DÁIL ÉIREANN

AN COMHCHOISTE UM SHLÁINTE

JOINT COMMITTEE ON HEALTH

Dé Céadaoin, 23 Bealtaine 2018

Wednesday, 23 May 2018

Tháinig an Comhchoiste le chéile ag 9 a.m.

The Joint Committee met at 9 a.m.

Comhaltaí a bhí i láthair / Members present:

Teachtaí Dála / Deputies	Seanadóirí / Senators
Stephen Donnelly,	Colm Burke.
Bernard J. Durkan,	
Alan Kelly,	
Margaret Murphy O'Mahony,	
Louise O'Reilly.	

I láthair / In attendance: Deputy Bríd Smith.

Teachta / Deputy Michael Harty sa Chathaoir / in the Chair.

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

Cancer Screening Programmes: Discussion

Chairman: The purpose of the first of our two sessions is to meet the Academy of Clinical Science and Laboratory Medicine, ACSLM, and the Medical Laboratory Scientists Association, MLSA, in order to gain a greater understanding of the screening programmes, with a particular emphasis on cervical smear tests. On behalf of the committee, I welcome Dr. Irene Regan, Ms Marie Culliton and Dr. Helen Lambkin of the ACSLM and Mr. Terry Casey, Mr. Gerard O'Mahony and Mr. Pat Naughton of the MLSA.

I draw the witnesses' attention 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 their evidence to the committee. However, if 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, persons or entity by name or in such a way as to make him, her or it identifiable. Any opening statement they make to the committee may be published on the committee's 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 Houses or an official, either by name or in such a way as to make him or her identifiable.

I invite Dr. Regan to make her opening statement.

Dr. Irene Regan: I thank the committee for inviting the ACSLM to attend. The academy wishes to offer its heartfelt sympathies to all those affected by the current cervical screening tragedy. Recent weeks have been an extremely worrying time for many women and their families and has also affected the healthcare professionals providing their care.

The academy is the professional body and competent authority representing medical scientists in Ireland. Medical scientists are a regulated profession. Since 1996, all medical scientists must hold qualifications accredited or approved by the academy. We welcome the reviews called for by the Minister and will work with him, the Department of Health, the HSE, CervicalCheck and all other agencies to achieve the best outcomes for women having cervical screening. The academy is part of the newly established expert advisory group on cervical screening. The academy will fully participate in, and make submissions to, any Government or statutory inquiry and use its expertise to contribute to initiatives to improve all cancer screening programmes.

In 2008, a decision was taken to tender for screening cytology, that is, cervical smear test analysis, which resulted in this service, previously undertaken in laboratories in hospitals in Ireland, being largely delivered by laboratories in the USA. The academy wishes to clarify that the Irish accredited laboratories that tendered for the cervical screening service in 2007 and 2008 were informed that they had scored highly in all areas - quality and turnaround times - except cost. The academy is on record as stating that the decision to outsource this screening service was short-sighted. One consequence of this decision is that the academy does not have access

to information from the laboratories in question and, therefore, is not in a position to comment on the quality metrics or standards of individual laboratories at this time. Should the Scally scoping report identify any suboptimal performance within laboratories currently providing this service, a rigorous approach to remedying these issues will be required to bring them into line with international standards.

Cervical screening is a screen, not a diagnostic test. Involving the pathological analysis of cells from the cervix for pre-cancerous changes, it still remains the most reliable and effective way of preventing and detecting early cancers. Screening that is done through a national, organised screening service, where regular smears are performed as part of a screening cycle, has helped to reduce the rate of cervical cancer in Ireland. The cervical smear screen is not 100% sensitive for detection of all cervical abnormalities, but when performed to a high standard as part of a screening programme, it should significantly reduce the number of women diagnosed with cervical cancer. In the UK, there has been a 50% reduction in cervical cancer since the implementation of its screening programme in the 1960s.

Medical scientists examining a smear are required to reach individual "pick-up" or detection rates of 95% or greater for high-grade abnormalities and greater than 90% for all abnormalities. The minimum standard that the academy recommends and would support for cervical screening in Ireland is for each smear to be examined independently by two medical scientists specialising in cervical cytology, under the governance of a clinical pathologist in accordance with CervicalCheck's "Guidelines for Quality Assurance in Cervical Screening". These guidelines are based on those of the British Association for Cytopathology.

The professional staff in cytology screening laboratories in Ireland are medical scientists and pathologists with specific qualifications and training. All cervical screening laboratories in Ireland practise to ISO 15189 quality standards. These professional and quality standards in cytology and other clinical laboratories ensure that the test method and verification, result interpretation and reporting are controlled, audited and inspected. This is in keeping with international best practice.

The academy fully supports the introduction of the primary HPV test and is available to work with the National Screening Service, NSS, to advise on future pathological service provision for this and other cancer screening programmes. The system chosen for HPV testing must be selected based on the sensitivity of detection, not cost.

The academy advises and recommends that, on the introduction of HPV screening, the entire cervical screening service should be re-established in Ireland to ensure an entirely integrated service for HPV, cytology, colposcopy and histopathology for women in the one health system, ensuring continuity of care and clinical governance. The academy advises that this laboratory service be configured, led and managed by consultant medical scientists and pathologists, a service configuration that is now emerging as standard practice in the UK. The academy recommends and advises that the cervical screening programme that is put in place be quality assured and subject to regular independent audit and review against current best practice. The academy's position, in the interest of public safety, is that all the clinical laboratory services must be fully integrated with clinical services and provided by qualified, registered professionals in a properly resourced and accredited system.

Mr. Terry Casey: The MLSA is deeply saddened by the impact of CervicalCheck's system failures on individual women and on public confidence in the cervical screening programme. The screening programme has saved lives but it is now clear that it did not operate to necessary

standards, culminating in the serious failings in the CervicalCheck audit and communication process.

Cervical screening was first introduced in Ireland in the 1960s. Although discussed at the time, a national screening service did not materialise. By the mid-1980s, there were 15 laboratories providing both a diagnostic and cervical smear screening service, with an estimated 145,000 smears per year throughput and many laboratories experiencing significant backlogs. In 1987, the then Minister of Health set up a working party whose terms of reference included recommending how to improve arrangements to deal satisfactorily with the workload. While the final report concluded that no extra Exchequer resources would be made available to the service, it recommended that three regional laboratories be developed to provide a diagnostic cervical cytology service rather than a screening service and that turnaround times should not exceed one month. However, the continued failure to resource the service appropriately resulted in continuing delays in issuing timely results to patients.

In 1996, the then Minister for Health advised the setting up of the Irish cervical screening programme, ICSP, based in Limerick. It reported that in 2001, 217,898 smears were received by cytology laboratories and 203,868 were reported. It noted that double screening was carried out for 17% of all smears, rapid review was performed in 13 of the 14 laboratories, one laboratory reported complete rescreening on all smears, and waiting times ranged from one week to more than three months.

In 2004, the ICSP published a commissioned report by Dr. Euphemia McGoogan, a leading UK expert, who reviewed the first pilot phase of the ICSP, now CervicalCheck under the National Cancer Screening Service, NCSS, in the mid-west and made recommendations for a successful national screening service roll-out within an acceptable timeframe. Among the recommendations of Dr. McGoogan were the need to develop and redesign the existing laboratory structures into four regional screening centres that would "serve a defined population through a network of professionals working in primary care, laboratories and colposcopy", and it was envisaged this would be in line with what was developed for the BreastCheck screening programme. In addition, a single standard screening should be agreed and a move to liquid based cytology, LBC, should be developed which would greatly increase laboratory capacity by increasing the number of slides screened daily by laboratory staff. Furthermore, each laboratory should employ a quality manager to assist with obtaining laboratory accreditation.

In June 2006, in response to continuing backlogs, the HSE with the NCSS took a decision to outsource the backlog of cervical smears on an ongoing basis from 1 August 2006 up to 31 July 2008, with an option to extend the service for two years. On the basis of "urgent medical need", the contract was awarded without a tender process to Quest Diagnostics, an American based international company. During this period, Irish cytology laboratories were undergoing transition from conventional Papanicolaou, Pap, smear tests to LBC preparation in addition to working assiduously through the process of achieving accreditation in preparation for the roll-out of the National Cervical Screening Service programme. Some laboratories had already achieved accreditation. At the same time, laboratory workloads were increasing year on year and the HSE staff moratorium from 2006 was also having an effect on staffing levels in laboratories. Following a tender process in May 2008, the National Cancer Screening Service awarded the full contract for screening to Quest Diagnostics.

The Medical Laboratories Scientists Association, MLSA, warned the HSE and the NCSS in 2007-2008 of the risks of the short-term decision to outsource testing to the USA, due to the different testing and screening protocols in place and the disconnect between the outsourced

screening programme and the clinical services in Ireland for women subsequently diagnosed with cervical cancer. Concern was also expressed about the loss to the State of the skills to provide the service.

As a result of the outsourcing of the testing, more than 60 highly skilled medical scientists performing cytology testing in Ireland were redeployed to other areas in pathology laboratories, with a consequent loss of their skills. As a result, the overall majority of Irish cytology laboratories were not in a position to tender for subsequent NCSS contracts since 2010. Following the decision to outsource the testing, the NCSS, the Department of Health and the HSE expressed no interest in the development of a cytology screening service in Ireland, in line with the recommendations of the McGoogan report, advising instead that it was their preference to close existing screening services in Ireland and redeploy staff to other laboratory disciplines.

The MLSA welcomes the upcoming review into the service and calls on the HSE to invest in the retraining and upskilling of medical scientists so that the testing service can be returned to Ireland. It must be acknowledged also that the recent controversy has also impacted greatly on all the staff who have worked diligently over the past decade to provide the CervicalCheck screening service in Ireland. Our members hope that lessons have been learned by the HSE and Department of Health about the need to invest in Irish clinical pathology laboratories so that such vital services can be provided within the State in accredited laboratories with essential links to clinical services.

Chairman: I thank Mr. Casey. This committee is very anxious to find out exactly what happened regarding the outsourcing and awarding of contracts for cervical screening testing. Having heard the two submissions, three issues arise, one relating to costs, one relating to standards and one relating to outsourcing. The witnesses might address the issue of their view of the HSE's decision to outsource. What were the criteria used? Was it due to the costs involved, was it the volume in that it thought Ireland did not have the capacity, or was it that the laboratories in Ireland did not reach a certain standard? What is the nub of what happened in 2008 when the indigenous laboratories in Ireland were not resourced and developed to deliver the service within the country? Was it related to costs, standards or capacity?

Dr. Helen Lambkin: I would like to make a statement on one of those issues. I work in the Dublin Institute of Technology as a lecturer. Dr. Euphemia McGoogan's report was published in 2004 in which she reviewed the ICSP phase 1 and made recommendations for the expansion to the full national programme. In her report she made a statement about laboratory capacity. She said that five major laboratories were screening sufficient numbers of smears at the time for quality assurance in practice and that, with appropriate funding and training, there would be sufficient capacity to provide the full service provided they all moved to liquid based cytology, LBC, which was a different way of taking the cervical sample into a liquid so that it could be prepared in a mono layer. This was much quicker and easier to read than the previous smears and it also reduced many of the repeat smears that were a problem up to that time.

There was another ICSP report in 2006 prepared by Dr. Marian O'Reilly which examined the way in which capacity could be expanded through training of further medical scientists in the field of cervical cytology. When the report was produced, the Dublin Institute of Technology was approached. We set up a degree, with support and financial input from the ICSP, to train a further 50 medical scientists for cervical cytology. We took in students in 2006, 2007 and 2008 and we were in the process of completing their training to expand the numbers, approximately ten per year, when we had to discontinue that programme because the outsourcing meant there would be no opportunities for those students either to train or to be employed, so

capacity was not an issue. Those were the matters on which I wanted to comment.

Chairman: Was there any issue regarding standards?

Ms Marie Culliton: In terms of standards, in 2004, 2005 and 2006, there was no agreed or funded accreditation of medical testing laboratories in Ireland. There was some funding and a requirement for accreditation of food laboratories but not for clinical diagnostic laboratories. Many of the Irish laboratories undertook, of their own volition, to be accredited using the clinical pathology accreditation from the UK. That was a set of standards, which looked, as all laboratory accreditation does, at the pre-analytical variables, the analytical part, which is what happens in the laboratory, and the post-analytical parts.

In 2005, on foot of the EU blood directive, there was a statutory instrument looking for blood transfusion laboratories to be accredited to the ISO 15189 standard, which is the international standard for medical testing laboratories. That was mandated for blood transfusion laboratories and that was to be achieved by November 2008. Specific funding was made available in terms of staffing and allocation of resources for the accreditation of blood transfusion laboratories but those alone. At that time the Irish National Accreditation Board, INAB, which provides accreditation to the ISO 15189 standards, was not resourced or scoped up to accredit all the laboratories in Ireland and it was working towards the blood transfusion laboratories. At the same time there was a European co-operation for accreditation, EA, regulation in Europe which provided that accreditation services were not a matter for competition and must be provided by the national accreditation agency. That stalled the accreditation process for Irish laboratories, as many people who had been preparing to go with the UK CPA accreditation had to realign themselves with the ISO 15189 standard, given that the CPA was, after a certain time, no longer allowed to provide accreditation services in Ireland.

Although the laboratories were not accredited, they were all working in a quality management system and most - the cytology laboratories certainly had - had applied for accreditation in anticipation of this tender. It was similar to the situation with hospital accreditation, where people were working to a standard and self-assessing but had not been inspected by the hospital accreditation system.

Chairman: Were Irish laboratories training cytologists and increasing capacity in anticipation of the national screening programme?

Ms Marie Culliton: Yes.

Chairman: That was prevented by the HSE outsourcing.

Ms Marie Culliton: Correct.

Chairman: The outsourcing led to the abandonment, as it were, of training cytologists because they would not have had any work to do.

Ms Marie Culliton: That is right.

Chairman: When the contracts were reviewed in 2010, there was not the capacity to apply.

Ms Marie Culliton: Correct. For someone to be able to do cytology, he or she must be doing a minimum number of smear slides per year, both positive and negative. It is not an automated system - one must keep an eye in and maintain one's competence. Once the work left the country, the scientists in Ireland no longer had the material to work with to maintain their

competence. The decision to outsource the service was a decision to outsource it permanently. This was warned about at the time.

Chairman: I thank Ms Culliton. Does Dr. Regan wish to add something?

Dr. Irene Regan: I wish to cite the Irish Cervical Screening Programme report. According to a 2008 statement, it was the opinion of the Irish Association for Clinical Cytology, IACC, that:

> Irish laboratories provide a quality screening service as evidenced by comparison of incidence and mortality rates to other European countries. Even without an organised national screening programme, this State compares favourably to the UK which has had an organised screening programme for more than 20 years.

Chairman: I thank Dr. Regan. I will invite members to make their contributions in order of party. The first contributor will be Deputy Donnelly.

Deputy Stephen S. Donnelly: I am sorry, but I missed the start of the meeting. Would it be okay to revert to me later?

Chairman: Yes. I call Deputy O'Reilly.

Deputy Louise O'Reilly: I thank the witnesses for attending. I received their presentations yesterday evening and have had a chance to read over them. I have a memory of this happening at the time. Mr. Casey and I are colleagues and we made comment on outsourcing at the time.

I will focus on what drove the decision to outsource. My memory is that it was a highly politicised decision. The comment that was made by the then Minister related only to price. As the experts in the field, are the witnesses able to advise us of the clinical drivers of the decision? We are hearing that the preference should have been for the maintenance of the service. If memory serves, there was a great drive to outsource at the time, and not just in this area. It strikes me that the then Government's decision was driven by price and not necessarily by quality. What are the witnesses' views on this?

Regarding the deskilling and redeployment of staff, what shape are we in to insource the outsourced work? With the introduction of HPV tests, I understand that fewer experts will be needed.

In 2006, a tender process - we only got these documents this morning - was undertaken by the HSE. It was cancelled in September 2007. The decision was made not to continue with the pilot programme tender and to develop specifications for a national programme from 2008. Presumably, that was in line with the McGoogan report and would have involved insourcing. Have the witnesses any insight to give into what drove the outsourcing?

People from the HSE and the screening programme appeared before us. We examined the documentation from the time. One of the assurances given was that there would be regular teleconferences - it was ten years ago, so we might say "Skype" today - between the Irish and US labs. Will the witnesses give us an idea of the frequency of those teleconferences? Are they regular, for example, weekly, daily or monthly, or are they scheduled as needed? A head is being shaken at me, so I suspect that to be the truth. According to the documentation from the time, there would be regular teleconferences. We were reassured of it at our previous session.

I will be brief with my next question, as I only have ten minutes and want to leave time for

answers. Will the witnesses explain for a layperson like me the differences in how screening is carried out in Ireland? We adhere to the ISO 15189 standard. Does the same standard apply in the US or is it a similar one? Does the US use different or similar accreditation? I am not certain about what we are measuring, as we are comparing apples and oranges.

Dr. Irene Regan: I thank the Deputy for her questions. I will address the capacity issue in bringing the work back to Ireland. My colleague, Dr. Lambkin, will elaborate on it further.

