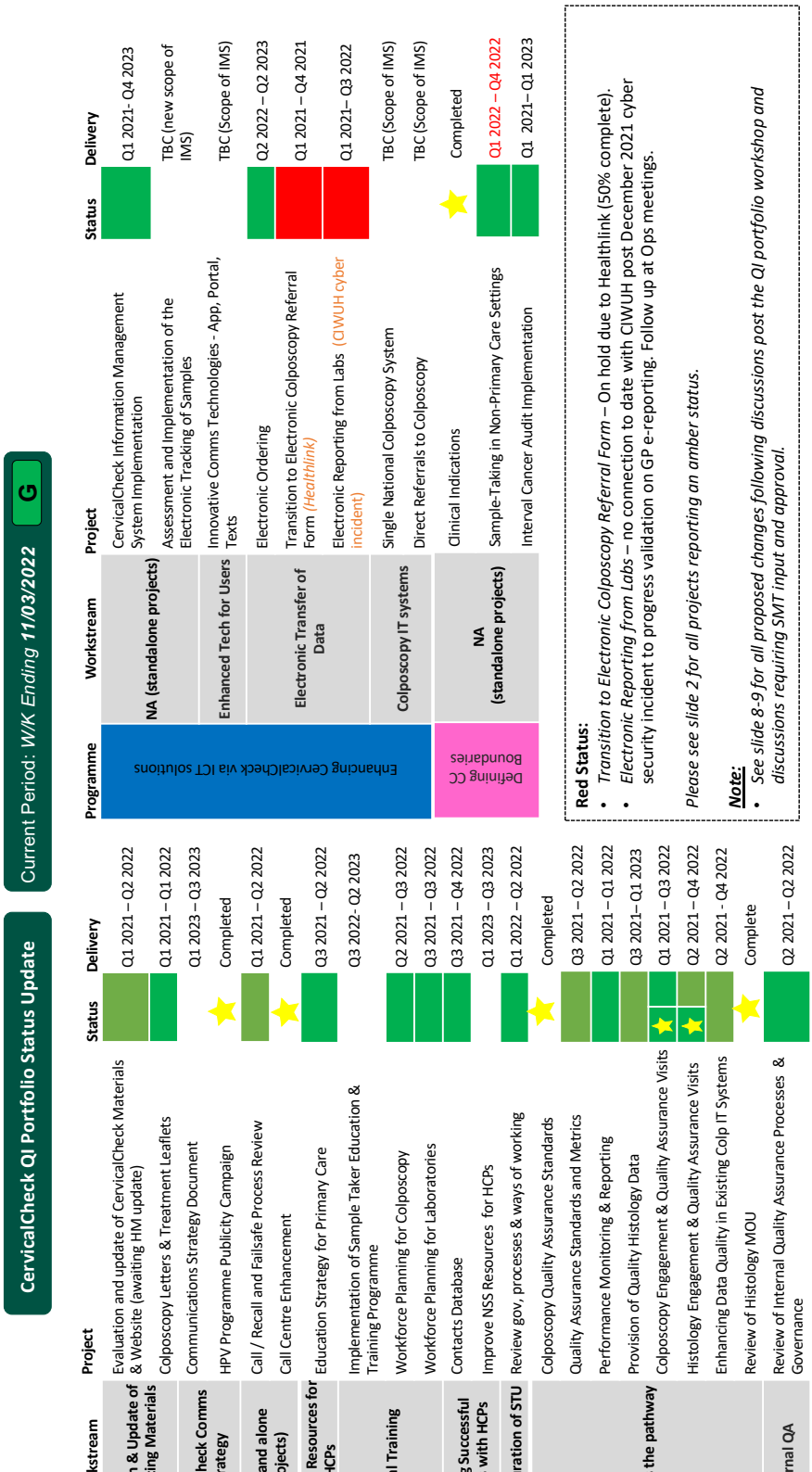


Summary of achievements

Following engagement with key stakeholders through a series of workshops, 33 projects were approved for inclusion in the portfolio (illustrated below). We completed a charter for each project and these were approved at advisory group level or through the CervicalCheck Senior Management Team meeting. Project teams met regularly and project managers provided status updates at a monthly project management meeting where risks and issues were addressed, and advice or support given. There was a defined escalation route through the governance structure (outlined above). The Senior Management Team received a quarterly report of progress, and the CervicalCheck Quality Assurance Committee was kept informed of progress.



As of March 2022, the below graphic demonstrates the QI Portfolio status. Gold stars indicate when a project was delivered. Seven projects were delivered in the first year of the portfolio.



An tSeirbhís Náisiúnta Scagthástála
National Screening Service

CervicalCheck
AN CLÁR NÁISIÚNTA SCAGTHÁSTÁLA CEIRBHEACS
THE NATIONAL CERVICAL SCREENING PROGRAMME