DÁIL ÉIREANN

AN COMHCHOISTE UM SHLÁINTE

JOINT COMMITTEE ON HEALTH

Dé Céadaoin, 29 Meitheamh 2022

Wednesday, 29 June 2022

Tháinig an Comhchoiste le chéile ag 9.30 a.m.

The Joint Committee met at 9.30 a.m.

Comhaltaí a bhí i láthair / Members present:

Teachtaí Dála / Deputies	Seanadóirí / Senators
Colm Burke,	Martin Conway,
Cathal Crowe,	Mary Seery Kearney.*
David Cullinane,	
Bernard J. Durkan,	
Gino Kenny,	
Róisín Shortall.	

* In éagmais / In the absence of Senator Seán Kyne.

I láthair / In attendance: Deputy Joe Carey.

Teachta / Deputy Seán Crowe sa Chathaoir / in the Chair.

Vaginal Mesh Implants: Discussion

Chairman: Senator Mary Seery Kearney is substituting for Senator Seán Kyne and apologies have been received from Senator Frances Black. Today's meeting will be split into two sessions. In the first session we are meeting representatives from Mesh Ireland and Mesh Survivors Ireland and in the second session we are to meet representatives of the HSE to discuss issues relating to vaginal mesh implants. The committee will also endeavour to examine issues relating to abdominal mesh on a separate occasion in the near future.

I welcome from Mesh Ireland Ms Mary McLaughlin, Ms Amanda Jackson and Ms Margaret Bolger. From Mesh Survivors Ireland, I welcome Ms Terri Martin, Ms Margaret Byrne and Ms Louise Keogh. All members and witnesses are again reminded of the long-standing parliamentary practice that they should not criticise or make charges against any person or entity by name or in such a way as to make him, her or it identifiable, or to otherwise engage in a speech that might be seen or regarded as damaging to the good name of the person or identity. Therefore, if the statements are potentially defamatory with respect to an identifiable person or entity, witnesses will be directed to discontinue the remarks. It is imperative that they comply with any such directions.

There is a pending litigation arising out of the use of mesh devices. Those cases have yet to come before the courts, which will decide the issues of fact and legal liability. In the light of the constitutional separation of powers and the respect the Oireachtas must show for the courts, this hearing should not prejudice or attempt to second-guess or influence the outcome of that litigation. Witnesses and members should therefore avoid comments which in effect prejudge the outcome of such cases, such as allegations of negligence or legal liability.

I call on Ms McLaughlin to make her opening remarks.

Ms Mary McLaughlin: Good morning, Chairman and members. I am grateful for the invitation extended to Mesh Ireland to discuss the issues relating to vaginal mesh implants. Mesh Ireland is an all-island group with 150 members. Two members join me today, Amanda Jackson and Margaret Bolger. The motto of our group is "For mesh injured, by mesh injured." We firmly believe that patient representatives must be the injured themselves, an approach not currently embraced by the HSE mesh pathways. The previous Minister for Health did not meaningfully engage with the Mesh Ireland campaign. I have represented Mesh Ireland at the 2018 to 2020 UK Cumberlege review and to governments in the North and Scotland. I have communicated in previous correspondence to the committee on my mesh advocacy activities regarding solutions to the non-availability of full and safe mesh removal surgeries in Ireland.

Mesh injury is a global scandal, the legacy of more than two decades of implanting mesh. Statistics convey the incidence of implantation and mesh injury. The HSE has not supplied its data. In NHS England alone, approximately 100,000 women had mesh implanted from 2008 to 2017. A former Chief Medical Officer for England estimated the mesh injury rate at 15-20%. The Irish State has no figures. The two groups here today represent 750 members. In recent years, Scotland and Quebec have introduced mesh removal costs reimbursement legislation, policies and funding for their injured. In the USA, justice departments have reached multi-state settlements with mesh manufacturers for actions based on endangering patients through deceptive marketing. The respective sums are $188.6 million, $344 million and $60 million.

In contrast, a different wind is blowing here in Ireland, where mesh-injured patients are

being obliged to finance their own full and safe removal of mesh implants. The local mood remains anchored in talking up partial removals of the implants as the best alternative. It is not the case that the low-volume HSE data of attempted full removals evidence the risk to patient safety. HSE surgeons may be coming under pressure to demonstrate skills to have a go at a full removal, whether they have the skill set and expertise or not. Mesh removal skills are a special skill set. It is a perfect storm scenario, which should be resolved by stepping up access to the treatment abroad scheme, not restricting it.

I will address the reasons full and safe removal is the best option. When polypropylene mesh implants are inserted, our internal tissues form scar tissue over the implant. It is the scar tissue which encases the implants and holds them in place. The incontinence tapes or slings are on average 22 cm long. The prolapse meshes are much larger than slings. They can run from the front of the pelvis to the rectal area, causing both urinary and bowel incontinence or retention when problems arise. I can best describe them as having the size of a ladies' panty liner with long strips going off at the sides. Some have six strips. Some are additionally secured internally by additional metal fasteners and staples. Their position in our bodies and the scar tissue surrounding them poses surgical challenges in removing them.

Partial removals, the default solution for two decades, are not the answer. If a woman has pain from mesh in her groin, removing the easily accessible few centimetres of mesh from under the bladder pipe will not ease that pain. Eventually surgeons have no access to the remainder implants, due to dense scar tissue. They simply cannot get in at the mesh. These women have only non-surgical treatment options open.

On access and funding, the principles of autonomy and informed consent tell us that women have a right to have the option of full and safe removal of their implants on the public healthcare system. Yet, for HSE healthcare patients the treatment abroad scheme is illusory. It is a catch-22. The patients must exhaust the treatment abroad scheme pathway to prove they tried the available routes but the system is stacked against them. First, the HSE's official position is that these surgeries are available in Ireland. We dispute this. This unequivocal and bold statement is a hurdle which our women alone cannot dismantle. Second, the HSE surgical community is deeply attached to partial removals which are its historical comfort zone. In our view, patients who reject the HSE surgical preferences will only receive minimalistic, lip-service support when they ask HSE consultants to provide necessary documentation to support their application for the public healthcare treatment abroad scheme.

Two women did travel to the USA with HSE consultant-authored letters of support. However, what differentiates these two cases from others is that these patients funded their surgeries through private healthcare and their own financial means. It is here that a two-tier system emerges. Private patients are passported through. HSE-reliant patients are kettled in local HSE pathways. Patient choice should not be determined by a medical community which dilutes its support for the identical medical procedure with the identical surgeon based on the financial means of the patients. HSE patients are currently experiencing a mindset akin to "like it or lump it", "partial removals or nothing." They deserve to be treated with respect.