The Minister has referred to bringing the laboratory testing part back. Were it to return immediately, we would not have the capacity. This is a direct impact of the outsourcing. That is the unfortunate thing. Our recommendation is based on continuity of care and clinical governance in a single health system as opposed to quality standards or the metrics. We are not commenting on the latter and saying, for example, testing in the USA is inferior. Rather, we are referring to continuity of care, which we have sought for a long time. We recommend that, on its introduction, HPV testing be implemented in Ireland. My colleague will discuss HPV testing and its advantages.

Dr. Helen Lambkin: In terms of increasing capacity, medical scientists who work in cytology generally undertake a four-year honours degree programme, either in GMIT, DIT or CIT and UCC. They will also complete a clinical laboratory placement training, which would not be in cytology but in all disciplines of the laboratory. Post graduation, they would have to train, usually for a year or a year and a half, in cervical cytology. It has that extra training because one must learn to recognise all of the normal cells, abnormal cells, infectious agents and patterns that are seen in smears. Those elements can be varied depending on the day of a woman's cycle, whether she has a previous smear history of abnormalities, etc. It takes a long period of learning before a medical scientist can sign out smears. In generating that capacity, we cannot just say that we will take all of the tests back in a month's time because we do not have the trained personnel *in situ*. We would probably have to bring in people from abroad to perform the smears. However, the Irish Cervical Screening Programme, ICSP, has been looking at the introduction of the human papilloma virus, HPV, test as the primary test on the cervical smear sample. The reason is Australia, New Zealand, Sweden, Italy, the United Kingdom and other European countries are all moving towards the idea that when a woman has a cervical smear taken in this liquid preparation, the primary test will be for high risk HPV. About 40 HPVs can be found in the anogenital region, but the ones that are high risk are oncogenic which can lead to cervical abnormalities. The recommendation in many countries is that the first test be for HPV.

HIQA brought out a report last year on the HPV test. It looks as if it will be tendered for. That is the future for the next developments in the service. In itself, it will take some time to implement. When it is implemented, if it is the primary test, for any positives for the high risk HPVs, smears will be prepared and examined as usual. The Irish laboratories have capacity to deal with the number when there is a reduction, but that will take several years. The academy's recommendation is that in the short term the plan be to implement the HPV test and then ensure all other testing, including smears, be performed in Ireland.

Ms Marie Culliton: It was indeed a political decision at the time. Laboratories in Ireland had been under-resourced for several years. Therefore, when the Irish laboratories were tendering for the services, they included the cost of achieving the accreditation standard, as well as the cost of building up the resources and the numbers needed to provide a service. I am also informed that one of the accredited laboratories which was part of a consortium was also required by its hospital board to include pension costs in the tender. They were total absorption costs, whereas the tendering commercial companies in the United States were absorbing the

work into their existing systems. There is a suggestion that they may have been looking for it as a loss leader because they were aware of a political intent to look at outsourcing in general.

Mr. Pat Naughton: It is hard for us to define what private industry and US companies do. As medical scientists in Ireland, we have a professional body which can stand over what we do. All of the standards are in place and we can relate them directly to the committee. In Ireland this sensitive test is carried out by medical scientists who are highly qualified having spent up to five years in college. Some of them have masters degrees and then go on to specialise in this area. They are not just cytoscreeners which they do not like to be called. They are highly qualified medical scientists who have specialised in this area. We know exactly who does the tests here and we can stand over what we do. However, it is hard for us to comment on what somebody else does. Fortunately, there is a centre in the Coombe hospital that does this important test. In 2008 the decision to lose the ability and autonomy of a nation to carry out its own testing for its people was short-sighted and led to this meeting. That must be borne in mind. If there is commitment to change this, there has to be a full and proper commitment.

Mr. Gerard O'Mahony: During the outsourcing in 2007 and 2008 there were continual teleconferences. They were held either once or twice a week. They also continued after the laboratories had disappeared off the scene because multidisciplinary team, MDT, meetings had to take place between gynaecologists and the pathologists in the United States who had done the cytology and the smear. The difference at the time between the screening in the United States and here was in the volume of work we were doing. In Ireland initially, when we started screening, we were doing about 32 screens per day. That changed with the introduction in the early 1990s of the rapid review which was the safety net. We worked on the basis that we would continue with 32 smear screens. At that stage in the United States they were doing 100 a day. Many of them said they had moved to using liquid-based cytology, which we accept. However, we found it difficult. We were dealing with what could be regarded as the original pap smear. We were changing to using liquid-based cytology between 2007 and 2008. In that case, we were hoping we would be able to increase the numbers we would do on a daily basis. The Americans still continue with a figure of 100, but we had a full rapid review of all negatives. In America they were doing a review of 10% of all negatives. That was the difference between the two.

Was there a clinical need to outsource? I do not believe there was. The service provided here is exactly the same. In fact, I think there was a better quality service here. On the question of capacity, the idea behind outsourcing was to achieve a 28-day turnaround time. One of the statements identified five laboratories that had a turnaround time of 28 days, but the rest of us could not achieve it. The reason we could not do so was the most essential report on the cytology service, especially the cervical side of it, the negative report. We were consumed by making sure it was negative. It had to be negative and that took much time.

In 2007 and 2008, when working in a laboratory, I had four people in training. They were qualified at honours degree level and had trained in the United Kingdom in September 2006. They had come back to the laboratory where we double-screened their work. There was a follow-up week in the United Kingdom in July and August 2007. They made a pre-exam visit to the United Kingdom and in Ireland in December 2007. We carried out a full review and brought in an international person to deal with all members of staff in April 2008. In June 2008 they were certified to report on liquid-based cytology. It took 21 months after completing their degrees and experience in the laboratory to be able to report in the cytology lab. There was a long lead-in period. They were essential members of staff. If one of them got sick or decided

to leave the job, we would have been back at square one in trying to get the expertise.

Deputy Stephen S. Donnelly: I welcome the delegates and thank them for attending.

The main concern for women throughout Ireland who have been and continue to be tested is the accuracy of the tests. There is a widespread belief the service offered by the US labs was not as good and potentially is not as good as the service offered in Ireland. That really is what women to whom I am talking want to know. Was a decision taken, based on cost, to knowingly outsource to laboratories which produced less accurate results? I was hoping we might get the delegates' views on that matter.

The academy is the professional and expert body. It has stated it cannot comment on the quality metrics. Yet, we have the quality metrics. The HSE provided the quality metrics several weeks ago. I have had the quality metrics examined by experts. The HSE has had the quality metrics examined by experts. The HSE has stated categorically that there is no difference in quality in identifying pre-cancerous or cancerous cells. The chief medical officer has stated that categorically and the clinical director of the HSE has stated that categorically. The independent expert I spoke to looked at the data. He said that while it would be great to have more data, the data the HSE released showed no difference in quality. If there is a difference in quality, we need to know and women in Ireland need to know. Given that the data have been in the public domain for several weeks and that the purpose of this Oireachtas meeting is to get a view on the quality issues, will the academy representatives address this question? I acknowledge there are labour and capacity issues and that these are important to the academy. In any event, the women of Ireland want to know whether they are being screened by substandard laboratories. Every expert we have had before the committee has stated categorically that there is no quality issue. The data provided seem to suggest there is no quality issue. The academy representatives have said they have no opinion on whether there is a quality issue. Why do they have no opinion? The data are in the public domain and this is the point of this Oireachtas meeting. Why can they not comment on the quality metrics? That is the purpose of our meeting, the data are in the public domain and that is what women in Ireland want to know.

Dr. Irene Regan: I will start off by commenting on judging the quality metrics and standards. The data in the public domain come from the 2014-16 audits. They are part of the serious incident management team report. They state that the positive predictive value is within international standards for all the laboratories. The report lays out the three laboratories: laboratories A, B and C. There is a variation in the reporting on the CervicalCheck quality assurance document or annual report. CervicalCheck reports total numbers. There seems to be variation in the way they are reported and the percentages reported. We have looked at that and we see there is variation and it needs to be clarified.

The annual report from CervicalCheck states that the figures include colposcopy. That could allow for the difference in figures. The serious incident management team report does not seem to include colposcopy. There is variation in reporting and that needs to be highlighted.

That is where we are on it. We know ourselves about the quality in our laboratories. As I said before, medical scientists examining a smear are required to reach individual pick-up or detection rates of 95% or greater for high-grade abnormalities. If we are talking about smears with cervical intraepithelial neoplasia, CIN, grade 2 or 3, as in the case of these women, we expect a detection rate for one independent medical scientist 95% of the time. My colleague, Mr. O'Mahony, will elaborate on this. We have two independent medical scientists reviewing a smear so the figure will be far higher.

We are talking about whatever is on a smear. We are not talking about the whole screening process. We are talking about if there are positive cells or abnormal cells on a smear. The figure for each medical scientist reviewing it by him or herself is 95% or greater. In reality, it is far better than that because we have two independent medical scientists or trained cytologists reviewing each smear. The figures are sent back to CervicalCheck quarterly. Medical scientists have to achieve this rate. The figure is greater than 90% for all abnormalities. We know that-----

Deputy Stephen S. Donnelly: I understand that. I am asking two questions. What women want to know is not the process used by the professionals. I know it is important but that is not the question they are asking. They are asking experts like Dr. Regan, whom we can trust, whether there is any evidence that the screening they have been provided with is substandard. The HSE has said there is none. In fact, the HSE has said there is categorical evidence that the quality is the same. The Department of Health has said there is categorical verifiable data or scientific evidence that the quality is the same. I am asking the Academy of Clinical Science and Laboratory Medicine as a professional body whether the academy agrees with the HSE and the Department of Health on the data and on the question of whether the quality is the same. Are the academy representatives asserting that they have data showing otherwise? We really need to know if the view of the academy is that the quality of the US laboratories is inferior to the others.

Dr. Irene Regan: I can answer on the statistics and what is in the figures of the serious incident management team report. We see a difference in laboratories A, B and C in the statistical difference between the reporting of the high-grade abnormalities. It is there in black and white. However, we cannot elaborate on that until the report looks at it because there may be demographic differences.

Deputy Stephen S. Donnelly: I am sorry to cut across, but in the interests of time-----

Dr. Irene Regan: No, I hear what Deputy Donnelly is saying. There may be demographic differences. There is a difference in the high-grade reporting in the three laboratories.

Deputy Stephen S. Donnelly: I want to ask about that because this made the front page of one of the newspapers as evidence that the laboratories were not as good in the USA. I brought this directly to an expert.

Dr. Irene Regan: We do not know which laboratory is in the USA.

Deputy Stephen S. Donnelly: We do. Laboratory B is in the Coombe. The other two are the US laboratories.

Dr. Irene Regan: No, there are three laboratories. There are two Irish laboratories and one US laboratory. We do not actually know which is laboratory A and which is laboratory C.

Deputy Stephen S. Donnelly: We know laboratory B is in the Coombe and we know the two US labs are laboratories A and C. I took the figure of abnormalities detected directly to an expert because it was on the front page of one of our national newspapers cited as evidence that the US laboratories were not as good. The expert said that was nonsense. He said laboratory B, which is in the Coombe, is showing a higher percentage of abnormalities detected because the Coombe is sent higher-risk tests. The expert said of course the Coombe would show a higher percentage. Furthermore, he said that the percentage of abnormalities detected is not what experts use to determine the accuracy of the laboratory. They use positive predictive value

because a false negative is so hard to get since it relies on self-reporting and because moving from pre-cancerous to cancerous cells can take ten, 12 or 15 years. He said, therefore, that the industry standard is positive predictive value, PPV. Moreover, he said that when we look at positive predictive value in two of the three years examined the Irish laboratory is the least accurate. Do the academy representatives believe that using the percentage of anomalies detected is a legitimate measure? I am being told by the experts that it is not and that it is potentially a determinant of socio-demographics, that is to say, different test results for different population groups. I am also being told that the Coombe may be getting what are already identified as high-risk samples.

Ms Marie Culliton: The results from the Coombe indicate that the results reported from laboratories A, B and C are programme smears and, therefore, exclude the tests that are already positive and that have gone through colposcopy. That is our understanding.

Deputy Stephen S. Donnelly: Can Ms Culliton say that again?

Ms Marie Culliton: Our understanding is that the results reported from laboratory B are what are called programme smears. Programme smears are the same whether they go to laboratory A, B or C. The Coombe also does smears from patients who are in colposcopy. They are the women who are already reported as having positive smears.

This is why when we look at the statistics it is really important to know what we are actually looking at, especially in the case of the Coombe. Are we looking at them with the positive colposcopy in or out? That will clearly change the percentage of high-grade smears reported by that particular laboratory. In different places they reported differently. My colleague, Mr. Gerard O'Mahony, can go into that with the Deputy in greater detail. If we look specifically at what has been reported by the investigation team from CervicalCheck, it looked specifically at 1,482 cases and said that in 442 of those one or more elements of their care required review. Of those, 209 had a variation in their cytology report and, of those, 175 should have had their treatment escalated. If we take that 175, it is 12% of 1,482 and 39.6% of those whose cytology was reviewed and it was found, based on that review, that there should be an escalation. I do not know where those cases came from because the report on 1,482 cases does not tell me in what laboratories or in what years the original slides were done so we need more information but I find it a little worrying.

Mr. Gerard O'Mahony: We are talking about the positive predictive value, PPV. I am a very simple man so I go back and look at definitions and give simple examples. In this particular case I go to CervicalCheck for the definition which is in most of its annual reports. It says the positive predictive value is reported as the percentage of women referred with high grade cytological abnormality who have a histological diagnosis of CIN2, which is high grade or higher. A simple example of that is taking three labs, X, Y and Z. In lab X, we give them 100 abnormal slides, they pick up 20 and 16 are accepted to be high grade. Lab Y picks up 40 and it is confirmed that 32 of those are of a high grade and lab Z picks up 80 and 64 are confirmed to be of high grade. That would mean that each of those labs working on the same amount of work has a predictive value, PPV, of 80%. It does not pick up false negatives. What it identifies are the individuals working in the lab and the number of positives they picked up which go on to colposcopy or biopsy and the confirmation of that. Each of those labs has picked up a certain pocket of positivity which is confirmed at 80%. That is what the PPV is. That is what it is defined as and it is defined over and over again.

The Deputy asked about ten years ago when the outsourcing started. Gibbons reported at

that stage that the norm across Irish laboratories was a percentage of 1.8%. The outsourced work at the time was giving a figure of 1.2%. He claimed a difference of 0.6%. That 0.6% is 0.6 per 100, six per 1,000, 60 per 10,000 and it works on like that. When one goes back and looks at the first figures-----

Deputy Stephen S. Donnelly: Can I ask Mr. O'Mahony about that because he makes a very important point? We put this to both the HSE and the Department of Health and the impression from what they told us was they were not terribly impressed with the analysis. What they told us, which we did not have time to get into in more detail, was that the testing and the samples being used were non-comparable and that the 1.8% and 1.2% were non-comparable. We did not ask for a technical note from the HSE or the Department to get into that. Does Mr. O'Mahony believe it was comparable? If so, what are the HSE and the Department of Health missing? They essentially refute that comparison and say it is not an accurate scientific comparison.

Mr. Gerard O'Mahony: At that particular stage according to the papers there were 60,000 smears outsourced. The HSE had figures on what was being outsourced and the incidence. That could have been compared back at that stage. Unfortunately at that stage there was too much focus on the 28-day turnaround time rather than looking at the quality.

Deputy Stephen S. Donnelly: On the issue of the 1.2% versus the 1.8%, because the Chief Medical Officer, who is the clinical director of the HSE, and various other people refute the comparison, does Mr. O'Mahony stand over that comparison?

Mr. Gerard O'Mahony: I am happy enough to stand over it.

Deputy Stephen S. Donnelly: I thank Mr. O'Mahony. Do I have time for one more question?

Chairman: We will come around again. I am afraid the Deputy's time is up. We will bring in our three remaining speakers, Deputy Kelly, Senator Burke and Deputy Durkan, individually.

Deputy Alan Kelly: I thank the witnesses for coming here today. They will have a huge role to play in the coming weeks. It is a very important role. Many people watching proceedings are depending on the witnesses. I know that because people have told me. There is a need for clarity and honesty. There is a need for the witnesses to explain what happened in the past. I have some of their documentation here. They flagged it in big red flashing lights in their professional analysis with regard to what some of my colleagues have addressed and which I will address with regard to the reviews, audits, processes and what has been delivered. I will also address the future. Let us not forget about that because obviously there will be a change. The dogs in the street know that.

We will bring this back as there would be an outcry otherwise. How do we resource for that in terms of human resources, IT resources, lab resources and all of that? How do we plan for it? Whatever is necessary has to be put in place. The witnesses will also be dealing with Dr. Karin Denton who is working with Dr. Scally on his work. I do not know if the witnesses have met or spoken with her yet. I expect the Department of Health is watching proceedings. Whoever in the Department of Health is watching proceedings, the Secretary General or whoever, will he or she please organise for these individuals to meet the representatives of the Scally team? I understand the relevant person is Dr. Karin Denton. Perhaps that would happen this week because it is very important.

