CervicalCheck Clinical Audit of Cervical Cancers – Q&A

What is CervicalCheck?

CervicalCheck is the national cervical screening programme in Ireland providing free cervical screening to women aged 25-60 years resident in the Republic of Ireland. The CervicalCheck programme is operated by the National Screening Service, part of the Health and Wellbeing Division of the Health Service Executive (HSE).

The goal of CervicalCheck is to reduce the incidence of and mortality from cervical cancer. The national programme was launched in September 2008 and has since provided screening to over 1 million women. The 5-year coverage of the target population is 79% (March 2016).

Over 40,000 cases of high-grade cervical abnormalities have been detected and treated (December 2015).

What is cervical cancer?

Cervical cancer is a cancer of the cells of the cervix (neck of the womb). Each year, about 260 women in Ireland are diagnosed with cervical cancer. Cervical cells change slowly and take many years to develop into cancer cells, making cervical cancer a largely preventable disease.

What is cervical screening?

Cervical screening is for women without symptoms. Cervical screening invites women in the population to attend a doctor for a cervical screening test. The test looks for changes in the cells of the cervix and may also look for the presence of human papilloma virus (HPV) infection with one or more of the HPV subtypes associated with cervical cancer. The aim is to identify cell changes before they develop into cervical cancer (pre-cancerous changes). It is not a test for cervical cancer and it is not used to detect any changes in the womb, the fallopian tubes or the ovaries, the vagina or the vulva.

What are the benefits of cervical screening?

Cervical screening can reduce the incidence of and the mortality from cervical cancer over time. The benefits of cervical screening are that it can detect changes in the cells of the cervix before symptoms occur. Monitoring or treatment of these cell changes helps to prevent the development of cervical cancer. The earlier abnormal cell changes are found, the easier they are to treat.

What are the limitations of cervical screening?

Cervical screening will not prevent all cervical cancers, even in screened women.
Screening cannot give a ‘yes’ or ‘no’ answer and a negative screening result does not mean that the disease will not develop in the future. In common with other screening tests, cervical screening is not 100% accurate. A result may be negative even though there are changes to the cells of the cervix (this is called a false negative – the test does not detect the possible presence of abnormal cells in an individual who actually has abnormal cells or even the disease). A test may report changes to the cells of the cervix when in fact there are none (this is called a false positive – the test indicates the possible presence of abnormal cells or the disease in an individual in whom those conditions are not present).

The detection of adenocarcinomas by cervical screening using cytology is known to be more difficult than the detection of squamous cell carcinomas.

Cancers will still occur in populations who have access to organised screening programmes and in women who have been screened for a number of reasons including:

- Failure to screen the population at risk
- Irregular uptake and compliance with screening programme
- False-negative cytology
- High-grade cytology reported as low-grade
- Failure to follow up low-grade cytology
- Delays or failures in referral of women recommended for colposcopy
- Delays or failures in investigation, diagnosis or treatment.

Reasons why screening may not always identify abnormal cells include:

- The abnormal area might be located in the endocervical canal and cells from this area are harder to sample
- Sometimes abnormal cells can look like normal cells
- There may very few abnormal cells in the sample
- Certain cytological patterns and abnormalities are difficult to recognize and may lead to a false negative report
- The subjective nature of cytology interpretation.

Reasons why colposcopy may not always identify abnormal areas of the cervix include:

- The abnormal area might be located in the endocervical canal and cannot be seen
- The abnormal area might not have been included in a biopsy sample
- Some abnormalities are difficult to detect.

Reasons why treatment for abnormal cells may not prevent cancers from developing include:

- The abnormal area might be located in the inside of the cervix and not easily treated
- The woman may not be aware of the need for follow up or the possible need for a second treatment.
What is the cervical cancer clinical audit process?

When screened women develop cancer it is of value to review their screening history to try to assess if any areas of the screening pathway could be improved and in this way improve the service provided to women in the future.

A clinical audit of cervical cancer cases can:

- Provide information to screened women about why their cancers were not detected or prevented
- Provide information about the effectiveness and limitations of screening
- Identify areas where potential improvements in practice or procedures could be made.

CervicalCheck initiated the development of a clinical cancer audit process in 2010 as part of the quality assurance framework of the programme. This is a similar approach to that taken by some other countries with population-based cervical screening programmes, including Finland, Norway, Slovenia and some parts of the UK.

How does the cervical cancer clinical audit process work?

The process examines the screening history of each woman for whom invasive cervical cancer is notified in a systematic way. This involves the examination of the various stages in the cervical screening pathway of a woman prior to the diagnosis of cancer: the history of the woman with the screening programme – invitation, re-call, failsafe – and the clinical outcomes of events in the woman’s screening history – smear-taking, cytology, colposcopy and histology.

A category and a classification are assigned to each cancer case according to the screening status, history and epidemiology of the woman prior to diagnosis.