The procedural mechanisms provide a slam dunk for rejecting applications related to full removal surgeries abroad. Weakly worded letters stating "patient feels she would benefit from this surgery" contrast starkly with letters supplied to private patients which embrace their choice of a more experienced surgeon abroad. Notwithstanding the letter, the HSE's official position that there is not just one but many surgeons who perform this operation locally means that the treatment abroad scheme pathway is a fool's errand. The door was never really open. The HSE

conducts an automated appeal. Rejection follows. The door is bolted from the inside.

Our women deserve to be treated with dignity and respect, concepts which underpin a fair and equal society. We have found that the State has a gap in its services. Currently, it is a David-and-Goliath battle - a war of attrition. Our women deserve access to full and safe removal operations performed by surgeons of their choice. In the hands of the right surgeon, this is an established surgical procedure which only lasts for a few hours. It is affordable to the State, and this pathway is the choice of many.

Ms Margaret Byrne: I will speak on behalf of Terri Martin. I thank the committee for inviting members of Mesh Survivors Ireland to speak here today. I also thank Amanda and Terri. This is the opening statement of Terri Martin, advocate for Mesh Survivors Ireland of mesh-injured patients. I thank the joint committee for inviting Margaret, Louise and me to appear as representatives for the Mesh Survivors Ireland group and Mary and her representatives on behalf of the Mesh Ireland group, to collaborate on the much-needed aftercare and supports that are required to assist in our daily living needs following these life-limiting medical procedures.

As members are aware, our journey in respect of the specialist aftercare relating to this medical injury began here in Leinster House in late 2017. Much has been discussed and achieved since then. Following all the delays relating to the global pandemic, the lifting of the unprecedented restrictions relating to it means that we can now have an honest and open discussion on all the suggested recommendations contained in the Chief Medical Officer's 2018 report and the HSE's implementation plan for mesh injury.

Covid-19 restrictions have been lifted for the majority of people. However, mesh-injured patients will never have the opportunity to enjoy the same quality of life again. We are extremely grateful for the support that the Government has given us to date, for our issues being heard and for all the background work that has been done in terms of the review of this horrific infliction. As recipients of this failed procedure, we are saddened to report that although there have been learning reports, CMO reports, implementation plans and advisory committees, nothing has changed. We still live with the after-effects of mesh injury limiting our quality of life. As a result, it is easier to try to navigate the necessary means that can be accessed through committee members, the powers that be, in easing this life-limiting health scandal for all involved as an optimistic view to improve our daily living needs and in assisting us to break free from the detrimental consequences and effects that were inflicted upon us with no informed consent. It is now widely known that there are minimal complete removal options of surgery for these surgical tapes here in Ireland, with no success or complication credentials as requested annually.

The following interventions are spread across Departments. They are necessary interventions that will make an exceptional difference to injured lives. The first is the issuing of medical cards to all recognised mesh-injured patients from previous pathways and Health Products Regulatory Authority, HPRA, registration to assist with medical costs, diagnostic need, medications, primary care, GP visits, and acute services, such as haematology, diabetic screening, optometry and dental care, required as a result of the associated side effects of mesh.

The second intervention is patient transfer. Although we are grateful for the designated two mesh centres in Cork and Dublin, they are not realistic or feasible for the majority of those in need of their services. Therefore, patient transfer is vital in order that we can avail of the CMO's recommendations. Those injured by mesh are subjected to very invasive, painful examinations and cannot be asked to travel such distances on public transport, which is rarely accessible in many cases, and suffer unconditionally following the process.

The third intervention relates to accountability and an apology for mesh injury from our HSE and the Department of Health because there were many warnings regarding the safety of these products from the Food and Drug Administration Authority. Although they came in through Europe's decentralisation system, they still ended up implanted in our bodies in national public hospitals run and funded by HSE and the Department.

The fourth intervention relates to patient advocates. The latter need to be included with the stakeholders in the decision-making relating to the upcoming steering committee on mesh injury. These patients hold the most valuable insight into the side effects endured following these failed procedures and the actions needed to prevent these horrific situations happening again.

The fifth intervention involves honest communication with all advocate mesh groups by the stakeholders. Such communication needs to be forthcoming and transparent in order for this whole nightmare to end. Trust needs to be re-established in order to rebuild confidence among those who promised "First, do no harm". Trust has completely broken down in light of all the gaslighting, ignorance and disrespect.

From the Woman's Health action plan, dates are required for when the agreed compassionate engagement from December 2018 in lieu of an independent enquiry into mesh injury are going to take place. We also need information on the form of protocol that is to be used for this review. Dr. Gabriel Scally's review into the other women's health scandal involving CervicalCheck raised many identical issues, and its findings resonate closely with mesh-injured ladies and their constant battle for justice.

When will the translabial scanner be available for use at the Dublin and Cork mesh centres? Previous correspondence from Government indicates that it has been available since 1 September 2021. This is not the case. There is an anxious waiting list of mesh-injured ladies awaiting life-changing answers as to what damage their mesh is causing internally so as to direct future intervention to ease their plight. These vital diagnostic machines came at great public cost and it would be a shame to leave unused such wonderful non-invasive investigatory tools in mapping the mesh placement internally.

In the context of the CMO's report, an update is required as to the treatment suggestions in aftercare and the efficiency and effectiveness of the budget allocated. According to patient reviews, these treatments are not working and patients are still made to feel as though they are guinea pigs. Intervention is needed as soon as possible as some patients are coming out worse from participating in these treatments.

Chairman: I will just ask Ms Byrne to stop there. I am conscious that we are eating into members' time and I want to have as much frank discussion as possible. Is that okay?

Ms Margaret Byrne: That is fine.

Chairman: I thank Ms Byrne for taking Ms Martin's place. She is on her way. The first question is from Deputy Durkan.

Deputy Bernard J. Durkan: I welcome our guests and thank them for their introductory remarks. We all empathise with women and with anybody who receives a service which results in their having an ongoing life-changing issue. How many post-mesh cases have been dealt with and have been recorded here in the South and on the island of Ireland?

Chairman: Who wishes to take that?

Ms Mary McLaughlin: Does the Deputy mean how many people have been injured?

Chairman: Yes.

Ms Mary McLaughlin: I gave the statistics from the NHS in England because the HSE does not have any data. There was a common problem with data collection prior to electronic records. This means that the first decade of mesh implantation was detailed in the form of manual records. Nobody wants to go back into manual records. There is also a problem in that these surgeries were not given the correct code, so even if you went back into the records, you might find that it has been logged under a general women's surgery rather than as a specific code for mesh implantation. That is why I gave the statistics from NHS England for the past decade. There were 100,000 and, according to the chief medical officer in England, the complication rate was 15% to 20%. The North does not have statistics. It has some statistics for the public healthcare system, which included 10,000 women. However, that number only relates to public healthcare system. Many women have had these surgeries through the private healthcare system. There is no data for that hidden sector.

Deputy Bernard J. Durkan: I thank Ms McLaughlin. She has kindly told us about full removal compared with partial removal. To what extent does partial removal continue to take place, if at all?

