DÁIL ÉIREANN

AN COMHCHOISTE UM SHLÁINTE

JOINT COMMITTEE ON HEALTH

Dé Céadaoin, 13 Feabhra 2019

Wednesday, 13 February 2019

The Joint Committee met at 9 a.m.

MEMBERS PRESENT:

Deputy Stephen S. Donnelly,	Senator Colm Burke,
Deputy Bernard J. Durkan,	Senator Keith Swanick.
Deputy Alan Kelly,	
Deputy Margaret Murphy O'Mahony,	
Deputy Kate O'Connell,	

In attendance: Deputies Colm Brophy, Jack Chambers and Bríd Smith and Senator Rose Conway-Walsh.

DEPUTY LOUISE O'REILLY IN THE CHAIR

The joint committee met in private session until 9.30 a.m.

CervicalCheck Screening Programme Update: Discussion

Vice Chairman: The purpose of this meeting is to engage with officials from the Department of Health and the HSE to discuss issues arising from the CervicalCheck programme. On behalf of the committee I welcome Mr. Jim Breslin, Secretary General of the Department of Health, and officials from the Department, Mr. Greg Dempsey, deputy secretary, Ms Tracey Conroy, assistant secretary, and Ms Celeste O'Callaghan, principal officer. I welcome Ms Anne O'Connor, interim director general of the HSE, Mr. Damien McCallion, national director of the national screening services, Dr. Peter McKenna, clinical director of the national women and infants health programme and Dr. Lorraine Doherty, clinical director of CervicalCheck.

I draw the attention of witnesses to the fact that by virtue of section 17(2)(*l*) of the Defamation Act 2009, witnesses are protected by absolute privilege in respect of the evidence they give to the joint committee. If, however, they are directed by it to cease giving evidence on a particular matter and continue to do so, they are entitled thereafter only to qualified privilege in respect of their evidence. They are directed that only evidence connected with the subject matter of these proceedings is to be given and asked to respect the parliamentary practice to the effect that, where possible, they should not criticise or make charges against any person or an entity by name or in such a way as to make him, her or it identifiable. I advise witnesses that any opening statements they make to the committee may be published on its website after the meeting.

Members are reminded of the long-standing parliamentary practice to the effect that they should not comment on, criticise or make charges against a person outside the House or an official either by name or in such a way as to make him or her identifiable.

I invite Mr. Breslin to make his opening statement.

Mr. Jim Breslin: I thank the committee for the opportunity to meet. I am joined by my colleagues, Mr. Greg Dempsey, deputy secretary of the governance and performance unit; Ms Tracey Conroy, assistant secretary of acute hospitals policy, and Ms Celeste O'Callaghan, principal officer of acute hospitals policy.

The issues relating to non-disclosure of the results of the retrospective CervicalCheck audit emerged in late April 2018. Since that time there has been considerable focus within the Department of Health and the HSE on the management and oversight of related operational challenges and strategic priorities and on the implementation of key Government decisions relating to CervicalCheck.

Resulting from the Government's desire to assist women and families affected by a lack of disclosure, the Government decided in May to provide a comprehensive package of health and social care supports for the cohort of 221 women and families for whom the audit carried out by CervicalCheck found discordance with the original reading of their slide or slides. The HSE has an established and stable process in place to ensure that these supports are being provided through designated liaison officers. In making its decision, the Government also decided that this comprehensive package of supports would be provided to any other woman for whom the independent clinical expert review being carried out by the Royal College of Obstetricians and

Gynaecologists identified discordance with her original smear test reading. In its invitation, the committee has referenced women not included in the 221, and I trust this clarifies the position in that regard. The HSE has recently completed a validation report on the status of the 221 group which has been shared with women and families within the group. It is intended that this report will assist in ensuring appropriate supports are provided to these women and families.

Also in May, the Government decided to establish a scoping inquiry led by Dr. Gabriel Scally. Dr. Scally's report sets out the impact of non-disclosure on the women and families affected by it as well as providing useful clarity on the limitations of screening and audit. He set out 50 recommendations aimed at addressing the shortcomings which he identified across a range of areas in screening.

In December, following Government approval, an implementation plan for all of the recommendations of the scoping inquiry was published on the website of the Department of Health. Some of the key elements include continuation of the current dedicated team within CervicalCheck to ensure access to medical records and slides; the inclusion of patient advocates on the HSE board; establishment of a national screening committee; actions to address recommendations on laboratory services and on procurement; the need for mandatory disclosure, which is addressed within the forthcoming patient safety Bill; establishment of an independent patient safety council, which will as its first action undertake a review of open disclosure policies; a number of actions to be led by the National Cancer Registry addressing data sharing, data definitions and collection of patient level details between it and the NSS, as well as governance; and establishment of an expert group within the HSE to review clinical audit processes across all cancer screening programmes, in which process patient advocates will be included.

I have referred to the independent clinical expert review which is being led by the Royal College of Obstetricians and Gynaecologists following a Government decision on 8 May 2018. Expertise for this review is also being sourced through the British Society for Colposcopy and Cervical Pathology. The review includes women who were part of the CervicalCheck audit and women who were not. Specifically, the scope of the review includes cases of invasive cervical cancer in Ireland since CervicalCheck was established, or approximately 3,000 cases, up to May 2018. These 3,000 cases includes the 1,482 cases which were notified to CervicalCheck since 2008. These women's screening histories were audited by CervicalCheck once it had been notified of their cancer diagnosis, and through that process the 221 were identified for whom there was discordance with their original results.

In addition to the cases notified to CervicalCheck, a further approximately 1,600 cases were not notified to, and therefore not audited by, CervicalCheck. Some of these women had been screened prior to diagnosis. The independent clinical expert review encompasses those women within the overall group of approximately 3,000 who were screened by the programme prior to diagnosis, or approximately 1,700 women who are currently contactable and comprehended by the review following a detailed validation process.

Where the expert panel's opinion of cytology results differs from the original results provided by CervicalCheck, the panel will endeavour to determine, wherever possible, any failures to prevent cancer or to intervene at an earlier stage and will prepare individual reports for those affected, setting out the facts and the panel's expert and independent assessment of those facts. The review will also produce an aggregated report which will be provided to the Minister and which is to include recommendations, where appropriate, with the aim of improving care for women.

A consent process has been undertaken over recent months, following an extensive process of validation of data. The HSE has advised that more than 1,070 women have consented to take part in the review. This is approximately 63%, which is a welcome level of uptake and will facilitate the production of a robust aggregated report. The expert review panel has been provided with colposcopy and other data from CervicalCheck in respect of women who have consented to participate, and the transfer of slides to the review laboratory has begun. The royal college has indicated a timeframe of at least six months to complete the review.

The Government agreed on 18 December to establish an independent statutory tribunal, chaired by Ms Justice Mary Irvine. Primary legislation will be required to establish the tribunal. Mr. Justice Meenan provided the Government with detailed recommendations on the establishment of the tribunal and the Department has been working intensively on the drafting of a general scheme. The required legislation is legally novel in providing for the determination of liability outside a traditional court setting. It is expected that the general scheme will be submitted to Government shortly for approval to draft the Bill. This Bill is a Government priority and is therefore included in the spring legislative programme. The Department is also working on the operational elements on the tribunal's establishment, including securing premises.

Separately, the Minister also confirmed in December that, in advance of the establishment of the tribunal, he would examine the early establishment of a non-statutory scheme to provide *ex gratia* payments to the women who were affected by the non-disclosure of results of the retrospective audit. The development of this draft scheme is in progress in the Department in advance of going to Government. The Department is aware that these are issues to which the utmost priority attaches, and it is working speedily to ensure their completion.

In his final report, Dr. Scally emphasised that continuation of cervical screening was of crucial importance. His report affirmed that the lifetime risk of a woman in Ireland getting cervical cancer was 1 in 135 in 2015, compared with 1 in 96 in 2007, representing a substantial improvement since the programme commenced. The HSE undertook detailed negotiations in the latter half of 2018 to extend the contracts of existing laboratory service providers to ensure continuation of screening. Dr. Scally also stated in his report that improved screening uptake, the new HPV testing regime, and the extension of the HPV vaccine to boys together create a realistic prospect of the virtual elimination of cervical cancer in Ireland in the coming decades. These are a key focus for the Department and the HSE in 2019. In parallel, and interlinked with these priorities, the management of current capacity issues remains a priority.

Vice Chairman: I thank Mr. Breslin. I invite Ms Anne O'Connor of the HSE to make her opening statement.

Ms Anne O'Connor: I thank the Chairman and members of the committee for the invitation to attend the committee meeting. I am joined by my colleagues, Mr. Damien McCallion, national director of screening services; Dr. Peter McKenna, clinical director of the women's and infants' programme; and Dr. Lorraine Doherty, clinical director from CervicalCheck.

Our focus continues to be on supporting women and their families who were impacted by the CervicalCheck crisis. We have continued to provide a wide range of supports in line with those agreed with the Department of Health. These have included the provision of 602 medical cards and the upgrading of eligibility for another 91 medical card holders, provision of access to a broad range of HSE and HSE-funded supports, and the reimbursement of €1.2 million in expenses and costs to those affected. In addition, we recently completed a detailed piece of work that updated the information on the group of 221 patients. This was done in conjunction

with the 221+ patient representative group and will help inform the provision of future supports for the group of 221 patients. We also continue to support women and their families in the provision of access to their records and ensuring women get their slides from laboratories where required for legal review. A new client services unit was established in our national screening service to support this process. A total of 109 out of 118 slide requests have been dealt with in 25 days on average, and there are only nine requests still being processed.

We continue to support the independent international expert panel review being undertaken by the Royal College of Obstetricians and Gynaecologists, RCOG, which was established by the Minister for women who were diagnosed with cervical cancer. The HSE supported the consent process which has seen 1,072 women or their next of kin consent to participation out of an eligible group of 1,702. This included establishing a national help desk, developing an eligible data set with the National Cancer Registry, and implementation of a client management system to support the RCOG. In recent weeks, the laboratories have commenced the transfer of slides. All slides have been transferred by the Coombe Women and Infants University Hospital. Quest Diagnostics and Sonic Healthcare have also commenced the transfer process with the imaging of slides for transfer, and a transfer schedule is being agreed this week with those laboratories.

We remain concerned at the length of time being taken to report cervical smears, which is on average at 93 days although it can take up to 27 weeks for the report to be provided. There is currently a backlog of approximately 78,000 slides. In 2018, around 370,000 women presented to the programme, which was an increase from 280,000 in 2017. This increase of approximately 90,000 was a result of the uptake of the out of cycle smear test and more women presenting to the programme, which would in normal circumstances be a positive step. We have worked with existing private providers, other private providers and public service providers in other countries to try to grow our laboratory capacity. Some of our existing providers have managed to reduce the wait times and we continue to work with others to try to find additional capacity. While we continue to pursue active leads, this has proved very challenging due to the global shortage in cytology. This has been caused as a result of the reduced cytology requirement as countries implement HPV primary screening which leads to a reduction of 80% for cytology requirements. We are actively trying to identify possible solutions that will help reduce the wait times which we know are causing a lot of anxiety for women.

As part of the laboratories' quality assurance process, we were also made aware of an issue with regard to HPV tests expiration at Quest Diagnostics. While the clinical risk was deemed very low, we have contacted all those affected and a number of women are being retested. These tests will be expedited by Quest Diagnostics to ensure a timely response for those women requiring a retest. A key risk to enabling cervical screening to continue in Ireland was the extension of the laboratory contracts.

The HSE has a signed agreement with one of the private providers and is working through the detail on a contract with the second provider with whom we have a heads of agreement. We also made a strategic decision to develop a national cervical screening laboratory in conjunction with the Coombe Woman and Infants University Hospital. This included an initial capital allocation of €5 million to progress the development of the laboratory. A project team and steering group has been put in place to oversee all aspects of this project. While this will take some time to develop, it will provide a better balance between public and private provision of laboratory services to the cervical screening programme.

The HSE is progressing plans to introduce HPV primary screening. A project team is in place and is progressing the various work streams. We have completed a review of interna-

tional HPV primary screening implementation, and ICT testing is under way. The development of education and training materials has commenced, and our procurement team has started the tender process for laboratory services, with a pre-tender market engagement session held before Christmas. We remain committed to implementing HPV primary screening as soon as possible.

The HSE has contributed significantly to the development of an implementation plan in collaboration with other State agencies in response to the Scally review recommendations. We have appointed a senior manager to oversee the implementation and established a HSE implementation oversight group, jointly chaired by our chief clinical officer and deputy director general for operations. We have developed a set of 94 actions arising from recommendations that are the responsibility of the HSE to implement. Examples of progress to date include key appointments and governance changes. An organisational review of risk management structures has also been commissioned by the HSE in addition to the establishment of an expert group within the national screening service to review clinical audit processes across all screening programmes. An interim revision of the HSE's open disclosure policy has commenced and will be communicated and implemented throughout the system pending a more detailed review during 2019. The HSE has also reviewed and updated its financial records management policy. All six recommendations from Dr. Scally's interim report have been fully implemented. The HSE has maintained open communication with patient representatives on the implementation plan and will continue to work collaboratively with them throughout 2019.

The HSE has continued to strengthen the governance and management of screening services. We have established an interim management team with the reassignment of senior people to key positions while we fill key positions on a permanent basis. We have recently appointed a director of public health, a CervicalCheck clinical director and a CervicalCheck laboratory quality assurance lead. In addition, a risk committee for our screening services, which is independently chaired, has been put in place since quarter 3 of 2018. An interim quality and risk manager was also appointed in quarter 3, and the implementation of Dr Scally's recommendations on strengthening our quality assurance processes has commenced. I assure members of the committee that the HSE is focused on stabilising the cervical screening programme to enable us to progress the introduction of a new enhanced HPV primary screening testing methodology. All possible resources are being directed at this challenge. My colleagues and I will endeavour to answer any questions from the committee.

Vice Chairman: I have one or two questions and then we will go to the members in order. Is that agreed? Agreed. My first question is on the offer of 28 April by the Minister of free repeat smear tests. We understand the climate at the time but I am more interested in the advice received by the Minister as to how wise the offer was. As the experts in the area, will the witnesses say who was advising the Minister before the offer was made? What discussions and consultations were held, specifically on the availability of resources? Clearly, we now have a backlog which can be traced in part to that announcement. What advice was the Minister given? From whom did he seek that advice? What information did he get and what resource provision was made in advance of the making of the announcement?

Mr. Jim Breslin: The source of the advice was officials in the Department of Health, including the chief medical officer. As the Vice Chairman said, the context was very much the anxiety among interested parties and on the part of concerned women who were ringing the helpline seeking clarity. There was a great deal of anxiety. There was undoubtedly a situation in which women who could afford to do so were going to present at their GPs while women who could not afford to do so might not. The Minister had, therefore, to make a rapid decision.

Negotiations on a fee took place with the IMO and the option to consult their GPs was provided to women. If, following a consultation, a woman and her family doctor decided to have a retest, that was paid for. That was the context. Officials were involved in the decision and provided the Minister with the advice I have outlined.

On the issue of resources, it is fair to say that in all of our discussions with the HSE during 2018 on foot of the CervicalCheck controversy, we were quick to put any resources in place that were required. Financial provision around the measures that had to be put in place to respond to the controversy was rapidly deployed and the HSE was in constant contact with us on costs, all of which were met over the course of 2018. The issue arising in this situation is not one of financial resources but of the ability to leverage additional capacity. The HSE can speak to the substantial amount of work it has done to increase the capacity of the screening programme. It continues to work in that regard, but there are constraints.

It was difficult to quantify when making the decision what the exact uptake of retests would be. We now know the level of uptake. The interest and anxiety around CervicalCheck continued for a protracted period which undoubtedly fed into that. It is worth noting that the finalisation of the Scally report allowed for clarity around the issue. However, the report took longer than was originally envisaged. There was a period while Dr. Scally was looking at the laboratories and doing his work when retests continued. As the Minister said in the House last week, he took further advice once the Scally report was completed. That advice led him to write to the HSE to say it was an appropriate time to bring retesting to an end. The HSE advised that while it would do so, the end of December should be the cut-off point as tests were scheduled into that month for women. That has now taken place.

Vice Chairman: According to media reports at the weekend, senior people in the HSE advised against this. Is that accurate? Did anyone in the HSE advise? There are people from the HSE here in person who may be able to answer.

Mr. Jim Breslin: I do not think that in the timeline in which the Minister made the decision, he received advice against it. Subsequently, over a longer period, different views have emerged. Some of the people who had a view at the time the decision was made changed that view subsequently. At the time, the Minister made the decision based on the advice available to him. He did not have advice to the contrary.

Vice Chairman: There was no advice in advance that this was not a good idea or that the resources might not be there.

Mr. Jim Breslin: It is my understanding that the Minister did not have contrary advice in advance of that decision.

Vice Chairman: There was none at all.

Mr. Jim Breslin: None at all.

Vice Chairman: Do the representatives from the HSE have any comment on this issue?

Ms Anne O'Connor: The Minister was not given any advice on this from the HSE.

Vice Chairman: That is contradicted by reports in the media at the weekend. Nonetheless, I am sure we will get to the bottom of this issue at some point. I accept it could not have been known what the precise number was going to be, but it would have been known there was going

to be an increase. Were any provisions made in advance to deal with that increase? When we examine this, it does not seem as if research was done, information sought or provisions put in place for the necessary increase in resources. I fully respect that the precise number could not have been known, but it was definitely known that there was going to be an increase.

That could have been known just from taking the so-called Jade Goody effect into account. Raising the profile was going to do two things. It was going to ensure that women who had concerns wee going to come back, and that would have been evident from the helpline. It also meant that women who had not previously presented for a smear test were also going to take up the offer. It does not seem that work was done in advance to ensure there was additional provision, and that has led to this backlog. That is why many people are angry. Mr. Breslin stated the Minister received advice from the Chief Medical Officer etc. but was anybody working on ensuring there was additional capacity?

Mr. Jim Breslin: The programme itself, how it is organised and its ability to increase capacity must be examined. The HSE can speak on that aspect. The contracts are not budget limited. We do not state to the HSE that there will only be a certain number of screens. The laboratories screen based on the tests taken. The reality, however, and this is relevant to where we are now, is the capacity of those laboratories to expand the numbers of screens is limited based on their ability to get the human resources to do so. The HSE would have been liaising, as it does as part of the normal programme, with the laboratories to try to scale up that testing. Significant issues have been encountered, however, in doing that in a situation where there are very significant constraints globally-----

Vice Chairman: The global situation aside, what was done before the offer was made on 28 April?

Mr. Jim Breslin: There was clarity that this would lead to more screenings having to be performed but it was not possible to predict a specific number for that increase.

Vice Chairman: I am sorry Mr. Breslin, but that is not making any sense to me. What clarity was there?

Mr. Jim Breslin: In making the decision-----

Vice Chairman: It is a fairly plain question. The Minster made an offer on 28 April that any woman who wanted could have a free retest. Did anyone do anything to ensure there was additional capacity, however that was purchased, in advance of that offer being made? Was it the case that the offer was made and then the backlog started to build up? I am speaking about the period before the 28 April.