I have a range of questions on the past, present and future. I have the very strong letter that Mr. Casey sent on 6 June 2008 to members of the Medical Laboratory Scientists Association. He pointed out that they would not be able to competitively tender into the future as a result of the decision and would not be able to develop capacity into the future which would have ancillary restrictions on the work its members do in the future. It is a very strong letter. Attached is a very strong statement from the time, which I read in a historical context given what we now know. It stands out very clearly. Mr. Casey talks about quality and detection rates, the future ability to tender, the creation of a monopoly, the reduction in mortality rates and the work that was being done on reform. His statement notes that Ireland stands relatively high on quality of performance. It is a very good letter and statement. Perhaps I will put a number of questions and the witnesses can come back on them because I have a range of questions. Mr. Casey said on quality in detection rates that "from recently adjusted figures, excluding urgent smear policy, at least 30% of cases with pre-cancerous cells will go undetected based on the data from the previous outsourcing exercise by the NCSS to Quest Diagnostics." I ask the witnesses to elaborate on that. It does not have to be Mr. Casey.

Mr. Terry Casey: Is that my statement? Has it been accredited to me?

Deputy Alan Kelly: It is a statement from the Irish Association for Clinical Cytology.

Mr. Terry Casey: That would be Dr. Helen Lambkin then.

Deputy Alan Kelly: I mixed up the two of them. It is my fault. I apologise.

Dr. Helen Lambkin: Could I mention-----

Deputy Alan Kelly: Let me finish. I have another question. That is the first point. We know now that the 70-30 rule has been cited all along. I was very much taken by the previous outsourcing exercise because it is a statement of fact. It also says: "We would be concerned that an increase in mortality and morbidity may result in Ireland by using a laboratory with low detection rates." There is a correlation with NCSS going to Quest Diagnostics and mortality rates. First, there is the 30% of cases that will go undetected based on data from previous outsourcing. Based on that data the mortality rate will increase because of using a laboratory with a lower detection rate. Finally, I also have a letter from Alison Malkin of the school of biological sciences in Dublin Institute of Technology, DIT, of 17 April 2007, which was sent to Mr. Drumm and copied to Mary Harney. Basically, it says that because of the decision to outsource, there would be concerns regarding differences between screening algorithms, reporting systems and quality assurance.

In fairness to all the witnesses, they flagged what transpired to become the main issues, which have left us in a situation where we have a range of problems going forward. My two questions to Dr. Lambkin are on the definite correlation between the previous outsourcing, on which she might elaborate, and the 30% of cases, and fears about mortality rates because of the outsourcing. What she said is quite scary now when we look at it in the modern context.

Dr. Helen Lambkin: I can reply, but I am not representing the Irish Association for Clinical Cytology because I was not on that committee.

Deputy Alan Kelly: That is fine. I use these for historical context.

Dr. Helen Lambkin: That is no problem. What I am quoting is the Dáil debate of 29 May 2008. Deputy Aengus Ó Snodaigh said: "Quest has won the tender to analyse 300,000 Irish

smear tests a year, but consultant pathologists [which are medical histopathologists] from the Coombe Women's Hospital, St. James's Hospital and St. Luke's Hospital in Dublin, and University College Hospital in Galway stated that missed cases would arise because the diagnostic rate of pre-cancerous cells at Quest Diagnostics in the US is 30% less than that of Irish laboratories."

Deputy Alan Kelly: That correlates with what Dr. Lambkin said.

Dr. Helen Lambkin: We did not make that statement. That is from consultant histopathologists associated with the faculty of pathology. They said that would be the case. The membership of the Irish Association for Clinical Cytology is medical scientists and consultant cytopathologists so it represents both the scientists and medical doctors involved. Our organisation would take huge cognisance of what they say because they are the experts working in the field.

Deputy Alan Kelly: What about the link with mortality rate?

Dr. Helen Lambkin: I am not able to comment on that. I am not sure what the question was.

Deputy Alan Kelly: It says: "We would be concerned that an increase in mortality and morbidity may result in Ireland by using a laboratory with low detection rates". That is a fairly definitive statement.

Dr. Helen Lambkin: What that means - I am just explaining, not making a statement on it - is that if there are 100 women with high grade abnormalities and the cancer in all of them is detected by the screening test, they will be treated and, therefore, their pre-invasive cancer will not become invasive cancer and they will be cured by colposcopy and laser excision. If cancer is only detected in 70 women, the other 30 will develop invasive cancer. What we are all concerned with is that whatever test the cytology screening programme is doing would pick up preferably 100% of those high grade cases to ensure that there is no mortality from cervical cancer. However, there is no test that is 100% perfect at that-----

Deputy Alan Kelly: I understand that.

Dr. Helen Lambkin: -----but they were concerned because they felt the pick-up rates were lower than in Ireland. That is what their opinion was and that, therefore, more women would develop invasive cervical cancer.

Deputy Alan Kelly: My point is all of these issues were flagged in 2007.

Dr. Helen Lambkin: These were all in the *Irish Medical Times* and in *The Irish Times*. It was also discussed in the Dáil.

Deputy Alan Kelly: I will move on because I have a range of questions.

Chairman: The Deputy has three minutes. He should make his questions concise.

Deputy Alan Kelly: I ran the clock on the others. I have more than three minutes.

I refer to the quality of the results being provided. Letters were issued to women. A total of 46 got them in time and others only received them recently. I have a copy of one. On the left it gives the previous result and, on the right, it is reviewed. I know from talking to people and through the audit which started in 2014 the volume of women who are going from P2 to P9.

There have been many conversations in the Oireachtas over the past two weeks about statistics, and I am a member of the Committee of Public Accounts as well. However, this is not just a case of carrying out these tests, the statistical comparison being 70:30 and these women being part of the 30%; this is catastrophic human error. A woman does not simply go from P2 to P9. The witnesses have a huge role in this. Do they believe that once the audit process was being conducted - and Vicky Phelan made it quite clear to us in the other committee that it was quite obvious that she had cancer and that it was human error - that there was a responsibility on the HSE when it saw as part of the process that there was such a movement from one reading to the other, to qualitatively analyse what was happening? That is a critical question.

Ms Marie Culliton: The Deputy is right. It should have rung some alarm bells. We can look at the statistics and say we have a change in results, so it moved from being negative to being borderline. That does not have a particular clinical impact. We need to look at the clinical impact of the established error without jumping to conclusions. I offer my sympathies to all the women who got a letter that indicates that there was a mistake in their treatment, but we have to wait until the Scally report is issued. He is doing an in-depth audit that will, hopefully, give us what we believe might be a heat map telling us if there is a problem in one particular laboratory, if it was with a cluster of years and if it was a cluster of people who were working there.

Deputy Alan Kelly: 2011 appears to have been a bad year.

Ms Marie Culliton: It may have been. I do not have the figures for the particular year but it seems to have been a bad year. This is not an exact science. One is looking down the microscope and one is comparing what one sees with what one knows to be normal or what one knows to be abnormal. If one now knows that this woman has been diagnosed with a tumour or that following colposcopy she has been found to have cervical cancer, then one goes back to look at the review slide with a different lens to a certain extent. One is looking to see if it was there. Sometimes one may find it in a slightly different way. However, we need to look very carefully - and Dr. Scally will do that - at exactly what was happening, where it was happening and who was doing it. Something that goes from P2 to P9 is not good enough.

Deputy Alan Kelly: I appreciate Ms Culliton's honesty. In fairness, she is spot-on. We have a memorandum-----

Chairman: This is the Deputy's last question.

Deputy Alan Kelly: I have many other questions but I will come back in again.

Chairman: We will come back to the Deputy.

Deputy Alan Kelly: I have many questions about the future in addition to the current situation. Let us consider the note that was prepared by the HSE for the Minister for Health and the Department only a month ago in April. It states there was no issue relating to quality. That is famously said in the memorandum. We all know now that was completely ridiculous and wrong. I refer to the audit process. When the review was carried out, it would have been glaringly obvious that the movement across was so seismic. In addition, the HSE did not see that there was a quality assurance issue involved and that the movements were so catastrophic that there were issues regarding what was going on and the laboratories. We need to break down the position in respect of the laboratories. I have a fundamental belief we need to chase the money relating to the laboratories, where the smears were conducted-----

(Interruptions).

Deputy Alan Kelly: Chair, I cannot get any rhythm when I keep being interrupted. In fairness, I do not think others have been interrupted.

Chairman: The Deputy has exceeded his time by five minutes and we want to allow other members to contribute.

Deputy Alan Kelly: Will I just leave? My point is that there is a requirement for a quality assurance review. It was quite obvious within the HSE and there was a failure there to notice this, which is obviously a process failure and a failure of management.

Mr. Pat Naughton: Many of Deputy Kelly's questions might need to be redirected to somebody else in the context of why that did not happen within the HSE.

I want to cross-reference the final point made by Deputy Donnelly. What we do is subjective. The emphasis here must be on pre-cancerous cells. That is the medical scientist who uses his or her knowledge and expertise to subjectively make a call on that. The integrity of the scientist is of paramount importance here. We do not want to mask results by bringing in other areas. We are talking about pre-cancerous cells and the subjective testing of them. I think that is very important to note. We need to focus our data on that.

Senator Colm Burke: I thank the witnesses for their presentations. The witnesses referred to 15 laboratories in the mid-1980s. My understanding is that there are now two laboratories in Ireland that do this work. Are there other laboratories doing other medical analysis that could take on some of this work if they got the staff? What is the position relating to laboratories overall in the country if we wanted to retain all of this work?

In order to retain the work, we would have to upskill people and ensure that we have an adequate number of individuals who are suitably qualified. A total of 60 people were redeployed as a result of the outsourcing. If we started a programme today to ensure that this many people would be sufficiently qualified, how long would it take us to ensure that we reached our target? Are there people conducting clinical analysis in other areas who could be switched with upskilling or must we start from the very beginning?

The witnesses talk about how higher-grade abnormalities should be identified in 95% of cases while all abnormalities should be identified in 90% of cases. I have seen different reports. I saw one, a document produced by Professor Brennan, which seems to indicate that his figures would vary somewhat from those of the witnesses. One of the issues that needs to be identified is the fact that the smear test - and the work done in this area - deals with that specific type of cancer; it does not identify other cancers. We need to get clarification as well on that because once a person got a clear smear result and even issues arose about which they were concerned, the immediate response was "Well, it can't be cancer. I've got a clear smear." Do we need to get an great deal more information out there to the effect that the smear test or even the HPV testing about which we are talking will not produce a finite result of 100%?

We are now in the area of litigation. If we take the figure of 95% of higher-grade abnormalities, what about the 5% where it is not identified? How do we deal with that from a litigation point of view? Last year, we paid out €300 million in claims through the State Claims Agency. For every €1 million paid out, there is €1 million less available to spend on healthcare. I am not taking from people affected by errors. Where genuine errors occur, people must be adequately compensated. All of the screening is not 100%. How do we now deal with this issue? I am

not doubting the 95% but there are still 5% of cases we cannot and will not be able to identify.

Dr. Irene Regan: I will take the first question. We discussed the capacity issue previously. Senator Colm Burke asked whether there are other clinical laboratories that can take on this workload. As we mentioned previously, medical scientists are highly qualified. They spend up to five years in undergraduate education, which includes an obligatory clinical placement. Cervical screening is very specialised so they need to train in that area so we just cannot take somebody and train them in a day. It does take up to two years to do that. They must meet competencies, look at 5,000 cases in order to be declared competent, be signed off and complete various courses. That is the protocol for that and the academy would definitely support that and expect nothing else in the future for that. There is a long training process. We are talking about quality here and training and standards are very important. This is what the academy is about. It is about professional standards and recommending. As a result, we cannot have a sticking plaster. If we bring it back here, we want the experts to do it and we want to assure the women of Ireland that they have a quality system operated by highly-trained experts who specialise in cervical cytology. It will not be a quick fix. We cannot just move people back and forth to do this. Clinical diagnostics is a very specialised area. We train for a long time to do it. Many decisions are made on the work we do so it is very important to get it right and to be qualified and expert in it. The academy would support that.

I will discuss Professor Brennan's report and my colleague, Dr. Lambkin, will elaborate on HPV testing because the Senator asked about that. There is a bit of debate and confusion regarding statistics concerning the 65% to 75%. This is about the screening process. This is the whole process, this is what the 65% to 75% concerns. It relates to if the smear is taken at the right time and in the right way, and what it picks up. There will be adenocarcinomas. There are different cancers that will not be picked up by a screening process. When he talks about the screening, it is the process and, of course, the laboratory analysis of that smear is included in that. He is talking about 60% to 75%. I think it has got lost and it very confusing for people out there. Women are thinking that it will pick up their positive result only six out of ten times. This is a positive result at which we are looking in respect of a smear. That is not six out of ten times. It is the whole process involving whether it is taken properly. The women about whom we are talking had positive results. The cells were on the slide. This is a very different thing to whether it was taken at the right time or whether they had pre-cancerous cells that could be picked up by the screening process. There is confusion out there and it is important to clarify what those statistics mean.

Senator Colm Burke: With regard to the 95%, Professor Brennan has said otherwise on the issue because it does not identify other cancers. When one considers the overall figure it is not 95% of all abnormalities. As I understand it, the screening process is 90% of all abnormalities in that particular area but not in other areas that are cancer related.

Dr. Irene Regan: The 95% pick-up is what is on the slide.

Senator Colm Burke: Yes, but 95% of that area that is being looked at. I am open to correction on this, but the tests would not pick up womb cancer for example. This information needs to be classified.

Dr. Irene Regan: That is the screening process, rather than what is on the slide. My colleague Mr. O'Mahony will elaborate on this point.

Mr. Gerard O'Mahony: I believe we are getting a bit confused here. The 90% and 95%

areas are observer error. In other words, out of 20 abnormalities at high grade there may be 5% missed. That is the entitlement of the medical scientist. We are looking for that 90% to 95% on target. Over all abnormalities, including low grade and high grade, one is looking for a return of 90%. If we do not achieve that then it is a case of retraining or looking again at the positives, or there is another form to get back to that level. That is the level at which we work. It is a very high level of detail and is very tiring, but it is the level at which the scientist works and the level he or she is permitted an error of maybe one in 20. If the scientist makes two errors in 20 then he or she comes off the bench. It is very simple.

Senator Colm Burke: That analysis relates to the screening programme being done. It does not deal with other issues around other cancers. The misinformation out there is very much that once a person gets a clear smear and a clear result she is totally clear and does not have to worry about it for three years, whereas there are other cancers that the tests may not identify. Would the witness agree with this?

Mr. Gerard O'Mahony: Yes.

Senator Colm Burke: I also raised the issue of the 5%. We are now into the whole area of litigation. The witnesses have referred to the 95% where it will be identified but there is 5% where it may not be identified, for one reason or another. If this arises through subsequent audits and reviews where readings were incorrect, as in this case, how do witnesses propose that this is dealt with?

Dr. Helen Lambkin: With regard to quality assurance CervicalCheck has a quality assurance document that gives protocols for how smears are examined and checked, what the quality audit is and so on. When an individual medical scientist looks at a smear, which may be 95% pick-up of high grade cells, another medical scientist will be screening that slide also as a second screen. That is the quality procedure as performed in Ireland. If there is a 95% pick-up by the first screen there is a good chance that the second person might pick up one or some of the 5%. This is why there are two people looking at the smear - to hopefully pick that up. There is always human error.

Some individuals who get cervical cancer have a form of cancer called adenocarcinoma as opposed to squamous carcinoma. Adenocarcinoma, generally, is harder to pick up in smears. Sometimes when a person gets a negative smear there may not have been representative cells of that tumour adequately present for it to be identified. The smear is most effective for the identification of cells related to squamous carcinoma.

Chairman: I thank Dr. Lambkin. Senator Burke may have one last question because we have to move on.

Senator Colm Burke: How does the witness propose to deal with the cases where everyone has worked to their absolute best in dealing with smears and the analysis, and for some reason or another an issue is not identified and we are into a litigation situation? How do we deal with this in the long term? It is now a challenge.

Ms Marie Culliton: Litigation can happen but if the test is inherently incapable of detecting the adenocarcinoma, if one has gone back to review the smear, and if one has reviewed the slide down the microscope and confirmed there is no abnormality present, then one cannot find anybody negligent with regard to litigation. Nobody has done their job incorrectly. No smear and no screening test is 100% detection. It is a screen, it is not a diagnostic. There are many

women present. When we speak with women we explain to them what is going on. Women are clever. Do not promise a woman that a negative smear means there is absolutely no risk that she has it at all. Be absolutely clear in the communication and be upfront with women, they will listen and accept it. We cannot accept, however, when there is clear evidence of an abnormality in the sample taken that it is not detected. This is where the litigation problem arises.

Chairman: We are moving on to another round of questions. I will bring in Deputy Bríd Smith on the second round. Deputy Durkan has given way to Deputy Louise O'Reilly. When we go to the second round of questions there is one question to be asked, for 30 seconds, to allow plenty of time for the answer. We need to try to bring the BreastCheck witnesses in at 11.15 a.m. I ask Deputies' indulgence in this.

Deputy Louise O'Reilly: I will be brief. I apologise that I must ask my question and then leave because I have an appointment.

My interest is in the decision that was taken in 2008 on outsourcing the screening service. It is pretty clear that it was a political decision. The witnesses might be able to fill the committee in on the clinical involvement at the time. What is the witnesses' understanding on where the decision to outsource came from? Was there a huge amount of consultation with clinicians in the run-up to the decision to outsource? My memory of it is that it was a purely political decision and not a clinical decision. In the run up to the decision being made, what was the level of discussion with clinicians, what were the issues identified and what was the ultimate deciding factor in 2008? We are all dealing with the consequences of the decision to outsource and it is very material to the discussions that will take place at this committee.