Ms Mary McLaughlin: My experience from talking to the women in my group from the South is that nobody has been offered full removal of the mesh. Those people who have already had partial removal, which might involve just a very small portion of the mesh, find that surgeons are reluctant not only to do anything more with the mesh but also to do any surgery at all. There is an added problem in that when women get older, their organs start to prolapse. At that point, because of the contentiousness of the surgery, new surgeons do not want to operate on them until they have had the mesh issue resolved. Many women have had extreme prolapse and have been directed to non-surgical options.

Ms Terri Martin: Options in the South seem to be directed only to partial removals. During the week, I read in the newspaper, as I am sure members did, that seven full removals have been done in the South. When we have asked for statistics about success rates, complication rates or how many procedures have been done, we have never been given statistics. I believe that only partial removals are conducted at the moment.

Deputy Bernard J. Durkan: It appears that there is a significant lack of data, information and advice about this matter. I am strongly of the opinion that there should be an immediate appraisal of the number of people on waiting lists, the number of people who have had treatment, the nature of the treatment and the results. Those data are required in order to address the issue fully. Is it possible to do that in the short term?

Chairman: I thank Deputy Durkan and call Deputy Cullinane.

Deputy Bernard J. Durkan: Wait a second. I would like the answer first. Can that be done?

Ms Mary McLaughlin: There is a problem with data collection for the women who are now trying to get medical records in order to find out which implants they have. There are three or four main types, and many different products. Not every product is identical. Surgeons need to know which product they are removing. When many women look at their medical records, the implant sticker, which is meant to be adhered to the surgical sticker sheet, is missing.

Ms Amanda Jackson: I have seen four different specialists over 19 years. Not one of them connected the mesh to my injury. I attended two mesh inquiry clinics. I was told at the second one, in Holles Street hospital, that my injuries were nothing to do with my mesh. If women are being told that their injuries are not connected to the mesh, then they do not know. There needs to be an information campaign in the media to inform women because their doctors are not informing them.

Deputy Bernard J. Durkan: How many minutes do we have?

Chairman: Five minutes. Deputy Durkan's five minutes are up.

Deputy Bernard J. Durkan: I know they are. The entire scenario seems to be surrounded by a lack of information, failure to address the issues and so on. I do not want to make too much comment other than to say that it is an appalling vista for anyone looking in from the outside to see women being treated in that fashion and put on waiting lists in that fashion. That does not solve the problem.

Deputy David Cullinane: I welcome the witnesses. It is not easy to come before an Oireachtas committee to address such a sensitive issue. I commend them on speaking out, agitating and campaigning for themselves and their members. Ms Bolger read the opening statement, but I have a number of questions for Ms Martin because I want to tease out some recommendations or requests contained in the statement. I will come to Ms McLaughlin in a few minutes too. The HSE will come in later, and we want to ask it some questions. Is there no automatic right to a medical card for mesh survivors? Are the witnesses seeking that?

Ms Terri Martin: Yes. First, I apologise for being late.

Chairman: There is no need.

Ms Terri Martin: People are meeting every possible barrier with medical cards. People might have husbands who work. With the injury caused by the mesh, the diversity in families and relationships has changed. I do not think one could necessarily say that a husband's wages, although people are married, will be put into a wife's medical card.

Deputy David Cullinane: It is means tested. We will tease that out with the HSE.

Ms Terri Martin: There are no allowances for the means test for the medical card. Women have been maimed. We went in with good faith to have this surgery done. It is not the fault of women, their husbands, their jobs or their retirement funds that they are in this position. It is necessary for women to receive medical cards if they were injured by a mesh. There is a register with the regulatory authority. If people are attending the pathways, they are registered with that. It knows exactly who has this device. It would be for necessities. I do not know if the committee is getting into the nitty-gritty of the price of hygiene products here, but these are available through community care and incontinence care from the public sector. Women should be entitled to those things and should not have greater expense through no fault of their own.

Deputy David Cullinane: I thank Ms Martin. We have limited time. I wanted to ask a number of questions. We will address some issues with the HSE later. I wanted to focus on two key matters. The available range of treatments is important to the witnesses. It seems to me that there is an option for a partial removal or a full removal, with pain management being available for cases where that is not possible. It seems from both opening statements that a full removal is not really an option in this State. Many women have to travel abroad, but the treat-

ment abroad scheme is not effective and barriers are being put in their way. I ask the witnesses to explain again what those barriers are. That is important. The HSE's opening statement mentions that the scheme is working effectively, yet the experience of the witnesses is that it is not working. The HSE talks about the two centres of the national mesh complication service in Dublin and Cork being up and running to treat patients. The translabial scan is obviously important. Is it the experience of the witnesses that the scanning equipment is operational in both Cork and Dublin? Is it only available in one or is it only partially available? What level of service is being provided? That question is for both Ms Martin and Ms McLaughlin.

Ms Terri Martin: Ten people injured by mesh went to Cork for the training of consultants on the translabial scanner. The scan was done. As far as we were concerned, the service was up and running from that point and everybody was trained on it. I received correspondence from the Minister. He was under the impression that the one in Holles Street is up and running. However, the patients attending Holles Street have been told they cannot be referred to Cork. The scanner they have up there is having technical problems. It is not up and running but the Government believes it has been running since 1 September 2021.

I approached a consultant in Cork and asked about the translabial scanner. I was told to tell the ladies to get a referral down to him and they would see what could be done, but there is nothing at the moment.

Deputy David Cullinane: Ms McLaughlin or Ms Jackson might answer the question about treatment abroad.

Ms Amanda Jackson: I tried to access the treatment abroad scheme. I had been with my urologist for three years and found out through a friend about mesh injury. I applied. My consultant had come to the end of his treatment plan and the only thing left was a hospital admission and IV treatment. He said he would support me. He wrote a letter and signed the form. He would not write a letter addressed to my consultant initially and then he implied in it that I had self-referred. The treatment abroad scheme said that treatment was not available because the patient had self-referred. Subsequently, I was told by the Ombudsman, who took up the case after I was referred, that my consultant should not have said there was no doctor in Ireland available to do it. The consultant is an assistant professor and I had been with him for three years. It was just very difficult. The Ombudsman caseworker told me she was not getting answers from the HSE when she asked if a similar treatment was available here in Ireland. She did not get an answer back. It seems the Ombudsman does not have the authority to get the information and to look for the evidence as a solicitor would. Therefore they have no clout to be able to make a judgement. Furthermore, they are not medically trained to understand, so the HSE can say what it likes.

Deputy Cathal Crowe: I welcome all our witnesses. I have been educated over recent weeks. On Saturday I spoke to one of the injured women. She wishes to remain anonymous. She is here and her story is one of pain and horror and not being believed or trusted by our so-called best physicians. I want to mention two people in the Public Gallery: Melanie Power, a solicitor in Limerick, who has led the spotlighting of this, and Kitty Holland from *The Irish Times*, who has kept a focus on this in the media.