Mr. Jim Breslin: Having lived through this, we are looking back on it in a way that was not how the real time chronology of events took place. We all lived through that. We are all sitting here now having been part of a discussion on the need for the programme to respond to public anxiety. The Minister was being pressed to make a call on that. People, including Members of the House, were calling for him to do that, phone calls to the helpline were calling for him to do that, and officials worked with him to try to make the best decision possible in that situation. That decision was made in hours and days, and not in weeks. If the Vice Chairman is asking me if a full capacity analysis was performed, if there was a full review of all of the capacity and the global potential to increase that, the answer is that there was not. There was a worthwhile and honourable desire to try to respond to the anxiety existing.

Some of that anxiety was based on misinformation and information that was not accurate. It was only when we got the Scally report that clarity was brought to the underlying issues. I lived through that period and I did not have the ability to go off and do a capacity study for weeks on end to try to come up with what the right number of retests was going to be. That was not the problem we were faced with. We were faced with a demand to make a decision because women were going to present to their general practitioner, GP, on Monday and Tuesday of the following week and the Government had to have a policy on whether that was going to be financed. That was how the decision was made.

Vice Chairman: That has answered my question anyway. As we are sitting here today, does Mr. Breslin know where all of the smear tests are going? An issue was raised about the re-outsourcing of the outsourcing and the re-outsourcing of that.

Mr. Damien McCallion: I will answer that question. In respect of the historical context concerning the laboratories, Dr. Scally is looking at those that were identified. Regarding the current laboratories, we have got assurances from those we are working with today. Where additional laboratories have been introduced, that has been through a formal approval and quality assurance process. We are confident about knowing the laboratories where the slides are going now.

Vice Chairman: Was that assurance given in writing?

Mr. Damien McCallion: Yes, that assurance was given in both verbal and-----

Vice Chairman: Will Mr. McCallion share that documentation with the committee?

Mr. Damien McCallion: I can certainly seek the documentation that is there.

Vice Chairman: I do not think there is anything in the documentation that this committee cannot have. It would be good if Mr. McCallion could share what exists with us. I thank Mr. McCallion. I have two more questions before we move on. In her statement, Ms O'Connor mentioned that a set of 94 actions have been developed arising from the recommendations of the Scally report. The examples of progress have been listed. Will she give us some examples of where progress is not being made and outline what the issues are in those cases?

Ms Anne O'Connor: Mr. McCallion can speak to the detail, but at a high level we have 94 actions. Of those, 29 are completed and 53 are in progress. We are only overdue in respect of one action being finished. Those are all of the actions set out that have formed part of the overall and overarching implementation plan with colleagues in the Department of Health and others. We have had wins in the areas of governance and appointments. Those have been critical to the continuity of the programme. I ask Mr. McCallion to speak about what we have not achieved.

Vice Chairman: I am sorry, but Ms O'Connor stated that 54 of the actions are in train-----.

Ms Anne O'Connor: There are 53 actions under way.

Vice Chairman: There are 53 actions in train and 29 are completed. Does that leave 22 not done? I am not brilliant at mathematics.

Ms Anne O'Connor: No. Nine of the actions are not due to start yet, two are overdue to start and one is overdue to finish.

Vice Chairman: That is a total of 13. Where are we missing some of the actions?

Mr. Damien McCallion: I will quickly recap. There are 53 actions in progress, one is overdue to finish, nine are not due to start yet, two are overdue to start and 29 completed. That should be 94 in total.

Vice Chairman: That is fine. That explains that.

Mr. Damien McCallion: On progress, in fairness we are only in the first quarter. Quarter four was the first quarter where actions were being undertaken. Dr. Scally has just done an initial review of the implementation plan and will be producing a report. Nothing at the moment is giving us concern regarding what is there and we have had discussions with Dr. Scally. Quarter one of this year is a key quarter where many of the actions are due to commence. The bulk of the actions are intended to be done in 2019.

Vice Chairman: I thank Mr. McCallion. My final question is on Ms O'Connor's statement. She said the HSE continues to support women and their families in the provision of access to their records and in ensuring women get their slides from the laboratories where they are required for legal review. How many of those are outstanding?

Ms Anne O'Connor: There are nine outstanding. We had a significant increase in requests around 14 January and nine of those are still outstanding.

Vice Chairman: Is there a timeline for those outstanding?

Mr. Damien McCallion: Of the nine left, one is from December and the balance are from either 14 or 31 January. We have a process where we review the situation with the labs each week. Of those outstanding, five or six are with Quest, two with Sonic and one with the Coombe. We go through those every week to get them accelerated and keep them moving. It is largely between the laboratory and the legal representative of the woman or her family.

Vice Chairman: All of the women concerned know that is in place.

Mr. Damien McCallion: They do. We link through their solicitors in respect of where that process is at. That is the mechanism. If a woman herself seeks it, and women have made requests, we will contact her directly, where that is requested. When we met the patient group recently, some women had enquires about their slides and we arranged to give them a personal call.

Vice Chairman: Those nine that are outstanding are in train.

Mr. Damien McCallion: Yes, and we are confident they will be turned around.

Vice Chairman: I call Deputy Donnelly.

Deputy Stephen S. Donnelly: I thank the witnesses for their time today and for the opening statements. The HPV test was spoken of with much interest last year. It represents a higher level of detection and, therefore, patient safety. The Minister sought to have the HPV test implemented last September. When that deadline was missed, I believe the Minister suggested having it live in January. It is now February. I note Ms O'Connor spoke of progress but the language she used was "as soon as possible". When does she expect the HPV test to be live and available to women in Ireland?

Ms Anne O'Connor: I cannot put a date on it. Our priority is to address the capacity challenges and set a date. I could pick one, but we must place it in the context of the work under way. Mr. McCallion can give the details of the very extensive work that is ongoing, but we are caught between addressing the current cytology challenges and trying to progress the HPV test. We must, first, sort out the current situation, address the issue of capacity and the backlog and move to the new model. If Mr. McCallion wishes to add to that-----

Deputy Stephen S. Donnelly: Does the HSE have a project plan in place? Does it, at least, have a target date for when it is hoped to go live?

Mr. Damien McCallion: There is a project scheduled. Ms O'Connor has mentioned that there are a couple of challenges in that regard, one of which is that we must eliminate the backlog as one must have a stable operating environment to bring forward a new test. The second challenge is that we will need to tender. We have started the tender process to find a partner to work with us. We had what is called pre-tender market engagement before Christmas. Our environment is somewhat challenging in securing a partner to work with us. As there is a real risk, we have selected a procurement method that will allow us to negotiate and give us more flexibility in trying to ensure we will secure a partner. We do not want to go the market, issue a tender and discover at the end that we do not have a partner which would then set the process back even further. The next stage is that we will place an advertisement in the next two weeks to seek that partner. That will allow us to get into what is called the competitive dialogue process. There are reasons we are reluctant to set a date. Until we hear what that partner says it can do and provide within a timeframe, we cannot set an absolute date.

Deputy Stephen S. Donnelly: On that point, does the HSE at least have a project plan?

Mr. Damien McCallion: We do.

Deputy Stephen S. Donnelly: I appreciate and accept that Mr. McCallion is not willing to say the HSE can guarantee that the test will be live by a certain date. I just want to understand whether it is at least working to a target date.

Mr. Damien McCallion: We have eight work streams in total for the project plan which include the procurement site, the laboratory reconfiguration, education and communication and training materials for health professionals. They are all being monitored weekly by the team. We have a dedicated team working on the project because, obviously, there are many other pressures on the programme. As for an end date, there is quite a variation, depending on what the private partner can supply. If it is an existing partner, it will be able to switch on more quickly, but if it is a new one, it could take longer. Our aim, therefore, is to have all of the other steps completed as quickly as possible in order that we can minimise the critical path in getting to the end point with an absolute end date. As Ms O'Connor said, our objective is to get there as quickly as possible. Until we get into that competitive dialogue, we will not really know what the lead time is when it comes to getting the partner over the line. It could be three, six or nine months. One important point in tandem with this is that we have made a decision to rebalance public-private provision in the programme. We are developing a national cervical screening laboratory at the Coombe hospital. It will still only involve a limited increase. Currently, the figure for the Coombe hospital is about 9%, before the end of this year; therefore, i will take time to develop. We are still very reliant on securing a partner to help us to deliver a HPV primary screening programme.

Deputy Stephen S. Donnelly: Is it possible that the HPV test will not be live in 2019?

Mr. Damien McCallion: The Deputy will appreciate that I do not want to get into speculation, whether negatively or positively. We are focused on trying to have it introduced as quickly as possible. We have a detailed plan, but the critical path is ensuring we will have a partner and understanding what it can deliver within the timeframes. Speculation would be unhelpful in that regard, accepting that we all want to get there as quickly as we can.

Deputy Stephen S. Donnelly: There is no guarantee, based on all of these issues, that the test will be live this year.

Mr. Damien McCallion: We cannot give an absolute guarantee, but clearly we are committed to having it introduced as quickly as possible. We have tried to isolate and secure additional resources with expertise that can help to guide us. For example, we recently appointed someone in the area of senior laboratory quality assurance, one of the areas Dr. Scally identified, in which we did not have pathology expertise. The man appointed had experience in Wales where he led on its programme and was involved on the laboratory side for eight years. It has been challenging to secure resources and expertise-----

Deputy Stephen S. Donnelly: I appreciate that.

Mr. Damien McCallion: -----but doing so has helped us to move on.

Deputy Stephen S. Donnelly: This might be a question for Mr. Breslin. Given the complexity - I absolutely accept the delegates' bona fides in saying they are trying to get this across the line as quickly as possible - the Minister set expectations in May or June last year, or whenever it was, when he said in the Chamber that he was aiming to have the HPV test go live in September 2018. We are hearing there is no guarantee, in spite of best efforts, that it will be live in 2019. In making the statement that he was aiming to have the HPV test in place by September of last year did the Minister seek advice and the detail about which we are now hearing of the difficulties experienced in going live?

Mr. Jim Breslin: We went into 2018 with a certain view of the screening programme, a policy objective to introduce the HPV test, a funding agreement for how we would do it and so on, but the world changed during the course of April and May 2018. What Mr. McCallion outlined has whole layers to it in terms of the capacity of the programme, the personnel within it, the multiple challenges they were facing daily and weekly, the need to solidify the programme and recruit under it to bring in new expertise and new personnel and put new processes in place. All of this undoubtedly has had implications for what this time last year would have been a steady state, go forward approach to move the programme from one test to another.

Deputy Stephen S. Donnelly: I accept all of that, but the question I am asking is at a political level. The Minister did not make a commitment, but he did raise the issue. He said he would try to bring forward the test in September. This set expectations among women all over the country. I cannot remember the date, but I imagine that the announcement was made around June last year. Did the Minister seek advice on how feasible it would be to go live in September, given that we are now hearing that owing to the complexities involved, it might not even go live in this calendar year?

Mr. Jim Breslin: In truth, that was happening on an ongoing basis and the position was changing by the week. The challenges the programme was facing were changing by the week. The potential work involved in dealing with factors other than the HPV test was changing by the week. There was an ongoing flow as the crisis - it was a crisis - evolved to take stock of

where we were and what it meant for the HPV test. This and the backlog have changed as we have moved along.

Deputy Stephen S. Donnelly: I appreciate that. I am just looking for a specific answer as the Minister made a public and very relevant announcement. Did he seek advice before making it?

Mr. Jim Breslin: Yes.

Deputy Stephen S. Donnelly: Was the advice that it might be possible to go live in September?

Mr. Jim Breslin: I think the Minister's announcement and his view on what would be possible were overtaken by events. He had received advice and had contact via officials in the HSE, but they were overtaken by events. We had plans in place at the start of the year which did not bear reality once the crisis took off. It is not that the Minister did not have advice but that the advice was overtaken by reality.

Deputy Stephen S. Donnelly: At the time of the announcement was the advice that it would be possible to go live in September?

Mr. Jim Breslin: I think it was the Minister's and our best hope that it would be possible to do so, but, in reality, that has not emerged as achievable.

Deputy Stephen S. Donnelly: Was the Minister given advice either way on whether it would be feasible?

Mr. Jim Breslin: As I said, I think the advice was based on the *status quo*, on the position that then obtained. It is not that the Minister did not have advice. He had advice-----

Deputy Stephen S. Donnelly: I am just asking what it was. Was it, "Minister, it is unlikely that you will be able to go live in September", or-----

Mr. Jim Breslin: No. The initial plan that would have been in place informed his position. It was in his and everyone else's interests to try to do it as quickly as possible. What was not as obvious at the time was that that plan would have to be torn up and rewritten because the challenges facing the programme were going to overwhelm the ability to deliver on it.

Deputy Stephen S. Donnelly: I move to the backlog of 78,000. Obviously, it is a source of serious concern for women around Ireland who are facing the delays. In his report Dr. Scally said that for every 1,000 tests, 15 women would be identified as having precancerous abnormalities. A backlog of 78,000 suggests approximately 1,200 women within that cohort will be or have been identified as having precancerous abnormalities and either have not yet been tested or have been and have not yet received the results of the tests.

I will ask two questions about the delays. My understanding is they differ throughout the country. There may be different priorities for different cohorts. Perhaps women who are at higher risk are identified and fast-tracked. My first question is as follows. Will the delegates tell the committee about the level of the delays? Where are things going well? Where are they not going well? Are there delays of six months or more?

Critically, my second question is, given that approximately 1,200 women within this backlog are likely to be identified as having pre-cancerous abnormalities, is there any clinical risk

associated with, say, a woman who has been identified as having an abnormality, be it low-grade or high-grade, and a potential wait of six months for her doctor and herself to get those results?

Vice Chairman: I am going to get everyone to stick as close as possible to the ten-minute time slot. That, therefore, will be the Deputy's last question.

Deputy Stephen S. Donnelly: Yes. I will finish on that question.

Mr. Damien McCallion: I will answer the Deputy's first question and I will ask my colleague Dr. McKenna to speak on the clinical risk element. Regarding the backlog, while there is some variation between laboratories in terms of what is there, we have prioritised colposcopy, which is the highest risk group, across the laboratories, and clear instructions and guidance were given on that. In addition, where one of the laboratories had pressure, we authorised what is called co-testing, where we ran the HPV test first, which allowed us to triage and ensure we were taking out the smears that have the highest risk. They are mitigation steps we have taken to try to reduce that risk.

The other group is women who are on short recalls. Deputy Kelly asked this question previously. We are working through trying to find the technology solution that might help to accelerate those. We do not have that at the moment but we believe we will be able to do something around that. We have tried to mitigate the at-risk groups as best we can within the context of how the programme functions to minimise that risk Deputy Donnelly has described in terms of what is there. Those steps are in place and functioning.

I will ask my colleague, Dr. McKenna, to respond to the other point the Deputy made regarding the development of cervical cancer.

Dr. Peter McKenna: We all share the concern that a waiting time in excess of a couple of months is far from ideal. It is probably true that the women who came for the reassuring test out of sequence probably have a lower incidence of abnormality than those who have waited five years for their smear. However, having said that, of course, women in that group, in the 80,000, will have abnormal smears. As I have said here previously, the natural history of cervical cancer is that there is a lead-in time of ten to 15 years. Most of those women who have abnormal smears will be a long way from developing cervical cancer but there will inevitably be some women who are nearer the stage of transitioning from pre-invasive to invasive. It is not possible to give an estimate of the number. It would be foolhardy to say there is no risk but, in general, the risk is low.

Deputy Stephen S. Donnelly: Can I ask a further follow-up question on that topic?

Vice Chairman: Yes, but the Deputy should keep it short.

Deputy Stephen S. Donnelly: I thank the witnesses for those responses. The concern people have raised with me is exactly what Dr. McKenna has identified, namely, that if they are beyond the point of the very first testing where there is a lead-in time, a delay of six months should not make that much difference because it might be ten years before it develops and there is plenty of time for intervention and treatment. Could he speak about the potential clinical risk for women where abnormalities have been detected beyond where, ideally, they should be? Is there a risk? The question I am being asked is whether there is a risk if treatment is delayed for some women to the extent of a four, five or six-month wait.

Dr. Peter McKenna: For the vast majority of women, the treatment will be the same in six

months time as it would have been if the smear had been reported now.

Deputy Stephen S. Donnelly: I thank Dr. McKenna for that..

Vice Chairman: I am going to try to keep everyone to the ten-minute time slot. I fully respect that Deputies Donnelly and I have not started well on that score but we will get back on track with Deputy Kelly.

Deputy Alan Kelly: Not with me the Vice Chairman will not.

Vice Chairman: I am in the Chair, Deputy, so we will see. I ask him to try to be brief because I am conscious we have to hear from Deputies Kelly, Senator Burke, Deputy Murphy O'Mahony and Durkan and Senator Swanick and that is before we move on to the non-committee members.

Deputy Alan Kelly: The ball was there, I had to hit it.

I will follow on from Deputy Donnelly's questions, and he has probably saved me some time because this is the issue I have been raising for some time and, in fairness to Mr. McCallion, I asked this question a number of months ago and he was very honest in his answer. Mr. McCallion told me that, essentially, there was no way to reprioritise or to distinguish totally in this respect. The delay is now 27 weeks. It was 24 weeks, and we were told by the Minister it had gone down to 22 weeks, but now it back up to 27 weeks. Dr. McKenna might explain why that is the case?

With short recalls versus routine smears versus those who are going for reassurance tests, the issue of the prioritisation of women is a concern. Let us be responsible about this. I agree with Dr. McKenna that when it is broken down, there is a low risk but there is a risk and it is accentuated for a small number of women because of the 27-week delay given they are further along the path and the transition from non-invasive to invasive. It is at the critical juncture. If one is caught in that 27-week delay because one is at that point of going from one stage to the other, that is a problem. There is no point in saying otherwise; it is an issue. It is a consequence of decision-making and all of that. I am not apportioning blame; that is not what I am getting at, but there is a concern in terms of how rapidly the delay is tackled because it creates risk. I have been told of cases of women who are probably at the point where they are moving from one stage to the other and this delay has now pushed on their diagnosis after having had a smear test. There is a concern about the impact of this disease on their health and the risk. The consequence for their health is worse because of this. I accept it is low risk. What I have outlined with respect to a small number of cases is possible, is it not?

Dr. Peter McKenna: There is nothing the Deputy has said with which I could disagree.

Deputy Alan Kelly: I am not apportioning blame but I have details of people who are affected in this way and they do not know their outcomes yet. We wish them the best but there is no doubt that what I outlined is how they ended up where they are. I hope it does not give rise to a range - it would be a smaller number of cases - of other issues for women's health.

Mr. Jim Breslin: A key performance parameter of a screening programme is to have an acceptable period within which the tests are read and so on. Some of us have the grey hair to have been around before CervicalCheck was introduced and we had-----

Deputy Alan Kelly: If Mr. Breslin did not get grey hair in the past few weeks, he will never

get it.

