INTRODUCTION
Cervical screening aims to detect and treat pre-cancerous cell changes in women without symptoms. The goal is to reduce the incidence of and mortality from cervical cancer. As with all screening tests, cervical screening is not 100% accurate. Screening cannot give a ‘yes’ or ‘no’ answer and a negative screening result does not mean that the disease will not develop in future. It is internationally recognised that cervical screening will not prevent all cervical cancers, even in previously screened women.

CERVICAL CANCER CLINICAL AUDIT
CervicalCheck has a comprehensive quality assurance framework. A cervical clinical cancer audit process is not a mandatory requirement of a cervical screening programme and is not undertaken by all programmes. CervicalCheck decided in 2010 to initiate an audit process following the standard set by programmes in Norway, Sweden and Finland. Attached is an overview of the methodology and data arising from the process.

Ongoing cervical clinical cancer audit is a complex, multi-layered, resource-intensive process. Since 2010 the process has been in development and continues to evolve. The value of an audit process of this nature is that it can identify areas when screening procedures, in any aspect of a programme, could be improved. It can provide information to women about why their cancers were not prevented and information on the effectiveness and limitations of screening. Overall it can demonstrate the importance of quality assurance guidelines. It is designed to deliver learning at a population level for the future.

CURRENT STATUS

Clinical Audit - Case Reports
At this time the process is approaching the stage of communicating individual case reports arising from the clinical audit with the clinicians looking after individual women diagnosed with cervical cancer.

There is always the risk that in communicating individual case reports to clinicians of an individual patient reacting by contacting the media if they feel that ‘screening did not diagnose my cancer’. This is a risk that is inherent in having a clinical audit process as part of the national programme. The clinical audit process will continue to generate case reports from hereon.

The specific issue is that there is now a batch/accumulation of clinical audit case reports that have been completed. The volume element of letters increases the risk of an individual reacting to the content if/when shared by their attending clinician. It is far from certain that this would happen.

All international screening programmes will have encountered a media headline that ‘screening did not diagnose my cancer’.

Most importantly during the conduct of the clinical audit to date no systematic quality problem of concern has been identified.
**Cytology Provider**
One of the cytology laboratory providers has sought legal advice into the right of the programme to communicate audit outcomes. The programme is liaising with legal team on this. This is not an impediment to moving forward with formal communication of audit outcomes.

The legal team are currently reviewing the content of case reports to be communicated and will advise on same.

**Patient Meeting**
Coincidentally a patient diagnosed with cervical cancer and currently in treatment has requested a meeting with CervicalCheck which has been scheduled for next week (3 March). This type of consultation is one that occurs regularly in every hospital. It is likely to have arisen even in the absence of a clinical audit process.

Patients always have the right to seek legal advice. CervicalCheck has always supplied information to patients’ legal representatives as and when requested since the outset of the programme in 2008.

**NEXT STEPS**

- Pause all letters
- Await advice of solicitors
- Decide on the order and volume of dispatch to mitigate any potential risks
- Continue to prepare reactive communications response for a media headline that ‘screening did not diagnose my cancer’.
AUDIT PROCESS METHODOLOGY OVERVIEW

Notification
Cases are continually notified to the programme through receipt of histology data, from colposcopy services and on from individual clinicians, general practitioners and from women’s representatives.

As cervical cancer will already have been confirmed in each case, the cases are therefore historic, each individual patient’s management pathway will have commenced and the majority will be completed.

Process
The clinical audit of a case of invasive cervical cancer involves the examination of the various stages of the cervical screening pathway of a woman prior to the diagnosis of cancer. This includes the examination of the history of engagement of the woman with the screening programme – invitation, re-call, etc. – and the clinical outcomes of screening events in the woman’s screening history. All cases are reviewed in a systematic and detailed way. The detailed nature of the audit process for each case is labour-intensive requiring substantial organisational time.

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

a. cases that may be closed with respect to the audit process: the category and classification are clear and there is no further learning to be obtained
b. cases where the category and/or the classification or the next step is uncertain for some reason, frequently due to a lack of sufficient detailed information
c. cases that warrant further clinical review of one or more elements of the cervical screening pathway.

