Memorandum

To: Public Accounts Committee

Date: 10 May 2018

Re: PAC Committee Meeting 10.05.2018

Attached is the briefing memo referenced earlier at the Committee meeting by the Director General. The briefing comprised three iterations of a memo which evolved from March to July 2016 and need to be read together.

The briefing memo prepared by John Gleeson, CervicalCheck Programme Manager is the most up to date memo and as such is the memo referred to by the Director General at the meeting today.
CERVICALCHECK - UPDATE ON CERVICAL CANCER CLINICAL AUDIT PROCESS
BRIEFING NOTE July 2016

INTRODUCTION
Cervical screening is a process to look for 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
Although 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 example set by programmes in the United Kingdom, Norway, Sweden and Finland.

Ongoing cervical clinical cancer audit is a 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.

CURRENT STATUS
Over 1,200 cases of cervical cancer have been notified to date (start of July 2016) to CervicalCheck related to the almost 8 year period of CervicalCheck operation. This is a subset of all cases of cervical cancer in that time. These cases have been logged as part of the audit process and have been categorised and classified following a defined system as outlined in the CervicalCheck “Clinical audit process for incident cases of invasive cervical cancer”.

Approximately 30% of the total notified cases have been flagged for a review of one or more elements of the cervical screening pathway – programme operation, screening, cytopathology and HPV testing, colposcopy and histopathology. The most common element for review, as anticipated for a cervical screening programme, is cytology (alone or in conjunction with another element of the pathway) – approximately 80% of reviews include a focus upon cytology prior to diagnosis.

Where a case is reviewed, the review findings are recorded. In February 2016, the Programme commenced the formal step of communicating cytology review findings arising from the clinical audit to the treating clinicians looking after individual women diagnosed with cervical cancer.

To date, a total of 86 letters have been issued to treating clinicians for cases where cytology was reviewed and a further approximately 200 letters will issue during July/August 2016 where cytology was reviewed. This will complete the communication of all historic cases for the early years of the screening programme (September 2008 – 2014) in addition to recent cases (2015 – 2016) as the review findings become available. Given the volume of letters that will be issuing over the coming weeks, it is possible that individual cases could appear in the public domain. From September 2016, letters communicating cytology review findings are likely to issue at the rate of 4 – 6 per month.

All international screening programmes will have encountered a media headline that ‘screening did not diagnose my cancer’. The CervicalCheck Programme has prepared communications materials to ensure transparent, effective and robust communications processes are in place so as to provide
clear information for the media and the public where appropriate on the CervicalCheck Clinical audit process and results.

Another issue is that key stakeholders such as the contracted cytology laboratories have reacted with concern in some instances to the CervicalCheck Programme communicating cytology review findings to treating clinicians and there has been legal correspondence in previous months. The NSS met with one of the laboratories in May 2016 and legal correspondence has ceased since that meeting. Discussion and engagement with senior personnel in both contracted cytology laboratories, and with the clinical and administrative leads in colposcopy services, are continuing as part of the ongoing process.

A ‘communications protocol’ has been prepared for consulting clinicians to address their questions. The spokesperson on matters related to this audit is Dr. Grainne Flannelly, Clinical Director, CervicalCheck Programme.

THE EFFECTIVENESS OF THE CERVICALCHECK PROGRAMME

It is important to note that 57% of the cases of cervical cancer notified to CervicalCheck in the nearly eight years since the programme’s inception were diagnosed following a CervicalCheck smear test and on their first visit to a colposcopy clinic. In addition, a little over 12% of cases were for women with no cervical screening history.

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 CervicalCheck 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. For the 5 years to the end of March 2016, coverage has reached 79%.

Each year, over 11,000 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 (pre-cancer) have been detected and treated since the CervicalCheck 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 CervicalCheck screening programme. Changes to the Programme that are directly or indirectly attributable to the cancer audit process include:

- Introduction of HPV testing in colposcopy services for the management of women post treatment and untreated women with persistent low grade abnormalities
- Changes made to the programme failsafe process to follow up abnormal results
• Changes made to the discharge protocols in colposcopy services
• 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
• Establishment of formal links for statistical reporting with the National Cancer Registry, Ireland (NCRI).

Work has commenced with the NCRI, who record all cases of cervical cancer, to correlate the incidence, mortality and survival rates for cervical cancer with the introduction and operation of cervical screening through the CervicalCheck Programme.

Prepared by
John Gleeson
CervicalCheck Programme Manager, National Screening Service
Health and Wellbeing Division

On behalf of
Dr. Stephanie O’Keeffe
National Director, Health and Wellbeing
INTRODUCTION
Cervical screening is a process to look for 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
Although 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 example set by programmes in the UK, Norway, Sweden and Finland.

Ongoing cervical clinical cancer audit is a 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.

CURRENT STATUS
Over 1,100 cases of cervical cancer have been notified to CervicalCheck in a 7.5 year period (a subset of all cases of cervical cancer in that time) and logged as part of the audit process. All cases have been categorised and classified following a defined system as outlined in the CervicalCheck “Clinical audit process for incident cases of invasive cervical cancer”.

Approximately 30% (317) of notified cases have been flagged for a review of one or more elements of the cervical screening pathway – programme operation, screening, cytopathology and HPV testing, colposcopy and histopathology.

Where a case is reviewed, the review findings have been noted. In February 2016, the programme commenced the formal step of communicating cytology review findings arising from the clinical audit to the treating clinicians looking after individual women diagnosed with cervical cancer.

To date, a total of 56 letters have been issued to treating clinicians for cases where cytology was reviewed and a further 200 letters will issue during July/August where cytology was reviewed. This will complete the communication of all historic cases in the early years of the screening programme (September 2008 – 2014). Given the volume of letters, that will be issuing over the coming weeks, it is possible that individual cases could appear in the public domain.

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

The CervicalCheck Programme has prepared communications materials to ensure transparent, effective and robust communications processes are in place so as to provide clear information for the media and the public where appropriate on the CervicalCheck Clinical audit process and results.
Another issue is that key stakeholders such as the contracted cytology laboratories have reacted adversely to the CervicalCheck Programme communicating review findings to treating clinicians and there has been legal correspondence in previous months. The NSS met with one of the laboratories in May and legal correspondence has ceased since that meeting.

A ‘communications protocol’ has been prepared for consulting clinicians to address their questions. The spokesperson on matters related to this audit is Dr. Grainne Flannelly, Clinical Lead, CervicalCheck Programme.

**THE EFFECTIVENESS OF THE CERVICALCHECK PROGRAMME**

It is important to note that 653 women (~60%) out of the 1,100 cases of cervical cancer notified to CervicalCheck in the nearly eight years since the programme’s inception were diagnosed following a CervicalCheck smear test and on their first visit to a colposcopy clinic.

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 CervicalCheck 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 CervicalCheck 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 CervicalCheck screening programme.

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

Prepared by
Simon Murtagh
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Health and Wellbeing Division

On behalf of
Dr. Stephanie O’Keeffe
National Director, Health and Wellbeing
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.

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 is 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’.