Cervical Screening

Update from the Serious Incident Management Team [SIMT]

Tuesday 1st May 2018

1. Background

CervicalCheck, the HSE's National Cervical Screening Programme has provided a population based screening programme for the women of Ireland since 2008.

Over the past week there has been considerable public focus on and concern about the Cervical Screening service. Much of this concern stems from an audit of ***1,482*** cases of cervical cancer reported to the Programme in the period between 2008 and 2018.

Cervical screening, in common with all health screening, is not 100% accurate and will not prevent all cervical cancers, even in previously screened women.

2. CervicalCheck clinical audit process

The CervicalCheck clinical audit process examines the screening history of all notified cases of cervical cancer, with a date of diagnosis since the programme commenced in September 2008.

The audit process is an opportunity to see if any aspect of a programme could be improved. The process can also provide more detailed information to women on the reasons why their cancer was not prevented, as well as information on the effectiveness and limitations of screening.

Of the ***1,482*** cases notified and logged to date, ***442*** cases (29%) were flagged for review of one or more elements of the cervical screening pathway – programme operation, screening, cytopathology and HPV testing, colposcopy or histopathology. The most common review type, as expected in a cervical screening programme, is of cytology [smear test], due to its inherent limitations as a screening test. Cases are reviewed by an internal review group, with the support of an independent pathologist.

3. Communication of Review results

In February 2016, the programme commenced formally communicating review outcomes of historical notified cervical cancer cases where prior cytology had been reviewed to the consultant doctor looking after an individual woman diagnosed with cervical cancer. All historical reviews were communicated to treating doctors by October 2016 and the programme has been communicating current cases since that date.

4. Open Disclosure

It is a core principle in healthcare that patients are entitled to all information which relates to their care. There is an obligation on healthcare services and those who work in them to communicate with patients in an open and honest manner.

While the audit process established by CervicalCheck is seen as good practice and has the potential to make an important contribution to improving the quality of the programme, there was some evidence that the women whose care had been reviewed as part of the audit process had not been informed either of the review or the outcome of the review as it pertained to them.

The women whose cases were reviewed, all had a diagnosis of cancer so the outcome of the review of their care would not have changed their diagnosis. They were entitled however to know that there case was reviewed and the outcome of that review. This was particularly important where the review team drew conclusions that were different to the original interpretation of the smear result.

5. Establishment of the Serious Incident Management Team [SIMT]

Due to the lack of assurance that the women whose care was considered as part of the review process had been communicated with, a Serious Incident Management Team was established on Friday 27th April 2018.

It held its first meeting at 5.30 pm that evening and has held 6 meetings since that time.

The Chair of the SIMT is *Mr. Patrick Lynch, National Director Quality Assurance and Verification,* and other members are *Dr. Colm Henry Interim Chief Clinical Officer, Dr. Jerome Coffey National Director National Cancer Control Programme, Mr. Liam Woods National Director Acute Hospitals and Mr. Paul Connors National Director Communications. On Monday 30th April 2018 the SIMT was expanded to include Dr. Peter McKenna Clinical Director and Mr. Kilian McGrane of the National Women and Infants Health Programme.*

6. Purpose of the SIMT

The purpose of the SIMT was to;

- **I.** Establish the number of women who have had a review undertaken and should have had the outcome of their review communicated to them.
- **II.** Establish the number of women who have been communicated with.
- **III.** Ensure arrangements are put in place for a senior clinician to meet with the women who have not been informed of the outcome of the review as it pertains to them.
- **IV.** Seek assurance that arrangements are in place for the helpline to support women concerned about cervical screening.

On Friday 27th April the CervicalCheck Programme identified the full list of women who should have been communicated with. These lists were distributed late on Friday night to ***13*** hospitals.

These hospitals are, *Castlebar; The Coombe; Cork; Dundalk; Holles street; Letterkenny; Limerick; The Rotunda; Sligo; Tallaght; Galway; Waterford and Wexford*.

