Scoping Inquiry into the CervicalCheck Screening Programme

Dr Gabriel Scally

Progress Report
11 June 2018

Contents

Foreword

Dear Minister

At the heart of the serious problems in the national cervical screening programme is a very substantial group of women who feel that they have been badly let down by a health service programme that they hoped and believed would help them avoid developing cervical cancer. These women, and the relatives of those who have already died, are naturally devastated that opportunities may have been missed to stop the development of the disease. Many of them are also angry that rather than being told in an open and honest way about the results of a re-examination of their tests from former years, the truth was withheld from them.

I am very grateful to the women who have contacted me and told me their personal experiences and how let down they feel. It makes me even more determined to fulfil the terms of reference that you have set for this Scoping Inquiry. I, and those who are assisting me, will be sparing no effort to establish the reasons why the cervical screening programme, that does such good work and prevents so many women from developing cervical cancer, has encountered these serious problems.

In this progress report, I outline what we have done so far. I also make recommendations in respect of capturing the experiences and knowledge of the women involved and providing them with some assistance.

Alongside the progress report, and in keeping with the terms of reference, I am also pleased to provide you with an assessment of the information provided to women by CervicalCheck. I make recommendations that, I suggest, will help women increase their knowledge and understanding of the screening process and will, in addition, make clear their rights to have access to the information, which is after all about their own bodies, that is held in the screening system.

There is much work to be done by this Scoping Inquiry to meet all of the terms of reference we have been set. When we commenced the Inquiry, we were working towards the end of June for delivery of a Final Report, but the volume of work to be undertaken means that a more realistic completion date is the end of the summer. I can, however, assure you that we are making good progress towards our goals.

Gabriel Scally

1 Introduction

1.1 Establishment of the Scoping Inquiry / Terms of Reference

On the 8th May 2018, the Cabinet agreed to establish a Scoping Inquiry into the issues which had recently come to light in relation to the CervicalCheck screening programme and I was appointed to carry out the Scoping Inquiry. I was tasked with reporting to the Minister for Health pursuant to the following terms of reference:

a) examine the facts including details of:

   i) The non-disclosure of information to Ms. Phelan relating to a CervicalCheck standard case clinical audit carried out following her diagnosis of cervical cancer in July 2014;

   ii) The apparent widespread practice of non-disclosure to patients relating to CervicalCheck standard case clinical audits;

   iii) The management and level of knowledge of various parties including, but not limited to the HSE, the Department of Health or other public authorities and any relevant service provider of:

      1) the Vicky Phelan case

      2) any other cases concerning CervicalCheck

      3) issues related to the non-disclosure of the clinical audit results

   iv) The manner and means through which the relevant facts were shared, escalated, reported and communicated;

b) engage directly with Ms. Phelan and any other woman affected or her next of kin, who may wish to have an input;

c) examine all aspects of CervicalCheck;

d) examine the information provided by CervicalCheck to those receiving a service;

e) examine why the policy of open disclosure was not implemented by CervicalCheck;

f) examine the tendering, contracting, operation, conflict of interest arrangements, performance information and performance management, accreditation and quality assurance of contracted cytology laboratory services by CervicalCheck from initiation of the programme;

g) examine the other screening programmes operated by the National Screening Service particularly in relation to quality assurance and clinical audit, open disclosure and governance;

h) incorporate further elements if identified, including through engagement with stakeholders;

i) have flexibility to issue discrete reports or findings on particular matters if it is in a position to do so and provide a progress update in the first week of June;

j) report to the Minister for Health by the end of June 2018 setting out issues and recommendations to be addressed by means of a Commission of Investigation, which can take a modular approach, together with recommendations to address other issues by such other means as is considered appropriate.

1.2 Organisation of the Scoping Inquiry into Modules

Recognising the scale and complexity of the requirements set out within the terms of reference, we have chosen to divide our work into a series of modules, some of which may be produced as separate reports to be issued as our work progresses. These modules are expected to cover (but may not necessarily be confined to) the following issues:

- Module 1: Non-disclosure to patients relating to CervicalCheck standard case clinical audits and related matters;
- Module 2: The operational functioning of the CervicalCheck service, including clinical, scientific, management and administrative matters;
- Module 3: Governance issues associated with CervicalCheck, including the Department of Health, HSE, and other entities;
- Module 4: The tendering, contracting, and operation of the cytology laboratory services contracted by CervicalCheck, including accreditation and quality assurance.