<table>
<thead>
<tr>
<th>Category</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>No screening prior to diagnosis (woman presented with symptoms)</td>
</tr>
<tr>
<td>2</td>
<td>Diagnosis following a smear test recommending referral to colposcopy</td>
</tr>
<tr>
<td>3</td>
<td>Diagnosis within screening interval after previous normal smear (interval cancer)</td>
</tr>
<tr>
<td>4</td>
<td>At least one normal smear prior to diagnosis but overdue re-call</td>
</tr>
<tr>
<td>5</td>
<td>Diagnosis after previous smear that recommended repeat cytology</td>
</tr>
<tr>
<td>6</td>
<td>Diagnosis following previous colposcopy</td>
</tr>
</tbody>
</table>

The category and classification facilitate assessment to determine whether a case warrants review. The focus of the review can be one or more of the steps in the screening pathway: programme operation, screening (smear-taking), cytopathology, colposcopy and/or histopathology.

Reviews form an important and routine part of the audit process within a quality screening programme. The outcomes of a review can assess if each step worked as well as it could and helps to inform changes to programme policy and direction.
What are the outcomes of the audit process to date?

A total of 1,120 cases were notified to the programme by December 2015.

Of the total, 80% were squamous cell carcinomas and 20% were adenocarcinomas.

Of this total, 653 women had a cervical cancer diagnosed following a CervicalCheck smear test with an abnormal result, while 133 women had never been screened (they were diagnosed at CervicalCheck colposcopy clinics having been referred as a result of symptoms such as abnormal vaginal bleeding).

In addition:
- 128 women had cancer diagnosed within three years of a previous negative smear test with a routine recall recommendation. These cases are termed interval cancers.
- 123 women had cancer diagnosed after a previous smear test showed a low grade abnormality and recommended a repeat test.
- 72 women had cancer diagnosed following a previous visit to colposcopy, some of whom had a previous treatment for abnormalities.
- 11 women had cancer diagnosed on an overdue smear test having had a previously negative test.

317 cases (28.3% of the total cases) were flagged for further review. The reviews focused on one or more areas (programme operation, screening (smear taking), cytopathology, colposcopy and/or histopathology).

In most (although not all) of these reviewed cases there may have been an opportunity for earlier intervention. This includes instances of pre-cancerous cell changes that were not detected, no referral or a delay in referral to colposcopy, and a delay in diagnosis or treatment.

How are the outcomes of the cancer audit process communicated?

When a case is reviewed, the review outcomes are communicated by letter to the woman’s treating doctor for inclusion in her medical record. If it is indicated by the outcomes of the review and if it is appropriate for the circumstances of the woman, the doctor is asked to discuss the cancer audit process, the review and the review findings with the woman. If she does not wish to be informed, her preference should be respected.

The outcomes of the cancer audit process are reviewed by the management of the CervicalCheck programme and of the National Screening Service. Summary outcomes are presented to various stakeholders and groups including staff briefings, NSS Quality Assurance Committee for Cervical Screening, HSE Health and Wellbeing, HSE Quality Improvement Division and the annual CervicalCheck Colposcopy Forum. The process and its outcomes are also communicated as key messages by the Screening Training Unit during training and update sessions for doctors and nurses.
What changes have been made due to the cancer audit process?

1. The introduction of HPV testing to improve the assessment of risk for women with low grade abnormalities (2014).
2. The introduction of HPV testing to improve the assessment of risk for women who have received treatment (2012).
3. Improvements in the way the programme operates a failsafe process to follow up women with abnormal cervical screening results who delay repeat testing or attending colposcopy.
4. Improvement in the communication of discharge information by colposcopy services to the programme’s cervical screening register.
5. The programme can now identify and automatically process a change in a cytology result received from the programme laboratory.
6. Laboratories make and store digital images of all cancer cases.
7. Improved monitoring of subsequent treatment and/or biopsy of women referred to colposcopy following a high grade cytological abnormality.
8. Improvements in the collection of detailed information for notified cancer cases.
9. Links established with the National Cancer Registry.

The effectiveness of the CervicalCheck programme

There is a natural tendency in considering the outcomes of a cancer audit process to focus on cancers which were not prevented. This needs to be balanced by the cancers which are being prevented.

Each year, around 250,000 women have a cervical screening test with CervicalCheck. The millionth individual woman was screened in July 2015 and the number of cervical screening tests carried out since the programme began almost eight years ago exceeds two million.

The majority of women within the screening age range of 25 to 60 years in Ireland are familiar with and have participated in the CervicalCheck cervical screening programme (2015 study). CervicalCheck is very close to reaching its target coverage of >80% of the population of women aged 25-60 years screened within a 5-year period. In March 2016, coverage was measured at 79%.

Each year, over 14,000 women are referred to colposcopy following an abnormal screening test result for investigation, diagnosis and treatment where necessary. Waiting times for appointments in colposcopy services and treatment have reduced dramatically since CervicalCheck was introduced. Now, women with high-grade abnormalities receive an appointment within 4 weeks, while those with low-grade abnormalities are seen within 8 weeks. Over 40,000 cases of high-grade cervical abnormalities have been detected and treated since the programme commenced (December 2015).

The outcomes of the audit process to date show that while the majority of cancers were detected as early as possible through cervical screening, not all cancers were prevented. The audit process has served to identify potential improvements in a number of areas that could benefit women who participate in the cervical screening programme.

Survival from cervical cancer has improved for the first time since records began (NCRI statistics).