Over the weekend the charts were retrieved for each of these women and appropriarte clinical staff reviewed the charts. The purpose of reviewing the charts was to establish if there was evidence that these women had been met with, to provide them with information on the outcome of the review.

7. Update on actions 1st May 2018

7.1 Number of women who should have been communicated with

The SIMT established that there were ***208*** women who should have been communicated with in relation to the review process. These were women where the CervicalCheck review

team interpretation of their smear result was different to the original smear interpretation. Of these;

- ***175*** cases reviewed had an interpretation that was different to the original smear result and based on the opinion of the review team, this would have led to a different clinical escalation [i.e. referral for biopsy / colposcopy].
- ***33*** cases reviewed had an interpretation that was different to the original smear result but based on the opinion of the review team, they would not have recommended different clinical management other than an earlier repeat smear.

7.2 Number of women who had been communicated with

On the 30th April 2018, following the review of patient charts over the weekend it was established that of the ***208*** women concerned;

- ***46*** women have already been communicated with.
- ***162*** women had not been told.

7.3 Arrangements for communicating with women concerned

Each Hospital Group was then required to ensure that;

- Each of the ***162*** women who had not been told of the review outcome would be phoned on Monday 30th April and Tuesday 1st May 2018.
- They would be offered an appointment to meet the appropriate senior clinician during the week ending Saturday 5th May 2018. The purpose of this meeting will be to go through the outcome of the review as it pertained to them. It was recognised that there may be a small number of women where it may be difficult to make early contact or arrange a meeting this week, for example if they are out of the country etc.

There were ***17*** women in this cohort who have died[1]. It has been established that ***2*** of these women had the results of their review communicated to them before their death. The SIMT have instructed that it is essential that each hospital establish the next of kin of the women who died without being told and that arrangements would be put in place to meet with them.

There were ***14*** patients identified who are outside of the public hospital system according to the records of CervicalCheck. Efforts are being made to establish contact with these patients or their next of kin.

It is acknowledged that in addition to a diagnosis of cancer, finding out at this stage that they were the subject of a review will be distressing. The SIMT is confident that the clinicians meeting with these women or their next of kin will be very sensitive to the context of this information.

[1] *The SIMT have not at this stage been able to provide any comment on whether any aspect of the patient's care history contributed to their death*

7.4 Helpline

Given the high level of public concern in relation to cervical screening, CervicalCheck established a helpline 1800 45 45 55.

Between Saturday 28th April and 4pm on Tuesday 1st May 2018 ***5305*** calls have been received. There has been a much higher than expected number of calls and the helpline staffing has been increased to respond to this demand. The HSE has issued a public apology for the technical issues which disrupted the service on Saturday 28th and Monday 30th April.

Of the ***5305*** calls received up to *4**pm on the 1st May 2018***, there is a requirement for a call back in the case of ***4876*** women. A specialist team has been put in place to provide these call backs and this is being supplemented due to the volume of requests for information.

8. Number of cases audited

During the course of its work it became evident to the SIMT that the number of cases audited by the Screening Programme varied from the number of cases of cervical cancer reported to the National Cancer Registry over the same period.

The SIMT immediately took action, escalating this matter to the Director General. This will result in;

- The National Cancer Registry being mandated to share its data with the Programme.
- The lists being reconciled.
- An immediate audit of these remaining cases being undertaken.

9. Continuation of the SIMT

The SIMT was established specifically to manage the immediate response to the women who had not been informed of the outcome of their review. It will continue in place to the conclusion of the process.

There are a range of issues that were not within the scope of the SIMT, particularly in relation to the why and who and when? These are matters that will require further consideration and will need to form part of any follow on process.

While there will be a statutory inquiry established which will report in the future there is a requirement to reflect on the issues that led to the establishment of the SIMT and to elicit early learning from them.

10. Conclusion

While the women who were the primary focus and concern of the work of the SIMT had all received a diagnosis of cancer at the time of their review and the review would not have changed this outcome, they were all entitled to know the Review had been conducted and its outcome as it related to them. This openness and transparency should lie at the heart of a caring and compassionate healthcare system.