1.3 Purpose of This Progress Report

This report constitutes the ‘progress update’ referred to in item (i) of the terms of reference; and also in keeping with item (i) of the terms of reference, I have provided a report and recommendations in respect of item (d) of the terms of reference concerning information provided to women participating in the CervicalCheck programme.

2 Arrangements for the Inquiry

2.1 Advisors

2.1.1 Overview

In order to undertake the Inquiry a number of advisors have been appointed to assist in the work programme and to carry out specific tasks relating to their professional expertise. A brief outline of their role and declarations of interest is provided here. Further information is available on the Inquiry website.

2.1.2 Dr Karin Denton

Dr Karin Denton is providing advice, as requested, on screening quality assurance. Dr Denton is a Consultant Cytopathologist at North Bristol NHS Trust and has had substantial involvement in the quality assurance of cervical screening programmes at a senior level in England.

2.1.3 Dr Hugh Annett

Dr Hugh Annett is providing advice, as requested, on quality assurance and clinical audit, open disclosure and governance in screening services other than cervical screening. Dr Annett is a former Director of Public Health in England and has wide international public health experience.

2.1.4 Professor Julia Verne

Professor Julia Verne is providing advice, as requested, on cancer registration. Professor Verne is a consultant in public health medicine and is currently Head of Clinical Epidemiology for Public Health England. She was previously head of the South West Public Health Observatory, with responsibility for cancer registration.

2.1.5 Mary Rose Gearty, S.C. and Emer Woodfull, B.L.

Ms. Gearty and **Ms. Woodfull** provided invaluable legal and practical advice at the outset of this Scoping Inquiry as to its remit, its priorities, and the powers and limitations of my role. They have been influential in shaping my approach to this work. Both have extensive legal experience but in particular in the field of investigative and quasi-judicial tasks and the relevant principles of law which apply to such work.

2.2 Support to the Inquiry

2.2.1 Crowe Horwath

Crowe Horwath is a professional advisory firm based in Dublin and part of the Crowe Horwath global network. They are providing logistical, project management, and analytical support to this Inquiry. Crowe Horwath are providing office and meeting space together with administrative support for the Inquiry.

3 Principal Activities

3.1 Overview

The Inquiry team has undertaken a number of key tasks to date, including establishing and managing communication with key individuals and organisations, notably with some of the women and families affected; requesting and reviewing relevant documentation; and engaging with some of those engaged currently or in the past in managing, or working, in the key organisations involved.

3.2 Communication

The terms of reference for the Inquiry included a clause, *b) engage directly with Ms. Phelan and any other woman affected or her next of kin, who may wish to have an input.* To date, communication with those affected has consisted of the following:

- Emails, phone calls, and meetings with women/families affected
- Creation of a website and dedicated email address for contacting the Inquiry

More than 20 women and/or family members affected by the issues have made contact with the Inquiry, either via the dedicated email address or by making contact with me directly. All those who have contacted the Inquiry have received an email or phone call in response.

An Inquiry website was created at www.scallyreview.ie This website includes information on:

- the terms of reference of the Scoping Inquiry;
- a Statement of Work;
- biographical details;
- a Declaration of Interests for each member of the project team;
- contact details for the Scoping Inquiry.

A dedicated email address was created to allow women/families affected to get in direct contact with the Inquiry scallyreview@crowehorwath.ie

A small number of women and family members have also met with me and further meetings are planned; however, as outlined in the recommendations, it is evident that a more extensive and sensitive engagement approach is required to be put in place for women and families directly affected by these events.

3.3 Requests for Information/Documentation

A key element of the Inquiry is the requirement to review documentation relating to the terms of reference.

To date, requests have been issued to the Department of Health, the HSE, the State Claims Agency and the National Cancer Registry of Ireland for a range of documentation, including in respect of the following:

- the case brought by Vicky Phelan and related cases;
- CervicalCheck's structure and operations, policies and procedures, and information dissemination to patients;
- the contracting out of cytology services by CervicalCheck;
- other cancer screening programmes;
- governance and communications involving the HSE, the Department of Health, and other relevant State agencies / interested parties.

In addition, we have been given documentation and information from women and family members affected, in relation to their own cases, such as clinical information, examples of communication between clinicians and the HSE, and legal advice.

The Inquiry team has sourced documentation available online such as published reports and other publicly available information of relevance to the terms of reference.

