

Scoping Inquiry into the CervicalCheck Screening Programme

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**First Report: Information Provided to Women Receiving
Screening and Treatment through CervicalCheck**

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1 Introduction

The terms of reference for the Scoping Inquiry announced on 8th May 2018 by the Minister of Health included a clause, (d), requiring an examination to be made of the information being provided to women who are having a cervical test. The Inquiry is making steady progress on all its terms of reference; however, it is still in its early stages. Nonetheless, it has been possible to address this important element in the terms of reference and review the information provided to women participating in the screening programme.

In the context of this Inquiry, the major concern is women who have been diagnosed as having cervical cancer and whether their previous screening tests, often stretching back over many years, have been incorrectly reported upon. If so, whether they have been properly informed when their tests were part of a retrospective audit. But there is also a more general concern, as reflected in this particular section of the terms of reference, as to whether the CervicalCheck programme is providing all women with accurate, complete and timely information about the screening process.

It has therefore been decided to review the written material provided to women by CervicalCheck and to compare the information provided to Irish women with that provided by cervical screening programmes in other countries. In particular, it is necessary to review whether it was made clear to women that the cervical screening process can and will, regrettably, miss some abnormalities which, if they had been spotted and treated could have been prevented from progressing to cervical cancer.

2 Consent and Information

Before anyone is subjected to any healthcare intervention, whether it be the prescription of medicine, the performance of an operative procedure or the undertaking of an investigation or test, such as a cervical test, it is necessary for the person to give their informed consent. For someone to give consent it is generally accepted that the patient must be, a) provided with enough information to enable them to make a properly informed decision, b) the information must be in such a form that they can comprehend it, and c) the patient's decision must be voluntary and unpressured.

A National Cancer Screening Service internal paper from 2009 provided a list of the key information elements that were required in the context of consent.¹ It is notable that the second item on the list is, 'the likelihood of false negatives and false positives'.

Informed consent in cervical screening would involve information about:

- the purpose of screening
- the likelihood of false negatives and false positives
- the uncertainties and risks of screening
- the significant medical, social or financial implications of the test and participation in the Programme
- follow-up care plans including the availability of counselling and support services.

The importance of clear, comprehensible and accurate information is thus at the very centre of the process of any medical procedure, including the carrying out of a cervical test, on a patient. In organised cervical screening programmes, there are usually two components to the provision of information to a patient.

Firstly, it is the norm in most countries that when an invitation to attend for a cervical test is sent to a woman it will be accompanied by an information leaflet describing:

- the nature of the screening programme;
- the reasons why it is a good idea to have a test;
- the process of having a test carried out, and
- what will happen subsequently in terms of results and possible further investigations.

¹ *Recommendation regarding the consent process in CervicalCheck to the Cervical Executive Management Team.* National Cancer Screening Service. 13th May 2009. Prepared by Dr Marian O'Reilly, Head of Cervical Screening, p9.

Secondly, there is the interaction between the woman and the health professional carrying out the test, usually a doctor or a nurse. This is the opportunity for the woman to ask for further information or seek clarification. It is also an opportunity for the health professional to assess whether the woman has understood the information she has received.

The combination of both components, written and oral information, is regarded as best practice in adult patient communication. The evidenced based NICE guidance from the UK on adult patient experience in healthcare makes two clear and simple points.²

- Give the patient information, and the support they need to make use of the information, in order to promote their active participation in care and self-management.
- Give the patient both oral and written information.

² *Patient experience in adult NHS services: improving the experience of care for people using adult NHS services.* NICE, 2012. <https://www.nice.org.uk/guidance/cg138>

3 Information Leaflets

The information provided to women in Ireland by CervicalCheck contains clear and helpful information about the screening programme and what it entails. Leaflets are available in a number of languages, in an easy to read version and online as audio files.

Leaflets aimed at women from the Republic of Ireland, Northern Ireland, England, Scotland, Wales, and New Zealand were reviewed for the information they contained about the predictable failure to detect cervical abnormalities in a proportion of cases.

The following tables set out the relevant content in information leaflets from the different jurisdictions.