I have two questions but mostly I want to hear from our guests. I assure them of my full support. Their story has been unheard and, arising from what we heard today, the Government must take a series of actions. As a Fianna Fáil member, I will meet the Minister, Deputy Donnelly later this evening to bring these to the heart of Government. I understand there are

two types of mesh in implants, namely, retropubic tape, TVT, and transobturator tape, TVT-O. The latter is the far more difficult type. It is implanted close to the obturator nerve in the groin area. I understand that, in Ireland, gynaecologists implant the TVT-O mesh whereas, in Britain, a gynaecologist is accompanied by an orthopaedic surgeon because of the complexity. There is obviously some discrepancy if, a few hundred miles across the Irish Sea, they believe two surgeons with different expertise and skill sets are required. In Ireland we do not see that yet. An eminent professor in Ireland, whom I will not name, has said that what is implanted in most medical cases should be capable of removal. Will Ms McLaughlin tell us why we do not use two surgeons in Ireland? Is anyone dealing with mesh removal in Ireland now and to what success? I use the term "success" very loosely.

Ms Mary McLaughlin: There is a slight discrepancy in the information. The two surgeons are required in England for mesh removal. The transobturator meshes are implanted through the groin on each side and through the middle. The problem is that the mesh is sitting in the obturator nerves. If you think of someone with a hamstring injury, it is the muscle band and internal thigh nerves going down. You cannot get at those two pieces of tape. If I had a 30 cm tape, I would have 10 cm in my groin on one side, 10 cm through the middle and 10 cm in the groin on the other side. Ms Kelly and I have been abroad and had those tapes removed. It leaves a large surgical scar on each side of the groin and that is why it is very important to go to someone who knows what they are doing, because there are a lot of tendons and muscle there, so if that is got wrong, women can lose the power in their legs. The two surgeons being used in the UK mesh multidisciplinary team, MDTs, are the surgeon from the urogynaecological field and either a plastic surgeon or an orthopaedic surgeon.

Deputy Cathal Crowe: Is there a lack of skills in Ireland?

Ms Mary McLaughlin: Absolutely.

Deputy Cathal Crowe: I believe it is necessary to do five surgeries a year to stay current and up-to-date. I presume that is not happening in Ireland. People are arriving, scalpel in hand, at a surgical table not fully skilled to perform surgery. Is that the nub of much of the problem here?

Ms Mary McLaughlin: It is part of the problem but, to clarify, in removal, the need for the orthopaedic or plastic surgeon is about the approach the urogynaecological surgeon takes to finding the end of the tape on each side of the patient's thigh. The world expert uses a tissue sparing, muscle sparing technique. If you have a plastic or orthopaedic surgeon in the operating room, the mesh surgeon goes in and uses a rougher way of getting at the end and he cuts muscle. The orthopaedic or plastic surgeon-----

Deputy Cathal Crowe: If Ms McLaughlin forgives me, the Chair is going to cut me off in 30 seconds and I have to put an important question to Ms Martin. It really disturbed me to hear some eminent physicians say this is a problem of the mind. One patient has told me there was a suggestion they had augmented pain syndrome, that is, that the women were imagining it. I am a man so I cannot begin to imagine the pain these women have gone through but I know if I have toothache or any type of pain, for someone to tell me it was in my mind would drive me mad. Will Ms Martin tell us what it has been like for the women who have been told the pain is not of their body and nervous system but all in their mind?

Ms Terri Martin: Many ladies have been attending doctors, GPs and everything over the years, and some have been put on nerve stimulant drugs and everything, only to be told it is a

problem of their mind and not a pain problem. We have stressed that it was a pain problem. It is because they simply do not know the solutions. These effects of this on all bodies include evidence for autoimmune diseases, pain and other things. It has been researched, and the more it has been researched the more things have been shown. There are blood disorders and 101 different case scenarios. It just destroys the body internally.

Deputy Cathal Crowe: Unfortunately, time has run out. Destroying patients' bodies and people losing their walk is not a figment of people's imagination. It is not something a woman dreams of in the night and wakes up believing she has a pain. It is very real pain. That this is real pain and an untold story is something that needs to be central to our work here. The Government and the HSE need to pave an appropriate pathway for these women.

Deputy Róisín Shortall: I welcome everyone here and thank them for their presentation. I am very sorry they have had such a negative and distressing experience of the Irish health service. It raises huge questions for the HSE and the Department of Health. It is our job to take those issues up with the authorities, which we will do later.

It strikes me there are two aspects to this. First, it seems the Irish health service is not paying adequate attention to this issue. I say that in respect of basic things such as a lack of data and any meaningful statistics. Ms McLaughlin mentioned the issue of errors in the coding. Is there anybody at a senior level within the HSE who is actually dealing with this issue? Is there a named person whose responsibility it is?

Ms Terri Martin: The national women and infants health programme seems to be running the whole show, but as the Deputy said, there is an issue with its oversight. All the boxes for the implementation plan for the HSE are ticked. It is just that there is nobody to oversee the implementation.

Deputy Róisín Shortall: Is it the view of both groups that if the implementation plan were to be implemented, it would address most of the issues? Do our guests think the plan is okay or are there problems with it? Do our guests not think the plan is okay?

Ms Terri Martin: No.

Ms Mary McLaughlin: No.

Deputy Róisín Shortall: Okay. I had that impression from what our guests were saying. There is no named senior person who is dealing with our guests and who has an overview of this entire issue.

Ms Amanda Jackson: I have been in contact with the Minister. I have been writing to him throughout my journey since 2020. I wrote to the Medical Council. I have spoken to the person who is heading the patient pathway and asked for statistics. My background is in healthcare. I was a midwife in the UK. Evidence-based practice is fundamental. I said we have been injured and need to know who is doing the surgeries, what is their experience and what are the outcomes for the women who have been operated on. She would give me no information.

Deputy Róisín Shortall: It is a fairly basic problem if there is no person with an overview and a handle on the situation. I will pursue that. The other aspect of the issue seems to be that there is clinical disagreement about the right approach to take. I do not know whether that is a genuine clinical difference of opinion or if it is a result of the fact it is cheaper to take the approach of partial removal and not cover the treatment abroad scheme, the costs of which are

substantial when travelling to St. Louis is involved. Is there a general acceptance of the best kind of treatment on a WHO level or at a European level? Is the clinical thinking that the best approach is full removal?

Ms Mary McLaughlin: The British Society of Urogynaecology recently updated all its information leaflets. It now has proper leaflets where the different stages of removal are illustrated and the risks are included. There is a view that partial removal is not the way forward. The Scottish Parliament heard evidence from a lead surgeon and I encourage the committee to arrange a videoconference with that surgeon who can tell it exactly what is going on.