Much of the documentation requested has been provided to the Inquiry team only in recent days, i.e. between the 6th and 8th of June, and amounts to more than 4,000 items at the current count, with more expected. It has not been possible at the time of this progress report's production to assess to what extent the material provided meets the requirements of the Inquiry in respect of addressing the terms of reference.

It is evident, in addition, that a significant proportion of the documentation provided in electronic format comprises scanned documents from hard copy format, which renders them non-searchable and, in some cases, difficult to read. It is disappointing and unclear why documents that would originally have been prepared in electronic format (including some very recent documents) are not available to the Inquiry in that format, rather than as a scanned version of the printed copy. It is my intention to request that an explanation is given for this and where necessary to request that documentation be re-sent in searchable Word or pdf format that assists search functions and guarantees the integrity of the documentation.

The Inquiry team will continue to review the documentation received, note key findings and contribution to understanding of events from this material; and identify any further documentation required, which will then be requested as necessary.

3.4 Interviews with Key Individuals

Engagement with those who can provide relevant information to enable the Inquiry to fulfil the terms of reference has been and will continue to be a critical element of the work of the Inquiry team.

This engagement has included conducting face-to-face interviews with individuals in the health system including officials from the Department of Health and the HSE and others with current or former roles, who would have insight and information in respect of the events under review and the underlying issues.

As noted above, meetings have taken place with some of the women and family members directly affected by the CervicalCheck screening issues. This engagement will continue to form an important element of the work.

Interviews with officials and others in the health system have been noted and the information is being compiled to inform findings and recommendations. Interview discussions have given the Inquiry team direction in relation to particular documentation requests and the identification of other key individuals with useful contributions to make.

Continued engagement and interviews with key individuals will take place to inform the Inquiry and its reports, and this will be informed by the analysis of new information as it arrives with the Inquiry.

4 Report in Respect of Section (d) of the Terms of Reference

4.1 Information for Women

In the terms of reference for the Scoping Inquiry there is a clause that deals with the provision of information for women accessing the cervical screening service:

d. examine the information provided by CervicalCheck to those receiving a service

Cervical screening is an enormously valuable public health programme that saves the lives of very many women and it is vital that work continues to encourage a high level of participation in screening. Part of that process is the provision of information to women about the programme and it must, of course, highlight the positive benefits of participation. But, in addition, it must also communicate to women that there are limitations to the programme.

The Scoping Inquiry has examined this issue and our analysis is published alongside this progress report as the first of what may be a series of reports on particular issues. As a result of the consideration of the information for women, four recommendations are being made and it is right that they should be included in this progress report.

4.2 Recommendations for Action

In the report, I make four recommendations:

1. 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.
2. 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.
3. 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.
4. 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.

5 Recommendations and Next Steps

5.1 Review of Timescales

Since this Scoping Inquiry was commissioned, we have put significant effort into establishing the review team and making the necessary arrangements to undertake the tasks required by the terms of reference agreed with the Minister for Health.

Central to our work is the need to engage with the women and families directly affected by the problems associated with CervicalCheck. To date, we have been contacted by more than 20 women who are amongst the reported 209 women not informed by CervicalCheck in respect of clinical audits of previous cervical smear tests. It is important that we fully understand the depth and scale of how these problems have affected these women, and to that end we plan further engagement with the women and families over the coming weeks, on a national basis.

Working through all of the complex issues set out within the four modules described above (Section 1.2) will take time. Even though this is a Scoping Inquiry which may lead to a full statutory investigation involving consideration of the issues in much greater detail, there is nonetheless a clear requirement for us to examine the facts and present the information we have gathered in a manner which will facilitate any future statutory investigation.

As noted earlier, more than 4,000 documents have been supplied by the Department of Health, HSE, CervicalCheck, National Cancer Registry of Ireland, and other entities. The vast majority of these documents were received between 6th and 8th June, and we are expecting another substantial body of documentation within the coming days. Each one of these documents needs to be reviewed, its relevance to the terms of reference established, and its content noted and analysed.

We also expect to have further meetings and other engagement with officials within the Department of Health, HSE and other State agencies, and also with a range of interested parties including the cytology laboratory service providers.

Given the complexity of the issues emerging and the volume of work to be undertaken, **it will be necessary for the timescales involved in conducting the Scoping Inquiry to be extended until approximately the end of the summer**. This will provide the Inquiry team with the time and space required to consider a substantial body of information, to assess the facts pertaining to CervicalCheck, and to provide an informed report at the end of the summer which will help to get answers quickly for Irish women, whilst at the same time identifying issues that may merit a further full statutory investigation.