Mr. Jim Breslin: We had six, nine, 12-month delays of totally undifferentiated tests. Some people were coming every year and some people were not coming at all.

Deputy Alan Kelly: I understand.

Mr. Jim Breslin: The great contribution of the screening programme, as seen in the mortality reductions, was to address that on a systematic basis. We have to get the system back to the timeliness of that.

Deputy Alan Kelly: I agree. That was my main question and I want to follow-on from Deputy Donnelly's questions. I wanted Dr. McKenna to confirm what I was saying.

I have another few brief questions. I have a deep concern that Dr. Scally's initial report on the laboratories is not accurate. Has Mr. Breslin any information on the outsourcing being worse than what was reported? We know from Dr. Scally's report that there were contracts which were not managed. Let us call a spade a spade. We all know they were not managed. There was no quality control in place. We now know from the report that as the HSE issued a contract, it was not aware that it was being outsourced again. On the scale of the outsourcing to contracted laboratories and perhaps one or two uncontracted ones, is it true that there was much more of it than was reported in Dr. Scally's report?

Mr. Jim Breslin: As the Deputy will be aware - and I am not adding anything to his knowledge in saying this - having completed his report, the Minister requested Dr. Scally to do a further detailed report on the laboratories. I believe that is due imminently. There will be findings in that around the extent of the issue that the Deputy has raised.

Deputy Alan Kelly: I do not believe I am inaccurate in what I said. Am I?

Mr. Jim Breslin: The likelihood is that further laboratories were involved in this. I believe Dr. Scally will go beyond that in trying to establish what the terms of that were, what the quality assurance arrangements were and so on. The very fact it has taken place is of concern but we would be equally interested in when that happened, in what context, for how long it happened for and what the quality insurance-----

Deputy Alan Kelly: When will that report be issued?

Mr. Jim Breslin: I am told it is imminent.

Deputy Alan Kelly: Will it be this week?

Mr. Jim Breslin: Potentially this week, but it will go to Government, and the Minister has undertaken to share it with the women as well.

Deputy Alan Kelly: Is it not incredible that in the initial process this was not found out? He had to dig a lot deeper to get an admission that the contracts that had been signed with these laboratories had, in turn, a whole range of arrangements in place to outsource to other laboratories, which for God knows how many years, no one had any clue about. Quality control was out the window.

Mr. Jim Breslin: Oversight is an issue.

Deputy Alan Kelly: That is an understatement.

Mr. Jim Breslin: The piece of work he is doing is also the quality assurance within the laboratories and it is important that that is satisfied. He identified in his report that this was an area he wanted to look further into. I completely agree that it is important that he has done that.

Deputy Alan Kelly: A couple of weeks ago, those of us who have gone into the detail of this noticed the differentiation between the 6,000 women who got the letters about having to re-scanned - that is a secondary test as Dr. McKenna pointed out previously and is quite a low risk-----

Dr. Peter McKenna: It is extremely low.

Deputy Alan Kelly: I should have said that it is extremely low. Then there are the 1,000 women who have experienced delays where the normal percentages obtain, but the delay is the concern.

I am not apportioning blame but the way the differentiation between these two sets of women was communicated on the one day was a complete disaster. I do not know what went on. I ended up doing a public service duty by going on national and local radio stations to talk about the differentiation and to say that a very low risk attached to 6,000. It is just an observation but what happened was a disaster. There was a mix-up somewhere along the line, which caused unnecessary confusion that we did not need. On this topic of all topics, we do not need additional confusion.

Mr. Jim Breslin: I take on board what the Deputy is saying with one proviso because the man is here. Dr. McKenna did us all a great service following the-----

Deputy Alan Kelly: I agree. I was following his lead and doing that myself, I have to be honest. The initial communication, in whatever way it went out, just did not work.

On the Royal College of Obstetricians and Gynaecologists, RCOG, review, can we be given a guarantee that it will be done? This was meant to be done by May. Obviously, it was absolutely insane to think Dr. Scally was going to report in the timeframe given to him and that the RCOG review was going to be done by May. Can we get a confirmation that the RCOG review will even be done within six months?

Mr. Jim Breslin: As the Deputy knows, RCOG is independent-----

Deputy Alan Kelly: I know exactly what is.

Mr. Jim Breslin: It has said it will take it six months to do it. The fact the slides are flowing to the laboratories to be reviewed will allow us to do that.

Deputy Alan Kelly: The fact of the matter is that women are getting their slides reviewed independently. The RCOG review was never realistic in its targets or timelines. I am glad Mr. Breslin is saying it will be done within six months. On day 15 in the High Court, Ruth Morrisey's case is proceeding. This is a very sensitive matter. The fact this woman is having to go through what she is having to go through with a terminal diagnosis is scandalous. Mr. Justice Meenan's report set up the tribunal. The Taoiseach made commitments on the "Six One News" and to Vicky Phelan in face-to-face meetings. I am being kind in saying that those commitments were not accurate or realistic.

As I understand it, this legislation is highly complex. It is the first time that such legislation has been drafted to set up such a tribunal. There is Brexit and other priorities of Government.

Yesterday a judge in the High Court said he is going to have to start doing two cases a day, one before lunch and one after lunch, because there is such a backlog and there is not enough court space and there are not enough judges. It is scandalous that these women and their families are having to go through this. Is priority being given to this legislation in order that we can get this up and running as soon as possible to prevent these women having to go through the court and that the Oireachtas can provide this tribunal in order that we can do our bit to honour what the Taoiseach did not do?

Mr. Jim Breslin: There is an absolute priority attaching to getting this done. I reassure the committee that the resources are being provided and that people who are working on this are not working on Brexit. The Government has said that everything has to go on hold for Brexit except for this. This is in the spring legislative programme. We have a draft general scheme and that will be finalised and brought to Government. There is a question for the committee. I believe the draft will be faithful to Mr. Justice Meenan's recommendations. There is a question for the committee as to the amount of scrutiny that the general scheme should receive. In my view, we could save some time by moving directly to the draft Bill, and bringing it through the House.

Deputy Alan Kelly: I think the committee would consider that if it helped to speed the process up.

I have been approached by a number of women who are not part of the 221 group but are in exactly the same category. For different reasons, they are in a different cohort. They are part of the cancer registry cohort which comes across. They are essentially in the same category as the 221 women. I have asked the Minister for Health, Deputy Harris, about this and I want the Department to look at criteria in order to bring them in so that they will fit under the same scheme as the 221 women as to the allowances they receive, such as medical cards, potential access, if necessary, to drugs, etc. A way will have to be found because it is not fair. They come under the cancer registry cohort and they have been let down in a similar way, it is just that they have come through a different channel. We are not talking about a huge number here but a very small number. I have already given cases to the Minister, and I gave him one particular case recently. I am asking the Department to consider this because these women deserve the same opportunities as those who happen to come in under the 221.

When it comes to the provision of the women's slides and the delays in returning the slides to them, there has always been a problem here. The timelines have kept moving. What is the status of that now and of those who are still suffering long delays? In some cases, the slides came back relatively quickly. Why is there such a differentiation between some women getting them back quickly and some others not? Why is this continuing?

Mr. Damien McCallion: I will take the slides question first. I think I provided a report to the Committee of Public Accounts, or possibly to one of the other committees as to the position. There were a number of requests subsequent to that committee meeting. As was said earlier, of the 118 requests, 109 have been released. There has been variation between laboratories and the Deputy is correct in that regard. In the early days there was significant variation. We have a full-time client services team that works with the laboratories and the solicitors involved to try to get the slides out as quickly as possible. Of the balance of nine, one of those was in December, one was at the end of November and the balance were on 14 and 31 of January. We are working those through. Effectively we are turning these around very quickly. There were delays in the very early stages.

Deputy Alan Kelly: What is the average time now?

Mr. Damien McCallion: The average time is around 25 days, if I recall correctly. I can confirm that formally in writing as I do not want to mislead the committee but it is of that order. What is important is that there was huge variation initially. Some women had to wait an inordinate amount of time. We had to put a whole team together. We never had this process before. All the debate then took place on getting a protocol which would ensure that the slide was protected and imaged appropriately.

There are a number of other requests outside of that that are to do with the pre-cancerous screening programme in some of the hospitals that were running cervical screening prior to that. We are trying to work with the solicitors. There are quite a number of those in two hospitals. They are a separate cohort we are trying to work through.

Mr. Jim Breslin: On the women who have cervical cancer and who are not in the 221 group, and Mr. McCallion may wish to add to this, as I set out in my opening statement, some of them will never have been screened and some of them will but they all have cervical cancer. In fairness to the Deputy, he was very active in highlighting that. The most pressing issue was probably access to the drug Pembro with which there was an issue. We have put in place a situation with the HSE where, based on a clinical judgment taken with an individual clinician, there is a route now. If that is decided as the best pathway for a woman, there is a means to address that. I believe that is progress.

Deputy Alan Kelly: I thank Mr. Breslin for that.

Mr. Jim Breslin: I would say in general, and it is part of our cancer strategy, that there is much greater understanding now of the holistic issues that arise for somebody who has cancer. I refer to the psychosocial supports that are needed in that situation. It is core to the cancer strategy that we build not just a clinically excellent cancer service but one that is patient centred. The patient advocates who are working with us on the cancer strategy are very much to the fore in identifying issues. Through the work of the liaison officers and the interaction with the women, the 221 group, we have now a very rich understanding of the range of issues that arise and we would look to try to address those.

The final point I would make is that, through the Royal College of Obstetricians and Gynaecologists, RCOG, process, we have identified that if a discordance arises, and it is in my opening statement, they would be eligible for the same package of supports. However, I would like to see us being able to say, across the entirety of our cancer services, and we have good models on different disease types where a wraparound support is put in place, that that is the standard of care and people can avail of that as part of a mainstream service. Mr. McCallion may wish to talk in more detail on it but our overall objective would be that we would move ahead on that basis.

Ms Anne O'Connor: May I make one observation on that? By far and above the biggest request from the most significant number of people has been from those who sought counselling.

Deputy Alan Kelly: I know.

Ms Anne O'Connor: Working with the national cancer control programme, and to support what Mr. Breslin said, we are looking to providing more psychological intervention because clearly that is something of which people would need to avail.

Deputy Alan Kelly: I agree totally.

Senator Colm Burke: I thank all the witnesses for their presentations. On the 221 group, Mr. McCallion said there were 118 requests. That means more than 100 people did not make a request. I presume the slides would be available to any one of those 100 women if they required them.

Ms Anne O'Connor: Yes. They are just the ones that have been requested.

Senator Colm Burke: Yes, but another 100 have not put in requests. If they put in requests, I presume they would be dealt with in a-----

Mr. Damien McCallion: Some of those requests are not just from people in the 221 group. Any woman is entitled to seek access to her slides so there would be a mixture of people who are in the 221 group and people outside it. That is just the total number. We would have a breakdown, if the Senator wishes to see it, of those who are in the 221 group and those who are not. That is the total number of requests. If anyone requests their slide, there is a process and a protocol to deal with it and we will try to work with the laboratories to expedite it as quickly as we can.

Mr. Jim Breslin: It is probably also relevant that because of the RCOG process, more than 1,000 women have consented to their slides going into the RCOG process. There may be women who have not looked for the slide because they are aware that it will be looked at through the RCOG process.

Senator Colm Burke: Fair enough. On the numbers, they went from 280,000 in 2017 up to 370,000 in 2018. Do we have any idea as to what it will level off at in 2019? The witness has given the figures for 2017. I presume the figures for 2016 and 2015 were still approximately 280,000. Do we have the capacity now, in view of the approximately 80,000 that have to be reviewed, to deal with those? If the figure levels out at 280,000 again this year, do we have the capacity now to deal with both issues at the same time?

Mr. Jim Breslin: I will get Mr. McCallion to speak on that, but it is worth saying that when we refer to capacity analysis, what we should be referring to is a demand and capacity analysis because one of the issues that has to be estimated is the demand going forward in terms of the uptake rate for the programme and how much capacity we have to address that. That is the piece of work that is under way. Mr. McCallion might address that.

Mr. Damien McCallion: The numbers in 2017 and 2016 were consistent, and then we had the spike in 2018. Our estimate for this year is that it will be between 290,000 and 300,000. It is impossible to get an exact figure due to a range of factors, but we expect that we will continue to see a number of women turn up by invitation who perhaps previously may not have because of the heightened profile around cervical cancer and screening. That is the number.

In terms of matching the demand and the capacity, as Mr. Breslin said, we have a difficulty with that at the moment. That is where the backlog has arisen, but we are constantly trying to look at how we develop that with existing providers, and we have done a trawl through the private providers also. We have talked to other public sector organisations and we are continuing to do that and follow up on any leads. One of the challenges in the cytology market is that it is a declining skill set because, in moving to HPV testing, we move from 100% to 15% cytology. Basically, people who work in the profession and providers are moving away from it. It is very challenging but we are continuing to try to source capacity from all possible angles, including

developing our own in the medium term at the Coombe Hospital.

Senator Colm Burke: I want to move on to that. One of the areas in which this country has done very well in recent years is attracting jobs here, yet in respect of a vital service we were sending work outside the country. We did not take a proactive approach to trying to keep that work and the jobs within the country. Ms O'Connor said that €5 million is being made available in respect of the development of laboratory services. What percentage of the work is being dealt with here at this stage?

Mr. Damien McCallion: Over 50% would be dealt with in the country. That is between one private provider and the Coombe Hospital, at 9%. What we are looking at in terms of developing a national cervical screening laboratory at the Coombe is trying to build that up. The €5 million is a capital allocation to try to build the facility. We also have revenue costs, which we made allowance for through the service plan this year. The challenge will be recruiting into that. The recruitment aspect of it is very challenging and will have to be built up over time to increase the amount that is in our public system. That will still take some time, and hence the need, as I replied to Deputy Donnelly, for the HPV tender to include a private partner to work with us from that tender.

Senator Colm Burke: If a plan was developed for this entire area, could we set out a programme whereby over the next four years none of this work would be going out of the country? Could we focus on trying to make sure that all of it stays here?

Mr. Damien McCallion: We are trying to balance the public and private piece to reduce the dependence in terms of that. Equally, we need to be conscious that in terms of the skills needed, unfortunately, there is a huge dearth of those in this country. Our strategy is to try to build up that public capacity and build the national cervical screening laboratory. We have worked with the Coombe Hospital on that. It has committed to that and is working with us around it, but that will take some time to develop. We need to be careful to maintain a programme and develop a programme. As we do the tender for that, it is clear we will need to have a partner with us. Whether that partner is in Ireland or outside Ireland, we cannot control that in terms of EU procurement rules and so on for that market. Our objective is to build up a greater presence here in the public system and then, within the procurement environment in which we work, see how we will have a partner that will allow us to continue the programme because the programme itself was at risk last October in terms of the contracts and so on. In terms of future HPV primary screening, our objective is to ensure we deliver a solution that will work for that for the immediate future as well.

Senator Colm Burke: Is there anything we can do to incentivise people to upskill and train into the system in Ireland?

Mr. Damien McCallion: We are started discussions with the colleges on how we can upskill and increase the manpower in that area to ensure we build up a public laboratory at the Coombe Hospital. The total number of people involved is very small, but the impact will be huge if we do not have sufficient capacity. We are trying to develop that and are committed to trying to make that work at the Coombe Hospital.

Senator Colm Burke: On the other issue of expertise in the area of cervical cancer, I refer to the backup support groups. Are we facing a challenge in respect of retaining people but also replacing those who will be retiring? Have we considered that issue in terms of the next four or five years? For instance, there are 450 or 500 consultant posts vacant in a number of areas

in the medical service. This is an area in respect of which one needs expertise. The HSE is competing on the world market. I wonder where matters stand in the context of long-term planning in that area.

Mr. Damien McCallion: Initially, I will speak and colleagues might want to talk on the wider challenge, particularly on consultant manpower. In terms of screening, there are two key roles. There are the screeners themselves and the consultant pathologists who work in that area. There are a small number of those skills in this country. One is talking about probably no more than four to five persons who have that skill set. We are looking at how we can develop that and ensure we have some succession planning in respect of it and then a recruitment plan for the new operation at the Coombe. The Coombe also operates with one of the universities in terms of training. It runs a good school in that regard. We are trying to continue that as well as bringing in the new skill set that will be needed in respect of HPV, alongside cytology. We are working through that.

The consultant issue, as Senator Colm Burke states, is a significant challenge across the board. Ms O'Connor may wish to speak to that.

Ms Anne O'Connor: Consultant recruitment and retention is a big challenge. We have a lot of work going on under Professor Frank Murray, within the HSE, who is heading up the medical manpower and planning unit. Professor Murray is doing a lot of work going throughout the country looking at exactly what are the challenges. We are looking at different models in respect of recruitment of consultants to try and ease that pathway. Clearly, there is a big issue in terms of some of the retention challenges as well and how we can make that career pathway attractive for people. That is across the board, not only in this area.

Senator Colm Burke: In the case of the expertise, other than that of the consultants that are required, does the HSE foresee a challenge over the next 12 months to two years in providing a comprehensive service everywhere such service is currently provided? Does it foresee a challenge in the context of staffing?

Mr. Damien McCallion: In terms of screeners, there are challenges around the world whereby those who work in cytopathology are moving away from the field. This is because of the general trend away from cytopathology and into HPV testing. Dr. McKenna may want to comment on this as well. Having said that, we will offer more opportunities in terms of the Coombe - the public system. What most countries have done is try to train people in order that they can operate both HPV and cytology and they obtain both skill sets. That has been the model. From our experience of looking at HPV implementation in other countries, that is one of the lessons. We will try to build that into our workforce plan in the context of screening. While, as I say, it is small in terms of numbers, we will do whatever it takes to ensure we provide career paths and skills for people and that they can operate within that. Equally, we will have to look when we go to tender at ensuring that whoever we work with will be able to maintain those skill sets and have sufficient capacity that can deal with fluctuations because we have had previous fluctuations in the programme. The Chair referred to the Jade Goody effect some years ago. In that period, significant backlogs emerged as well. This can happen in the future. We need also some capacity to flex the programme so that it is not so tight that if an issue arises there is not capacity to grow.

In terms of the public system which we have direct control over, we will certainly make sure we develop that further, develop skills and work with the various bodies to try and do that. There are discussions on that all the time. Separately, in terms of the contract that we will need

to put in place for HPV, we will ensure that whoever we select, one of those criteria will be to make sure that it is sustainable and also that we can flex the system somewhat, as we might need to do in any event.

Dr. Peter McKenna: The decision to export the work was not popular in the medical community. There are many of my colleagues, in both pathology and colposcopy, who would have advised against it, but it was considered necessary at the time. This has lost a significant amount of expertise in this area. That is not something that could be turned around quickly. Training in this area is lengthy and intensive and will take some time. It would be helpful if there was a policy statement that the intention in the medium to long term, even, indeed, the short term, is that this work would be repatriated and that for the foreseeable future every effort would be made to keep it here within the jurisdiction. One cannot compel people to train in a particular area.