As patients, we are asking for choice but we have a body of surgeons who never went to the bother of learning these skills over the years. Women are going into appointments and being told when they ask for their mesh to be removed that they do not really want that. They are told that full removal is a very dangerous operation. Operations are always dangerous if the relevant medical community does not have the skills. The skill set is not there. It was not there in the UK, Australia, Canada or anywhere else around the world. We are not unique in that regard. A professional cannot gain that special skill set by doing a few operations.

Deputy Róisín Shortall: The question of the skill set could be addressed if proper funding was supplied for training. I note that the NHS in Scotland is contracting with St. Louis, rather than training its own people. We will raise that issue afterwards.

I have a couple of quick questions to which I am not sure if our guests are in a position to provide answers. There has been mention of the discrepancy between public and private patients. Are private patients being covered by their insurance companies to travel abroad for full removal?

Ms Mary McLaughlin: They are.

Deputy Róisín Shortall: Have many of those taken place?

Ms Mary McLaughlin: I know several women in our group who have done so. Many of the women in the group are private and do not tell us.

Deputy Róisín Shortall: I appreciate that.

Ms Mary McLaughlin: I do, however, know of examples where private health insurers have paid for some women's treatment.

Deputy Róisín Shortall: I think another of our guests is suggesting private patients are not covered. Okay. It likely depends on the insurance company.

Ms Mary McLaughlin: I can forward the Deputy that information.

Deputy Róisín Shortall: I would appreciate that. Have any full removals taken place in this country?

Ms Mary McLaughlin: Not that we are aware of.

Deputy Gino Kenny: I wish good morning to everybody. I have a number of questions but I do not want to repeat some of the questions that have already been asked. This procedure was paused in the State in 2018. Is it still available outside the State? Is it still available in Europe, for example? Can women get it done?

Ms Mary McLaughlin: Is the Deputy asking about the implantation?

Deputy Gino Kenny: Yes.

Ms Mary McLaughlin: To the best of my knowledge, the bans in Europe are only pauses. To the best of my information, those procedures are still taking place.

Deputy Gino Kenny: How many women have accessed the treatment abroad scheme thus far?

Ms Mary McLaughlin: There have been none, to my knowledge.

Ms Amanda Jackson: I did it last year. I tried to access it.

Deputy Gino Kenny: Was Ms Jackson successful?

Ms Amanda Jackson: I was unsuccessful. I went to the Ombudsman, who posed questions to the HSE. When I spoke to the caseworker, she said some of those questions were unanswered.

Deputy Gino Kenny: Why does Ms Jackson think she was unsuccessful in accessing the treatment abroad scheme?

Ms Amanda Jackson: The answers did not make any sense. I was told I had not accessed the patient pathways. I had been to two mesh clinics. I had been in touch with the patient pathways and I had been continuously with one urologist for three years and was seen frequently prior to my application. It did not make any sense. I self-referred.

Deputy Gino Kenny: Do our guests know how many women have tried to access the treatment abroad scheme? There does not seem to be a collection of data around this issue.

Ms Amanda Jackson: There is not.

Ms Mary McLaughlin: The HSE's position is these surgeries are available in Ireland. For the administrators of the treatment abroad scheme, the official position is women can get the surgeries here in Ireland so they should not be given access to public funds for treatment abroad.

Ms Terri Martin: The translabial scanner became available in 2019, which I acknowledge was before the pandemic. It was March 2019 that access to the treatment abroad scheme was taken away. Access had been granted by Deputy Harris when he was Minister for Health but it was taken away in March 2019. The most recent correspondence I received stated the treatment abroad scheme was available for complications that cannot be dealt with in this country. In the meantime, we have a member who was sanctioned for the treatment abroad scheme for one surgery in the UK but the treatment required reconstruction after the initial removal, which was not sanctioned. That meant she could not go ahead with the treatment because only one part of it was available to her under the treatment abroad scheme. I heard nothing more about it until the most recent correspondence with the Minister in which he said the treatment abroad scheme was available again for complications that could not be dealt with in this country.

Deputy Gino Kenny: It is mostly in the United States where that procedure could take place.

Ms Amanda Jackson: Yes.

Ms Mary McLaughlin: If I could explain in respect of the mesh pathways, we have a local multidisciplinary team, MDT, which deals with what it calls non-complex complications. The women concerned have to go through that step, and only if that local MDT deems that they can go to the mesh complications MDT do the women go to the next step. The mesh complications MDT then decides if it can operate. If it decides it can operate then the woman is kept in the local services. It is a non-complicated level, a complicated level and a complex level. It is only if the complex team says it cannot do it that they then start to look elsewhere. There are a lot of steps to get through and the women falling at the first hurdles.

Ms Terri Martin: There is no patient-centred care involved with mesh injury. We must rely on people who are indirectly affected by it to sign forms for us to avail of the suggested services.

Deputy Gino Kenny: Ms Jackson's injury must be compounded by being told that this is psychosomatic, with certain medical professionals saying that this is all in her head and is not related to the procedure that was done. How does it make Ms Jackson feel about healthcare in Ireland when people are saying it had nothing to do with the procedure that was done and it is all essentially in her head?

Ms Amanda Jackson: You are hoping that the mesh clinic is going to bring a resolution. It is the last stop. Then you are told it is not the mesh, the mesh is not your problem. The clinic said it had lots of young women coming in with infections. To not even examine me, having waited all of those years with hope deferred, makes the heart very sick. I was really sick walking out of the clinic.

Ms Terri Martin: I do not want to be egotistical, but if I hear a consultant saying that the problem is not the mesh, I think to myself "Do you even have the credentials to have this job and this position of trust you are in?" This is the way I look at it now. It is not a reflection on us. As I have said, we trusted in those who were supposed to help us. It is not a reflection on us that they cannot fix what has been caused to us.

Ms Amanda Jackson: With respect, having a scanner does not mean that a person has the skills to be able to use what is found, having used the scanner. The scanner itself is not an answer. International best opinion would say that the consultant who inserted the mesh is not always best placed to remove it but may feel duty bound to do it because he or she has put it in and it has caused all of the issues. A completely different skill set, however, is required. It is a sub-specialty that needs a specialist clinic with one or two doctors who consistently only carry out that procedure. Our doctors are involved in multiple other disciplines within urogynaecology. It is just not possible here because Ireland is too small a country to gain that level of expertise with good outcomes. They are quite right to say that they could not do it or that it is not recommended. It is not recommended because the skill set is not available to them. It is not a reflection on the doctors. There are huge constraints on our medical field.

Senator Martin Conway: A couple of the questions I was going to ask have been asked already. I welcome the witnesses and I applaud them for their bravery. It is certainly a horrific situation. Like others, I am relatively new to the consequences of this but it is something that must be dealt with. I will recommend to this committee that we will send a short report to the Minister after this engagement with the witnesses and with the HSE. Clearly, the level of supports are not acceptable. The recommendations that have been made are fairly clear cut, certainly in terms of medical cards. Such supports should be a given.