Mr. Gerard O'Mahony: I will explain our position. In 2007 there was a backlog of screening in the State. A number of us were invited, along with the National Cancer Screening Service, to look at where we could find laboratories across the UK and France that might be able to take our backlog, or help us with our backlog. We researched this and had procurement people from the HSE with us that led the team. We came back with information on people who were training and people who were being educated in colleges in this discipline, but like a bolt out of the blue, in March of 2008 we were told that the work would go to tender. I am trying to remember dates but we had travelled to the UK and to France in May and June and it was later in the autumn out of the blue the decision was taken that the work would go to the US. I certainly did not visit the laboratory in the US, and I know nobody of the cytology fraternity at that stage who had visited a laboratory in the US.

Deputy Louise O'Reilly: So the clinicians were not involved in the selection of that particular lab.

Mr. Gerard O'Mahony: No.

Deputy Louise O'Reilly: That is very interesting.

Dr. Irene Regan: Ireland seems to be the only country that outsources any part of its screening programmes to any other country. It is very rare for this to happen. We have done the lists through searches and it does not happen.

Chairman: I ask Deputy Durkan to be concise.

Deputy Bernard J. Durkan: Does the Chairman wish me to stick to ten minutes?

Chairman: Less if possible.

Deputy Bernard J. Durkan: I thank the witnesses for coming before us this morning. Their information is quite enlightening. I have a number of questions about the two-year training programme, which is regarded as the ideal situation. Does this apply in the United States of America and in other laboratories outside of Ireland, and does the sector here have any control over that?

I must mention that I am biased with regard to the need to retain laboratory facilities at home in Ireland. I have always been strongly of this view. I do not see any basis at all for outsourcing, except in very short-term situations and emergencies. We have a right to have the best information available to us in the shortest possible time, and this is the only way to do it. Did the witnesses have any forewarning, before recent events, that something might be wrong? Can they shed any light on that now?

How long would it take to increase laboratory capacity in this country to meet demand at the present time?

How does the turnaround time in this jurisdiction compare to that in the United States?

Two people deal with every sample. Are there any procedures which might be dealt with by more than two people, particularly where people get tired? Is there a checking system where a screen may be looked at for a second time immediately in the laboratory, rather than having the person present for a repeat screening?

I have spoken, and I am sure we have all spoken, with women who assert that something is wrong. Even when laboratories and clinicians tell them that nothing is wrong and that all the tests are okay they still insist that something is wrong but the problem is they have been proven correct. Can the witnesses tell us why that might be? I am talking about some of the most voracious forms of cancer. My theory is that the patient, who is the person in the eye of the storm, knows best. They do not have the medical knowledge required to describe what is wrong. However, if they feel something is wrong, they are usually correct. That has to be borne in mind.

Dr. Irene Regan: I will take the capacity issue again. The Deputy asked how long it takes to train people. We have to look at one year, three-year and five-year strategies. Given the current environment, it will be very difficult to encourage people into cervical cytology; it is seen as a high-risk area now. It takes a minimum of two years to train people up in this area, and we have to look at how sustainable that is in the long term to ensure that we will have people working in that profession in the future. The Academy of Clinical Science and Laboratory Medicine is concerned with expertise, not just training a person up quickly. It will take two years, and it involves encouraging people to take up what is seen as a high-risk, difficult profession.

Mr. Gerard O'Mahony: To meet the current capacity of over 300,000 smears between 30 and 40 well-trained staff are required. There are screening, quality control and retraining elements while unusual cases have to be looked at. Time out is also required; staff need their breaks. If HPV testing was introduced, some 60,000 and 100,000 samples would be generated for cytology, so approximately one third of the 30 or 40 staff required would be needed to meet that demand. We are close enough to those figures at the moment with public laboratories, and we are certainly over it when private laboratories are taken into account. If we went to HPV testing to generate 60,000 to 100,000 samples, and we should be in a position, between private

and public sector staff, to be able to deal with that in Ireland. One laboratory is dealing with over 25,000 tests currently, and I believe one private laboratory is dealing with over 130,000, which gives a total of 155,000.

Ms Marie Culliton: The turnaround times that are required under the programme were quoted; some 95% of the results are provided within ten working days. That, presumably, is the standard with which we would have to comply should the work be repatriated here. That might have to be modified slightly because if a primary HPV test followed by a cytology examination on those that are positive from that test are required, the turnaround time will be slightly longer given two tests rather than one will need to be done. I appreciate that women want their results back in a short space of time. They are worried after the smear and they want to know the result. I am fairly confident that they would prefer to have the correct result back in two weeks rather than an incorrect result in ten days.

Deputy Bernard J. Durkan: Is there any way to compare the quality of the tests in the various laboratories here and in the United States?

Ms Marie Culliton: We will have to wait for the Scally report, which will look at the results from each of those laboratories, and the audit carried out. We know what standards we expect in Ireland, and that CervicalCheck has a quality assurance and cytopathology document it expects all laboratories to adhere to. We know that all laboratories are expected to return statistics to CervicalCheck on a regular basis. Laboratories here are inspected by our national accreditation board. We do not know what the inspection regime in the United States is because they do not all operate to the same ISO standard that we do. There is a different accreditation system in the United States. ISO might be used but the laboratories might also be using the American scheme.

Deputy Stephen S. Donnelly: I thank the witnesses for their contributions. This entire episode has been marked by tragedy and misinformation. There is a widespread misunderstanding among many people as to what has happened. There are three issues, the first of which relates to the laboratories. Some people believe that the US laboratories have been less accurate but the data do not back that up. However, we should wait to see what the future investigation shows. Perhaps there are areas where there are difficulties, and we need to investigate them thoroughly. At the moment there is no data to show that the United States laboratories were inferior.

The second issue is the question of who made the decision. The assertion has been made at this committee that this was a political decision. One or more witnesses have just answered Deputy O'Reilly's query concerning whether clinicians were involved in the decision. The answer provided, when we look at the transcript, will say that there were none involved.

I would like to quote a speech from the former Minister for Health, Ms Harney, in 2008, because it is important that we understand who made this decision and why:

> The tender was examined not by the Minister or any official from the Department of Health and Children, but by a group established by National Cancer Screening Service, [which at the time was independent of the HSE, with an independent board] which included doctors ... who has been running the service in the mid-west, and a doctor from Northern Ireland, who was charged with the responsibility for quality assurance there and who is also involved in the accreditation process in the UK.

The former Minister went on to say:

> The National Cancer Screening Service did not have to go to tender but chose to do so for reasons of transparency, fairness and equity to make sure it got the best quality assured service.

The Minister, in 2008, explicitly stated that there were no politicians, no officials or civil servants involved, and that an independent body, the NCSS, brought a group of doctors together to make the decision and to run the process. The witnesses have just said that there no doctors or clinicians involved and that it was a political process. Was the Minister lying? Was she completely unaware of the process she had just overseen? Why do we have such a massive discrepancy?

There is a widespread belief among the public that there is a clinical link between non-disclosure and clinical outcomes for women. That has been categorically refuted by everyone that I have put that question to at these committee hearings. Most women I have spoken to believe that the HSE sat on data that it could have provided to doctors, which could have helped them. That is what most people believe because of deeply irresponsible statements that have been made by Oireachtas Members.

Mr. Casey said the MLSA is "deeply saddened by the impact of the system failures on individual women." I acknowledge the association is not trying to add to the confusion but that kind of language adds to it. The phrase suggests a causal link between non-disclosure and clinical outcomes for women. The majority of women to whom I have spoken believe that to be the case. I will outline what happened. In 2008, a national cancer screening service or CervicalCheck was set up, which was great. In 2014, an audit process was introduced. We are one of the only countries that carry out such an audit process, and that was a good development. In 2015, CervicalCheck decided to provide full feedback to the doctors for ongoing communication with the patients. Ireland was one of only two countries that conducted such an audit and gave feedback. All of these developments were good. In 2016, CervicalCheck communicated with doctors on the assumption that they communicate onwards. The systems failure in all of this is that the doctors did not tell their patients. The doctors have replied that even if they had told their patients it would have made no difference to their treatment. I know that I have gone on but it is important that we get clarity on this matter. I do not believe it was intentional but I believe the association's opening statement unintentionally supports the causality argument, which we have been told by every expert that we have questioned is false.

I have two questions. The Minister at the time said that no politician or official was involved and a group of doctors with international expertise was brought together. We were told earlier that a political decision was made without the involvement of clinicians. Which of those two statements are true? Is it the witnesses' opinion that there was, or was not, a causal link between non-disclosure and clinical outcomes for the women?

Mr. Terry Casey: I shall respond regarding our statement. I accept that the failing was in terms of the communications process that related to the audit. If there is confusion, then I accept that point.

Regarding the decision to award the entire tender to Quest Diagnostics, I assert that I do not genuinely believe that a Government would allow a service of that nature to be outsourced to a different jurisdiction and that it would not have had any input whatsoever. Ten years ago when we strongly advocated against such a move, we were not aware that the entire service would be shut down. That was what we were advised would happen. Subsequently, the Coombe Hospital stated that there was a requirement for the training of non-consultant hospital doctors,

NCHDs, and, therefore, the retention of quality, which is welcome. It is a credit to the staff at the Coombe Hospital for insisting that the service would remain. It is absolutely our view that it was a political decision. I can back that up because around the same time we were presented with a report that effectively was a proposal to tender for much more of the pathology testing, particularly relating to co-laboratory work and primary care. At the time we worked hard to show that that would be the wrong thing to do. We even presented our own report that showed from a cost perspective insourcing would be the right thing to do and we, ultimately, have won that argument. We remain stridently of the view that it was a Government decision.

Mr. Pat Naughton: I ask Deputy Donnelly for his definition of a clinician.

Deputy Stephen S. Donnelly: Within the committee, when we refer to a "clinician", we are typically talking about doctors, nurses or registered physiotherapists but people who are clinically trained and registered.

Mr. Pat Naughton: That is what I thought. We are medical scientists and we are the ones who do the screening. I have a question for Deputy Donnelly. Were we invited to the dialogue on outsourcing?

Deputy Stephen S. Donnelly: The reason I sought clarity was because Deputy Louise O'Reilly explicitly asked whether clinicians were involved. She was told "No" by the witnesses. The Minister at the time not only said that clinicians were involved but that the scheme was clinically-led and then went on to essentially identify the clinicians who were involved. I have sat through weeks of misinformation being put into the public realm, which has had a damaging effect and eroded confidence in the service. I hear what has Mr. Naughton is saying. In my non-qualified opinion, the scientists should have been involved. Let me outline why I asked about the clinicians. I fear that the public will, based on answers given to the committee, say that they did not even bring doctors in.

Mr. Terry Casey: The NCSS had a group that worked on the tenders, which included clinicians. That is a fact.

Deputy Stephen S. Donnelly: Were clinicians involved in the process?

Mr. Terry Casey: Of course there were.

Ms Marie Culliton: We all know that when many people talk about clinicians they are talking about doctors. There is quite a difference between an orthopaedic surgeon and an ophthalmologist. I would not expect one or the other to comment on the outsourcing of their services. There may well have been clinicians involved but the majority of the clinicians working on the cervical programme are not laboratory medicine-based clinicians. A decision, therefore, was made about the outsourcing of laboratory tests probably without significant input from clinicians. When I say "clinicians", I mean both the pathologists and the scientists who are also clinicians in a regulated profession.

Chairman: Is Ms Culliton saying that it was not the correct clinicians that were involved? Is she saying that it was not the people who had the expertise in the area that were involved?

Ms Marie Culliton: They may not have had sufficient expertise in laboratory medicine, and the way laboratories are organised and controlled and their capacity when making the decision. I do not say they were not medical doctors. I am sure a number were involved. They may have used experts from the UK but the configuration of laboratories in the UK and, indeed, in other

parts of Europe, differs from the configuration in this country. The qualifications of the scientists in this country are the envy of the rest of Europe, and yet our qualification was put to one side and the contract awarded on a cost basis.

Mr. Terry Casey: In terms of the decision to outsource, the statement by the NCSS and the Minister at the time was that it was based on quality and turnaround times. We have spent a great deal of time talking about the fact that a number of the laboratories were accredited but there was an insufficient capacity within the service. Our issue at the time was that the Dr. Euphemia McGoogan report was not implemented. We were never told that we needed to sort this out, resolve our capacity problem or amalgamate laboratories. There was no engagement whatsoever. The rug was then suddenly pulled out from under us and the service was outsourced.

Deputy Stephen S. Donnelly: It has been said that a political decision was made. An independent group, the cancer screening service, with an independent board, was legally in charge of this process and brought in an international expert group that was involved in accreditation, and they ran it. I would imagine that the contract documents flowed through them and so forth.

Mr. Terry Casey: Yes.

Deputy Stephen S. Donnelly: Mr. Casey has said that it was a political decision. Is he alleging that there was political interference in an independent process?

Mr. Terry Casey: No. The Minister was apprised of the position and knew. I do not believe that the NCSS took a decision without the Minister being aware of it.

Deputy Stephen S. Donnelly: I do not say that Mr. Casey is wrong but it is an important allegation that will be picked up on nationally and, potentially, in the Dáil. It has been established and verified that there was an independent process with an independent board, and an expert group brought in. None of us is contesting those facts. If the witness is saying there was no political interference in that process, how then can it have been a political decision?

Mr. Terry Casey: Clearly-----

Chairman: I ask for a short answer from Mr. Casey.

Mr. Terry Casey: It was asserted at the time that it was a completely independent process. The NCSS is a separate body but it is still a statutory body under the auspices of the Minister for Health. That is-----

Deputy Stephen S. Donnelly: To be clear-----

Mr. Terry Casey: -----why I think-----

Chairman: I am sorry Deputy Donnelly, I have to move on. We have another important meeting coming up.

Deputy Stephen S. Donnelly: I am looking for clarification from Mr. Casey. There was either political interference or there was not. Mr. Casey cannot assert that there was no political inference in an independent process but that it was still a political decision. He cannot maintain both of those positions. There was either political interference or there was not.

Chairman: I do not think that is a fair question to put to Mr. Casey in respect of his opinion.

Deputy Stephen S. Donnelly: It is.

Deputy Alan Kelly: The decision was at a political level rather than-----

Chairman: I am going-----

Deputy Bríd Smith: It is not fair to be quizzing these witnesses about the political apparatus.

Deputy Stephen S. Donnelly: To be clear on this-----

Mr. Terry Casey: I think I have probably answered it.

Deputy Stephen S. Donnelly: Whether it is thought fair or not, I am trying to get to the bottom of what Mr. Casey is-----

Chairman: I understand that but it is not fair to put Mr. Casey in this position. I call Deputy Kelly.

Deputy Alan Kelly: To summarise, I think it was ultimately a political decision rather than political as in party political or ideological. I have some questions and I am going to run through them so that the witnesses can answer at the end.

Chairman: Quickly please.

Deputy Alan Kelly: Incidentally, Mr. Naughton's intervention with Deputy Donnelly was very worthwhile-----

Chairman: I ask Deputy Kelly to concentrate on the questions.

Deputy Alan Kelly: -----for the people watching.

I asked earlier about the 209 and the trend in the audit. There were catastrophic differences between P2s and P9s. Given the witnesses' professional expertise, I ask whether a quality audit should have been carried out by the HSE. I ask all six witnesses for a "Yes" or "No" answer at the end. I am not trying to catch anyone out. I just want the professional opinion of the witnesses, given that we now know about these catastrophic changes. I have seen a few audit reports, including one where there were four errors in a row and then there was a catastrophic change. I have it here. It is redacted but it showed me something.

My next question is about Professor Gráinne Flannelly. She was on "Morning Ireland" on 27 April 2018 and the figures have been repeated so I am not going to go through them. I refer to the figure of 1,482 cases. It breaks down that 277 were reviewed. There was no change in 71 and we ended up with the 209 figure. That shows that 75% of the 277 cases were misread. In light of that, do the witnesses believe - given the percentages - that there was a need for some random sampling of normal smears to establish whether the level of accuracy underpinning the whole programme was working?

My next question concerns the audit process methodology which we have received. The witnesses will have seen the outcomes of audits between 2008 to 2015 document. There are levels one to six. Diagnosis after a previous smear that recommended repeat cytology is No. 5 at 11%. It says to review some cases. The word "some" has been troubling me. That means that some were reviewed and some were not. How, scientifically, was that done? How are some picked and not others?

My last question relates to the HPV test into the future. This is important to me and I raised it in the Dáil weeks ago. There is no way in hell that the witnesses will be able to do these tests without receiving huge resources quickly. Human resources are going to take time and the witnesses have explained eloquently why that is. Laboratories need changes and IT needs upgrading. I am a big eHealth person. What needs to be done and what is the quickest timeframe in which it could be done? I was quick as I could be. I ask the witnesses to start with the first question.

Dr. Irene Regan: I will take the outcomes of the audit and what we are going to be able to tell from that. I refer to the Scally report. We are here talking about laboratories because that is our expertise.

Deputy Alan Kelly: Exactly.