Senator Colm Burke: Absolutely.

Dr. Peter McKenna: The way the public service is constructed means it is difficult to incentivise specific areas. However, such a statement would be reassuring and helpful.

Senator Colm Burke: Finally, what percentage of women are going for screening outside of CervicalCheck? The vast majority of women are under CervicalCheck but Deputy Kelly already referred to the women who are seeking screening elsewhere. What percentage are going outside CervicalCheck for screening? Is it a small number?

Mr. Damien McCallion: We would not have access to that data. I would suspect it is relatively small only on the basis that the number of providers who can offer that privately is quite small. However, I do not have any numbers on that.

Dr. Peter McKenna: There is not a private laboratory in the country that is accredited to do cytology. As far as I know, in the private sector, they leave the country as well. I am open to correction on that.

Deputy Margaret Murphy O'Mahony: I welcome all of our guests. I take every opportunity I get to ensure that women continue to get their smear test done, despite what is happening and the delays. It is important it goes out from this committee that women should continue to be tested.

Mr. Breslin referred to the independent clinical expert review and the women who are currently contactable. What efforts are made in relation to those who might not be immediately contactable? Does the Department merely move on or does it make big efforts?

Mr. Jim Breslin: I might ask the HSE to comment on that.

Mr. Damien McCallion: I did not catch that.

Deputy Margaret Murphy O'Mahony: I asked in regard to contacting women under the independent clinical expert review.

Mr. Damien McCallion: In terms of the RCOG, the eligible group was 1,702. Some 1,072, including next of kin, have consented. While we had a cut-off date, if someone chooses to come in late, we would try and facilitate it where possible up to a certain point. Those slides have started to move. We would have contacted all of those. Everyone would have received two letters as a reminder and we had a helpline that would have received a significant number

of calls. We would also have dealt with people who clearly were anxious. They are all women who have had cervical cancer or partners or next of kin of women who had cervical cancer. We would have tried to deal with those as well in terms of explaining what it was and what the process was.

Deputy Margaret Murphy O'Mahony: There was a big effort made.

Mr. Damien McCallion: Yes. We have a full team that is dedicated separately working on this to all of the other streams of work that are going on around the programme. We brought a completely new team in to manage this. There is a full database set up and a helpline set up. There is both basic information and clinical access as well. We have a consultant who comes in and works for us on a part-time basis in order to help. I refer to circumstances in which there might be complex calls whereby people are worried or concerned, or maybe even distressed, as a result of receiving the letter. They can have a conversation with someone about what it means. We have tried to support it as best we can.

Deputy Margaret Murphy O'Mahony: That is good to hear. In a few sentences, why are matters deteriorating rather than improving? Why are matters getting worse rather than better with regard to waiting time?

Mr. Damien McCallion: In terms of the backlog?

Deputy Margaret Murphy O'Mahony: Yes.

Mr. Damien McCallion: There are two factors. In some ways, unfortunately, it is simple. First, the demand is continuing to be slightly higher, although it has abated somewhat from the peak at which it would have been. Second, the capacity is constrained. Without going back over the earlier pieces, we are trying to source all possible capacity with existing providers - those who are currently working with the programme where it is much easier to, for want of a better phrase, connect them in. We are also looking outside. We have done a trawl of the market. We have also talked to other jurisdictions - Northern Ireland and Scotland - and we are in contact with some of the trusts in England which would operate this service to see what capacity is available. Unfortunately, it is not merely a simple plug-in for a new provider. There is quite a lot of work involved and there is a lead-in time to do that. We continue to have meetings - we have one this afternoon with a possible lead. We have looked in Europe, in France and Holland, where we have some possibilities.

It is difficult to get these over the line in increasing the capacity that is available to the programme which ultimately will help. The steps I outlined earlier are to try to mitigate that. The prioritisation of colposcopy where the laboratories would have excessive backlog, by running HPV first, effectively triages those who might have the greatest risk. We are trying to minimise the impact where possible.

I will not say it is easy. It is very challenging. Globally, we have this issue. Our own environment also probably presents challenges to some of those who are looking to work with us. However, we have leads that we are continuing to pursue.

Deputy Margaret Murphy O'Mahony: It is amazing that it is going on so long and there has been no improvement. In fact, we are going backwards. There is significant interest, as Mr. McCallion probably heard. On "Morning Ireland" earlier, it was the first item. That does not happen easily. The public is really holding on to this. The HSE is probably doing its best but it is going on so long now that it should be improving rather than deteriorating. The Minister is

not here to defend himself. Did he get it wrong by inviting women to be tested without having been called for testing? Obviously, he did not think it through. Even his officials recommended not going down this road. Does Mr. Breslin think the Minister got it wrong?

Mr. Jim Breslin: I dealt with this issue in my opening remarks. The Minister's officials did not advise against this course of action. Rather, we worked on it with him. I acknowledge that the Deputy is reporting what has been stated by others, but, as I set out at the start of the meeting, the advice from officials was that women would present to their GPs because of the degree of anxiety that had been caused. Women were ringing the helpline to say that and to ask for the State to pay for out-of-cycle testing. We were faced with a situation whereby some women would be able to afford to pay for private testing but others would not. The decision was made in a rapidly developing situation. We agreed with the IMO that a fee would be paid to GPs for the sampling. In quite a high proportion of cases, women met their GPs, had a conversation and arrived at the conclusion that they did not need another test. The programme put in place was of great benefit in terms of reassuring people. Some women, in consultation with their GPs, decided to have another test. In fairness, at that point many people in addition to civil servants and the Minister, such as commentators and people directly affected by the controversy, believed it was the right thing to do. In trying to respond to the anxiety which existed, it would have been just as big a mistake to be totally dispassionate and hard headed and decide there was no need for the measures. It was decided that the programme would be reviewed after three months. As I mentioned, once we had the benefit of the Scally report, which was of reassurance in regard to laboratory standards, the Minister decided to bring the programme to an end.

Deputy Margaret Murphy O'Mahony: Surely, adequate resources should have been made available.

Mr. Jim Breslin: It is linked to what the Deputy discussed with Mr. McCallion. The financial resources were available. The difficulty regarded accessing enough capacity globally to increase the testing to the level required. It is worth noting that the other contribution to the backlog is the increased uptake by people being tested for the first time. The backlog does not result entirely from retests. The significant public response demonstrates an awareness of the importance of cervical cancer and being screened. That formed part of the demand for the programme, albeit in the face of a crisis and controversy none of us wanted. The HSE is struggling to increase capacity to deal with that increased demand.

Deputy Bernard J. Durkan: Who suggested that officials advised against the process that was followed? From where did that suggestion come?

Mr. Jim Breslin: Many of the relevant officials are present. Throughout our clarifications, dealings with the media, responses to parliamentary questions and committee presentations we have been fully consistent with the Minister's statements on the advice which informed his decision. He did not make the decision contrary to the advice we provided.

Deputy Bernard J. Durkan: Has that suggestion been attributed to somebody in particular in the media or elsewhere?

Mr. Jim Breslin: I do not know. Sometimes such suggestions take hold. They are not always based on fact.

Deputy Bernard J. Durkan: This issue is the source of a great deal of stress and anxiety for women. Anything that raises questions about the integrity of the system being followed will

cause more distress and concern for women. That should be borne in mind. Everything that has been done has been in an attempt to address the issue. What is the status of the cases of the 221 women?

Mr. Jim Breslin: Is the Deputy asking about the progression of their illness?

Deputy Bernard J. Durkan: Yes.

Mr. Jim Breslin: The HSE compiled a report which examines what the women have been through, which is very significant, and what is their current health status. Perhaps the officials from the HSE will speak to that report.

Deputy Bernard J. Durkan: What is the expectation in regard to the women?

Mr. Damien McCallion: We worked with the group of 221 patients to develop a report outlining the current factual position. We will circulate the report, which is publicly available, to the committee because it may answer some members' questions. The primary purpose of the report was to inform us on the supports that exist. It set out the various procedures the women have had, the difficulties encountered and their current health status. However, it does not represent their individual journeys. We met the group. The women and their next of kin have gone through a very difficult experience. The report provides a factual position but cannot reflect the traumatic experiences many people have had as a result of the disease. We will circulate the report to the committee as it may answer some questions.

Deputy Bernard J. Durkan: I would be grateful for a copy of the report. What progress has been made in regard to the 78,000 people currently on the waiting list for a look-back review? There is a waiting time of approximately six months. What is the long-term projection in respect of the waiting list? When will the waiting time be significantly reduced?

Mr. Damien McCallion: The challenge we face is finding capacity. Until we get sufficient capacity, we will not be able to diminish the waiting list. We need laboratory capacity to carry out the testing. That capacity is severely constrained within our three existing providers and internationally because laboratories and countries are moving to HPV testing, which brings about significant challenges because cytology is being reduced and laboratories in implementation mode are not in a position to provide services to us. We have carried out a global trawl for providers who could beef up our capacity. If we expand capacity sufficiently, we will be able to catch up on the curve. It is a battle to get ahead of the curve but we are considering all possible sources, public and private, here and internationally to do so.

Deputy Bernard J. Durkan: How can the 78,000 people awaiting results rest assured that everything that can be done to shorten the waiting time and ensure that their health does not deteriorate is being done?

Mr. Damien McCallion: We are trying to mitigate risk for certain groups. As was mentioned, women who need a smear from colposcopy have a higher priority and clear instructions have been given to the laboratories to prioritise them.

Deputy Bernard J. Durkan: What progress is being made on those high-priority cases?

Mr. Damien McCallion: They are being monitored by the programme with the laboratories that currently provide colposcopy services. There is a small number of those case but they are easily identifiable and are being prioritised by the laboratories.

Deputy Bernard J. Durkan: Does that eliminate the waiting time for testing?

Mr. Damien McCallion: It reduces the waiting time.

Deputy Bernard J. Durkan: By how long?

Mr. Damien McCallion: I do not have those figures but I will forward them to the Deputy. The wait times for colposcopy testing are significantly shorter. The numbers are relatively small, but the cases are important in terms of priority.

In addition, we have sanctioned HPV prioritisation for laboratories experiencing particular challenges. That process triages the outstanding slides and smears to ensure that those which may have the high-risk types of HPV move into cytology earlier. Thus, smears with a greater risk of abnormality move into cytology and receive results more quickly. We authorised and implemented that before Christmas in one of the labs. We have tried to prioritise testing and at-risk groups as best we can within the confines of the programme structure. As stated, we are trying to source capacity from all sources, private and public, while we develop our own capacity. The latter will take some time and will not provide a solution to the backlog.

Deputy Bernard J. Durkan: What progress is being made on the changeover to HPV testing?

Mr. Damien McCallion: A dedicated team is working on the project. We are focusing on two key issues. We are working to stabilise the programme because one must have a stable programme in order to move to a new test. One cannot jump from the current scenario to the new testing regime.

In terms of the tender, we ran our pre-tender market engagement before Christmas which invites the market to look at what is available. We have used a process of competitive dialogue which will allow us to engage with those interested in providing the service. There is a risk that if we went to tender in the current environment people may not bid. We could end up having run a procurement process with no one to work with us. We believe the competitive dialogue process will allow us to secure a partner to work with us. The advertisement for the next stage of that, the EU tender, will be placed in the next few weeks.

We are moving along all the other elements we can, such as the training and education materials, communications and IT system changes that need to be made to go live. The team working on this have either visited or had conference calls with the people who have gone live on this in Australia, New Zealand, the Netherlands and Wales. They have also discussed it with people in England, Northern Ireland and Scotland who are in the middle of their implementation processes. Most of those are planned to go live in the coming years.

As I mentioned, the critical path on HPV testing going live is when we run the tender to see how long the partner will take to establish and link into our system. At that point, we will have greater stability on a date for the programme for HPV testing going live.

Deputy Bernard J. Durkan: Is Mr. McCallion satisfied that sufficient interest has been expressed to reassure him that this is the way to go and that it will work?

Mr. Damien McCallion: HPV primary screening is undoubtedly the way to go. HIQA approved it.

Deputy Bernard J. Durkan: What about its accuracy?

Mr. Damien McCallion: Its accuracy is much higher. It is not infallible.

Deputy Bernard J. Durkan: What is much higher?

Mr. Damien McCallion: I do not have the test rate here, but Dr. McKenna or other colleagues present may have the actual difference. There is still a false negative rate as is described in screening. I think it is a factor of maybe 15% versus 25%. We can confirm that later. It is not an infallible test, but it is a much more reliable test because it prioritises women who have a particular form of HPV which would account for a large proportion of cervical cancers but not all of them.

Vice Chairman: Does Dr. McKenna have some idea of the accuracy difference?

Dr. Peter McKenna: I can confirm that it is much more accurate. I believe it will miss 40% to 50% fewer cases of women who have abnormalities.

Deputy Bernard J. Durkan: Is that of the 20% that the cytology tests do not-----

Dr. Peter McKenna: Yes.

Vice Chairman: I understand the witnesses cannot give us the figures now, but I am conscious that during deliberations figures get thrown around. Women may be watching this and in the interest of putting factual information on the record, I ask that Dr. McKenna would circulate that.

Dr. Peter McKenna: We can do that.

Vice Chairman: Where there is room for any doubt, it is not fair on people.

Mr. Jim Breslin: Prior to the decision being made - the decision was made prior to the controversy - HIQA conducted a health technology assessment of the HPV. We can also make that available to the committee.

Vice Chairman: To avoid speculating, that would be very helpful.

Deputy Bernard J. Durkan: It would.

The figures mentioned were 80% accurate and 20% doubtful. Dr. McKenna has said that 50% of those should be narrowed down into a more accurate area. Once the tenders are cleared, etc., when are we likely to be able to rely on the HPV system and taking the women out of the cytology programme in order to eliminate the doubt, concern, stress and continuing queries over it?

Mr. Damien McCallion: It is probably important to restate that the future test has a HPV test but it still has cytology for 15% of those. We can provide information such as the HIQA report that Mr. Breslin mentioned which sets out how that works. While it is a more reliable test, none of those tests is 100% accurate and there is a defined rate on that. We can circulate that so that people who are watching are clear what those percentages are.

Deputy Bernard J. Durkan: Will there also be a look-back at the HPV tests? For instance in some cases they are not entirely accurate - we cannot get 100%. What protection will there be for the ones that may not be accurate and fall off the shelf, as it were, in that test?

Dr. Peter McKenna: There is a process under way to establish the correct way to conduct

an audit of interval cancers. This is taking place in the various cancer programmes. This process has begun and it will make recommendations as to the best way to audit interval cancers irrespective of the methodology of screening. Irrespective of whether it is cytology or HPV, the process will be the same, should be the same.

Mr. Jim Breslin: That is one of the recommendations from Dr. Scally's report. We are reporting on progress on that through the implementation plan.

Deputy Bernard J. Durkan: Have we resolved all the other difficulties such as non-reporting to the patient on time? I trust we are not likely to trip over that again.

Mr. Jim Breslin: The new clinical audit process that Dr. McKenna mentioned will reflect on all of the learning and ensure it is absolutely in line with open disclosure and is a fully robust process from end to end.

Deputy Bernard J. Durkan: Have any comparisons been made over the success or failure rate of women who may have had private tests done? Do any outstanding issues arise?

Mr. Damien McCallion: Is the Deputy referring to laboratories offering services to people privately outside the programme?

Deputy Bernard J. Durkan: Yes.

Mr. Damien McCallion: We would not have access to data. As we said earlier, we believe the number of women who would have pursued the private route is relatively small. Only one of our existing laboratories would have a very small private capacity. I know of a laboratory in Northern Ireland, but people would have very limited opportunities to get a smear read privately. We would not have access to-----

Deputy Bernard J. Durkan: How limited would it be? Would it be ten, 20 or 100 people?

Mr. Damien McCallion: We would not know. Indicatively we would expect it to be small simply because the number of laboratories offering the service is very limited. The number of people who would go privately is very small. We would not have access to those data.

Deputy Bernard J. Durkan: I am trying to make a comparison as to what their experience was. Proportionately, would women who were prepared to go that route have been reassured at an earlier date? Would they have had a more accurate test? What is the case?

Dr. Peter McKenna: They probably would have got their results quicker. I do not think there is any doubt about that. Would they be less likely to develop cancer subsequently? The answer is that they are an entirely different population who would be much less likely to develop cancer anyway irrespective of the quality of the testing.

Deputy Bernard J. Durkan: That is useful information.

Vice Chairman: I am conscious of time.

Deputy Bernard J. Durkan: I am also conscious of the time. I was sitting here all morning as well, sad as it may be.

Vice Chairman: I understand that and I am not trying to hurry the Deputy unduly. I am just reminding him. His colleague is waiting to come in as well.

Deputy Bernard J. Durkan: To what extent do the witnesses remain satisfied as to the accuracy of the Scally report? Will the issues raised be addressed in the fashion suggested? Will it be possible to deal with the issue that has become such a problem for so many women and their families?

Mr. Jim Breslin: We are unequivocally implementing all 50 of Dr. Scally's recommendations. We have put the whole of the mandate of the Department and the HSE behind that. We have a full robust process with public reporting on how well that is going. As we mentioned, Dr. Scally is due to do a further report on the laboratories. We await that and it should be with us very shortly.

Deputy Bernard J. Durkan: I refer to the retaining of the services within the country, the use of laboratories within the country and the development of the necessary technology to ensure that the appropriate laboratory facilities are available. We have fairly sophisticated laboratories in the country, some of which are located in my constituency. I have raised queries about these in the past. We tend to refer abroad where we have a lack of capacity at home. My last question is about the merging of the requirements with the capacity, which was referred to earlier. How are we working on that? Are we working on a particular deadline and objective?

Ms Anne O'Connor: We set out that we are working with the Coombe Hospital to develop a national screening laboratory there. In terms of capacity, it is the number of available personnel that is a problem regardless of the number of facilities. As it would not make sense to try to staff too many facilities, we have a plan to develop a national centre. We are investing €5 million in that and working very closely with the Coombe to develop that in order to have greater capacity within our own system.

Deputy Bernard J. Durkan: When will that be completed?

Ms Anne O'Connor: At the moment it is at the stage of planning. We have to develop that laboratory. The hospital currently does not have it. That will require investment in the infrastructure, the building and equipment.

Deputy Bernard J. Durkan: Particular emphasis should be put on that, keeping in mind Dr. McKenna's wish to retain services nationally and to train the personnel nationally.

Vice Chairman: Thank you. I am conscious Deputy Bríd Smith has been waiting patiently but, as is the convention at this committee, I will take committee members first. I call Deputy O'Connell. We have all been making every effort to keep within our time, although I have not given out any gold stars. This could be her opportunity.

Deputy Kate O'Connell: I have lived my life looking for gold stars.

Deputy Bernard J. Durkan: The early starters were the biggest offenders.

Deputy Kate O'Connell: I thank the witnesses for coming in. Has a new director of public health been appointed? What is the status of the independent patient safety council, if the witnesses have that information?