Deputy Shortall touched on the issue of private health insurance, and what is covered and

not covered. Is there any surgeon or consultant operating in the private sector specifically who has had any advancement in this area in Ireland?

Ms Mary McLaughlin: No. Not that we know of.

Senator Martin Conway: Deputy Shortall asked about health insurance covering people going abroad, which is happening in some cases. Are there issues with health insurance covering procedures in this country?

Ms Mary McLaughlin: There is no surgeon to do the procedure that we want.

Senator Martin Conway: Has anybody, anywhere, been successfully treated in resolving this issue?

Ms Mary McLaughlin: I have my had my mesh removed but it was done in America.

Ms Amanda Jackson: I had my mesh removed last September and I am a different woman now.

Senator Martin Conway: It was successful?

Ms Amanda Jackson: Absolutely.

Senator Martin Conway: At least there can be a successful medical resolution to it.

Ms Amanda Jackson: Yes.

Ms Louise Keogh: There is a huge cost to it also. If you do not have private health insurance, there is a huge cost to going abroad. Many women have borrowed €20,000 to €30,000 from credit unions and banks to get the procedure. I still have the mesh inside me and, unfortunately, I cannot financially afford to have it taken out at the moment.

Ms Mary McLaughlin: The cost would have been affordable for the State in 2018 when I first wrote to the State. I had contacted Dr. Veronikis to say that I had a group of women who are not getting any services. I asked him if I were to contact the Government and were it to bring him to Ireland whether he would come on a wait list initiative. Dr. Veronikis said, at that time, that he would come for six weeks and operate six days per week. He does this procedure every day. He does not need to come to Ireland. He could sit in St. Louis and do his work. Dr. Veronikis thought it was a worthy project. I wrote a letter to say there was this doctor to whom I would like to connect those concerned if they would like to speak to the doctor. There was no substantive response. I then took that campaign to Scotland. This doctor interacted with the Scottish Government. Basically, the problem was that there was not a single medical professional who would fill out the paperwork to bring this esteemed surgeon in. As a background to it, there is a lot of litigation going on and the women do not have any records. Our records do not state that we are mesh injured. That is a background story as to why the medical community may be averse to bringing in an independent expert. In the time we have sat here, at least one woman could have had her mesh removed.

Senator Martin Conway: It would seem a very logical approach to it if somebody of that calibre was prepared to relocate here for a period of time to perform surgeries. Again, this is something on which we can engage with the HSE. If we draw up a short report we could put this to the Minister. I have no doubt that I speak for everyone when I say that we as a committee would be very supportive of trying to get a resolution for the witnesses.

Ms Amanda Jackson: I thank the Senator.

Ms Mary McLaughlin: I thank the Senator.

Senator Martin Conway: We would certainly do our best in that regard.

Chairman: Was the blockage at a political level or was it within the medical profession that someone did not feel they could make a promise themselves?

Ms Mary McLaughlin: The First Minister of Scotland got involved at one stage. The chief medical officers were involved. The doctor in America hosted the Scottish surgeons. Every time he was meant to be coming into Scotland, there was delay on delay. At some point he felt as though he was being used with the promises of hope that he was coming. He was not prepared to be used any more. He said that the women thought he was coming in the spring but he told us that it was not on the table. Nobody had approached him in that regard. They had procured his services and to date not a single woman from Scotland has been sent out. On the face of it, there is progress but for the women, our lives are exactly the same. I lie in bed for 16 hours a day, as my son said me the other day.

Senator Martin Conway: Absolutely. I thank the witnesses very much.

Deputy Colm Burke: I thank our witnesses for their presentations here. It has been a very difficult time for everyone involved.

I wish to address the issue of treatment abroad. There is an issue with regard to treatment abroad and the cross-border healthcare directive. I was involved at European Union level with the cross-border healthcare directive. My understanding of the cross-border healthcare directive is that you are entitled to medical care under the cross-border healthcare directive in another member state of the European Union if you cannot access treatment in your own country or if there is undue delay. The difficulty with the cross-border directive is that if you go abroad for treatment under the cross-border directive, you have to pay for it and then seek a refund. That is the disadvantage of it. Has anyone tried to use the cross-border directive to get that care? I acknowledge the problem is that you have to pay for it first and then get the reimbursement, but has anyone gone through it? The cross-border directive is different from treatment abroad and I am wondering whether anyone has gone through that mechanism.

Ms Amanda Jackson: I think they mentioned that but, because the treatment abroad scheme, TAS, stated that there were doctors in this State who are doing the surgery here, that it was not necessary.

Deputy Colm Burke: If there is undue delay, that is quite clear. I was involved in the drafting of it ten or 15 years ago.

Ms Amanda Jackson: Okay.

Deputy Colm Burke: There is quite a clear directive providing for when there is lack of access or, alternatively, undue delay. The undue delay mechanism could be used in relation to use of the cross-border directive.

Ms Amanda Jackson: Excellent.

Ms Terri Martin: Prior to Brexit, one of our members went over, through the cross-border directive had surgery, came back and applied for the reimbursement. That is in the hands of

the Ombudsman at present because it turns out the person in question had private insurance but there was a discrepancy with that as well. The private insurance would not pay out but it had reimbursed some of the money from her normal direct debit every month. When she applied for the cross-border directive, they said about this being with the Ombudsman for the insurance company. It is on hold since.

Deputy Colm Burke: My view on this issue is that the cross-border directive was specifically designed at a European level. They started it in 2007 and it went through and came into Ireland in 2012 eventually. It was transposed into Irish law. It is an effective way of using that mechanism. If the funding is refused, I believe it is a judicial review issue to get an overall decision on that. That is one issue.

The second issue I want to touch on is about figures we got from the HSE about the special clinics it has set up in Cork and in Dublin. The figures the executive gave us are that 40 have attended Cork, 69 have attended Dublin and there are 16 on a waiting list. Those figures seem small compared to the figure the witnesses are talking about, which is 750. Is there a specific reason people are not going to these clinics? Is it only that they are not aware of these clinics or they are not being referred to them?

Ms Terri Martin: They are not aware they have the problem. I was at a consultant last week and I happened to meet a lady in the waiting room. Like that, the lady has had numerous surgeries over the years. She has had bits of organs removed and everything. I do not know where she saw something about the mesh. She was going in to ask him directly whether it had been the mesh that had caused her problems over the years and her answer to that question was, "Probably."

Deputy Colm Burke: We have approximately 160 obstetricians and gynaecologists in this country. Surely it is an easy mechanism to get information out to them and that they would be aware of these special clinics. Is Ms Martin saying that women are not being referred, either by GPs or by consultants under whose care they are, to these specialist clinics?

Ms Terri Martin: The learning reports were sent out to the maternity hospitals of the country, that is, the group level hospitals, but primary care such as GPs, casualty, or accident and emergency were not informed of it. I am sure they are aware of it now, after hearing about it and having so many people come and go at different times, but there is no implementation of it, even in the hospitals.