Dr. Irene Regan: A number of outcomes can come from that audit. We have been talking about heat maps. They can tell us whether the error rate, or the pick up rate or whatever, is the same across all laboratories. If an error rate is consistent across all laboratories - on a ratio basis because some are doing more tests that others - we would see that one of the outcomes and conclusions could be that this is a limitation of the cervical screening test. We talked about specificity and sensitivity. However, if there is a cluster or many of those errors are being found in one place at one particular time, then it would warrant analysis. It could be seen as a systematic failure. I am not suggesting it is but we need the heat map and we need to know where the errors are happening. We do not have that information so we cannot judge it. Deputy Kelly said it is out there but it is not and it is very important we have it. We will then be able to see and judge what is happening. I hope that I have adequately answered that part of the question.

Deputy Alan Kelly: I asked the same question of all six witnesses on whether the HSE should have conducted a quality audit when it saw the returns. I asked for a "Yes" or "No" answer.

Mr. Gerard O'Mahony: This would have been a natural part of the screening programme anyway. Audits would be done all the time in correlations-----

Deputy Alan Kelly: It did not happen.

Mr. Gerard O'Mahony: We do not know. We have not got any figures. It would appear that Deputy Kelly has information we are not privy to.

Deputy Alan Kelly: No, it did not happen. We have asked this question before. It did not happen after the audit. The women were not even told.

Mr. Gerard O'Mahony: It is a automated system. Information is put in and if something was coming up it would be flagged immediately.

Deputy Alan Kelly: It was a management failure that it did not happen.

Ms Marie Culliton: On eHealth, there is an ongoing project, which is moving slower than we would like, called the national medical laboratory information system, MedLIS. It is examining a single laboratory information system for the entire country. In respect of the management of HPV testing and results, when this is repatriated and the testing is done in Ireland, that system will then be in a position to manage the dissemination of results nationally. All public laboratories will be feeding into that system.

Deputy Alan Kelly: How quickly will we be able to do HPV testing?

Ms Marie Culliton: HPV testing is being trialled in some areas. The Coombe is doing some. Whether it can scale up to do them all is a different matter. Other laboratories are doing HPV testing but not on this particular medium. We would need to look at getting that in place. The quickest way to do it is probably to send some of our scientists to places where it is happening so they can learn from that. They can then bring that expertise home and set it up. We need a project that looks perhaps at going to tender or setting up in designated large centres-----

Deputy Alan Kelly: Are we talking years?

Ms Marie Culliton: No, I do not think I am talking years. I am probably talking about two years.

Deputy Alan Kelly: Oh dear, that is-----

Chairman: I thank Ms Culliton. I ask Deputy Kelly to move on.

Deputy Alan Kelly: We will move on but can I have my questions answered? There is the question regarding the sum from a laboratory point of view.

Dr. Helen Lambkin: I am not sure which one Deputy Kelly saw.

Deputy Alan Kelly: It is available publicly.

Dr. Helen Lambkin: I do not know which one it is.

Deputy Alan Kelly: I referred to diagnosis after a previous smear that recommended repeat cytology, 11%, and 123 of the cases in sum. Is there a scientific reason that the witnesses are aware of?

Dr. Helen Lambkin: We would have to see the whole report.

Chairman: We have to move on because we have another important meeting.

Deputy Alan Kelly: That is no problem.

Chairman: I thank Deputy Kelly. I will take a brief question from Senator Colm Burke. We will then take a question from Deputy Durkan, followed by Deputy Bríd Smith and then we will conclude the meeting. I ask Senator Burke to keep his question brief.

Senator Colm Burke: On the cervical screening programme, I understand there is a 7% reduction in cervical cancer each year for the last four years. If HPV testing is introduced, what kind of reduction can be expected in cervical cancer? How long do we need to have it up and running before we can see really positive results?

Dr. Helen Lambkin: I can give some information but I could not give an exact percentage. The aim of any screening programme is to reduce the overall rates of cervical cancer, preferably by 100%, over many years. If one has a very good cervical screening programme, one would hope to reduce it by perhaps 80%. The UK has had a very effective screening programme since the 1980s over its whole population, where they have reduced the overall rate by at least 50%. The introduction of HPV testing will not completely cure cervical cancer but it might allow it to be detected more effectively and more quickly than with the cervical smear alone.

It should also be borne in mind that it is a period of huge change for all screening programmes. First, we are moving towards HPV testing as a new way of investigating. Cervical cytology has been the test for 50 years so this is a significant change for all national programmes to introduce that. Second, vaccination is now in place. Now that girls are being vaccinated in most countries, it will have an impact on the number of cases of cervical cance, which should drop and hopefully by a dramatic level. There is lots of research on change. Changing programmes is a massive undertaking which takes years. It is not feasible to follow recommendations such as stopping the sending of samples. It must be planned very carefully and it would take a three to five-year programme review and alteration. If there were errors in one lab, they might be remedied by introducing additional quality control measures and so on. Switching to HPV testing is not a panacea. There continue to be many other considerations, research and tracking of the types in the population, and so on.

Chairman: I thank Dr. Lambkin.

Ms Marie Culliton: Once the HPV testing has been introduced, it will be possible to reduce the screening frequency from three years to five years by using HPV triage, so one will also change the programme.

Chairman: That would obviously have capacity implications.

Ms Marie Culliton: Indeed it would.

Deputy Bernard J. Durkan: I have a short comment. In a previous incarnation, I tabled parliamentary questions on cancer research, the incidence of cancer and its various forms in different regions of Ireland prior to the National Cancer Registry being established. It has done an excellent job and a huge amount of work, but since it was established one can no longer get parliamentary replies on the matter. It is a distinct disadvantage as an occasional probe into the system can often alert people within the system to things that might have passed them by, without there having been any deliberate attempt on their part or the part of others to avoid it.

Dr. Irene Regan: The Academy of Clinical Science and Laboratory Medicine has always said that any programme requires an independent audit and review. Ongoing and continuous audit is very important; we all include it as part of our daily processes but it is equally important that all these programmes are subject to an independent review.

Deputy Bríd Smith: I thank the Chairman for letting me in and apologise for being late. I have two brief questions, one of which follows from Dr. Regan's remarks.

I want to ask about the measures taken by the cervical cancer national cancer screening services quality assurance in cytopathology. Quality assurance site visits to laboratory providers is listed as one of the things that must be undertaken, however, it does not say how many visits are required. In a recent parliamentary question, I asked how many site visits had been carried out on all the labs since outsourcing began and was told there had been two, one in 2011 and the other in 2014. Do the witnesses think that is good enough? How bad is this State's oversight on outsourcing of the CervicalCheck programme?

My second question is one I keep asking and am told that I will be given the answer. Before he left, Tony O'Brien was before the health committee where he gave a commitment to me that of the 209 misread tests, he would make me a list of the specific laboratories from which they came. One of his officials, Mr. John Gleeson, said that they would name them lab A, lab B, and lab C, when Mr. O'Brien interrupted and said, no, he would give me the names of the

labs. I have not received them. At a private meeting with the Minister, Deputy Simon Harris, with representatives of the health spokespersons from each party, I asked the same question. The Minister said "We will get that for you Deputy Smith". Recently when the Minister for Finance, Deputy Paschal Donohoe, was filling in for the Taoiseach at Leaders' Questions, I asked him and he promised he would get it for me. All this time has passed and we still have not been given this information. How difficult or how easy would it be to get the information about which labs the misread tests came from? Was it ten from one, 20 from another and 30 from the other? It is a simple question that I have asked repeatedly and cannot get an answer. The last time I raised it I was told that it would be part of the scoping exercise. I have no problem with that but when what seems to me to be a simple question is asked, an answer should be available. Is this a hard question to answer or not?

Dr. Irene Regan: We know exactly where the smears go. We know that 45% go to the US. In the Leinster region, tests from Carlow, Kilkenny and the Well Woman Clinic go to the Coombe. The rest of Leinster go to the US.

Deputy Bríd Smith: That is including Dublin.

Dr. Irene Regan: Yes. The rest of Ireland go to Medlab pathology. It should be very easy to tell from that where these women's smears have been tested. That is my plain and simple answer to that question.

Deputy Bríd Smith: Each individual test would have an origin and we would know which had been tested in Medlab, Texas and so on.

Dr. Irene Regan: If I am from Kildare, I should know where my smear has gone. If a woman was located in Kildare at the time then her test would have -----

Deputy Bríd Smith: Therefore, among those 209 cases, it should be very easy to tell the Dáil or any particular Deputy where those tests originated.

Dr. Irene Regan: It may be confidential information.

Deputy Bríd Smith: I am not asking the names of individuals, only whether there were, say, 35 in America, 120 in Medlab. I am only asking for numbers.

Dr. Irene Regan: With the exception that maybe when they went to a particular lab, they were outsourced to another lab, in general we know where women's smears go.

Chairman: When smears go to Medlab, they are not necessarily read in Ireland, are they?

Dr. Irene Regan: I understand that they are.

Chairman: They could be outsourced?

Ms Marie Culliton: Initially, when the contract was awarded and moved to Medlab, some tests were being done in the US and some in Ireland. I believe the majority of those going to Medlab are done here. There may be occasions when they outsource them to a sister lab in the UK.

Deputy Bríd Smith: In a recent parliamentary question, I was told that some had gone to Britain.

Ms Marie Culliton: I believe some have gone to Britain.

Dr. Irene Regan: We are still able to track where our samples go. We have very good tracking mechanisms. We know where our samples go.

Ms Marie Culliton: Every specimen that is ever taken has a unique identifier put on it so one will know where it was actually tested.

Deputy Bríd Smith: It should not require a scoping exercise to get an answer to this.

Mr. Gerard O'Mahony: The contracts for testing in 2008, 2009, 2010 went to the US to Quest Diagnostics. From 2010-2012, a second laboratory, Sonic, was added. Medlab required an 18-month lead-in for ISO. At the end of that two-year contract, it was being done in Ireland and the US. I believe the only Irish public lab that started doing work was in April 2013.

Deputy Bríd Smith: The Coombe.

Mr. Gerard O'Mahony: I am told it was an Irish laboratory in April 2013.

Ms Marie Culliton: Irish laboratories are accredited to the ISO 15189 standard, which is the international standard for medical testing laboratories. Irish laboratories are inspected annually by the national accreditation board.

I cannot comment on inspection cycles in the US nor can I comment on whether CervicalCheck has done its own site visit to the US.

Deputy Bríd Smith: The answer to the latter question is there were two visits, one in 2011 and one in 2014. That was the answer that I was given. I am asking if two visits are sufficient in a ten-year period.

Ms Marie Culliton: If the laboratories are subject to standard accreditation, if they are performing well in respect of their internal and external quality assurance and providing sufficient reports back to CervicalCheck, that may be enough or it may not.

Chairman: It is important to remember that cervical screening saves lives and has saved a significant number of lives over the past ten years. The issue we are dealing with is quality control and how those who were missed were dealt with. It is very important that we maintain confidence in the cervical screening programme because it saves lives. Cervical screening picks up early changes, people are treated easily and their disease is prevented from progressing. It is important to keep that in mind when we are examining these issues. The programme is a very positive, effective and important part of our health service and it is vital that it is continued and confidence in it is restored.

Ms Marie Culliton: That is what we wish.

Chairman: On behalf of the committee, I thank the witnesses from the Academy of Clinical Science and Laboratory Medicine and the Medical Laboratory Scientists Association for coming in to give evidence. Those names are tongue twisters. We will suspend for a few moments to allow our next group of witnesses to join us.

Sitting suspended at 11.41 a.m. and resumed at 11.48 a.m.

Chairman: The purpose of this second session is to meet representatives from the BreastCheck screening programme to establish its effectiveness. I welcome Professor Arnold Hill, Mr. Damien McCallion, Professor Risteárd Ó Laoide and Professor Ann O'Doherty and thank

them for their attendance.

I draw the witnesses' attention 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 their evidence to the committee. However, if they are directed by the committee 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 also advise that any opening statements made to the committee may be published on the committee's 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 Houses or an official, either by name or in such a way as to make him or her identifiable. I invite Mr. McCallion to make his opening statement.

Mr. Damien McCallion: I thank the committee for the invitation to attend this meeting. I am joined by my colleagues, Professor Ann O'Doherty, who is the national clinical lead for BreastCheck, Professor Arnold Hill, who is the national cancer adviser, and a representative from the Royal College of Surgeons faculty of radiology, Professor Risteárd Ó Laoide.

BreastCheck is one of our four national screening programmes alongside BowelScreen, diabetic retinopathy and CervicalCheck. BreastCheck plays an important role in preventing breast cancer and has identified more than 11,500 breast cancers since the programme commenced in 2000. It meets the highest international standards for breast screening and, following a detailed audit process, the programme has been internationally recognised as one of Europe's leading breast screening programmes. I will now ask my colleague and the national clinical lead for BreastCheck, Professor Ann O'Doherty, to provide more information to the committee on the success of the programme and the future plans for the programme.

Professor Ann O'Doherty: By way of background, I am a practising clinician and the lead clinical director for BreastCheck. I am very pleased to have this opportunity to reassure the elected members of the quality and safety of our breast screening programme in order that they in turn can reassure women of the quality of our programme. The past four weeks have been very difficult for Irish women, and it is incumbent on those of us who deliver the breast screening service to provide the reassurance necessary. I have devoted my professional life to the diagnosis of breast cancer both in the screening and the symptomatic setting. I established the first breast screening programme in Belfast in 1988. I was appointed clinical director of the Merrion BreastCheck unit in 1998.

BreastCheck is the national breast cancer screening programme. The screening programme aims to diagnose cancers at the earliest possible stage, when there is a better outcome and the cancer, it is to be hoped, may be treated less aggressively and with less morbidity. The programme was established following the publication of seminal randomised controlled trials in Sweden and other countries that demonstrated a reduction in breast cancer mortality of up to 30% by mammographic screening. BreastCheck offers mammograms to women every two years. Initially, they were offered to those between the ages of 50 and 64, but over the past two years we have been extending the age to 69 on a phased basis.

It is important to note that since the establishment of the programme in 2000, we have performed more than 1.5 million mammograms, and in that time more than 11,500 women have

been diagnosed with breast cancer. BreastCheck is fortunate to be well funded and to have state-of-the-art equipment. Every mammogram is read independently in the static unit by two consultant breast radiologists. The Irish programme mirrors the UK programme in almost every aspect but with two important differences. Our programme screens at two yearly intervals as opposed to three yearly intervals. Recognising that diagnosing breast cancer does not save a single life, we have included treatment and, in particular, the surgical management of screen-detected breast cancer in our programme. We have been fortunate to have the opportunity to train our radiographers and radiological staff to the highest international standard. I must mention at this stage that we have had wonderful co-operation from our host hospitals. Even with the pressures on beds and theatre time, we have been greatly facilitated in the treatment of screen-detected cancer in this country.

BreastCheck has four static units, two of which are in Dublin. One of these two units is on the St. Vincent's University Hospital campus and the other is on the Mater Hospital campus. The other two units are on the Cork University Hospital and University Hospital Galway campuses, respectively. In spite of this, most screening happens on mobiles. Our aim is to deliver the service as near as possible to the patient's home. All patients recalled to assessment who have a mammographic abnormality on their initial mammogram are recalled to the static unit. Patients recalled to assessment have all further tests, tomomammography, ultrasound, biopsy and clinical examination carried out in the static unit. Patients who require biopsy are discussed at a multidisciplinary meeting and then return for results. There is a dedicated team of specialist breast care nurses to support patients through diagnosis and surgical treatment.

The programme was established with stringent quality assurance parameters and key performance indicators. These key performance indicators pertain to every aspect of the programme and are supported by extensive standard operating procedures. We publish an annual report and we have a multidisciplinary quality assurance committee comprising, *inter alia*, radiologists, radiographers, pathologists, surgeons, epidemiologists, medical physicists, nursing and administration overseeing the quality of our programme.

Approximately 2,600 breast cancers are diagnosed every year in Ireland and, unfortunately, 680 women die from the disease. It was noted in the 2016 annual report that BreastCheck screened more than 145,000 women in the previous year. Of these, 986 women were diagnosed with screen-detected breast cancer. The aim of our programme is to reduce mortality by 20%. To achieve this goal, we need 70% of women to accept their invitation to screening. This is why it is important for us to enlist the support of our public representatives to maintain acceptance rates. If we do not maintain our acceptance rates, we will not reduce mortality, which is the ultimate goal.

On a happier note, over the past five years, survival from breast cancer in this country has improved from 75% to 83%. I have no doubt that breast cancer screening has contributed to this improvement in survival together with improved treatment in the symptomatic centres and improved drug management in women with breast cancer. The programme detects approximately seven cancers in every 1,000 women screened. It is important for us to keep the recall rate as low as possible, preferably lower than 7%. The reason for this is that every woman recalled to assessment will experience a diagnosis of breast cancer, and we know from evidence in the literature that it takes women two years to get back to baseline anxiety levels about breast cancer following a recall to assessment. There is a constant balance to be struck between keeping recall rates low and cancer detection rates high, and this is a challenge to every cancer screening programme.

A women's charter is in place to ensure that the service is delivered in a timely manner and in line with promises made to women when the programme was established. Since the outset of our programme, we have understood the need to produce and publish our data. We have also understood the necessity of external accreditation. Since the outset of the programme, we have had three external reviews carried out. The most recent inspection was by the European Reference Organisation for Quality Assured Breast Screening and Diagnostic Services, EUREF. Following a very detailed inspection, including protocols, procedures and interval cancer documentation, we were awarded reference status last year, indicating that our policy and practices are an example for other national programmes to follow. EUREF has only awarded six screening programmes accreditation since 2009, only two of which have been awarded the highest quality of accreditation, which is category 4 reference centre accreditation, and BreastCheck is one of those two.