I do not want to repeat questions that were already asked and I have been keeping an eye on what has been going on. In terms of the eradication of cervical cancer, and we have spoken here before about the Australians being on track to eradicate cervical cancer within ten years from when they started, how we are we doing with our target? I know it was discussed here and

that the witnesses could not give a date for HPV testing technically superseding, although not getting rid of, cervical screening. While the witnesses cannot give a date, I am very conscious that on 10 October, Dr. Denton, the lady from Scotland who was here with Dr. Scally, said that from the inception of the idea of bringing in HPV testing, theoretically, the system could be up and running within a year. Are we on target? Can the witnesses give some information on that?

We have a backlog of screening, an issue that was dealt with this morning. In terms of knowledge and awareness of cervical cancer, reference was made to the Jade Goody effect ten years ago, when she tragically died at a very young age from cervical cancer and there was a massive uptake of the cervical programme in the UK and Ireland. In light of all that has happened, is it true that more women in the cohort are engaging and are more aware? We heard from the victims but also the medical evidence that there were gaps in people's information and perhaps there was an over-reliance on smears without consideration of symptoms such as bleeding and discomfort. Perhaps one of the witnesses could speak to that point.

To go back to HPV testing, there will be a transition period from the current CervicalCheck programme to the more robust, more accurate, but not perfect HPV screening, and Dr. McKenna mentioned it would require 15% cytology. In terms of our lab capacity, I am very conscious of Quest Diagnostics. While I did not bring Dr. Scally's report with me this morning, there was an issue with the ISO accreditation in those labs and how Quest in particular had accredited itself to an American standard over the ISO standard. When it comes to the transition to HPV testing, my question is whether we can, as a committee, be sure the contracts will be correct and that in regard to those who get the contracts, whether in Ireland or elsewhere, there will be no discrepancy between the standards in the contract and the standards in the labs.

Mr. Jim Breslin: I will deal with the patient safety council. The proposal is very well advanced. The Minister has signed off on the proposal and we are finalising the membership and the precise terms of reference on that. It is important to say there will be a very strong component of patient involvement around that council.

Ms Anne O'Connor: With regard to the question on appointments, we have made three key appointments. We have appointed an interim director of public health while we go out for a permanent competition, and that is Dr. Caroline Mason, who is working with us. Dr. Lorraine Doherty, who is here today, is in her second week in the role of clinical director for the CervicalCheck programme. We have also appointed a laboratory quality assurance lead, Dr. David Nuttall, who has joined us and commenced today. They are three critical appointments that were identified as absolutely necessary in terms of the implementation of the Scally recommendations.

In terms of-----

Deputy Kate O'Connell: Did we ever have a quality assurance lead before?

Mr. Damien McCallion: That clinical role was not in place. It was a gap that was identified. We did have quality assurance people and they are still there, but the laboratory quality assurance - that higher level, consultant level role - was not there.

Deputy Kate O'Connell: What were they doing if they were not looking at the quality of the lab? What quality were they assessing?

Mr. Damien McCallion: It is not that. The quality assurance role that was there did look at the laboratory quality assurance as well, but this role was a gap identified in the consultant level

experience that was not in the programme. It was a gap identified by Dr. Scally.

Deputy Kate O'Connell: The people we had in charge of quality were not up to scratch, essentially.

Mr. Damien McCallion: It would not be fair to comment on them in that sense. What he identified is that an additional skill set is needed to provide that greater level of expertise around it. It would be unfair to say some of the individuals in the roles-----

Deputy Kate O'Connell: Saying an additional skill set is needed is essentially saying it is not up to scratch.

Ms Anne O'Connor: It is a different role. It is a more senior post at a consultant level that we did not previously have.

Deputy Kate O'Connell: It was needed, clearly.

Ms Anne O'Connor: Yes.

In terms of the transition, as we discussed earlier, one of our key challenges is that we are trying to transition to a new model yet we have to address the old model, so we cannot transition until we address the backlog. There is a tension there in terms of moving to something without clearing the backlog. I will ask Mr. McCallion to talk about the other elements of that.

Mr. Damien McCallion: On HPV testing, there are two key things we need to move on in order to move to primary HPV screening. One relates to the selection of a partner to work with us. I mentioned earlier we had a pre-tender market engagement before Christmas. I told Deputy Durkan we had positive input from that because, obviously, one of our concerns was whether we would get a partner to work with us, which would have put the whole project at risk. We are more optimistic as a result of that and an advertisement will be placed in the next number of weeks.

A separate team is working full-time on all of the other aspects of this, for example, IT system changes, communications, education, development of materials for health professionals, laboratory reconfiguration, procurement and quality assurance standards for the new test. There are eight workstreams in total and they are all being progressed.

In regard to determining a date, when we get to a point where we are clear that we will select a partner and know the timescales in which it can work with us, that is the point when we will be able to give greater certainty in regard to a date to move that programme live.

Dr. Peter McKenna: The Deputy mentioned symptomatic patients, such as patients who are bleeding, and I thank her for mentioning that. We will not reduce deaths from cervical cancer by focusing on cytology alone. We need to have rapid access to symptomatic gynaecological clinics. At the moment there are possibly 28,000 to 30,000 women waiting for gynaecological outpatient appointments. One must bear in mind that whereas 80 to 90 women die of cervical cancer, 80 to 90 women will also die of endometrial cancer and nearly 300 women will die of ovarian cancer. Cervical cancer is not the only cancer that will kill women, although it clearly has been the focus of our attention recently. Therefore, we must have resources to improve access for symptomatic women in gynaecological clinics. Without that, no matter how much resources we have in cytology and colposcopy, there is only so far we can get.

Deputy Kate O'Connell: With regard to auditing, Dr. McKenna referred to the auditing of

interval cancers. My understanding is that what he is saying is that there would be a standard way of auditing as opposed to different areas having different ways of operating.

Dr. Peter McKenna: Correct.

Deputy Kate O'Connell: How are we on that system regarding how to audit?

Dr. Peter McKenna: That process has begun. There is a steering committee that will establish principles and there are subcommittees of that committee looking at how to audit in respect of bowel, breast and cervical cancer. Their work has just begun and they will be making recommendations. The process will probably take three to four months.

Deputy Kate O'Connell: An issue that was raised here last week and again this morning is the option to have an additional smear test. There seems to be constant reference to whether it was a good or bad idea. As somebody who sometimes works in the community and engages a lot with people in community health, I would point out to the committee that there was significant demand when there was an information vacuum. People with private health insurance were presenting in private clinics in the early days of this scandal offering to pay for a smear test to be done. Regardless of whether it was right or wrong, the logic of it was it was their free choice to do that. I know many women who paid. I supported the idea of that reassurance smear being offered. At the time, a class gap was forming. In an information vacuum and when we were all, and still are, up to our necks in this and it was very stressful for all of the witnesses, members of the committee and the public, a two-tier system had emerged where some women who could afford it were presenting in private clinics, while other women with the medical card or who did not have the means were feeling somehow disenfranchised. Hindsight is wonderful and we would all love to have it. Looking at this through the lens of all the information we have now is fine but as somebody who was engaging with groups of women and GPs, I can tell the committee that a massive discrepancy was arising between the types of people who were or were not getting a free smear test. Although in hindsight, it may have contributed to the backlog, if we had not done it at the time, it would have been a far more stressful situation for women and would have increased the amount of fear.

Mr. Jim Breslin: We can see part of the reassurance and taking some of the stress out in the difference between the number of women who had a consultation with their GP and the number who went on to have the re-test. Many women sat down with their GPs and were reassured through that consultation, which was paid for by the State. This was a good outcome in terms of managing the anxiety that was there.

Vice Chairman: I thank Deputy O'Connell for her class analysis of the health service as well. Deputy Bríd Smith has been very patient.

Deputy Bríd Smith: I thank everyone for their answers. I came in with one question and now have about three or four but I will not be long. The first one concerns the issue raised by Dr. McKenna, namely, the decision to export the screening process in, I think, 2008. It was not a popular decision. I have read over the record from the Academy of Clinical Science and Laboratory Medicine and the Medical Laboratory Scientists Association, which resisted it fiercely at the time. They contended that had a programme of intensive training of new clinicians been introduced, we could have kept the service at home. We did not do so and the rest is history. Perhaps the question is for Mr. Breslin to answer. When Dr. McKenna requests of us that there should be a policy statement that there is a willingness or political ambition to repatriate the service, does that come from the Minister?

Mr. Jim Breslin: I think the Minister's statement on this subject has already been made, along with possibly that of the Taoiseach, which is that it would be desirable for this to take place.

Deputy Bríd Smith: But is it a policy statement?

Mr. Jim Breslin: Once the Minister speaks on the subject, he determines policy. The one caveat in that, with which Dr. McKenna would agree, is that we must continue with the programme. The repatriation must be consistent with us trying to match the demand for testing. We cannot do this overnight, we could not do it in one go and we must build up the services in the Coombe for us to be able to achieve that. It will be a progressive development that certainly will see the balance shift towards more public activity but it is desirable-----

Deputy Bríd Smith: Dr. McKenna said it would be very helpful if there was a policy statement.

Mr. Jim Breslin: The Minister is on record in the House in terms of his support for that.

Deputy Bríd Smith: Is that the same as a policy statement?

Mr. Jim Breslin: It is.

Deputy Bríd Smith: Dr. McKenna has his policy statement. We will be keeping an eye on it because it goes to the heart of everything that went wrong with this service. I probably have to say this because I get a lot of criticism for it. When I take the angle I am about to take, I am accused of being negative about CervicalCheck. I am not. I am a recipient of that service and a complete advocate for it. I am not trying to do it down. I am trying to examine forensically what went wrong, why it went wrong and how we should deal with things like this in the future.

This brings me to my next question. I think Mr. McCallion mentioned the EU rules on public procurement in terms of being able to deliver this service. My ears pricked up - not least because we are surrounded by problems involving public procurement in health. Could Mr. McCallion tease that out? I was looking at the services provided for screening around Europe because it struck me as very strange that we would always go to the US instead of trying to source from Finland, Germany or other parts of Europe that have state-of-the-art clinical laboratory testing. Could Mr. McCallion explain what the problems are?

Mr. Damien McCallion: In the public system, the Coombe accounts for about 9%. We have two providers that provide roughly the balance equally between them. In terms of moving forward with the new tender for HPV testing, we have made a commitment that we are going to invest in the Coombe to build up public capacity but we know that will take time on the construction side and probably, more importantly, in terms of the skills and all of the things alluded to by the Deputy earlier. We are committed to doing that and building it up over time and the Coombe is committed to working with us on that. That is coming from the most senior levels within the Coombe so that will help.

In the meantime, we must run a tender to find a partner that will work with us as we develop the Coombe over a number of years to help us provide the new test and screening service. Under that tender, we will offer a tender out through the market. We are using a process that will allow us to have a dialogue because there was a real risk that we would go to the market and nobody would respond in light of our difficulties in Ireland. We had a serious concern about that. Through the approach we have taken, we are more confident that we will secure people

who are interested in working with us. In that respect, we ran what is called a pre-tender market engagement before Christmas where we sought the views of the market and were able to build that into tender process. Our advertisement for that will be placed in the next number of weeks. We are hopeful that we will see people respond to that, which will allow us to move forward in terms of HPV primary screening. To be clear, at the moment, we are dependent on finding a partner to work with us from wherever. The process will look at who is the most suitable regarding the service, the quality and so on around that over the next number of years while we build up public provision to try to balance that so that we are not as dependent on the private sector as we move forward.

Deputy Bríd Smith: Mr. McCallion's description of the EU procurement process is understood but what is the problem with it because he said earlier that there are problems with it?

Mr. Damien McCallion: It is probably not an issue with EU procurement. It is simply whether we will get people who will be prepared to work with us in this country. That is the challenge. From our pre-tender market engagement before Christmas, I am more confident that we will secure people who will work with us. We have done a lot of work to try to ensure that we get providers that will work with and help us to deliver HPV primary screening.

Deputy Bríd Smith: I understand that it will not happen overnight but I very much welcome the fact that it has been stated here today that the Government has a policy of repatriating the service in the longer term. That is clear from what has been said by the Department here today.

I want to return to the issue of the laboratories in the US and outsourcing. I have been asking questions since this time last year and have repeatedly been told that I would get answers yet I still have not received them. My simple question concerned the identity of the laboratories from which the 221 failed tests came, where they were tested and whether we could get a breakdown. I was repeatedly told by Ms O'Connor's predecessor and then several Ministers that this information would be made available. I could take down a rainforest with the amount of paper I have and the questions I put. The latest information I have been given is that:

> Following significant efforts on the part of the HSE, a person with appropriate expertise was identified in late 2018 to carry out this analysis, and this work is ongoing. The HSE has advised it expects this work to be completed within the coming weeks.

Mr. McCallion said earlier that any of the 221 women who wanted access to the information on their slides could get it.

Mr. Damien McCallion: That is right.

Deputy Bríd Smith: Regarding the information about that slide, the first bit of information one sees on the record is where that slide went. It will state the name and address of the laboratory. Why has it taken so long to get this information? What is this analysis? Is it the same work which I was told last year and this year is being carried out by the Royal College of Obstetricians and Gynaecologists?

Mr. Damien McCallion: I apologise to the Deputy for the delay. The analysis is completely separate from the work of the Royal College of Obstetricians and Gynaecologists. The Deputy sought an analysis of the 221 incorrectly read tests, the laboratories those slides were sent to, where they came from and how that might have transpired. I secured someone from Northern Ireland who agreed to do this work but she had a reliance on someone within the programme

and, unfortunately, a number of other issues meant that link could not happen. They were not able to meet because we had a gap in terms of our laboratory skill set and the resources we had. The recent problem with the HPV expiration required our resources to be assigned to that and hence they were not able to close it out.

I made contact with the team yesterday to see when we could finish it. The analysis is simply taking the numbers and considering factors such as which laboratories were with the programme for longer periods. Laboratories that were with the programme from the start will have a higher prevalence of cervical cancer than others that joined the programme later. This is a proper analysis that will inform, rather than just throwing out raw numbers that could be interpreted in all sorts of different ways. It is putting a skill set on it.

As I say, we secured someone from Northern Ireland who has agreed to do that work for us. I am hopeful we can get that information to the Deputy now that we are out of the particular piece of work around the HPV expiration. I apologise again for the delay in getting that information to the Deputy. That analysis will be important in ensuring the context for the figures is understood and wrapped around it and proper information is provided to the Deputy and others.

Deputy Bríd Smith: With respect, I asked Mr. McCallion a simple question. In which laboratories were the 221 tests conducted? I do not want a breakdown of the clinical analysis, just where the tests were carried out. Having seen the paperwork, I know that when one picks up a piece of paper to see where one's test went, the name and address of the laboratory is on the front page. That is the information I want. The way in which that interpreted afterwards is work that could be done for me later. Will I get that information? Will this work be carried out?

Mr. Damien McCallion: Yes, that work is going head. The individual from Northern Ireland spoke to me yesterday and she is now working with the woman in the programme on the laboratory side. We will get back to the Deputy as quickly as possible, within a matter of weeks, I suspect. Perhaps I could confirm a date with the Deputy separately and directly, if that is agreeable.

Deputy Bríd Smith: It will be at least a year after I asked for it. The reason I asked, in case anyone is in any doubt, is that I am convinced at this stage that it will show that the outsourcing of this service brought us to this point. We outsourced this work to laboratories with lower standards for profit, research, medicine and clinical activity, as opposed to public health. This has brought us to where we are and that is the grave political mistake that was made. We should learn from that and never again make that mistake. Unfortunately, we seem to outsource an awful lot of our health services.

Deputy Stephen S. Donnelly: I will go back to where the choke points in the process are and what we can do about them. As I understand it, and this is not a perfect understanding, there are essentially four steps. There is the capacity of general practitioners to meet women for a consultation and do the smear tests. There is then cytology, which involves looking at the cells on a screen and carrying out a HPV test afterwards if abnormalities are detected. I understand that if the test is clear, a clear test result will be sent back to the GP and the woman will meet her GP, or maybe the results are sent directly to the woman. If it the test is not clear, colposcopy is then involved, which means the woman will see a consultant gynaecologist, a specialist in colposcopy, who will do an examination and take a biopsy. That biopsy will then go to a histopathologist who is a consultant doctor and a multidisciplinary team will take it on from there. I am sure there is much more complexity but the clinical specialties and capacity needed are general practice, cytology laboratories, colposcopy and histopathology. I am sure

there is considerable specialty and complexity around that.

We know there are issues of capacity in general practice. Will the witnesses identify where the choke points are? This goes back to the six-month delay. Is it that women cannot get to see GPs quickly enough? Is it that the cytology laboratories are holding samples and cannot put them through quickly enough? Does the delay arise when abnormalities are detected and there is referral to a colposcopist?

Dr. McKenna noted, although not in relation to cervical cancer, that there are between 28,000 and 30,000 people awaiting a gynaecology outpatient appointment. Are growing colposcopist waiting lists one of the choke points causing the six-month backlog? Is part of the backlog that we do not have enough histopathologists and biopsies are being delayed? Will the witnesses give us a quick overview as to where the pinch points are in this process?

Dr. Peter McKenna: Deputy Donnelly's analysis of the various points is correct.

Deputy Stephen S. Donnelly: Thank God.

Dr. Peter McKenna: The reason there are 80,000 smears waiting to be read has nothing to do with primary care or colposcopy clinics. It has to do with the lack of capacity in the laboratories to look at, analyse and give a result on the cervical smears.

Deputy Stephen S. Donnelly: If a company in Dublin, Cork, Kerry, London or Edinburgh that does 1 million tests a year were to indicate it could handily take on another 10,000 tests each week for Ireland, would that essentially fix the problem?

Dr. Peter McKenna: It would be a great help. We are currently looking at the capacity of the colposcopy clinics to cope with the expected increase in numbers of referrals when the change comes to HPV. There are 15 colposcopy clinics and we are looking at those. We have visited six of them so far. The story we are hearing is pretty much the same, in that there is a small lack of physical capacity and staffing issues. We are doing a business plan as to how these can best be addressed. At the moment, that is not the main problem. The main problem is the 80,000 smears that are in a laboratory. When those results come through, there will then be an increased referral to colposcopy and that will begin to be a pinch point.

Deputy Stephen S. Donnelly: I thank Dr. McKenna for that. Let us say we could get these 80,000 tests done very quickly, which obviously we all want to happen. I have spoken to colposcopists and histopathologists around the country and they are saying, particularly the colposcopists, that they have enormous waiting lists. Dr. McKenna made the point that there are tens of thousands of women awaiting gynaecology outpatient appointments. If the pinch point is currently 80,000 samples waiting to be tested, and they begin to flow through in the next few weeks and months, and please God, they will, will we then be in another quandary wherein we do not have enough colposcopy and histopathology resources?

Dr. Peter McKenna: The main problem we are hearing from the colposcopy clinics that we have visited, and from colposcopists around the country, is that there is an increased number of inappropriate referrals to colposcopy. They are not inappropriate referrals but they are inappropriate referrals to colposcopy.