Outcomes

Outcomes of the audit process to date: 2008 to 2015 (7 years)

<table>
<thead>
<tr>
<th>Category</th>
<th>Count</th>
<th>%</th>
<th>Review case</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 No screening prior to diagnosis (woman presented with symptoms)</td>
<td>133</td>
<td>11.9%</td>
<td>No</td>
</tr>
<tr>
<td>2 Diagnosis following a smear test recommending referral to colposcopy</td>
<td>653</td>
<td>58.3%</td>
<td>No</td>
</tr>
<tr>
<td>3 Diagnosis within screening interval after previous normal smear (interval cancer)</td>
<td>128</td>
<td>11.4%</td>
<td>Yes</td>
</tr>
<tr>
<td>4 At least one normal smear prior to diagnosis but overdue re-call</td>
<td>11</td>
<td>1.0%</td>
<td>Yes</td>
</tr>
<tr>
<td>5 Diagnosis after previous smear that recommended repeat cytology</td>
<td>123</td>
<td>11.0%</td>
<td>Some</td>
</tr>
<tr>
<td>6 Diagnosis following previous colposcopy</td>
<td>72</td>
<td>6.4%</td>
<td>Most</td>
</tr>
<tr>
<td></td>
<td>1,120</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

The majority (58.3%) of notified cervical cancer cases were diagnosed following a CervicalCheck smear test that recommended referral to colposcopy. Some cervical cancer cases were notified for women where there was no cervical screening prior to diagnosis (11.9%). These cases do not warrant further review – there is no additional learning to be gained for the screening programme.
Review
All cases that fall into categories 3 (interval cancers) and 4 and many cases in categories 5 and 6 are flagged for further review. With these cases, the focus for the review is selected: one or more of programme operation, screening (smear taking), cytopathology, colposcopy and histopathology.

To date, 317 cases have been flagged for further review. It should be noted that cases will continually be notified to the programme.

<table>
<thead>
<tr>
<th>Focus for review</th>
<th>Count*</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Programme</td>
<td>7</td>
</tr>
<tr>
<td>2 Screening (primary care)</td>
<td>7</td>
</tr>
<tr>
<td>3 Cytology</td>
<td>251</td>
</tr>
<tr>
<td>4 Colposcopy</td>
<td>72</td>
</tr>
<tr>
<td>5 Histology</td>
<td>11</td>
</tr>
</tbody>
</table>

* a case may be reviewed for more than one programme area.

For cytology, colposcopy and histology reviews, the original laboratory or colposcopy service is requested to review the case. The outcome of that internal review may lead to a request for an external independent review. For example, if an internal cytology review of a smear test confirms a negative result and routine screening recommendation in the case of an interval cancer, the slides are sent for external review. The review process for a case may take several months to complete.

Logging
All cases that are flagged for further review will be logged as incident cases of cervical cancer on NIMS (National Incident Monitoring System).

Communication
The review outcome is also communicated to the woman’s treating clinician, in order to support the clinician’s interaction and communication with the woman.

Process Development
The cancer audit process continues to evolve since it was initiated in 2010. The audit process, outcomes and proposed developments have been presented to and developed in conjunction with:

- CervicalCheck Colposcopy Forum
- Programme colposcopy services and histology laboratories
- Cytology laboratory providers
- Quality Improvement Division
- State Claims Agency (NIMS).

Monitoring
The NSS Cervical Executive Management Team reviews the process and outcomes, and examines overall outcomes to determine if any patterns or trends that warrant attention are identified. To date, no trend or pattern has been identified.

Continuous Improvements
Learnings from the audit process to date include:

- Change to the programme failsafe process to follow up abnormal results
- Changes to the discharge protocols in colposcopy services
- Programme can now identify when a cytology result change is received
- Laboratories required to make digital images of all cancer cases
• Monitoring of subsequent treatment and/or biopsy of women referred to colposcopy following a high grade cytology abnormality.
• Improve the collection of detailed information for notified cancer cases
• Link with the National Cancer Registry.