5.2 Supporting Women

From discussions with women affected it is clear than many of them are suffering from their illness and even those who have had effective treatment are suffering from the side effects of that treatment. In some cases, it has had a profound and destructive effect on their lives and wellbeing and on that of their families. Some women have been unable to work and support their families, and some find it difficult to afford the travel costs to attend meetings with doctors and access other services related to their illness. This has been amplified by the highly charged atmosphere in the public realm about the failings of CervicalCheck and, in far too many cases, the difficulties they continue to experience gaining access to information about their own case.

In the light of this exceptional and very difficult situation, it is incumbent on all parties to try and assist women as much as possible. I am aware that the HSE is offering a package of support. However, I would recommend that the Minister give urgent consideration to making a modest *ex gratia* payment available to each woman involved and to the next of kin of the deceased. At this stage it is important that women do not encounter any financial obstacles to participating and making their voices heard in relation to both this Scoping Inquiry and any resulting Commission of Inquiry. This would of course not be a bar to further payment in due course.

Recommendation

That the Minister of Health offer an immediate *ex gratia* payment to each woman affected and to the next of kin of the deceased.

5.3 Listening to Women's Voices

In the limited time since the initiation of the Scoping Inquiry, direct contact has been established with a significant number of women, and with relatives of some of those who are deceased. As they live all across the country, most of the conversations have taken place on the telephone. Some women have provided the Scoping Inquiry with written narratives of their experience of the screening programme. These telephone conversations and written accounts have been enormously valuable. Not only do they help our understanding of how women interact with CervicalCheck and the health service, but they provide important insights into how they have been treated by the system. Their accounts strengthen my resolve to ensure they receive the answers they want, and need, about screening and health services in the light of their own experience. This information is also of importance to every woman who avails of screening services in the State. Therefore, my team and I will continue to talk and meet with those affected throughout the course of this Scoping Inquiry.

It is very clear from the conversations and narratives, that each woman's account is unique and different. Of course, common themes emerge, but it is striking how important and insightful each woman's personal account of her own experience is. Details of the lived experiences of individual women whose lives have been so profoundly altered, in particular by their interactions with the health service, deserve to be captured and the lessons learnt.

It is not possible, because of the necessity to make progress on other aspects of the Scoping Inquiry within the time constraints imposed, to have all of these accounts documented in a form and with the thoroughness they so clearly deserve unless additional measures are taken enabling this to happen. Also, the accounts from these women, and of course from the relatives of those who have died, should be captured by trained personnel in an objective and consistent way.

Having read closely the report of the Inquiry by Mr. Justice Quirke into the Magdalene Laundries, it is clear that his recognition of distress and suffering was vitally important to those affected. The process of hearing and recording the views of the women in question, whose needs had been ignored for so long, was crucial to resolving serious issues that were outstanding for decades.

I am convinced that the voice of each and every woman affected by the serious defects in the cervical screening process needs to be heard. I believe that it will be invaluable to any future Commission of Inquiry that may follow. These accounts would also be valuable in the operation of any approach to dispute resolution that may be put in place as a result of its investigations.

It is also important to ensure that there is accountability for any failings that a future Commission may uncover, and I note such requests have already been made by bodies representing the women affected by these events. I believe that the accounts of the women affected will be invaluable to any Commission of Inquiry that may follow. These accounts will also provide guidance as to how the matter of compensation might be best addressed and will also be valuable in the operation of any approach to dispute resolution that may be put in place.

Recommendation

I therefore recommend that a process be commenced as soon as reasonably possible, to hold structured conversations with every woman affected who wishes to have her experience documented, and with the relevant surviving family member/s of any affected woman who has died if they so wish.

It will be necessary to identify, engage and provide adequate resources for, suitably qualified individuals who, with appropriate training and preparation, can engage in these conversations with a view to producing an account that reflects both the woman's experience of the cervical screening programme and the problems that they are currently experiencing. I am of the view that this is the most effective, sensitive and dignified option. Therefore, appropriate persons should meet and conduct the relevant conversations with the women as soon as possible.

The processes developed and utilised by Mr. Justice Quirke's commission should greatly help and guide this work. It is important that it is clear to all concerned that the focus is to be on the direct experiences of the women, their problems and current situation. In order to ensure the transparency and efficacy of the exercise I recommend that a small number of the women, or relatives of the deceased, should be invited to assist in oversight of the process.