Deputy Stephen S. Donnelly: Are they from the laboratories?

Dr. Peter McKenna: No.

Deputy Stephen S. Donnelly: Are they from GPs?

Dr. Peter McKenna: Yes, they are from primary care. Whereas this time last year, a colposcopy clinic might have seen approximately ten patients a month with an abnormal looking cervix or abnormal bleeding, it may now be seeing 60 or 70. This is clogging up the colposcopy clinics. These are patients who more appropriately should be seen at a rapid access gynaecology clinic.

Deputy Stephen S. Donnelly: Is more professional training needed for GPs? Is that the issue with inappropriate referrals?

Dr. Peter McKenna: That may be a small factor but a more important one is lack of capacity. Virtually every gynaecology clinic in the country is getting more referrals than it has capacity to see patients and, consequently, the waiting lists are not improving.

Vice Chairman: Deputy Kelly and Senator Burke are indicating they have questions. I have some follow-up questions too.

Deputy Bernard J. Durkan: I also indicated.

Vice Chairman: My apologies to Deputy Durkan. Deputy O'Connell will also be added to my list forthwith.

The former director general of the HSE said on RTÉ at the weekend that the commitment to roll out free smear tests has had consequences the Minister did not foresee. With the benefit of more rounded advice, the Minister might have come to a different decision. The director general was not aware that the decision was going to be made or announced. He suggested to the Minister and Department officials that the decision should be walked back as quickly as possible. My questions arise from that. Looking back on it, is Mr. Breslin now of the view that this person should have been involved in the consultative or thinking process that led to this announcement being made? As to the advice given by a very senior person that it should be walked back as quickly as possible, will he give us an indicative timeline of when that conversation happened and when that advice was given? What processes were in place to start that walk-back? Was it the case that the advice was noted and not acted upon? I will not say that it was ignored. I am curious as to why a decision like that was not discussed at a very senior level. I fully appreciate the pressure that was on people at that time but that pressure was on because of an emerging scandal and because the confidence women are entitled to have in this service had been rocked. The solution to that should have warranted discussion with the most senior person in the HSE.

Mr. Jim Breslin: I can only tell the Deputy what happened, which is that the Minister made the decision based on advice. He received very senior clinical input in making that decision. He did not have advice to the contrary when he made it. He communicated that decision and the HSE worked with the Department to put systems in place to allow that to happen. These included allowing payments to flow to the smear takers and so on.

Vice Chairman: Was that before or after the announcement was made?

Mr. Jim Breslin: We moved rapidly in implementing the decision-----

Vice Chairman: It was after the announcement. The announcement was made and then-----

Mr. Jim Breslin: -----because women were going to present at GPs almost immediately. It

was under way. On the question of a walk-back, the decision was made with a view to it being reviewed further.

Vice Chairman: Can Mr. Breslin give me some dates in that regard?

Mr. Jim Breslin: I cannot.

Vice Chairman: We know the announcement was made on 28 April but we do not know what discussions were held in advance of that, although Mr. Breslin has told us they were at a senior level.

Mr. Jim Breslin: I have told the Deputy very clearly what discussions were held in advance of the announcement. It is very clear that there is a misunderstanding on that issue, which I want to clarify. The Minister made his decision based on the advice of officials, including the CMO. No contrary advice was provided to him before he made that decision. I was very clear about the advice given to the Minister before he made his decision.

Vice Chairman: He did not seek advice from the director general.

Mr. Jim Breslin: He did not. He did not seek advice and advice was not offered to him. He made the decision based on advice, including that of the CMO, and then we worked with the HSE to implement it. I note what the former director general has said. Records exist which show that some people who welcomed the decision subsequently asked for the decision to be reviewed. This did subsequently lead to people raising issues about the decision. The decision was made with a review date. Dr. Scally's report, which I believe was due in June, was delivered in September. It made clear that some of the issues which had been raised about the programme and about the laboratories were not properly grounded. In that situation the Minister made the decision to bring an end to the retest programme. He informed the HSE of this decision and the HSE wrote back to him saying that it would bring it to an end but suggesting that it carry out the tests scheduled to December.

Vice Chairman: What were the issues in respect of the decision on the laboratories that were not properly grounded?

Mr. Jim Breslin: There was massive public anxiety and the veracity of the whole programme was being questioned. In light of the Scally report, the situation moved towards a whole series of very serious issues, but not towards some of the issues that were being debated and which were out in public in the teeth of this. The report narrowed down the issues to those we are now working on under the implementation plan. In that situation, in which the Minister had been reassured about the quality assurance within the current laboratories, he wrote to the HSE to say that he was going to bring an end to the retesting.

Vice Chairman: The Minister was reassured about the quality assurance within the report by the Scally report.

Mr. Jim Breslin: Yes, by the Scally report. Absolutely.

Vice Chairman: Is it correct that Dr. McKenna said that six of the 15 laboratories have been visited?

Dr. Peter McKenna: Is the Deputy referring to the colposcopy clinics?

Vice Chairman: Yes.

Dr. Peter McKenna: Yes.

Vice Chairman: With regard to the laboratories in the US which are used for analysis, is there a programme whereby people from the HSE visit these laboratories? I will tell the witnesses why I am asking this. There was a concern that tests that were outsourced were then being outsourced again and, possibly, outsourced a third time. I ask my questions as somebody who uses the service and as somebody who wants women to have confidence in it. It is important. The service saves lives and I back it 100%, but women deserve to have confidence in it. Is it correct that somebody representing the bodies who contracted for this service, either the HSE or the Department of Health, has set foot inside those laboratories? Have they all been visited, only some, or none? Is it not necessary? Is it done by another group? How is it done? I worked in an industry that is big on quality assurance and our place of work was visited by an army of people with clipboards and forms to be filled out. The people who were contracting out to these companies wanted to be sure that the money they were spending was being spent in the best way possible. Do people physically set foot in the laboratories? If so, do the same people carry out the visits or is it different people? What is the system in the case of laboratories who contract out again to provide the services?

Mr. Damien McCallion: The historical context is one of the things at which Dr. Scally is looking. His report will identify where that happened. On quality assurance, a range of measures make up the quality assurance in respect of laboratories. It included site visits. The frequency of these was once every three to four years. With the appointment of a new pathology quality assurance lead, we will move to annual reviews. He has been asked to make ensuring annual reviews one of his priorities. That will be one part of overall quality assurance. Part of it is the monitoring of figures, including positive predictive values, PPVs: negative predictive values, NPVs; and various other indicators relating to laboratories.

Vice Chairman: I am not trying to be awkward but does that involve someone being physically present in these places?

Mr. Damien McCallion: It did, yes. Historically laboratories received a number of quality assurance, QA, visits. They were done every three to four years. It is clear from Dr. Scally's report that we need to strengthen that. One of the priorities of the new appointment has been to build a team that will visit the laboratories annually. All of the laboratories will have their own accreditation, which I suspect will involve visits from their accrediting bodies similar to those the Deputy has described. These visits for the programme will be over and above that. Historically there were visits every three to four years but we will move to an annual review of each of the laboratories. That is one of the priorities for Dr. Nuttall.

Vice Chairman: Are we not moving to repatriate services? I understand the need for the dual focus. To go back to my earlier question, this involves people being physically present every three to four years.

Mr. Damien McCallion: That is right. There is a team visit every three to four years.

Vice Chairman: Is Mr. McCallion able to say with confidence that we have had somebody physically present in every laboratory in which samples taken from women in Ireland were tested?

Mr. Damien McCallion: The Deputy referred earlier to Dr. Scally's identification of a number of laboratories that were used without the prior knowledge of the programme. Clearly

the visits would not have included those laboratories. As I understand it, Dr. Scally will report on that separately. The visits to the other laboratories every three to four years happened physically; there were boots on the ground. The laboratories were inspected against a quality assurance standard which is probably not dissimilar to what the Deputy has described. There is a set of metrics and other things which one goes through. Dr. Scally's report again identified that this assurance needed to be strengthened. One of his recommendations has been implemented through the appointment of a pathology QA lead. We have said that we will move to annual visits. We should do that on a regular basis, irrespective of whether a laboratory is in Ireland or in England, France or America. That will be one part of an overall quality assurance system, which will include monitoring of key metrics that give an indication of the quality of the work of the laboratories. There is a range of indicators specific to the programme in that regard.

Vice Chairman: As we sit here, could there still be tests going to labs which have not had a formal physical inspection or in which there has not been anybody present to oversee quality assurance?

Mr. Damien McCallion: When Dr. Scally made us aware of the issue, we immediately had conference calls with the laboratories to get assurance about the laboratories they are using. We are also seeking additional laboratories for capacity. One additional laboratory has requested to work with the programme. We go through a process to approve it with regard to its accreditation and so on.

Vice Chairman: The company I worked for would have been delighted if the people doing quality assurance would have accepted a conference call. It was an on-site visit. My final question relates to the €5 million allocated for the national CervicalCheck laboratory. Will that be affected by the cost overrun in respect of the national children's hospital?

Mr. Jim Breslin: Absolutely not.

Vice Chairman: That is excellent news. I call Deputy Kelly.

Deputy Alan Kelly: Nothing is going to be affected by cost overrun.

Vice Chairman: Everything, however, might be re-profiled, but that is not an impact.

Senator Colm Burke: It is a €7 billion budget.

Deputy Alan Kelly: Yes, but it is still €450 million in cash.

Deputy Bernard J. Durkan: Is the glass half full or half empty?

Deputy Alan Kelly: It is the following year that is the problem, but that is a side issue. I want to get back to the report Dr. Scally is about to issue. I presume he is not just looking at the labs and the extra outsourcing but that he is also looking at quality assurance. Is that part of his remit?

Mr. Jim Breslin: Yes, it is.

Deputy Alan Kelly: Is Mr Breslin certain?

Mr. Jim Breslin: I do not have the terms of reference with me but he has committed to providing a supplementary report into certain further aspects of the laboratories such as procurement, quality and accreditation arrangements, and governance standards. The terms of

reference were published in October.

Deputy Alan Kelly: That is good, because we have had many questions on quality assurance. I expect all of those questions to be answered this week or whenever the report comes out. I do not mean that in jest. We all have many questions and there is a lack of traceability. We do not know to where this process has been outsourced. It is gathering all of the time and, as a consequence, we are not reassured about quality assurance historically or currently.

Mr. Jim Breslin: Historically, as Mr. McCallion stated, there is clarity-----

Deputy Alan Kelly: There have been improvements, but Dr. Scally's report will be coming up to the current date.

Mr. Jim Breslin: Yes, but the labs currently being used are those accredited and with which there is a contract. If other labs were used in the past outside of that, Dr. Scally will look at their accreditation, the circumstances in which they were used, what period of time related to what factor-----

Deputy Alan Kelly: And the level of quality assurance that obtained.

Mr. Jim Breslin: That is correct. We are awaiting the report and, therefore, people can speculate about it. We would like to see that it is tight, that the labs are all accredited, that they form part of a proper governance structure, etc. What happened should not have happened. Dr. Scally's report will be important in providing information on the circumstances-----

Deputy Alan Kelly: I want to make sure, from a quality assurance point of view, that everything historically is now being examined. We need to get to the bottom of all of this. In his first report, Dr. Scally found that quality assurance was non-existent. We will now be getting into the detail of that first finding.

Mr. Jim Breslin: He did not state that. We distinguished earlier between what the CervicalCheck programme had in place-----

Deputy Alan Kelly: He effectively said that.

Mr. Jim Breslin: -----and what the labs had in place. When Dr. Scally visited the labs, he saw the quality assurance systems in place and he was able to-----

Deputy Alan Kelly: He effectively stated that, from an oversight point of view-----

Mr. Jim Breslin: Yes, but he was able to comment on what the labs themselves had and comment on that in his report.

Deputy Alan Kelly: I accept that but that is not what I said.

Mr. Jim Breslin: I am not trying to have a row with Deputy Kelly, but quality assurance embraces both that of the labs and that of the programme.

Deputy Alan Kelly: Dr. Scally was referring to the programme.

Mr. Jim Breslin: Yes, I am just making that distinction. If he criticised the programme, that is not saying there was no quality assurance-----

Deputy Alan Kelly: I never said that. What I am saying is that there was no process or

oversight in place from the point of view of managing the contract, the management of the labs and the outsourcing of work by the latter. Dr. Scally stated that previously. In this report, he is going to examine both sides of that equation, the oversight as well as the situation within the labs. I look forward to that. It is a real issue and we get many questions about it. In reply to a parliamentary question I tabled recently, the Minister referred to Dr. Scally discovering that there was more outsourcing from labs to other labs. Is the Department of Health or the HSE reviewing the contracts with the labs? I am aware of the extension of coverage some months ago and of all of the issues, but is there any review of the contracts as a consequence of what Dr Scally is now finding?

Mr. Damien McCallion: On the learnings, Dr Scally's report had a number of recommendations regarding procurement, the balance of contracts, emphasises and criteria. We will be building those into the HPV procurement process. The contracts we extended were clearly for the purpose of trying to sustain the programme for a period-----

Deputy Alan Kelly: I accept that.

Mr. Damien McCallion: -----so that is slightly separate in respect of what is there. On the learnings identified by Dr. Scally on the procurement side, those will be built into the HPV process-----

Deputy Alan Kelly: Has any assessment of the contracts been undertaken on the basis of what Dr. Scally is discovering?

Mr. Damien McCallion: That is a slightly different question because it is historical. The current contracts are geared to bridge us through to HPV and sustain the programme until then. The recommendations Dr. Scally made on the procurement side are being implemented. Those recommendations were in his report. In this context, we will see them as part of the HPV tender and that is where they will come through.

Deputy Alan Kelly: Those contracts will have to be examined as soon as Dr. Scally's report comes out. Mr. McCallion addressed this question earlier, but when are we going to have HPV? Are we going to have it this year?

Mr. Damien McCallion: The key part in doing that, as I mentioned earlier, concerns the tender. We are concerned with two things. The first is to stabilise the programme. We have discussed how important that is and the challenge we have to do that. The second is that we are well advanced with the tender. We have had the pre-tender market engagement and we are more confident now that we will actually get a tender. There was a risk we might not get a partner to work with us on the programme, given where we are at now. We now move to the next phase of having an advertisement placed in the next couple of weeks and that will then dictate the timeframe. We are trying to move all of the other work streams along that I mentioned earlier, such as materials-----

Deputy Alan Kelly: Is McCallion confident that it will be done this year?

Mr. Damien McCallion: We are dependent on that tender process. We are trying to get there as quickly as we can. Everybody is interested in getting that done. We all want to get to that point as quickly as we can. Until we get into that tender process, I am loathe to get into speculation-----

Deputy Alan Kelly: I do not want Mr. McCallion to do that but we are continually asked

about this issue.

Mr. Damien McCallion: I appreciate that and we are absolutely committed. We are trying to move the other work streams, including the IT, the materials, etc. along-----

Deputy Alan Kelly: I am not going to pursue that because I do not want to create a vacuum. Regarding vaccination and the concept of herd immunity, I am on the record of the Dáil as being a strong advocate of boys having this vaccination. Where do we stand regarding herd immunity and getting boys and girls the HPV vaccination?

Ms Anne O'Connor: I will ask Dr. McKenna or Dr. Doherty to answer that question.

Dr. Peter McKenna: A decision has been made to vaccinate boys.

Deputy Alan Kelly: Yes, that is correct.

Dr. Peter McKenna: I am not sure when that is starting.

Deputy Alan Kelly: We have been told previously that the starting date will be in the fourth quarter of this year.

Dr. Peter McKenna: There is no doubt that vaccinating both-----

Deputy Alan Kelly: I just want to know when it is starting. Is it definitely happening in September? I want to know that there will be no delay.

Ms Anne O'Connor: It will be in quarter 4.

Deputy Alan Kelly: That is fine. It will be part of the school run.

Ms Anne O'Connor: Exactly.

Deputy Alan Kelly: I just wanted to make sure that it was not being put back.

I have three more questions. I have done some research and I am intrigued. When did the delay with the slides increase to 27 weeks?

Mr. Damien McCallion: Those are just the figures from this week. We have updated them in the last 48 hours, from Monday. We have a weekly process where we review the timeframe. There can be some spikes in the figures. If there is an increase in the throughput in a particular week, it will not be an even distribution in respect of the capacity-----

Deputy Alan Kelly: It is a big spike because last week, according to the parliamentary question answered by the Minister on 5 February, it was-----

Mr. Damien McCallion: It was 22 weeks.

Deputy Alan Kelly: -----22 weeks. That figure came down from 24, so we thought it was going to go from 24 to 22. I am looking at the trends rather than having a go at the fact that there is a spike. I thought that it was going to go to 24, then 22 and keep going down. Now, however, it has gone up from 22 to 27.

Mr. Damien McCallion: We do get spikes, especially through the Christmas period and into the new year. In the run-up to Christmas, for example, women will typically not seek to get a smear result so the figures drop off. There are also seasonal variations so it is not ever

an even distribution of both demand and capacity. My key point, however, is that until we get additional capacity we are still going to face significant challenges with the timeframe, whether that is 22 weeks or 24 weeks. We have to find that additional capacity and that is our priority at the moment.

Deputy Alan Kelly: Is the delay going to keep increasing?

Mr. Damien McCallion: The imbalance in the process is certainly a risk factor. What we are trying to do is to get capacity through either existing providers or other providers. We are following every lead we can, including the public system, and we are even working with other European countries to see what we can identify there.

Deputy Alan Kelly: I appreciate that this is an international process. My final question is one I have asked previously. It relates to a matter I have not got to the bottom of yet. The audit stopped on 1 January 2018. We all know about the issues that were part of the audit, etc. Examining this, all of the other variables have stayed the same. I am referring to the labs, etc. The audit has stopped.

Mr. Jim Breslin: Yes.

Deputy Alan Kelly: I appreciate and welcome what was said earlier about the process by which there will be new auditing procedures and processes across the whole screening programme. Are we not at a risk here because if all variables stay the same and auditing stops, does that not create a situation where the same issues that we are talking about here today and have been talking about for the past nine to ten months are also going to be there, in percentage terms, from 1 January 2018 until now? Is that inaccurate? If it is, show me the variable that has changed to make it inaccurate. Given that the audit stopped on that date and all the variables stayed the same, is there not going to be a lower percentage of the same issues because of the lower timeframe?

Mr. Jim Breslin: The audit is not part of the treatment pathway.

Deputy Alan Kelly: I know that.

Mr. Jim Breslin: The fact that there is no audit is not affecting the treatment pathway.

Deputy Alan Kelly: I understand that. If there is no audit, however, it is not a double-deck then, it is not picking up-----

Mr. Jim Breslin: The design of the audit was for quality improvement.

Deputy Alan Kelly: Of course, it is good to do an audit.

Mr. Jim Breslin: Where the audit fell down was in the non-disclosure aspect. That is the issue that we have to get right when we introduce the audit on the next occasion.