Country	Paragraph heading / relevant content of cervical screening leaflet
Ireland ³	<p><i>What are the limitations of cervical screening?</i></p> <p>Cervical screening will not prevent all cases of cervical cancer. Cervical screening tests, like other screening tests, are not 100% accurate.</p> <p>A result may be negative even though there are changes to the cells of the cervix (this is called a false negative). This is why it is important to have regular tests and to consult your doctor if you have any symptoms.</p> <p>A result may be positive even when there are no changes to the cells of the cervix (this is called a false positive). If your result is positive, you will be offered a more detailed investigation called a colposcopy. Some women may be treated for abnormalities that may have cleared up on their own.</p>
Northern Ireland ⁴	<p><i>How reliable is cervical screening?</i></p> <p>Cervical screening prevents around 7 out of 10 cervical cancers. However, like any screening programme it is not a guarantee that you will not develop cancer. An abnormality may develop and turn into cancer before your next test is due. There is also a small chance that the test misses an abnormality.</p>
Scotland ⁵	<p><i>Can the test detect all changes?</i></p> <p>No. The test can sometimes miss changes and changes can also happen between tests, so it's important to go for a smear test every time you're invited.</p>

³ <http://www.cervicalcheck.ie/fileupload/WomenPublications/CC-PUB-CC-1%20About%20your%20free%20cervical%20screening%20test.pdf>

⁴ <http://www.publichealth.hscni.net/publications/cervical-cancer-its-best-take-test-english-and-11-translations>

⁵ <http://www.healthscotland.com/documents/24327.aspx>

Country	Paragraph heading / relevant content of cervical screening leaflet
Wales ⁶	<p><i>How reliable is cervical screening?</i></p> <p>Regular cervical screening can prevent around 75% of cancers developing, but like other screening tests it is not perfect. It does not always detect early cell changes that may lead to cancer. Abnormal cells in your sample might be missed because:</p> <ul style="list-style-type: none"> • Sometimes they do not look much different from normal cells • There may be very few abnormal cells in the sample • The person reading your sample may miss the abnormality (this happens occasionally, no matter how experienced the reader is.)
England ⁷	No Relevant Content
New Zealand ⁸	<p><i>The cervical smear test</i></p> <p>Cervical screening, like all screening, is not 100% effective and some women will still develop cervical cancer despite regular screening. While the risk of cervical cancer can be reduced, it cannot be eliminated by screening.</p>

There is very substantial variation in the information in the patient information leaflets accompanying the cervical screening programmes in the different countries. Perhaps the most unusual leaflet is the one currently in use in England. It contains no mention of the fact that screening may fail to detect abnormalities due to the lack of sensitivity of the test, or though human error. This is a major departure from the previous leaflet in England, which had been introduced in 2006 and contained a clear and comprehensible statement about the limitations of the screening process.

England (2006 version) ⁹	<p><i>How reliable is cervical screening?</i></p> <p>Early detection and treatment can prevent around 75% of cancers developing but, like other screening tests, it is not perfect. It may not always detect early cell changes that may lead to cancer. Abnormal cells on your slide may not be recognised because:</p> <ul style="list-style-type: none"> • sometimes they do not look much different from normal cells; • there may be very few abnormal cells on the slide; or • the person reading your slide may miss the abnormality (this happens occasionally, no matter how experienced the reader is).
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⁶ http://www.cervicalscreeningwales.wales.nhs.uk/sitesplus/documents/1032/79663_CS13_Facts_ORANGE_Ver_10_ENG1.PDF

⁷ <https://www.gov.uk/government/publications/cervical-screening-description-in-brief>

⁸ <https://www.healthed.govt.nz/resource/cervical-smear-tests-what-women-need-know-%E2%80%93-english-version>

⁹ <http://www.drloew.co.uk/sitebuildercontent/sitebuilderfiles/04126874.pdf>

There are more detailed explanations of the potential shortcomings of the screening test in some of the online documents that provide women with more detail about the cervical screening programmes. For example, the New Zealand programme has a 47-page public information booklet that contains a more detailed paragraph on the accuracy of the screening test.¹⁰

How accurate are cervical smear tests?

Cervical screening, like all screening, is not 100% effective and some women will still develop cervical cancer despite regular screening. While the risk of cervical cancer can be reduced, it cannot be eliminated by screening.

There is a small chance that some abnormal cells will be missed during sampling or slide reading (called a false negative). Abnormal changes to cervical cells progress very slowly. It is likely that any abnormal cells missed at one regular check will be picked up at the next.