While mammography is the best screening test available for the early detection of breast cancer, it is neither 100% sensitive nor 100% specific and is not an ideal screening test from that point of view. Not all cancers are detected by screening mammography, and we need to understand that a screening test is not the same as a diagnostic test and has an inherent false negative rate, as publicised in the international literature. Women attending for screening are informed of this in all our documentation. In fact, women who attend for screening sign a consent form that includes a statement to the effect that breast cancer screening does not detect all breast cancers. In addition, when a woman gets a letter advising her that her screening mammogram is normal, it is stated in the result letter that if she develops any symptoms at any time, she must present to her general practitioner and, if deemed necessary, she should be referred to one of the eight symptomatic breast cancer centres in our country.

Breast cancer detected in the interval between screenings is deemed an interval cancer. There is an international standard for interval cancer rates in screening programmes. The expected rate of interval cancers is two per 1,000 women screened. It is a very important determinant of the quality of a screening programme. BreastCheck interval cancer rates are in accordance with the international published literature. In fact, we ourselves published our interval cancer rates in the *Journal of Medical Screening* in April 2015. Interval cancers rates are an important parameter of the quality of a programme because, unlike background cancer detection rates, they are independent of the background incidence rate in a country. We find our interval cancer rate in the following way. BreastCheck is informed of all cancers by the National Cancer Registry. BreastCheck then determines if a woman has attended for screening and validates if it was within the past two years and if at the time of diagnosis the cancer was invasive. If these criteria are fulfilled, it is deemed to be an interval cancer and included in the rates published in our literature.

The formal review has been ongoing since the establishment of our programme 20 years ago and in the UK programme for the past 30 years. It is by necessity a retrospective and complex process. The current validated data are available up to 2011. In association with this, and while the review is ongoing, there is a practice performed in exactly the same way as in other European and UK countries. In conjunction with this, however, any woman diagnosed with an interval breast cancer can request a review of her screening mammogram, or her clinician can do so on her behalf. That review happens in real time at the earliest possible convenience. It is performed by two consultant radiologists who were not involved in reporting the screening mammogram. The information is then communicated to the patient. While screening aims to reduce mortality from breast cancers by 20%, there are definite downsides to screening of which we must be aware. The most important one is interval cancers. Anxiety associated with

recall is a downside of screening.

Another downside is over-diagnosis, which has been prominent in the literature over the past five years. This is when we commit women to open surgical biopsies for benign disease. In other words, they have surgery that they would never have needed if they had not come for a screening mammogram because it is for benign disease. Our aim is to make sure we do not perform any unnecessary surgery. We may, through breast screening, detect breast cancer that may not affect a woman during her lifetime. We may diagnose and treat a woman for breast cancer that she may have died with, rather than from. Unfortunately, we cannot tell when we diagnose breast cancer which cancers will progress. We do not have that ability at the moment. With increased and more complex genetic marker testing in breast cancers that may be in our gift in the next decade but at the moment we do not know which cancers will kill women and which will not. Therefore, we have to treat all breast cancers. Giving a woman a diagnosis of breast cancer when she may not have died from it is termed lead-time bias and it is an inherent problem associated with breast cancer screening.

It is appropriate and necessary that we outline our plans for open disclosure. Open disclosure has been a policy for the HSE since 2013 but it is planned to introduce it for breast cancer screening. However, open disclosure is not a facet of, and does not happen in, other UK screening programmes. It has, however, happened only in the past year in England. On foot of the duty of candour legislation published in England in 2014, a detailed process was put in place to introduce open disclosure. Even while there was a requirement and a wish to introduce it as quickly as possible, it was introduced only in 2017. Scotland and Northern Ireland have not yet commenced open disclosure. We are very fortunate in that we have had a lot of discussion with the English programme and it has shared its methodology and training videos which were released in May of this year, following the UK local elections. It has released all its information on how it did this to us. We look forward to implementing open disclosure in early 2019 but I emphasise that open disclosure in screening is very complex. It is not the same as the symptomatic service or other diagnostic areas. This complex process will involve many stakeholders, particularly women, counselling agencies, the symptomatic breast cancer service, the State agency, the HSE and the Department of Health. We may need the help of this committee as legislators in navigating the complex issues surrounding the legal aspects of open disclosure.

I hope that the committee realises that the Irish breast cancer screening programme operates to the highest international standard. There are, however, challenges, the main ones for the future being: recruitment and retention of staff which is a real issue, maintenance of acceptance rates in excess of 70% if we wish to reduce mortality, open disclosure and litigation. I hope I have given the committee reassurance on the quality and safety of our screening programme.

Chairman: Is there an organised programme of audit carried out on interval cancers that occur between one mammogram and the diagnosis of cancer? I am quite surprised to hear that there is no policy of open disclosure in respect of BreastCheck because that has been the central issue that we have been dealing with in respect of CervicalCheck. It has been a policy of the HSE since 2013 and within the ethical guidelines of the Medical Council there is a requirement that there should be open disclosure. Could Professor O'Doherty comment on the fact that there is no reference to that?

Is it the case that the woman who may have had an interval cancer is only informed that there is a review if she requests it? Professor O'Doherty said the recall rate is 7% but the diagnostic rate is 0.7%. Is that the case?

Professor Ann O'Doherty: Yes, it is seven per 1,000.

Chairman: So 7% are brought back but only one tenth of those will have cancer lesions.

Professor Ann O'Doherty: Yes. In answer to the first question, the interval cancer reviews are not patient-centred but programme-centred in order to determine the interval cancer rates. That has been happening since the outset of the programme for 20 years. We do not contact patients retrospectively when we carry out the review. We have a very open policy. If patients want to know about their breast cancer when they present to the treating surgeon, we will do it but we do not trigger it automatically. We have had the benefit of the UK experience being shared with us. Only 45% of women have requested open disclosure since the UK brought it in. It is important that if we are to have open disclosure we make sure the woman wants it and that we have counselling services available. It has not historically been part of any UK or European programme. We are not doing anything in this programme that has not been part of established practice and that is not in the published literature. In every aspect of this programme we have mirrored international best practice. No other programme contacts women cold. For many of these women it would have been a long time ago. Unless they have requested it this takes quite a long time to filter through. I am not at all reticent about telling women. We are very happy to feed the information back to any woman who has requested it. It has not been a part of any other screening service anywhere in the world.

I cannot recall the final question, there were several.

Professor Arnold Hill: A woman is diagnosed with breast cancer in the symptomatic service where I work. Every time we diagnose a patient with breast cancer who has had a mammogram in the previous year, be it in the symptomatic programme or the screening programme, we openly discuss that with the patient. We ask if she would like to see her previous mammogram and we will have it reviewed. There is an excellent process in the screening programme whereby if a woman has had a screening mammogram, we contact the service to say that she has been diagnosed. The service will offer to sit down with her and go through the mammograms. Frequently, it may not have been seen on the previous mammogram. That is the nature of this test. There is real openness there.

What I find in my personal practice when I am dealing with a woman who has just been diagnosed with breast cancer and discussing this openly with her is that it is the last thing on her mind. What she wants to know is the plan of treatment, will she have chemotherapy and how long it will take. They are the sort of major issues. There is a policy and all practicing breast surgeons will offer this to women but is very rare for them to take it up. If they do want to, there is a superb service in BreastCheck whereby two independent people will review the mammogram and the clinical leads will meet the patient. It is very rare that women want this. They want to get on with their treatment, be it surgery or chemotherapy.

It takes approximately nine months for a patient to undergo all her treatments between chemotherapy and radiotherapy. We see her in follow up. We follow her up for five years and we frequently ask if she wants to go through that but she usually wants to move on. It is not a major issue in clinical practice but there is a very open climate about asking if she wants to look back. We know this is going to happen because of the limitations of the test. A mammogram is not a perfect test. We are familiar with this. Where we see approximately 400 breast cancers a year, there will be 30 or 40 women each year in the symptomatic service whose previous mammogram did not show it. We are very familiar with the environment and what to do in that case. There is a really open plan to discuss it with the women.

Chairman: In what percentage of cases was evidence of lesions in previous mammograms not picked up?

Professor Arnold Hill: International figures published show that approximately 1.6% of women who have been through a symptomatic service where they re-present within 18 months will develop a cancer. In a small minority of those there will have been something on the mammogram. It is not a perfect test. If ten people are asked to look at a mammogram one or two might say that in hindsight now that he or she knows the person has breast cancer perhaps that vague shadow could have been considered. It is not a perfect test. It is really important that is understood. It is the best test we have but it is not perfect.

Mr. Damien McCallion: I will ask Professor Ó Laoide to respond to the second question regarding the Medical Council.

Professor Risteárd Ó Laoide: The Faculty of Radiologists, which I am representing here today, has involved itself in open disclosure since it was launched in 2013 by the HSE. We have engaged proactively with the HSE in this regard because this is a very important issue for us in radiology. It is important in radiology because it is one of the specialties where this is a most difficult and nuanced issue because radiologists work in a profession where mistakes are made all of the time. In other words, for a practising radiologist, international best practice would be an error rate of 3% to 5%. We are working in a profession where we know errors will arise. It is in our interests and in the patients' interests primarily that we have a good open disclosure process to deal with that. Historically, it has not been there and we now need to put it in place.

When the national document was launched in 2013, we engaged with other jurisdictions, such as The Royal College of Radiologists in London and the Royal Australian and New Zealand College of Radiologists, that have similar methodologies to ours. We also engaged with patient representatives and the State Claims Agency and we produced a document on open disclosure relatively quickly in 2015. This document was subsequently updated in 2016 and is available on the faculty website. It sets out our approach to open disclosure.

We are also mindful of the ethical guidelines from the Medical Council on this issue. We do realise this is an evolving process. We heard at an Oireachtas committee meeting last week that the Civil Liability (Amendment) Act 2017 was enacted in November 2017 but that it is still awaiting implementation and regulations through the Department of Health, which is outside my ambit. While we need that legislation implemented, we need more than that. To do open disclosure properly we have to focus on the patient and in this regard, the environment must be such that the patient is counselled and supported through the process. There are a number of doctors in this room. We have all made mistakes. The serious mistakes that I have made in my career are seared into what I do and so I am very conscious of this. We need to have a process where the people who are involved in the incident, the patients primarily, are dealt with in a supportive way through appropriate counselling and appropriate infrastructure. As for the infrastructure required for this process, it has been proven internationally that it has to be provided in a learning environment, a non-judgmental environment and an environment where a single issue does not explode into one of national prominence. Unfortunately, given Ireland is a small country, we suffer a little bit of the fish bowl effect such that a single issue can suddenly explode into one of national prominence. I worked in California for a number of years, which is supposed to be a highly litigious society. The background effect of open disclosure and litigation there was seemingly a lot less because it does not suffer the fish bowl effect that we have in Ireland.

In radiology, when we make an error we are not sure whether that error precisely causes harm. It has to be looked at in the overall clinical context of the patient and we have to do a systems review of it. In summary, as radiologists, we are keen to do this but we do need a framework and we need the help of the Oireachtas in creating that framework. To do this, we need a supportive environment, one where people can learn from their errors without the risk of litigation. We also need to be honest. We want to have an open process but we want the whole process to be open on the table. To be open on the table we need to know the number of errors it is anticipated will happen in our services. For example, we in radiology, can say that in a model 4 hospital might have approximately 10,000 errors per year. How is it proposed to legislate to have open disclosure for all of these cases? If it is proposed to compensate everyone for every error, that then needs to be set out clearly in legislation. We need to move forward together in this regard because at the end of the day it is the patient who will benefit.

Chairman: I thank the witnesses for their contributions. We will now move to questions from members and I ask members to confine their contributions to ten minutes.

Deputy Stephen S. Donnelly: I thank all of the witnesses for their attendance. I recognise all of the work they do in trying to save lives.

The audit on open disclosure kicked off this discussion. It was stated earlier that BreastCheck looks forward to implementing open disclosure in early 2019, in respect of which I have two questions. First, how can it be that the HSE implements open disclosure in 2013 and a unit that is part of the HSE does not and six years on is only proposing to implement it now? Second, was this planned anyway or is it now happening next year because of everything that has happened in CervicalCheck?

Professor Ann O'Doherty: Screening is different to diagnostic services because we expect errors. Screening was in the HSE open disclosure implementation for 2018. It was commenced in 2013 and put in place in all of the acute hospitals. We were on the list for 2018. I sat on the UK committee for implementation of breast screening for 30 years. I was allowed to remain on that committee because I was one of the founding members of the committee with the UK programme. I am very lucky that since coming to Dublin, I have been allowed to continue as an observer on that committee. The duty of candour legislation was introduced in the UK in 2014 but open disclosure around screening only commenced in 2017. In terms of how they did it-----

Deputy Stephen S. Donnelly: I apologise for cutting across Professor O'Doherty but in the interests of time, is the answer to the question that the breast screening service did not implement it in 2013 because the HSE 2013 policy did not apply to what the service was doing?

Professor Ann O'Doherty: No, it is not that it did not apply to what we were doing. We were in the plan in terms of implementation but there was no process to commence it. There is no other international programme that does it and we were watching with great interest what was happening in England. We were awaiting developments there and we are now lucky to have at our disposal the methodology by which it was implemented there. There is no other programme that has done it, other than England. Scotland and Wales have not done it yet. We are in the HSE plan for implementation in 2018 but realistically I think it will not happen until early in 2019.

Deputy Stephen S. Donnelly: It will seem strange to the public that the HSE introduced a policy in 2013 and that five years later, parts of the HSE are proposing to implement it next year.

On the audit, we know that CervicalCheck introduced an audit for all diagnoses from 2014 onwards and that it also audited a batch from before then. As I understand it, currently in BreastCheck there is not an automatic look-back undertaken once there is a diagnosis. Is that correct?

Professor Arnold Hill: That is not true. As I explained, the person will present to the symptomatic service and I or one of the other 26 breast surgeons in the country will meet that patient. If the person has had a mammogram the previous year we always ask if she would like to have it reviewed. In the vast majority of cases they do not. It is very rare. I see 400 patients with breast cancer each year and only a small number opt for a review of their mammogram. It is not their focus.

Deputy Stephen S. Donnelly: My question is whether there is an automatic audit, as is the case in CervicalCheck?

Professor Arnold Hill: I will explain. If a woman is diagnosed with breast cancer and she had a mammogram in BreastCheck the previous year, I, or one of my radiology colleagues, will contact BreastCheck and it will review that mammogram. The patient is welcome to meet with our radiology colleagues to discus the mammogram. As I said, very few women take it up.

Deputy Stephen S. Donnelly: I appreciate that. My question is whether that process is automatic. In regard to CervicalCheck, my understanding is that once there is a diagnosis, as part of its internal processes a look-back is done at previous screening regardless of whether a doctor or patient seeks it. My question is whether that is the case in BreastCheck.

Professor Ann O'Doherty: As part of the quality assurance, we have to produce an interval cancer rate and so, yes, it is done but it is considerably behind the real time in which we are operating. For the past 20 years, we have not had an interval cancer rate. The Deputy may be asking if I am sitting on a list of patients that I have not told whether they have------

Deputy Stephen S. Donnelly: No, I am not. Every time there is a diagnosis of breast cancer,-----

Professor Ann O'Doherty: We have done it in a-----

Deputy Stephen S. Donnelly: -----is there a process that automatically performs a look-back? Yes or no?

Professor Ann O'Doherty: There is, but it is currently validated up to 2011 because we have to finish the two-year cycle before we can start, then we have to get the download from the cancer registry. It is a long and tortuous process, but it is done. It has been validated for between when we started and 2011. We published it in 2015 in the *Journal of Medical Screening*.

Mr. Damien McCallion: The Deputy may recall that one of the issues with the cervical cancer audit was that it was incomplete in terms of the dataset around the number of women who were impacted. We worked off the 1,482 number and the National Cancer Registry was not involved. BreastCheck takes the totality of that. For various reasons, it is well in arrears in terms of the time to diagnose, the cancer registry and so on. At the moment, BreastCheck reports back to 2011. That is the year for which data is being worked through.

Deputy Stephen S. Donnelly: Just so that I understand, does that mean that, since 2011, there is an outstanding batch of diagnostics? Let me try to ask in a simpler way. Are the tests

of women who were diagnosed with breast cancer in 2012 and onwards being examined retrospectively?

Professor Ann O'Doherty: Only if they ask, but they will be examined when we get around to them.

Deputy Stephen S. Donnelly: Only if they have asked.

Professor Ann O'Doherty: It will all happen. It is just not done in real time. It is done for anyone who asks. There is no problem with that. For us to validate and produce our rate, we have to finish the two-year cycle. It will be done. We just do not have it yet.

Deputy Stephen S. Donnelly: As of now, it has been done up to 2011.

Professor Ann O'Doherty: Unless the woman asked.

Mr. Damien McCallion: The key point is that it is six years in arrears because of the notification of the cancer and the nature of the breast screening programme and breast care. There is a longer cycle than there would have been in our conversations around cervical cancer cases.

Deputy Stephen S. Donnelly: I thank the witnesses. Where it has been identified, and we do not know for the past seven years' worth of patients or diagnoses-----

Professor Ann O'Doherty: Unless they contact us, we do not know in a systematic way.