Deputy Alan Kelly: It is bigger than that now, in fairness. I get the non-disclosure bit. The Department is also not finding out basic facts about the quality of the programme and issues. There are other issues; it is is not just about communications and non-disclosure.

Mr. Jim Breslin: Restarting it robustly is the answer to that. By redesigning the audit, taking the weaknesses that were identified out of it, and putting it back in place, at that point we will be best in class, because we were already ahead of a lot of other countries. When we next

do it, we are not going to be ahead of them in terms of timing, but we will be ahead of them in the quality of the system that we use. That is the best way to address the issue that the Deputy is identifying.

Deputy Alan Kelly: There should be a continuous audit.

Mr. Jim Breslin: We risk repeating issues if we do not redesign it.

Deputy Alan Kelly: I accept that and have no issue with that. I am 100% with Mr. Breslin in getting that right. Because there is no audit in place since 1 January, the essential question is whether that creates any risks.

Dr. Peter McKenna: We agree that audit is an essential part of this. The difficulty is what type to do. That is what we are exploring. It has been acknowledged that the audit that has brought us all here together had flaws.

Deputy Alan Kelly: Absolutely.

Dr. Peter McKenna: That certainly cannot be recommenced. Which one does one recommence? How does one review the slides? Should they be blinded? Should they go to somebody who knows the results already? These are the questions that need to be explored. I would not dispute for a minute that audit is an essential part of this. The place we are trying to arrive at is what is the best form of audit to do. There is a degree of urgency in starting that.

Mr. Damien McCallion: Can I just add to that, please?

Vice Chairman: Can Deputy Kelly finish, please?

Deputy Alan Kelly: I am finished.

Mr. Damien McCallion: On the cancer audit, this is a very important part of the overall quality assurance of the programme. There are other elements as well that we need to focus on while that expert group is working. I mentioned earlier the appointment of the laboratory quality assurance, QA, lead in strengthening that. There are other indicators that are monitored by the quality assurance within the programme in relation to colposcopy, laboratory, and even things like in GP practice, and so on. The Deputy is right that elements need to be strengthened, as Dr. Scally identified, and that is what we are trying to do. Entering the cancer audit is just one part of the overall circle of quality.

Vice Chairman: I am obliged to offer a break if anybody wishes to take one.

Mr. Jim Breslin: One minute would be fine, but there is no need to suspend the meeting.

Vice Chairman: Our witnesses are absolutely allowed to do that.

Mr. Jim Breslin: If I do not come back in, it could be more serious.

Vice Chairman: We will press on, if that is agreeable.

I call Senator Burke now to speak.

Senator Colm Burke: My question relates to the laboratories, the adverse coverage that occurred here, and the discussion that is in the public domain on this matter. It also concerns the legal issues that have occurred. In dealing with the laboratories now, what kind of relationship

do we to have in our engagement with them and getting the work done? Are there alternative laboratories available if, for any reason, one of these laboratories decides that they do not want to take on new work? Where are we with this issue? Is there a plan B there should a laboratory decide to opt out of any new work? The Department and the HSE has already outlined that we do not have capacity in this country to deal with it. How would we then deal with that situation if one of the laboratories decided to opt out at this stage?

Mr. Damien McCallion: On the relationship, it was very challenging to get the contracts through in order to maintain the programme back through October. We are still in the process of concluding some aspects of that. As to alternative laboratories, as part of searching out capacity to deal with the backlog, we are trying to find those sort of laboratories that would either give us capacity to address the backlog or give us contingency in the event of any other scenario arising. I will not say that that has proved easy. It is very difficult to attract that capacity, because as I mentioned earlier, as people move to HPV screening, we are finding very limited cytology capacity available.

We are constantly trying to follow leads and looking to try to secure additional capacity. That same capacity would be available to address the backlog, or in the event of a worse scenario. We are not awash with options and we are having to work very hard to try to find additional capacity, primarily to deal with the backlog.

Senator Colm Burke: In dealing with some of these issues it has clearly been established that there was negligence in the way slides were read. The laboratories will also put forward the view that they are within the international norm, in that there is not a 100% capacity to get every screening result correct. Is that now raising a problem where the laboratories are looking for the Department to give further undertakings on this matter, or are we still able to deal with the issue in the same way as we were two years ago?

Mr. Damien McCallion: In relation to the environment with the laboratories - which is what the Senator is referring to here - it is certainly much more challenging. That speaks for itself in terms of what has happened. We are trying to work with the laboratories in a secure way. We look at the numbers and indicators for the laboratories from a public health perspective, which are reviewed and are within the norms. Matters of negligence are, of course, a matter for the courts, as to individual cases, so I would not comment on that.

We are still working with them and they are working with us to try to provide capacity. They are one of our solutions to the current problem we face in the delays that women are experiencing getting back the results of their slides. They are working with us and continuing to work with us, which is important for us, notwithstanding all of the difficulties, in order to ensure that we maintain a screening programme

Senator Colm Burke: .With the difficulties that we have gone through over the past six to eight months, what is the level of risk of one of those laboratories now withdrawing service?

Mr. Damien McCallion: I think there is always a risk, but in reality we have secured contracts and heads of agreement for finalising contracts with a second laboratory. We have worked with it to get a solution in order to maintain the programme. We have heard the figures, which Mr Breslin referred to at the start, on the improvement in cervical cancer survival rates in Ireland. There are many other figures on the number of abnormalities that the programme picks up. We have worked constructively as best we can in the circumstances to ensure that we maintain a programme and we are continuing to do that at the moment. Our challenge at

the moment is more - and there is always a risk as the Senator has stated - to secure additional capacity over and above what we have from whatever means we can find in order to address this backlog, which is our main concern for people.

Senator Colm Burke: I am sorry now to focus on this-----

Mr. Jim Breslin: I am sorry to interrupt the Senator, but can if I just come in for one moment? I can say this because I have observed it - the HSE has worked tirelessly to keep the laboratories and the programme going. It was not guaranteed, given how the controversy was raging in Ireland. There is a distinction with other countries, in that these are not public laboratories and are not as embedded in our system as a public facility would be. They have options elsewhere and the HSE worked tirelessly to keep that capacity within the programme. It is more assured now than it was in earlier months and Mr. McCallion discussed earlier the contractual situation. The fact that we are moving to HPV screening is also helpful in that regard. However, all the work Mr. McCallion and his colleagues have done allows us to be more stable in this situation than perhaps we were at the peak of the controversy.

Senator Colm Burke: However, if one of the laboratories decided to withdraw in the morning, we would have a major challenge.

Mr. Damien McCallion: We would. That is one of the things we have tried to manage through the contracts, and we are trying to mitigate it further in respect of looking at alternative capacity, primarily to address the backlog and, obviously, trying to accelerate the HPV project so we can get to that point through the tender. There is always a risk but we are trying to mitigate it as best we can, monitor it, work with the laboratories and address the issues that members have raised here in parallel with that. We have tried to strengthen the resource in the programme with the appointment of a senior person as the laboratory quality assurance lead for the programme and to bring in more resource and expertise to help do that because, clearly, many things are happening in the laboratory space.

Deputy Bernard J. Durkan: I wish to review the original audit. Perhaps the witnesses will remind me of how that took place. We dealt with this months ago but could they refresh my mind as to how it started? Did it relate to the number of women who were diagnosed with cancer after being cleared by the system? Was that the first issue?

Dr. Peter McKenna: No. The screening programme was notified about patients who had cervical cancer. Unfortunately, it excluded the patients who were notified to the cancer registry so it was incomplete in that regard.

Deputy Bernard J. Durkan: Why did it exclude those patients?

Dr. Peter McKenna: There was no cross-notification system in place at that time. That has since been amended.

Deputy Bernard J. Durkan: It was amended as a result of the lack of that facility at that point.

Dr. Peter McKenna: Yes-----

Deputy Bernard J. Durkan: It was not a case of some cancers being referred to the cancer registry but not all.

Dr. Peter McKenna: No. The cancer registry, we imagine, is complete, but the cases that

were notified to the screening programme were only about half of those that were being notified to the cancer registry.

Deputy Bernard J. Durkan: From the point of view of reassuring women now, how certain can we be that the system is accurate in determining the state of health of women who may be passing through the system now?

Dr. Peter McKenna: That is a slightly different area. The flaws in the previous audit have exposed the fact that if one had cancer, one would not necessarily be notified to the programme. That was a major flaw, which has been rectified.

Deputy Bernard J. Durkan: This has been very negative from the point of view of the women who have been affected and gone through much trauma, suffering and anxiety as a result. I have a question on information we got a long time ago but it is not obvious just now. How many women had a positive result from the screening? Did the screening detect on time and enable the women detected to receive treatment which, in turn, was successful?

Dr. Peter McKenna: There are two sets of figures I could use to answer that. One is that the number of women who have been dying of cervical cancer has been falling since the programme started. It is very satisfactory to report that because that is ultimately the goal of the screening programme. In that regard, it has been successful. The other issue is that of the 221 women who managed to make it into the audit, the majority had very early stage disease. They had micro invasive disease and those women are doing very well. Flawed as it may have been, the audit has provided some reassuring data that the majority of women are alive and well. That is not in any way to minimise the impact of those who have died or, indeed, the impact of those who are suffering from complications of treatment, but the majority are alive and well due to the fact that the programme identified them at an early stage.

Deputy Bernard J. Durkan: We know that the number of women dying of cervical cancer has dropped, but is there any way of measuring the number of women who were screened, whose pre-existing condition was identified and who subsequently were treated successfully?

Mr. Damien McCallion: We have that data. There are thousands of people every year and abnormalities are picked up through the programme. One woman in every two days is diagnosed with cervical cancer as a result of screening through the programme. The data on the abnormalities that are picked up through cervical screening for women are published regularly.

Mr. Jim Breslin: Since the programme was introduced in 2008, 1,200 invasive cancers were identified through the programme and more than 50,000 women with high grade abnormalities have been diagnosed and treated. That does not fully answer the question because obviously many of them would be cancer free now, but some of them would have gone on to be unsuccessful in their treatment. However, one can see the sheer numbers that have been detected by the programme, with women being identified either for follow-up or for treatment. That has contributed to the mortality reduction, identified by Dr. McKenna, that we have achieved as a country in this area. There is no doubt that at the population level this programme has been hugely successful. That is not to take from the individual issues that have arisen, but I do not believe anybody would question that the decision in 2008 to develop a national approach to cervical cancer was the correct thing to do.

Deputy Bernard J. Durkan: To return to the screening and the look back, has the HSE been able to determine the number of women who were identified as having a pre-existing con-

dition that required treatment? Has it the exact number?

Dr. Peter McKenna: That is a matter of seeing how many the colposcopy clinics have treated for pre-invasive cancer over the years. That number can be got but it would be into the thousands, as Mr. Breslin said.

Deputy Bernard J. Durkan: Could we get it?

Dr. Peter McKenna: That number is published in the-----

Deputy Bernard J. Durkan: Can we get a reasonable number as of now?

Dr. Peter McKenna: Yes. Thousands of women have been treated for pre-invasive cancer that has been stopped from going on to be invasive cancer.

Deputy Bernard J. Durkan: With regard to the 221 women who had different results and ultimately some having satisfactory treatment and so forth, when they were discovered, did alarm bells go off anywhere in respect of the laboratories to which their tests had been sent? For example, if one received a report and suddenly discovered that ten, 15, 20 or whatever number of results showed a negative in terms of accuracy, would it be normal to find out which laboratory dealt with them, particularly if a series of issues arose with one particular laboratory? I realise the matter is ongoing and has not been determined yet, but in terms of micromanagement it might be possible to find out where the first 50 or 60 cases came from.

Mr. Damien McCallion: We have committed to providing that to Deputy Bríd Smith. The only cautionary piece is that the analysis is important. Some laboratories that were with the programme in the earlier years had a higher number of women with cancer because there was a higher prevalence in the early years. Some laboratories also looked at younger populations in terms of where they served. There are factors in that but we have committed to make that available to Deputy Bríd Smith. We can make it available to the committee.

Deputy Bernard J. Durkan: With no disrespect, my question was slightly different from Deputy's. She was seeking to ascertain the laboratories from which the inaccuracies came. I am asking a different question. When the first results became available, was a pattern established in the first 20, 40 or 50 women, instead of waiting for all 221? If all the test results came from one laboratory, I would be inclined to pull the emergency brake and find out what was going on. If they were scattered among all the labs, however, that might create a different situation. It might lead to the conclusion that there is a fault in the system if they are all making the same mistake or are all falling into the same trap. Which would it be? There is no harm to remember that it has to be possible to determine this fairly readily. It would have indicated that one needed to watch what was coming from a particular laboratory, to check what that laboratory was doing, or if a particular laboratory had no negative results at all, to ask why that was the case.

Mr. Jim Breslin: We are back into the Scally report, which looked at how the audit was managed and how the linkage back into the labs took place. From the CervicalCheck programme we have identified recommendations to improve that. At the time the results were coming through, they were seen to be within the expected levels for a screening programme and for laboratories. Dr. Scally-----

Deputy Bernard J. Durkan: Was that equally across all the laboratories?

Mr. Jim Breslin: Dr. Scally deals with that but this is not to say that the systems that were

in place were as robust as they should be. This is the importance of his recommendations going forward.

Deputy Bernard J. Durkan: The same systems were in place for all the laboratories.

Mr. Jim Breslin: The overall CervicalCheck systems were the same. Each laboratory then has its own systems.

Deputy Bernard J. Durkan: That would immediately lead into the question I am trying to ask. Because the labs had their own systems, it alerts us to ask whether their systems were good enough. I am aware that this goes into the Scally report also. In the initial stages it should have been possible to become alarmed if there was a particular trend. A trend had to have been established long before the 221 women were in that particular category.

Mr. Jim Breslin: There are two things, one of which is travelling back in time to see if there was a trend. To identify if there was a trend one has to do some reasonably sophisticated analysis. It is not sufficient to say that a percentage was there and another percentage was over there. One has to look at the different risk factors the laboratories have. Dr. Scally goes through that. Importantly, Dr. Scally positions us going forward so that we can all be reassured that quality systems operated by the programme would be fully robust in identifying any issues that emerge, within the context of a screening programme where there will always be an element of false negatives. One will not eliminate that fully.

Deputy Kate O'Connell: Following on from Deputy Durkan's point, is Mr. Breslin really saying that we cannot look at lab A's results and lab B's results and compare them because the tests going into the labs could be different patient cohorts? More women over the age of 55, for example, would automatically show cell abnormalities. The lab's results would depend on the batch. If thousands of smear tests for 22 year old women are sent to one lab, and if thousands of tests for 60 year old women are sent to another lab then the laboratories are not dealing with the same disease spread. Is this really why we cannot compare? I am trying to help to clarify.

Mr. Jim Breslin: It is not that I am saying it; it is Dr. Scally who is saying it.

Deputy Kate O'Connell: Absolutely. I am just trying to add to it.

Dr. Peter McKenna: A more likely explanation is that if one laboratory, for example, had a disproportionate number of colposcopy clinics, they would be more likely to have a higher number of invasive disease.

Deputy Kate O'Connell: They have already been triaged as more than likely with something wrong.

Dr. Peter McKenna: Correct. As Mr. McCallion has said, there are reasons different laboratories could have identified different expected rates of invasive cancer. Getting back to Deputy Durkan's question, I understand that every laboratory appears to have had a number of interval cancers and no laboratory stands out as having none. That would need to be confirmed, but initial inquiries suggest that no particular laboratory has any very obvious issues with regard to identifying interval cancers.

Deputy Kate O'Connell: On the issue of HPV herd immunity, we went down to a rate of 52% immunisation with girls. Where are we now with percentages of HPV vaccine uptake after all of the catch-up programmes? Are we still going up the graph as opposed to down the

graph for uptake of the vaccine among young girls? Although I am very supportive of boys also getting the vaccine in September, it is very important to not take the eye off the girls because it will not work out if we do not keep the pressure on with the uptake among girls. I assume there is a robust team in place for marketing and awareness around the HPV vaccine to parents and for boys so that we do not end up in the type of situation previously that left a door open for people to attack the vaccine as a of waste money. I spoke at length with Professor Ian Frazer, a co-creator of the vaccine in Australia, about the barriers they came up against in terms of prejudice and scaremongering and about the savings to be made by using the 9-valent HPV vaccine, where two strains also deal with genital warts. The positives of using this vaccine is that younger boys tend to respond very well to knowing that a particular vaccine can stop a visible sexually transmitted infection, STI. Are we ready to go with the process of bringing in the boys' vaccine and are we definitely doing it right? We do not want the same pitfalls we had with the girls where there was an initial high rate for uptake and then it pulled back, and we could be back in the same situation again.

Dr. McKenna referred to rapid access gynaecological clinics. Are we going to get one of these for the 20,000 to 30,000 people? How will we deal with the backlog of women waiting who are symptomatic and, as Deputy Donnelly has said, the next tranche of women who will come through as a result of the increased awareness? Members have spoken about the maternity strategy in recent years and about how many women's physical issues in obstetrics and gynaecology tend to be put on the long finger. There is the attitude that if a woman is able to cope and get through her day, then she will be fine. How are we dealing with that end of it with regard to the rapid access clinics?

Dr. Peter McKenna: I believe there must be a more serious look at rapid access for gynaecological clinics. I agree that a lot of benign gynaecology has been overlooked in the justifiable rush to look after malignant gynaecology. There are, however, very serious benign gynaecological complaints that are not cancer but are life changing. It would be true to say-----

Deputy Kate O'Connell: Dr. McKenna might give some examples to the committee. I am thinking of prolapses and so on. Perhaps Dr. McKenna could indicate what these 20,000 to 30,000 women are living with.

Dr. Peter McKenna: One would hope that the vast majority of them are living with relatively minor issues but there can be very serious life changing conditions. The most obvious gynaecological issue is women who have incapacitating menorrhagia who would be anaemic. It is possibly due to large fibroids. It can be difficult to get prioritised for surgery because there is no doubt that benign gynaecology has been seen in the past as a soft target for cancellation when accident and emergency departments get busy. There needs to be greater emphasis on day case surgery, outpatient investigations and the ability to operate on those few patients who need full hospital care.

Deputy Kate O'Connell: I refer to work days lost. Most people in that position who have, as Dr. McKenna described, constant bleeding and are anaemic would be affected at work and would have sick days and so on. There is a significant Exchequer issue when 30,000 women-----

Dr. Peter McKenna: The hope is that the majority of these are relatively minor issues that could be dealt with as a-----

Deputy Kate O'Connell: Minor depends-----

Dr. Peter McKenna: I appreciate that but one does not wish to overstate the case either. There are certainly some women who have incapacitating issues of both pain and bleeding that are life altering.

Deputy Kate O'Connell: Somebody mentioned a fivefold or sixfold increase in referral to colposcopy. I imagine there is a certain amount of stress among general practitioners and doctors to make sure that nothing is missed. Has work been done to develop care pathways for primary care practitioners so that we do not end up with a sixfold increase in unnecessary colposcopy?