There is also a small chance that a result will say that abnormal cells have been found when the cervix is quite normal (a false positive). If the result from further testing shows that there are no abnormal cells, no treatment will be needed.

A cervical smear has a false negative rate of about 20 percent for high-grade lesions. The test is not reliable in the presence of clinical symptoms.

There is a second short leaflet that is made available to Women in Ireland entitled, *About your cervical screening result*.¹¹ This leaflet is designed to help women understand what the result of their test means for them. As well as outlining the treatment and further screening details of the programme it contains the paragraph:

It is important to understand that no screening test is 100% effective. If, at any time, you have concerns or symptoms such as pelvic pain, irregular vaginal bleeding, spotting or discharge, you should contact your doctor without delay.

¹⁰ <https://www.healthed.govt.nz/resource/prevention-cervical-cancer-guide-women-new-zealand>

¹¹ <https://www.cervicalcheck.ie/fileupload/WomenPublications/CS-PUB-CC-2%20About%20your%20cervical%20screening%20result.pdf>

4 Consent

There is a very substantial variation between countries in the way in which consent is obtained from women as part of their participation in the screening programme. Often there is no formal process of obtaining consent. In these cases, the woman's oral consent will either be obtained by the healthcare professional asking the woman directly if she consents, or, alternatively, consent is simply presumed because the woman has chosen to attend.

The situation in Ireland is rather different from elsewhere in that there is a Cervical Screening Form that the woman should be asked to sign at a screening appointment.¹² The woman's signature is taken as indicating that she both understands the information that she has been given and that she consents to take part in CervicalCheck. The form is accompanied by an A4 sized 'Information Sheet for Women' which contains information about cervical screening and the requirement that she give her consent to take part in the screening programme, including the sharing of information. Amongst the information provided is a section titled, 'What are the limitations of cervical screening?'. The text of this section is identical to that quoted above in the introductory leaflet provided to women with their invitation to be screened.

¹² <http://www.cervicalcheck.ie/fileupload/Health-professionals/HPForms/CS-F-LAB-2%20Cervical%20Screening%20Form.pdf>

5 Open Disclosure and Access to Records

In the information given to women about this screening programme there is no significant mention of either a woman's right to access her screening records, or, in the event of an error being made, or a missed diagnosis, that there will be full and open disclosure of the facts. In particular, it is clear from my discussions with women affected that they attach enormous importance to having unfettered access to their clinical record. Their sentiment can be summed up as, "If it's my body; it's my record." I could not agree more strongly.

6 Conclusion

As far as can be ascertained from our consideration of available resources, the provision of information to women in Ireland is comparable with that available elsewhere and, in some respects, is better. The statement on the limitations of screening that appears in both the main screening leaflet and in the information sheet accompanying the consent form could, however, be strengthened to note the various reasons why the test, in a small proportion of cases, might not identify a significant abnormality that is present and thus give false reassurance.

The process of completing a consent form at the time of screening is a major strength of the CervicalCheck programme and it is commendable that an information sheet is provided to women at that point in the process. It is, however, important that there is regular auditing of clinical notes to ensure that consent forms have been completed properly and that consent is part of the file or record.

Women, quite correctly, feel that they should have access to their full screening records if they so wish. Similarly, in a spirit of honesty and openness, full disclosure of any error or missed diagnosis for any reason, should be given to the woman involved. It would be entirely appropriate for these two assurances to be provided to women at the earliest stages of the screening process and to be reflected in the information accompanying the consent form.

7 Recommendations for Action

- A more comprehensive guide to the CervicalCheck screening programme should be provided online so that women who wish to learn more about the programme can obtain the information easily.
- The information statements provided to women about the limitations of the tests should be more explicit about the possible reasons why screening might miss abnormalities that are present as these can result in the development of cervical cancer. This information should be included in the leaflet sent to all women with their screening invitation, and in the information sheet accompanying the consent form.
- The information for women accompanying the consent form should guarantee that they will have full and open access to their cervical screening record on request.
- The information for women accompanying the consent form should guarantee that should there be a problem or error of any significance with the screening or reporting process, open disclosure of all the details will take place in a timely, considerate and accurate manner.