Deputy Stephen S. Donnelly: Where a false negative is identified, is there a process whereby the clinician and-or the patient is informed of it?

Professor Ann O'Doherty: No.

Professor Arnold Hill: It starts with the clinician and the patient. We do the request. We are the people who diagnose the breast cancer and we inform BreastCheck via the patient, and it reverts to us. The patient and I know whether it was seen. The patient is entitled to sit down with a radiologist and go through the details. It is an open process.

Deputy Stephen S. Donnelly: Help me bring the two positions together. From the perspective of the process as opposed to the clinical relationship with the patient, everything up to 2011 has been done automatically and it is the intention to go through 2011 onwards.

Professor Ann O'Doherty: Yes.

Deputy Stephen S. Donnelly: At the same time, the witnesses are saying that, on an ongoing basis, it is happening for patients today anyway, just not automatically.

Professor Ann O'Doherty: Yes.

Deputy Stephen S. Donnelly: Do the witnesses have a sense of what percentage this voluntary way covers compared with an automated process that is up to date?

Professor Arnold Hill: We perform a look-back for everybody who wants to know.

Deputy Stephen S. Donnelly: How many want to know?

Professor Arnold Hill: Very few. That is the point I was making. When we talk to people, they want to know more about what their treatment will be and whether they will get chemo-

therapy or radiotherapy. That is their focus. That lasts-----

Professor Ann O'Doherty: When people in the UK are asked whether they want their tests reviewed, that figure is 45%. Presumably-----

Deputy Stephen S. Donnelly: What is it here roughly?

Professor Ann O'Doherty: We do not have a figure. I cannot say.

Professor Arnold Hill: I do not have a figure. It is rare in my practice. We offer it to every patient in that situation.

Deputy Stephen S. Donnelly: Just so that we understand, it is rare among the 5% or the 45%?

Professor Arnold Hill: I would say it is less than 10%. That is my-----

Deputy Stephen S. Donnelly: But every patient is offered it.

Professor Arnold Hill: Absolutely. When one tells a woman that she has breast cancer, she is more interested in the stage, the treatment, whether she will need chemotherapy and if she will lose her hair.

Deputy Stephen S. Donnelly: I understand that.

Professor Arnold Hill: It is a really traumatic time.

Deputy Stephen S. Donnelly: The service does not have an automated system in place up to the current day, but the clinicians-----

Professor Arnold Hill: That is incorrect. The process is: when I diagnose a patient with breast cancer and her treatment goes through, that goes on the National Cancer Registry. It is a structured process whereby the cancer registry works with BreastCheck and reconciles the data. Perhaps Professor O'Doherty will discuss that process.

Professor Ann O'Doherty: That is the process. The Deputy is right, in that it is not automated, but it will be eventually once we reach a certain point. It is important to understand that we are judging through recent legislation what happened historically. No other screening programme in the world has done it. There is nothing that we have done in this programme that has not mirrored that experience. We are a small country with a population the size of greater Manchester.

Deputy Stephen S. Donnelly: Yes. I am not making allegations. I am just trying to establish where we are.

Professor Ann O'Doherty: We will eventually have audited everyone, but we have not been telling women retrospectively because no other country has. We do not have it as a woman-centric review, but a system review. I am not out at the BreastCheck Merrion unit sitting on a list of women we have not told. That is not how it is done.

Deputy Stephen S. Donnelly: I am out of time, so I want to revert to the last question I asked. An automatic process is in place, it has got as far as 2011 and it is moving forward.

Professor Ann O'Doherty: Yes.

Deputy Stephen S. Donnelly: Professor Hill is saying that every woman who gets a breast cancer diagnosis is offered a look-back and that fewer than 10% of those women request one.

Professor Arnold Hill: I am saying that that is conventional practice in my practice. I have trained many of the breast surgeons in this country and that would be the routine. I cannot guarantee it, however, as I cannot speak for everyone. I can only tell the committee what is conventional good practice.

Deputy Stephen S. Donnelly: If a false negative is found, is it always communicated to the patient?

Professor Arnold Hill: Of course.

Deputy Stephen S. Donnelly: Professor Hill says "Of course", but the CervicalCheck scandal happened because the doctors did not communicate that onwards.

Professor Arnold Hill: I will make a comment on why I am here today. I started in BreastCheck 18 years ago. It is something of which this country should be proud. It is a fantastic service. It was funded well and was set up in a careful way. It has been externally validated over 18 years and receives the top mark from European accreditors every time.

My concern is that what has come to light about another screening programme over the past month has the potential to force the country to stop screening. BreastCheck has saved lives from breast cancer. It has been a fantastic programme. It is well run and everyone who has been involved is complimentary about it, but I am worried that the current situation will spiral out of control. We need the committee's support for introducing open disclosure in the balanced, careful and structured way that Professor O'Doherty discussed. The screening programme costs €40 million. If the State pays out €100 million in medical legal costs, the taxpayer will have to say "Stop the screening programme". That means women will die from breast cancer who do not need to. We have a great programme that is saving lives and doing well. I encourage the committee to try to ensure balance. BreastCheck is the best part of the Irish health service. Its quality assurance parameters are fantastic.

There is no need for me to tell members all of this. I work in the symptomatic service. BreastCheck is something that I am proud of, but I am worried as one of the clinicians involved that it could be destroyed for poor reasons. We require members to ensure there is a balanced opinion out there, the screening programme continues and women turn up for it. To make it justifiable, we need 70% of the women invited to turn up. It is good and will save lives. Please protect it.

Chairman: I thank Professor Hill.

Deputy Louise O'Reilly: To be crystal clear, we are having this hearing on screening programmes because of a scandalous withholding of information from women, albeit by another programme. What the Dáil and this and other committees have discussed is the apparent paternalistic attitude of people within the health service towards the women who are users of that service. With respect, that is why Professor Hill is here today. It is not because of any failing on behalf of this particular screening programme. However, if there is a lack of confidence in the screening programmes overseen by the HSE, the blame for that does not lie at the door of the politicians or the women themselves. The blame lies at the door of the HSE. We are discussing it because we, as elected representatives, have received calls from constituents who are panicking.

I am a major supporter of Professor Hill's service. I can count at least two women in my life who I am reasonably confident owe their lives, and certainly their health, to that service. I encourage all women to use it. I would love to see the rate climb far above 70%. We are all busy but women need to believe that when they present themselves, they will get the best quality service. Where there is a misdiagnosis, whether or not a woman wants to go back on that road, there should be some learning by the organisation. We fully appreciate that human beings make mistakes but if there is a perception of people trying to cover up those mistakes or withholding information, issues would arise. I am very happy to join all the witnesses in encouraging all eligible women to respond to that letter and keep their contact information up to date to ensure they get themselves tested. The responsibility of the witnesses is to ensure that when women present themselves, they can have confidence in the process.

When we ask a question about the look-back and whether it is automatic, it is partly for the woman sitting in front of the doctors who may not want to go back. Surely learning can only happen if we go back and where there is a misdiagnosis it is examined for what was missed, how it was missed and how we can improve things and ensure it does not happen again. We need to get a sense that it is happening.

Professor Arnold Hill: That is done. Professor O'Doherty might recap as that is exactly the process.

Professor Ann O'Doherty: It is what we do. Two independent readers look at it. We look at our misses and our triumphs, as some of the cancers we pick up are at the very edge of perception. It is an absolute and open learning environment in screening. The biggest downside is that we do not pick up all the breast cancers. I work as the lead clinician in symptomatic services at St. Vincent's University Hospital. I do not go in every morning with an expectation I will miss cancers because I have ultrasound and other tests available. Unfortunately, screening mammography is an inferior test. As clinicians we must face it that we will let down women. Not only are we going to let down women but we are going to let down their families as well. It is a real downside to what we do.

When we see cancers that should have been picked up - let me tell members that there are some cases where we ask ourselves how they were missed - the only way to survive knowing a disservice has been done to the woman in question or her family is to think positively about the pick-ups we have made. We are the most transparent, quality assured, introspective group of people members will have met. We are informed by the symptomatic service of an interval cancer. I can remember at least ten times in my life asking myself how we missed a cancer but when we got the symptomatic mammogram, the cancer may have been in a completely different place. We are busy and self-critical. I assure members that we are the most neurotic, self-absorbed group of people running the breast cancer screening service in this country. Unfortunately, even with the best will in the world, we will miss things, including some obvious ones in hindsight.

Deputy Louise O'Reilly: We all watched the "Prime Time" episode in February on Ms Alison McCormack, and the issue there was the withholding of information. I respect that the witnesses offer women the choice to look back and Professor Hill has said it is most probably done. Is it not written down somewhere that it should be done?

Professor Ann O'Doherty: No.

Deputy Louise O'Reilly: There was a 300-page document on open disclosure in 2013. In

what way was it transposed into everyday practice? Have there been seminars or discussions on it? Have any protocols been introduced? We were told by very senior people within the Health Service Executive and the Department, as well as some politicians in here, that we did not need mandatory open disclosure or legal underpinning of the concept because it was being done anyway since 2013. Now the witnesses are telling us it is not done. The witnesses may practise it in their everyday work but it is by no means a rule. While I fully appreciate that the witnesses have come to instill confidence in the system for women, a key tenet must be open disclosure. Maybe a woman does not want to know and is more concerned about her hair falling out. I do not know that and the witnesses would have more experience of it than I do. Perhaps a woman would want to know but she is not being asked. She could be traumatised and very ill. Surely it should be the first port of call to share that information. If the woman does not want it, that is grand. There is nothing wrong with having too much information when one is sick. People can always say they do not want to deal with it. It strikes me as odd that this is not par for the course or part of the daily practice. It might be encouraged and individuals may do it but to my mind, it is a policy failure if it is not happening universally. Members were wrong to vote through the civil liability legislation without a mandatory requirement for open disclosure. Open disclosure should be mandatory and have legal underpinning.

Professor Ann O'Doherty: I am very sad that all we are focusing on is disclosure as I would dearly like to bring some understanding to the fact that we have such a high cancer detection rate and our programme is underpinned by such quality. I would like to focus on that and I hope that reassures women, as it is absolutely essential that women should be reassured by the quality of our programme.

Screening is different and in hospitals we have an open disclosure policy. This is not something we have suddenly come to. We have been watching this happening in England and we have learned from the experience there. It will make my life much easier and I will be very happy if we get formal open disclosure. We have already designed a consent form and we can give it to women.

We hope the State Claims Agency and legislators will do something to protect the screening programme. One of our concerns is that screening must be cost-effective. I have no desire to hide anything from anybody but the medico-legal position in this country is very different from other countries. It will be of great concern to me if we reach the stage where we cannot afford to do screenings. It is not that we have not been disclosing. We have been doing exactly what every other European and UK programme has been doing. We can just say that is what we have done. I am sorry if the Deputy thinks we have been remiss as we have been working very hard.

Deputy Louise O'Reilly: No, at no stage did I use the word "remiss". Will Mr. McCallion explain from a policy and administrative perspective what exactly happened to the 2013 open disclosure document. In no way have I tried to disparage the programme. As I have said repeatedly, I am a supporter of the programme. It is important to me that the women I represent have confidence in that programme. Perhaps the witness could be less defensive and share a bit more information with us so we can get to that.

Mr. Damien McCallion: Open disclosure is different across an entire screening programme and we can see the lessons learned from CervicalCheck in terms of original planning and execution with respect to rolling out open disclosure in the programme. Those lessons clearly need to be applied to the three other programmes, including BowelScreen and diabetic retinopathy.

The English experience - the process has still not been activated in other parts of the UK -

with duty of candour legislation began with its introduction in 2014. It took three years to start a policy of rolling that up with all the necessary elements that needed to be put into place-----

Deputy Louise O'Reilly: I must interrupt the witnesses as my time has run out. I have a very quick question. In 2013 did the service take the view that the open disclosure policy did not apply to the screening programmes or were people advised that it should not apply? Does it apply to the programmes but there is an elongated process to put it in place?

Mr. Damien McCallion: I cannot comment on historical matters as I stepped into this role in recent weeks. I can come back to the Deputy on the history. We have seen what happened in CervicalCheck and the roll-out of open disclosure. It has not arisen in BowelScreen or diabetic retinopathy at this point. A plan has been in place that Professor O'Doherty has set out around the breast screening programme. That is continuing and based on the experience of the only other jurisdiction in the European Union which has rolled it out. I suspect the primary reason it has taken that length of time since 2013 to do it is screening is different from normal day-to-day services and in order to roll it out it is clear from the experience in other countries such as England that it takes time to put it in place. The plan that has been developed is based on the experience in the only country in Europe which has rolled it out in screening programmes so far.

Deputy Louise O'Reilly: The open disclosure policy was put in place five years ago. Mr. McCallion has not answered my question. Is there a list which shows where it does and does not apply? I know that my time is up, but sometimes delegates do not help their own cause when they attend committees.

Chairman: The Deputy can come back in on that question later.

Deputy Alan Kelly: I welcome the delegates.

As a public representative, I take every opportunity to remind people of how successful and important cancer screening is. I even wrote an article on it for a Sunday newspaper. However, as a public representative, I also have a role in getting to the facts. Unfortunately, this comes under the same tiered structure in the HSE which has let down many women. We need to see if there are issues which need to be dealt with by the committee. The reason the delegates have been brought before the committee is there are issues with CervicalCheck and we want to get to the facts. I hope we will not have real concerns. In our position we know the difference between screening and diagnostics. We know that programmes have a percentage of issues.

I am concerned that Professor O'Doherty said she would be happy to implement the open disclosure policy. She does not have a choice. I become concerned when I hear people keep talking about best international practice. It is correct that our screening programmes be mirrored against others. I hate the phrase "best practice". I do not believe in it. I believe there is practice and that there are circumstances. I believe in the Kilmeaden cheese version, namely, take the best and get rid of the rest because no two circumstances are perfect. Professor O'Doherty must adhere to what is in the law and policy. A policy of open disclosure should have been implemented but it was not. To be fair, she has been very open about it, but she has no choice. In the future it will have to be implemented and should have been in the past. As a result of what has been said today, the committee must move up the food chain and through Mr. McCallion determine why this did not happen. That is one outcome from the meeting.

I was the first to raise the issue of National Cancer Registry Ireland, NCRI, and the sharing of information. At the Committee of Public Accounts last week its director was open about the

four screening programmes and where there was sharing and where there was not. Will the delegates outline in detail what is being shared? I do not want to find out that information has not been shared at some level. We have had ridiculous data protection issues.

As clinical director of BreastCheck, does Professor O'Doherty have concerns which she would like to express to the committee about how the HSE supports the programme? Deputy Bernard J. Durkan is coming after me and will probably chase the same question.

Deputy Bernard J. Durkan: I will not.

Deputy Alan Kelly: We know about issues at screening level and that everything is not perfect. We know about Ms Melissa Hamilton and Ms Eileen Fennessy. We know from information made available several days ago that the State Claims Agency has stated there are four cases pertaining to BreastCheck. How many letters of apology have been issued by the HSE regarding incorrect readings since the BreastCheck programme began? How many have been issued in the past year? I saw one that had been issued in the past few months.

Professor Ann O'Doherty: On the question concerning NCRI, BreastCheck is different from the other programmes because of the consent form women sign. They cannot have a mammogram until they sign the consent form. It states BreastCheck will keep their details in a safe way and, at all times, in agreement with data protection legislation. It also states we may need to share information with NCRI. That is why we can do it. Before women can have a mammogram, we tell them that we may need to share the information. That is the only reason we have been able to download and ensure we have an audit. This has been in place for 20 years. Every woman who has attended for screening in the past 20 years has signed that permission form.

Deputy Alan Kelly: Is there complete two-way sharing of information?

Professor Ann O'Doherty: Yes. While I cannot speak for any other programme, it is the case for BreastCheck.

With regard to the HSE, I can say with hand on heart that BreastCheck has been well set up and well funded. If there was anything, we could do with more money in the symptomatic service in which I work. From the outset, there has been an understanding of the requirement. If one is to screen healthy women, one must be better if they present because one is dropping a letter on their doorstep and inviting them to come for screening. There has been an absolute understanding. I cannot complain about anything in the resourcing of our service. I mentioned the challenges in radiographic recruitment. We are doing our best. It is not an issue of funding. There has never been any issue with funding.

I do not have a comprehensive knowledge of what litigation cases are in front of-----

Deputy Alan Kelly: The State Claims Agency has stated there are four cases.

Professor Ann O'Doherty: I do not know about this. I am personally aware of the HSE having written only one letter of apology on behalf of BreastCheck. There could be more, but if there were, I would have thought the matter would have come before our executive management group. The one of which I know went to a high level.

Deputy Alan Kelly: When was that letter issued?

Professor Ann O'Doherty: I cannot say, but I imagine it was in the past year. That is the

only one of which I know, but I would not necessarily have a comprehensive answer.

Deputy Alan Kelly: Is it normal for a letter like that to be issued?

Professor Ann O'Doherty: This is all hearsay. However, I know that it came up at a meeting of our executive management team that a case had been settled and that one of the things the plaintiff wanted was a letter of apology. There was much discussion about who should sign it. It was issued. That is the only case of which I know.

Mr. Damien McCallion: There are four cases which are all at a tentative stage. We are seeking further details of the individuals and the cases.