Deputy Colm Burke: Does Ms Martin accept that if we are talking about a figure of 750 who had this treatment-----

Ms Terri Martin: I would say it is more like thousands. I would say care homes are full of people with mesh.

Deputy Colm Burke: How many did Ms Martin say? Apologies, I did not get the figure.

Ms Terri Martin: Personally, I think the number is in the thousands. Care homes are full of people with mesh.

Deputy Colm Burke: In relation to the collection of data, as I said, there are approximately 160 or 170 obstetricians and gynaecologists in the country. Surely the number of obstetricians carrying out this procedure would have been quite small in real terms. Would it have been 15 or 20?

Ms Terri Martin: Nineteen, I think it was.

Deputy Colm Burke: Surely it would be easy to go through their records to identify the real numbers we are talking about.

Ms Terri Martin: You would think so.

Deputy Colm Burke: What is the mechanism? Why is that not being dealt with?

Ms Terri Martin: I do not know. As Ms McLaughlin was saying, there needs to be a public media campaign for anybody.

Deputy Colm Burke: Ms Martin is saying that there were only 19 consultants dealing with this issue.

Ms Terri Martin: There were 19 who put it in group level hospitals.

Deputy Colm Burke: That is what I am saying. Nineteen put it in and we are talking about a period from 2000 to 2018.

Ms Terri Martin: No, 1998. When did Ms Byrne have the procedure?

Ms Margaret Byrne: I was done in 2000 but there were a few before me.

Deputy Colm Burke: We are talking about 20 years.

Ms Margaret Byrne: Twenty-two years.

Deputy Colm Burke: In real terms, if one is talking about 19 consultants over that period, and maybe two or three would have retired halfway through, surely we could get all of those and that information as regards identifying the real numbers. The other issue is about making sure that every one of those patients is made aware of the follow-up care that is now available in these clinics.

Ms Terri Martin: That would be brilliant. Like that, at the time when they were putting them in, there was, with the HPRA, actually only one consultant who had reported an adverse reaction to the mesh because it is not compulsory for them to do so. Regulations in Europe have done a great deal since. People need to be aware. People do not know they have it.

Deputy Colm Burke: I thank Ms Martin.

Senator Mary Seery Kearney: I thank the Chairman. I am here substituting for Senator Kyne.

I thank the committee and our guests for coming in. This is something I have been aware of for a number of years. When Senator Kyne gave me the opportunity to come in and speak, I thought that finally there will be a tranche of this getting out into the public arena. I am mindful of people such as Ms Kitty Holland, who has spoken about it over the years.

No woman should have to come before a committee and speak about matters of such a personal nature in order to get action. Unfortunately, there is quite a history of women having to do that and bare their souls in order to get action.

I will be rudimentary in how I bring my argument through because it is based on some of the cases and instances that I know of. In the first instance, women may not necessarily know.

They know they had a treatment but do not know that the treatment was mesh. Would that be the case?

Ms Terri Martin: Yes.

Senator Mary Seery Kearney: That is an important for us to say. Women have complications. They do not even know the right questions to ask. I know I had my appendix out when I was a child because there is a scar. If, however, a woman knows there was an intervention but it was not necessarily mesh, she is already disadvantaged, which brings up the whole question of consent in the first instance, but let us move on from there.

I have a concern over consent with regard to treatment if you have a medical community that in the first instance, in some instances is denying the existence of the complications because it is saying they are psychosomatic. If that is the first resort, and in the case of one woman I know of, that is exactly what she has been told repeatedly, trying to move beyond that is difficult. If the first recourse is that this is one's imagination, for instance, there is the lady Ms Martin mentioned who has had numerous other interventions and then goes back eventually, it is nowhere on the checklist of consultants to check whether there is a mesh here and maybe there are complications because they are not even in that sphere to consider it.

When a treatment is recommended, if there is a final decision to treat or to intervene, in that instance, if they are not open to a full removal and they are limiting the options, it is not fully-informed consent to intervention. Is that not the case?

Ms Mary McLaughlin: Yes.

Senator Mary Seery Kearney: That is something I would ask this committee to make sure is in the report. The consent being given to this intervention in this country is not adequate. One of my questions is what is motivating the denial and obstructionism. I think Ms McLaughlin answered that very clearly. It would appear that litigation, or the fear of it, is limiting progress. A mechanism must be put in place. This committee should recommend what needs to be set aside. Whatever has happened has happened. We need to drive progress. I know from a number of situations in which I have been involved that St. Louis is fantastic, particularly on microsurgery. It has the leading people in the world in many areas in microsurgery. Clearly their expertise is in the sheer level of finesse that is required for removal. The witnesses have given me the answers I want. I must leave so I will not be here for the HSE piece. When women are giving their consent to an intervention in Ireland, even if they get to that place, it is not fully informed and that needs to be dealt with.

Ms Mary McLaughlin: I will give another reason the mesh pathways do not have a large uptake. Women who have been treated for ten or 20 years and have had urodynamics and vaginal examinations that are very painful - all these options - are now finding that these new mesh pathways have been created but with the same doctors and the same soft diagnostics. Many of them are saying that they are not travelling to have urodynamics and internal examinations and to have this humiliating process repeated. The informed consent is nearly coerced in respect of not doing the pathway but saying that you have had all this stuff done and you just want it out. You are being forced into all these tests and translabial scans and it is delay after delay. It can take years to get an appointment. Women wait for an appointment, go to the hospital and find out it is not even the consultant. They have a junior doctor who does not know anything about mesh. The women are in tears in the car parks after coming out.

Senator Mary Seery Kearney: Meanwhile people are suffering.

Ms Mary McLaughlin: Exactly.

Senator Mary Seery Kearney: And that needs to come to an end.

Deputy Joe Carey: I welcome all the witnesses and thank them for this really positive engagement. I compliment both groups for their campaign on this issue. It was brought to my attention recently by a constituent whose life was turned upside down. To have that conversation with that lady and understand what she has gone through is unbelievable. It is life-changing. Ms Jackson said earlier that when she had her surgery, her life changed for the better.

Ms Amanda Jackson: Yes.

Deputy Joe Carey: That is key. The full removal of the mesh seems to be the optimal solution but it is how to get there that is problem. We do not have the skill set in this country to do it. Women have no confidence when it comes to engaging with the current system-----

Ms Amanda Jackson: No.

Deputy Joe Carey: ----- so that needs to be changed radically. What type of engagement occurred with the two groups in setting up the current pathways? Was there any engagement with the HSE?

Ms Mary McLaughlin: No.

Deputy Joe Carey: Would any of the groups have met with the Minister for Health?

Ms Amanda Jackson: I have been in correspondence with him since 2020 documenting my story. His secretary said he is committed to women's health but nothing has happened. I have documented to him the gaslighting I experienced and the cognitive dissonance that was so apparent.