Dr. Peter McKenna: I am not saying that they are unnecessary but that they would be better directed to a general gynaecological clinic if one could get access to those quickly. The programme has an educational component about what a normal cervix looks like and individual colposcopy clinics are reaching out to their catchment areas to educate those general practitioners who would benefit from it.

Deputy Kate O'Connell: Is there a strategic programme here or is it *ad hoc*?

Dr. Peter McKenna: There is within the national programme and in individual clinics that feel they have pockets of practice that could be improved.

Deputy Kate O'Connell: I am a little uncomfortable with this new quality assurance, QA, lead, a consultant-level position. We had many QA people already in cervical services. Do they still exist?

Mr. Damien McCallion: Yes. There is a wider quality assurance need but a specific gap was identified.

Deputy Kate O'Connell: I got that. We had a QA team and none of them were consultants. What were they? Were they doctors or from industry?

Mr. Damien McCallion: There was a mixture. It depends on the programme.

Deputy Kate O'Connell: Could I have a breakdown of the QA people from before? Were they doctors, pharmacists or laboratory people? We had no consultant-level pathologist ever assessing the contracts to see if they were the right standard.

Mr. Damien McCallion: There are a number of issues. Dr. Scally identified areas for improvement in contract management, which was assessed. Those are part of the implementation of-----

Deputy Kate O'Connell: Dr. Scally was very clear. From memory, I think it was page 52 of the report. A box on one of those pages shows that the contract was for ISO accreditation. A particular laboratory said not to mind the ISO and that the American college of whoever says it is doing everything fine. Contracts have been awarded and been operational and these laboratories have been looking at smears. I am fine with the different discrepancies and such. From what Dr. McKenna said, it looks as if there is not an outlier here. I am trying to get down to how this could have happened. How could we not have ever had a consultant-level pathology expert looking at the laboratories to which we were sending all of the smears to see if they were up to scratch? What were the quality assurance people doing?

Mr. Damien McCallion: They would have been checking against a quality assurance standard that was defined based on best practice, most of it taken in from the NHS. Dr. Scally is

saying that the extra level of consultant-level input that is needed was a gap in the programme and a pathology-led programme-----

Deputy Kate O'Connell: We were taking the standards from the NHS and applying it to the contracts that we were giving to other countries. When this person was comparing it with what the standard was supposed to be, he or she missed that Quest Laboratories did not have the accreditation that the contract stated it should have.

Mr. Damien McCallion: The equivalence of that is a slightly different issue. Dr. Scally is looking at whether the accreditation standards are equivalent or not. I understand that the tender at the time went for ISO or equivalent. The discussion was whether the College of American Pathologists, CAP, standard in the United States was equivalent to the ISO standard. Dr. Scally is looking at that following our discussions and will report on it.

Deputy Kate O'Connell: Nobody looked at that before Dr. Scally.

Mr. Damien McCallion: In his report, he highlighted how the original decision on equivalence was made. The programme looked at the quality assurance standards as set out and prescribed by the programme. We would have circulated a quality assurance document-----

Deputy Kate O'Connell: From memory, how many quality assurance people were working on CervicalCheck? Was it six, ten or 12?

Mr. Damien McCallion: There were probably a couple of people working on QA. The laboratories have to be accredited-----

Vice Chairman: Two people were working on it. Was it their full-time job?

Mr. Damien McCallion: It was for one person and the other had a number of other roles historically. That is why we are trying to strengthen this on the back of Dr. Scally's recommendations.

Vice Chairman: At least one person was employed full-time to do this.

Mr. Damien McCallion: For quality assurance across the programme, yes. Each programme has a QA lead and they co-ordinate the response to that.

Vice Chairman: What grade was the whole-time equivalent person?

Mr. Damien McCallion: I would have to check the grade. The pathology gap is something that Dr. Scally said the programme needed to strengthen. We have moved to secure someone and that person has started in that role. That will mean, going forward, that we have that extra experience and senior-level input to the quality assurance process of the laboratories.

Deputy Kate O'Connell: It is more like a canyon rather than a gap not to have somebody who is an expert on this.

Ms Anne O'Connor: With regard to the HPV vaccine, the uptake by girls is 65% and increasing. It is continuing to increase and we are one of the few countries in the world that has seen such a reversal. The boys' programme is outside of this programme but it is being worked up through public health and the national immunisation office. Based on the success of the girls' programme, we will roll out the same type of programme, targeted at boys. The HPV vaccine uptake by girls is still a good news story.

Vice Chairman: They are few and far between but 65% and rising is definitely good news.

Deputy Kate O'Connell: We had a great rate with the girls, we went back and then we came up again. Are we mitigating against the same thing happening again?

Ms Anne O'Connor: Absolutely.

Vice Chairman: I thank Deputy O'Connell. I call Senator Conway-Walsh who has been waiting very patiently.

Senator Rose Conway-Walsh: I was watching proceedings earlier. Going back to 2008, I agree that the national cervical screening programme was absolutely the correct thing to do. There are no ifs and buts on that but we need to separate that from the decision to outsource to the USA. That was deadly dangerous and unforgivable. The witnesses may dispute that. I think that Dr. David Gibbons resigned over this because he felt so strongly about this. As resignations are not that common, we need to take heed of it and maybe not just pass it over. At the time, he pointed out that there were one third fewer diagnoses than there were in Ireland at the time. It is a public servant's job to give advice and recommendations but at the end of the day a Minister and Cabinet made that decision. No matter how all of this unfolds when we go down the road, that was a deadly decision and it feeds back into the matter of accountability and us all being accountable for the decisions that we make. I want to ask some specific questions which go back to the review and audit for the 1,800 smears. When will that audit begin and when will it finish? Why do the witnesses think the Taoiseach promised that they would be completed last May? Was he misguided in doing that?

Mr. Jim Breslin: I do not mean to be disrespectful but I am here as a civil servant, to give factual information. The Senator is asking me to pass judgment on political decision-making in 2008 and on the Taoiseach's statements. I am happy to answer the questions if they are posed in a different fashion but I am not engaged in either support or criticism of political figures. That is not the role that we seek to play at this committee.

Senator Rose Conway-Walsh: I would not expect the witnesses to do so. That is why we also need the Minister here. What information would Mr. Breslin have given the Minister, such as whether the resources were in place, so that he could say that the audit would be completed in May, as he said at the time? Have there been any changes that did not allow it to be done?

Mr. Jim Breslin: It has taken much longer than anyone would have expected to get the Royal College Obstetricians and Gynaecologists, RCOG, audit under way. That was not envisaged at the time. It is certainly the case that things developed in a way that was not originally apparent. It is important to consider what was happening then. People were seeking to address issues as quickly as possible and there was an onus or responsibility on all of us to do so. It was said for good reasons. We have experienced all the processes that had to be gone through, which the HSE has outlined and can repeat. The process is now under way. The slides are moving to the laboratory and RCOG has commenced its work, which it says it will complete within six months. There is now clarity on this that was not previously available.

Senator Rose Conway-Walsh: When did it start? I refer to the 1,800 women contacted in relation to the Royal College Obstetricians and Gynaecologists audit.

Mr. Jim Breslin: Mr. McCallion can speak to the process, including that of agreeing how the RCOG would do this, the transfer of the data to the RCOG and the transfer of the slides.

Senator Rose Conway-Walsh: I seek the start and finish dates so that we can tell women when it is likely to be completed. People feel let down because they were promised that it would be done in May, without going through all the processes involved.

Mr. Jim Breslin: Mr. McCallion will have to give the Senator the detail because women had to be written to and asked for their consent.

Senator Rose Conway-Walsh: That is correct, yes.

Mr. Jim Breslin: Therefore, it started but there were other steps along the way. The data have moved to the RCOG and the slides have moved recently. Mr. McCallion might walk us though the process.

Mr. Damien McCallion: The stages were as follows. First we had to build the link with the National Cancer Registry, which was one of the gaps that identified 1,702 women who were eligible, and it was necessary to establish next-of-kin in many situations. Then we moved to a consent process of writing to everyone and giving a second option. There was a support line and a system built to manage all that. We are now in the phase when in recent weeks the laboratories have started moving slides to the RCOG. As Mr. Breslin said, it has committed that it will take it six months to conclude on receipt of the slides. The slides have started moving to the RCOG in recent weeks and will continue in batches over coming weeks. A total 1,072 women have consented to partake in the audit. I do not have an exact figure here but probably several thousand slides will need to be moved, as each woman may have several slides.

Senator Rose Conway-Walsh: Would Mr. McCallion say that they will all be moved by, say, 31 March?

Mr. Damien McCallion: Yes, and it is hoped before that. The process has started and the schedules that are being agreed at the moment would certainly see it come in earlier than that. The RCOG will be moving the slides to laboratories to be read once it has a quantum so that it is not waiting for everything.

Senator Rose Conway-Walsh: Can we say that they will all be completed, that is, that the full audit will be complete, by September this year?

Mr. Damien McCallion: The timeframe is a question for the RCOG. Its says it will take six months from when it begins working on the slides. We will probably have to reconfirm this with it.

Senator Rose Conway-Walsh: Who is in charge of it all?

Mr. Damien McCallion: The RCOG is undertaking an independent review. The HSE's job is to facilitate and support that in terms of managing consent, getting the slides, working with the laboratories and the RCOG, and having weekly meetings with the college along with colleagues in the Department. A separate dedicated team has been set up purely to support the RCOG within the HSE.

Senator Rose Conway-Walsh: Who is accountable?

Mr. Damien McCallion: The RCOG review is an independent review commissioned by the Minister.

Senator Rose Conway-Walsh: Therefore is the RCOG accountable?

Mr. Damien McCallion: The RCOG will produce the report for each woman and also the overall piece of work which it has undertaken.

Senator Rose Conway-Walsh: Therefore the RCOG is accountable. Part of the reason I ask is that one person in particular has been campaigning for answers since last April about the death of his partner of 22 years who died of cervical cancer in 2017. He is getting no response whatever. He consented to the smear being audited as soon as he was asked but he has no idea. Think how this must compound his grief when the Minister refuses to answer his letters. Nobody answers him.

Mr. Damien McCallion: If it is helpful, I will take his details offline. We have a helpline and a senior clinician who has spoken to people who have been affected by this. I am happy to have a conversation myself or perhaps through one of our consultants that we might talk to him directly.

Senator Rose Conway-Walsh: I would appreciate it if Mr. McCallion could do so as this is what I mean when I speak of accountability in communication. I do not think any of it is acceptable, including the empty promise that was made, which was surprising from someone with a medical background. I completely understand what Mr. McCallion is saying in terms of being able to comment on any of that.

Mr. Jim Breslin: We do a lot of work with the committee. My one principle is that we do not politicise. There is a day when it might be nice to do so or one where it would be hard, but we just do not -----

Vice Chairman: No one is asking Mr. Breslin to politicise anything. The committee is happy to receive the clarification and we are not seeking at all to politicise anything.

Mr. Jim Breslin: I will do factual but I will not get drawn into conversation on politics.

Senator Rose Conway-Walsh: Nor would I expect Mr. Breslin to do so. The committee's job is that of public representatives.

Mr. Jim Breslin: The members have a different job.

Senator Rose Conway-Walsh: We have to do that. If we all do our job and we are all accountable, then things will be much easier. I refer to the breakdown of packages with Quest Diagnostics. Have packages been negotiated?

Mr. Damien McCallion: What does the Senator mean by packages?

Senator Rose Conway-Walsh: What has been agreed with Quest Diagnostics with regard to compensation packages?

Mr. Damien McCallion: We would not be party to that. Any cases that were taken through the court were worked through the State Claims Agency. We would not be party to that. We would have read what everyone else has read from the media but we would not have been a direct party to those discussions.

Senator Rose Conway-Walsh: Therefore it is directly the State Claims Agency.

Mr. Damien McCallion: Yes, in the cases through the court.

Senator Rose Conway-Walsh: I will take it up with the agency. Why does the HSE think

that there has not been immediate action to implement the open disclosure policy which was recommended by Dr. Scally?

Ms Anne O'Connor: The recommendation was a review of the open disclosure policy. We have committed to doing our interim review by quarter 2, for which we are still on target. That is not just about changing the language in the policy. There is a significant amount of consultation with patients who are involved in that. That process is under way. We are awaiting feedback from patient groups on some of those elements. We are on target and that is part of the implementation plan. The date has always been quarter 2 of 2019.

Senator Rose Conway-Walsh: Therefore it will be concluded by the end of July.

Ms Anne O'Connor: The HSE interim review will be done by the end of quarter 2.

Senator Rose Conway-Walsh: People involved are concerned that it is taking so long.

Ms Anne O'Connor: That was the date we always had for the timeframe.

Senator Rose Conway-Walsh: We are getting one date right.

Vice Chairman: I thank the Senator and call Deputy Jack Chambers. I appreciate that Deputy Chambers has just arrived but the witnesses have been here all morning so I ask him to be as brief as he can.

Deputy Jack Chambers: I acknowledge that. I know that it has been a long morning. I have some specific questions. How do Irish guidelines adhere to the European guidelines for quality assurance in cervical screening? Have these been updated? Cytotechnologists recommend five minutes per slide and one minute for documentation. Have we a real-time analysis of where the Irish position rests with those guidelines? Do we need to address anything to meet the European gold standard? I can ask a few questions together if that is quicker.

Vice Chairman: That would probably make more sense.

Deputy Jack Chambers: There is a significant waiting time of 27 weeks. What is the gold standard waiting time for screening in terms of a slide being analysed? How does that slide pathologically deteriorate in this time?. There is widespread concern on this and perhaps the witnesses can give some certainty on this. Mr. Breslin said we should not get into politics, and he is right, but can he confirm whether it was a political or professional decision to offer that? One of the concerns I have is that there is a general concern about screening. The Minister said as much last week. Looking at the inverse care law, the cohort which may, because of their circumstances, be the most likely to have a difficulty may be the least likely to take the free test. Looking beyond the reassurance and the strategy that was in place, has there been a look back on previous smears and the risk that may have been attached to a particular person's clinical characteristics? Do they need to be notified about future tests? Someone who may not have taken up the opportunity of having a free test may in fact be the person who requires it based on their own clinical backgrounds. I know that is a complex piece of work. Perhaps Dr. Scally is examining it, or perhaps there is no necessity to do it.

Has a risk profile been developed to determine what is an urgent smear and what is not? Are certain smears being prioritised over others within the 27 week wait time?

This may have been asked already - I was at the Joint Committee on Justice and Equality all morning - and I apologise if it has been, but when will the human papilloma virus, HPV, vaccine

be extended out-----

Vice Chairman: That question has been asked already.

Deputy Jack Chambers: I apologise; I do not want to ask any question that has already been answered.

Mr. Jim Breslin: I can give a very quick answer to that question. It will be rolled out in September of this year.

The decision to carry out retests was made by the Minister based on professional advice, and we have been through that issue over the course of the morning. The Minister received advice, including the advice of the Chief Medical Officer. We could speculate on the inverse care law, but there are a couple of things we should consider. Without the State saying that it would fund a consultation, those with the means to do so would have participated and others without the means would probably have been least likely to participate. The fact that the State provided funding equalised things to some degree. It also must be considered that there is quite a fall-off between the number that had consultations with their GPs who then went on to take a test. It seems that the very fact that they were reassured was sufficient for them at that stage. Ultimately, if people did not come forward, get a retest or go to their GP, the programme still has those people and will continue to call them for uptake. They are still within the programme; it is not the case that they have fallen out of it. They will still be in the programme and called according to the timescale set out therein.

Mr. Damien McCallion: In terms of the European guidelines, while it would have been an input into the previous quality assurance, QA, standards, one of the actions from Dr. Scally's recommendations is to update the QA standards in line with best practice, which would include the European guidelines, and look at those in other jurisdictions as well. That is also being done from two perspectives. The first is the current programme and the second is another process for HPV testing which is now under way and which will require a new QA model.

The standard turnaround for tests before the crisis was 17 days, and covered the period from when the slide went to the laboratory to when results were supplied to the GP or the patient. We are clearly some way from that turnaround level at the moment, and the challenge of addressing it was what we discussed this morning. We need to find more capacity to address the backlog that is in place. In terms of risk mitigation, we have prioritised the colposcopy clinics where there is clearly a need to read those smears much earlier. We are working on solutions which address the point the Deputy made about clinical backgrounds. A woman in a programme could be on a six month, one year, three year or five year recall, and that, in some way, reflects the risk to the woman. We are looking at whether a technological solution could be developed in this area. It is quite complex. Unfortunately the group for six months to one year recalls has a higher risk profile than the normal three to five year recalls. In addition, we had concerns about one of our laboratories, which had a quantum of the backlog, and so we sanctioned the use of HPV testing as a way of triaging the situation. By running them through HPV screenings those smears that were perhaps in a higher risk category were identified and moved to cytology much earlier. Those are the sorts of actions we have taken to try to mitigate the risk, while still trying to find capacity to get us to a stable point.

Deputy Jack Chambers: For those on a six month cycle of smear testing, is it possible that some of them could be waiting six months for the outcome of their tests?

Mr. Damien McCallion: That is a risk at the moment, and we are trying to address it by putting in some sort of solution that would identify those cases in some way. It is quite complex.

Deputy Jack Chambers: That is important. There should be an urgent profiling of those categories, because they have obviously been identified as being at particular clinical risk. It might be difficult with the providers being used at the moment, but it has to be addressed quickly. It could lead to greater risk for these women.

Mr. Damien McCallion: I accept that. The highest risk group is that made up of women who require colposcopy. It is being prioritised and worked through. We are trying to work through the others using prioritisation, and we are also triaging for a laboratory that has experienced significant delays in order to move those tests through the system much quicker. It effectively prioritises in the same way that HPV screening will when it goes live.

Vice Chairman: Mr. McCallion might provide an update for the committee on that work. The points made are very valid.

Mr. Damien McCallion: I will.

Vice Chairman: Was the advice provided to the Minister by the Chief Medical Officer prior to 28 April written down?

Mr. Jim Breslin: My recall is that it was written down in the context of the press statement that went out. They worked on that to come up with the precise announcement that would be made, that is, a consultation with a GP, and if in that situation it was merited.

Vice Chairman: In the consultation and the deliberations in the run up to that-----

Mr. Jim Breslin: We have done the freedom of information work, and it has been released.

Vice Chairman: On behalf of the committee, I thank Mr. Breslin, Mr. Dempsey, Ms Conroy, Ms O'Callaghan, Ms O'Connor, Mr. McCallion, Dr. McKenna and Dr. Doherty for appearing here today. This has been a really useful engagement. Sometimes committees get a bad press, but it is really important that we have conducted our business in a very respectful way. It sends the message to women that everyone here wants them to have faith in the screening service. That is what I believe our focus should be. I know this has been a marathon session, so I thank the witnesses again for their patience and their answers.

The joint committee adjourned at 1.10 p.m. until 9 a.m on Wednesday, 27 February 2019.