Deputy Alan Kelly: There are people with concerns and there are serious individual issues. I agree fully with Professor Hill that we have to get to the bottom of why these cases happened, especially where there were multiple errors for several years. By the way, I have seen that letter and I know the case – it is from the south of Ireland.

Professor Ann O'Doherty: It is in the south of Ireland and it is the only such case I know of.

Deputy Alan Kelly: From a public health point of view I am 100% supportive. My family uses the screening process and my neighbour was saved by it. I need to figure out where to go with this. There are four cases with the State Claims Agency. We know of two cases, including the case of Melissa Hamilton and the other case that is now public. They date from June 2015 and June 2016. That is not long ago. We now have another issue with this letter, which dates from February 2018. The case involving the other person was earlier.

As a public representative I realise there are errors and there always will be errors but we need to figure out the scale. Moreover, we need to figure out whether there is something else. I am saying this in an even-handed way, to be fair. The question is whether there is a bigger issue or another process that we need to have examined.

Professor Ann O'Doherty: We would welcome that question.

Deputy Alan Kelly: We do not want to be sitting here with issues again in future. By the way, I think it would help the national breast screening programme.

Professor Ann O'Doherty: I welcome that question. The interval cancer rate is two per 1,000. We screened 145,000 in the year I referred to. If there are two per 1,000, then there were 290 interval cancers in that time.

I have been working for 30 years in breast screening. I reckon I would not have had more than one medical legal case - a case with solicitors involved - per year. In my unit in the past two weeks we have had 15 such cases. My great concern for this country is that the litigation will cost so much and that this will result in the Parliament telling us to stop screening since it is costing so much. Moreover, I fear all the resources will instead be put into symptomatic breast cancer. There is a significant requirement for resources in symptomatic breast cancer. We have gone from 7,000 attendances nationally to over 40,000. I am concerned that we may be asking as a country whether we can afford this. There have been 15 cases in the past two weeks but previously the rate was not even one per year. The same solicitors are involved. There has been a major focus on solicitors and litigation in the media. We are now seeing that in my numbers and there are four units in total. There is a major concern over whether we will

be able to continue screening.

Deputy Alan Kelly: I wish to follow up with a crucial point. Everyone in the committee has concerns about this for multiple reasons. First, we need to get to the facts. I have outlined some of the cases to the witnesses. We know of four. I know of another one and there were two previous cases. There is a timeline for these cases as well. These are the facts. We cannot judge the four cases with the State Claims Agency but those are the facts. We then have the issue of the dial-up from a litigation point of view and so on.

Let us consider this committee as a forum to help the screening service. What can we do? We know there is a process. CervicalCheck is on a completely different spectrum and it is a completely different issue. It is on a completely different scale and it is a different scandal and so on. Anyway, what can be done to ensure, for want of a better phrase, an audit or process is put in place to deal with this and to help renew confidence?

Professor Risteárd Ó Laoide: I am not in BreastCheck but I understand Deputy Kelly's question. I welcome what Deputy Kelly has said because it is critical. Professor O'Doherty has explained to the committee the level of interval cancers in the system. They are the cancers that have arisen for whatever reason. Probably 10% of these are errors while in 90% of cases when we look back we do not see anything.

Deputy Alan Kelly: The term should be "double errors". It applies where there are multiple errors.

Professor Ann O'Doherty: We do not have multiple errors. We have a screening mammogram. We look at it to determine whether there was an error. It is not a question of the same patient with multiple errors. That does not happen – I can say that much.

Chairman: Let us concentrate on Deputy Kelly's question.

Professor Risteárd Ó Laoide: I will address that question unless something else is going on that I am unaware of. The audit and the way the screening programme comes up with the interval cancer rate is probably the internationally recognised way of determining whether there is a problem.

Professor Ann O'Doherty: There might be multiple errors in symptomatic services. I do not understand it.

Professor Arnold Hill: It could only happen once from looking at a mammogram. There could only be one error.

Professor Ann O'Doherty: Maybe it is the case that two consultants have made the error.

Deputy Alan Kelly: What if it happened over multiple dates?

Professor Arnold Hill: It is a great question and I would love if something would come of it. The issue in the health service arises where we have a test. If we lined up 100 women with breast cancer and carried out a mammogram on all of them, it would not show in ten of those women.

Deputy Alan Kelly: I understand that.

Professor Arnold Hill: In this country those ten women, if they got good solicitors could

get a large sum of money ranging up to €1 million. I suspect that sum will go higher in the years ahead. That is unsustainable. We could do anything. When a woman comes to have a mammogram in BreastCheck she signs a document and understands that it is not a perfect test. In this country, a patient among those ten women is virtually entitled to €1 million in medical legal costs, and that is unsustainable. I suggest that there needs to be urgent medical legal reform. We have known this for a long time. The problem is that vested interests will block it.

Mr. Damien McCallion: I think the Deputy has taken it right back to the root of open disclosure in the context of a screening programme and what has been described. A framework is needed. I suspect that is one of the reasons it has taken several years to get to a point where we can roll out open disclosure in the screening programme. It is different to adopt it for an individual service or facility or in the practice of a professional individual. When we talk about a framework, we are talking about supports to women, training of the professionals involved and the medical legal framework. A range of things need to be put in place. Screening is different because we are doing a review across a range of people. We know there is an accepted normal error rate. We need not call it that – there is different language for it.

The points being made do not only apply to BreastCheck but to all screening programmes. There is some useful learning from the UK or England, where they have done this. Let us bear in mind that England is the only country in Europe that has put this in place for breast screening. I appreciate that people can refer to the difference between 2013 and what is happening today. The way the screening programme is rolled out is important. It should be a model that is effective for patients and cost-effective for the service.

Deputy Alan Kelly: I heard what Professor Hill said 100%. I am with him because we could not sustain it otherwise. However, in the case of the letter, abnormalities were missed twice. I have seen it.

Chairman: I wish to consider Deputy Kelly's question. The committee has been experiencing the response to this during the past month. If there was a policy of open disclosure that was delivered the moment an issue arose, then perhaps Professor O'Doherty would not have the flood of 15 cases coming down the line in a two-week period rather than one per year. If there is open disclosure, patients are accepting of receiving accurate information in a timely way. The purpose of open disclosure is of course to disclose. However, a side issue is that once patients are informed, they are satisfied that no negligence was attributed to the miss. They are happy to accept that and may not go down the litigious route. If information is kept from them, however, and then they discover it through other means, they become litigious. The point of open disclosure is to try to prevent litigation and to maintain confidence in the programme. That is the point that has come out in this committee and other committees in recent weeks. The view is that open disclosure will prevent litigation and maintain the financing of the service. It should not end up being overburdened by litigation.

Mr. Damien McCallion: That is a fair point. There is a subtle distinction with screening programmes. Let us consider the period looking back to 2011. The real-time hospital setting, as described earlier, is how open disclosure should work best. The idea is that when it happens, the error is disclosed, the conversation takes place and then it moves on. The case of screening would involve examining retrospectively to 2011. It means a long period has elapsed since the episode. Other aspects of this need to be factored in with regard to how any measure is rolled out.

Professor Ann O'Doherty: May I make one point? If a woman has been harmed or an

error has happened, we are not against her receiving a payout. However, the payout should be commensurate with the error and not depend on whether she has the most aggressive solicitor. When we discussed the issue, we did not conclude that women should not be compensated but that a mediation process should be provided because we are scared that we will be unable to deliver a screening service if it becomes extremely costly.

Deputy Alan Kelly: It needs structure.

Professor Ann O'Doherty: Yes, and we need the committee's help with that.

Chairman: I thank Professor O'Doherty. I call Senator Colm Burke and he will be followed by Deputy Durkan. I ask members to be brief as we under time pressure.

Senator Colm Burke: I thank all of the witnesses for their presentations this morning and for the work they do.

How much does BreastCheck cost per annum? It is important that we have that figure for comparison purposes now that we have litigation. I listened to Professor Hill's comments, especially the worry that screening programmes may have to be closed down to reduce the level of litigation, which is clearly not the way forward. It is important to have figures on the annual cost of BreastCheck and the problems we will face. The witnesses identified that we are within international standards in terms of the number of cancers missed. The service is comprehensive and everything is done by all the staff to get the most accurate results possible. When cancers are missed, if everyone opts for litigation we will end up paying out more in compensation than the entire cost of the service.

I had an interesting conversation with a consultant from Ireland who recently attended a conference in the United States at which the level of compensation paid out in Ireland for medical negligence was outlined. The attendees were surprised that Ireland appears to pay out much more in compensation than is paid out in the United States. On the one hand, we want open disclosure. On the other hand, we want to provide a comprehensive screening system. If money is taken away from the latter to pay the costs of litigation, there will be a problem. How have other countries dealt with this issue? A mediation process was mentioned. Do other countries provide a mediation service? If so, does it work?

We heard that 145,000 people avail of the BreastCheck service each year. That is a significant number. On the basis of an interval cancer rate of two per 1,000 people, approximately 290 cases will be identified each year. That is a small number, although a missed cancer diagnosis is a big issue for the person concerned. How can we deal with this complex and difficult issue, particularly in terms of what has occurred in the past four weeks? As a practising solicitor with a legal background, I share Professor Hill's concern about the level of litigation that will arise as a result of what has happened over the past four weeks. Litigation will not serve the best interests of the medical service or those who practise medicine on whom it also has a traumatic effect. That message has not been conveyed to the general public but we must ensure it is heard. I ask the witnesses to elaborate on the issue of mediation.

Professor Ann O'Doherty: If I may reassure the Senator, in terms of the two cases per 1,000 interval cancer rate, approximately 10% of them are detected in hindsight-----

Senator Colm Burke: I accept that.

Professor Ann O'Doherty: -----because 70% of them could not be picked up owing to the

nature of the tests, and they are not there in retrospect.

I will respond to the Senator's other point, which was very well made. My younger colleagues who have joined breast radiology over the past five years all want to leave after what has happened over the past four weeks. This is not funny because there is considerable demand for radiologists and they can all walk away.

Senator Colm Burke: Yes.

Professor Ann O'Doherty: I do not know who will provide the service so something needs to be done in terms of clinicians who make an error.

In terms of the word "negligence", I make errors on a daily basis and I report thousands of them. I am not negligent because I make errors. Even the term "medical negligence" upsets me because it is extremely upsetting when one misses a cancer.

I am not a solicitor so I do not know how we could provide mediation. We need to find some method of compensating women in a way that reflects what has happened to them. As I indicated, many cancers do not progress and a cancer that was not picked up the first time may not have progressed when it is diagnosed. However, some cancers will kill within a year. Cancers vary greatly. We need a great deal of advice from the State Claims Agency and solicitors on a mediation service.

Professor Risteárd Ó Laoide: Senator Burke made a very good point. The issue is even broader than screening. We know we have predictable errors in radiology and we can provide figures on the large number of errors that will occur. Thankfully, most of them do not harm patients. However, some do and one cannot predict which one will cause harm. If we want a good and open disclosure process and an open environment, everything must be put on the table. We need to be open and decide what to do when litigation occurs. We must decide whether to put patients through the traumatic process of going through the courts and being brought to the footsteps of the courthouse. That seems to be an horrendously cruel process. We need to consider everything. We are intelligent people and I agree with Deputy Kelly that we do not need to copy what has been done in other countries if we can do it better here. We need to consider ways of doing it better here and I firmly believe that we can do so because at the moment it is poorly done.

Deputy Bernard J. Durkan: I thank our guests for their attendance and for being so open in the manner in which they have discussed this issue.

Incidentally, I have always been a strong supporter of the BreastCheck programme. I was also my party's spokesman for this area many years ago. If the programme is to be successful, it must be efficient, effective and protect itself. Those involved in the programme cannot leave themselves open to allegations of negligence, in particular. I accept that people will make mistakes. To err is human but to cover it up is a different story. I do not suggest there has been a cover up. I suggest that for the organisation to protect itself it needs to be open about disclosures in the event of a mistake taking place.

I have a few questions for Professor Hill. Let us say a woman is diagnosed with breast cancer after availing of a BreastCheck examination at some time in the previous couple of years. I understand why she will not want to know about anything except treatment. Can she be told at that stage that the failure to detect the cancer in the BreastCheck test was fundamental to her condition? My next query relates to the point made by my colleague earlier. I am not certain

as to how such a scenario automatically opens up the litigation gates given that the screening system cannot be 100% accurate.

Professor Arnold Hill: I ask Professor O'Doherty to comment on litigation in terms of what has happened in the past few weeks.

Deputy Bernard J. Durkan: I am trying to separate that issue from the rest of this discussion. I want to isolate it and direct it at the group present.

Professor Arnold Hill: If we are open with patients, show them the mammogram and tell them the cancer was there or not there, there is no problem and the people concerned will not sue or litigate.

Deputy Bernard J. Durkan: Would a patient ever ask a consultant why a test conducted six months, one year or two years earlier did not show a cancer?

Professor Arnold Hill: That is the difficulty. We have to explain the limitation of the test and that a cancer will not be picked up in 10% of cases. A mammogram test is not a perfect test. It is a very good test and the best one we have but it is not perfect. We need people to understand that the test is limited in its value but it is the best one we have.

Professor Ann O'Doherty: It is never the patient. I find my patients are absolutely delightful. I can honestly say that it is when the patient returns home to her family that the litigation starts. We have to be realistic about that aspect. I am not criticising; I am just telling the Deputy the truth.

Deputy Bernard J. Durkan: As strange is it may seem, the odd patient comes to us politicians to make a complaint from time to time. I often wonder whether it might be better for the system to respond without prejudice and to talk about arbitration or whatever the case may be. One can achieve quite a lot without massive costs. This is not a stroke against my colleague or anything like that but I have to mention a recent experience I had where a legal practitioner became very animated when it was discovered I had been probing the system to ascertain what went wrong. It was not a deliberate mistake but it was a simple thing that could happen. Like Murphy's Law, if it can happen it will happen. The point I am trying to get as is we need to use open disclosure to a greater extent, particularly when it is there. It is there for a purpose. I do not think it undermines the case. I do not think it will open up floodgates. If it does open up floodgates that has to be looked at again. The United States is a classic example. We all know about that. It has been that way for the past 40 years at least. It is getting better or worse as the case may be.

To go back to Professor Hill, when the patient is diagnosed with cancer, and let us assume she goes home and discusses it with friends and family, which is a natural thing, it is a very difficult, isolated and frightening position to be in. Can Professor Hill tell her with any degree of certainty, given that the screening system is not 100% accurate, that it is 75%, 80% or 90% accurate?

Professor Arnold Hill: It is higher; it is in the high-90s.

Deputy Bernard J. Durkan: Somebody said 99%.

Professor Arnold Hill: It is in the high-90s. If there are 100 women with breast cancer, a mammogram will show it in over 90%.

Deputy Bernard J. Durkan: That is good. It is fine but it is not accurate. If a woman happens to be one of the 10%, she will obviously feel aggrieved. Is there anything we can learn or do to try to narrow that any further? We have listened to the witnesses' submissions. Repeated mammogram tests might not be the answer either. It might cause greater stress and so on. Is there any way we can deal with that particular aspect of the system? To move away from open disclosure and to become secret and defensive about it will not work in today's climate, unfortunately.

Professor Ann O'Doherty: There is no other test that is better than screening mammography. When we are in the symptomatic service we do ultrasound on every woman with a lump. Ultrasound on its own picks up 60% of breast cancers. Mammography on its own picks up somewhere in the mid-80s. The two together have a negative predictive value of 97%. Ultrasound is incredibly time-consuming and operator-dependent. We could not possibly have a screening programme using breast ultrasound. We do not have a better test available. We might in ten years' time when we have genetic markers and blood tests. It may well happen in our lifetime but at this moment we do not have a better test. I wish we did but we do not.

Deputy Bernard J. Durkan: I compliment the BreastCheck system for all it has achieved and for the tremendous work that has been achieved in terms of identifying and putting in place the necessary treatment.

Deputy Alan Kelly: I have a final short question. The meeting has been very useful and informative for members and I hope that is true the other way around too. That is part of the reason we do this. We have a duty to try to tease things out. I am not saying there are a huge number of issues but where there are issues, the witnesses should make sure that the process by which communications go from BreastCheck to clinicians forwards and backwards works. There are concerns it is not working.

Professor Arnold Hill: It is very good actually because most BreastCheck clinicians-----

Deputy Alan Kelly: Perhaps I will talk to Professor Hill after the meeting.

Professor Arnold Hill: Most of them work in the symptomatic service as well. There is a very close relationship. It is not like in the other programme where there was a distance. They are working in the same units together.

Chairman: The purpose of this hearing and this committee is not to be in any way destructive. The purpose of the committee is to be constructive. I understand the misgivings the witnesses have but we are trying to be constructive. Questions have been asked about how we can improve the service. There are obvious lessons that can be learned from today's hearing. From my own experience, lack of communication leads to greater litigation. The greater the communication the less litigation there is. Fundamentally breast screening is a very important service. We do not want to in any way damage that service by having our hearing today but we want to improve the service and examine the aspects of it that can be improved.

I thank the witnesses for attending and taking time from their other work. I thank Professor Hill, Mr. McCallion, Professor O'Doherty and Professor Ó Laoide for attending.

The joint committee adjourned at 1.06 p.m. until 9 a.m. on Wednesday, 30 May 2018.