Deputy Joe Carey: Obviously the groups would like to meet with the Minister. In her opening statement, Ms Martin outlined eight or nine different issues that need to be addressed and Ms McLaughlin outlined those as well. We have moved on and have come through a pandemic as well so it is time to refresh what was there, upgrade it and make it fit for purpose for women. Obviously the system is not working.

Ms Amanda Jackson: Yes.

Deputy Joe Carey: Deputy Shortall mentioned the collaboration between Scotland and St. Louis. Would the groups have confidence in this option if the medical people from St. Louis had a clinic or presence in Ireland to carry out these type of surgeries involving the full removal?

Ms Mary McLaughlin: It is only one surgeon who is 63. When I started this, he was not yet 60. Women around the world travel to him. He has been insulted by the treatment he received with regard to the Scotland project so the Government would have to engage with him. If he was treated with respect, the women could be operated on here and would have their families around them. Someone making that journey from the US to here after that major surgery would not have had her family and friends with her when she had her operation. I do not know if the world expert would engage. He spent two and a half or three years talking to the Scottish Government but it has sent nobody out to him.

Chairman: I am conscious that we are talking about another jurisdiction but this committee would have written to the Department. A specialist was coming from London to upskill many of the surgeons in Ireland but we know there was a delay to that individual coming over because of the pandemic. The last correspondence we had said that this upskilling work had gone ahead. Again, this is something the committee can follow up on.

I probably should have made a confession at the start that I have had a mesh implant. I have had cancer. The witnesses spoke about an informed decision. I had to make that decision when all the scandals had broken a number of years ago, particularly about women. I had that long conversation with surgeons about whether it was right for me. I was reading and hearing about the horrific injuries caused by these devices. I am one of the lucky ones but having gone through it, I am conscious of the fact that we need to do more for those failed by the system.

I made a commitment at the start of the meeting that the committee would follow through on this. We will have our next meeting with the HSE but we also said that when we resume in September, we will look again at this. I give a commitment on behalf of the committee that we will follow up on many of the issues raised by the witnesses. Members have made suggestions about what we should do in a review and report on this. I give a commitment on behalf of the committee that we will not stop at today's meeting. Let us look at today's meeting as the start of a conversation and let us hope that those who clearly need supports will find them and that we can clear away some of the barriers.

The Cumberlege report was mentioned. It would be a good starting point. I am conscious that it is a different jurisdiction but for any jurisdiction looking at this issue, and I am thinking about Ireland, the recommendations in the report would be a good starting point for anyone trying to address the issue. It is not about reinventing the wheel. It is about addressing some of the harm that has been done to women and men through the use of these mesh devices. The report has a series of recommendations, many of which would be hard to disagree with. It recommends a safety commissioner that would be independent, with statutory responsibility, and which would champion the value of listening to patients and promoting users' perspectives and so on. It also addresses the questions of company responsibility, upskilling of people and missing data. Maybe the committee could look at the report and other ways of helping the women represented by today's delegations so they can have a pathway to recovery and care.

Unfortunately, we have run out of time. I hope the witnesses and those in the Gallery found the meeting useful. I hope everyone felt welcome. As I said, we have given a commitment to follow through on the issue and we wish the witnesses well as they move forward in their recovery.

The joint committee went into private session at 11.01 a.m. and resumed in public session at 11.10 a.m.

Chairman: In this session, we are meeting representatives of the HSE to discuss issues relating to vaginal mesh implants. I welcome: Ms Catherine Donohoe, general manager, commercial unit, who has responsibility for the treatment abroad scheme and cross-border directive acute operations; Dr. Clíona Murphy, clinical director, national women and infants health programme; Mr. Robert Kidd, assistant national director, acute operations; and Dr. Suzanne O'Sullivan, urogynaecologist, Cork mesh centre. Dr. O'Sullivan is only available for the first half an hour of the meeting. If members have questions about mesh centres, they should indicate this to the clerk and we will deal with those questions first.

All witnesses are reminded of the long-standing parliamentary practice that they should not criticise or make charges against any person or entity by name or in such a way as to make him, her or it identifiable, or to otherwise engage in a speech that might be regarded as damaging to the good name of the person or identity. Therefore, if the witnesses' statements are potentially defamatory with respect to an identifiable person or entity, they will be directed to discontinue their remarks. It is imperative that they comply with any such directions.

As I said earlier, there is a pending litigation arising out of the use of mesh devices. Those cases have yet to come before the courts, which will decide the issues of fact and legal liability. In light of the constitutional separation of powers and the respect the Oireachtas must show for the courts, this hearing should not prejudice or attempt to second-guess or influence the outcome of that litigation. Witnesses and members should therefore avoid comments which in effect prejudge the outcome of those cases, such as allegations of negligence or legal liability.

I call on Mr. Kidd to make his opening remarks.

Mr. Robert Kidd: I thank the Chairman and members for inviting us to update the committee on vaginal mesh implants and the services we put in place to support people affected by complications in the use of implants. As the Chair mentioned, I am joined by Dr. Clíona Murphy, Ms Catherine Donohoe, and Dr. Suzanne O'Sullivan.

Mesh is a medical product used in a range of surgical specialties, and our focus today relates to mesh used in two urogynaecological procedures for women - the treatment of stress urinary incontinence, SUI, and pelvic organ prolapse, POP. In November 2017, following the experiences of many women who had mesh implants that were causing pain, infection or other complications, the then Minister for Health, Deputy Simon Harris, requested the Chief Medical Officer, CMO, to review the clinical issues involved. In July 2018, the HSE paused the use of vaginal mesh implants for the treatment of SUI and POP.

The CMO's report, The Use of Uro-gynaecological Mesh in Surgical Procedures, was published in November 2018. The report gave a comprehensive history of vaginal mesh implants and their purpose, and detailed the problems experienced by some women, which led to the pause in use of such implants. The report contained 19 recommendations covering two broad areas: responding to the needs of women experiencing vaginal mesh implant complications and consideration of how clinical practice in the use of vaginal mesh might operate should the pause be lifted. To date, 11 recommendations have been completed, five are ongoing and three are no longer deemed clinically appropriate to progress. The five ongoing recommendations are prospective clinical recommendations and will be implemented if vaginal mesh implants are used again in the future.

I will outline the work done to meet the needs of women and people affected by problems with mesh implants. In order to initially identify and assist the patients who needed support, assessments or had questions about their care or experience, a dedicated page on the HSE website was created with detailed patient information and guidance. The information was promoted in news reports and on social media, and it was ensured that the page was easy to access on search engines. Each hospital group identified specific contact details for its patients, and these were provided on the HSE site. Communications from approximately 70 women were received, and all of the women who made contact were offered appointments either at the time or subsequently.

A new national mesh complications service was established, with a centre in Cork and in

Dublin, that has the option to refer people for specialist care abroad if needed. The HSE put in place a three-tiered response to mesh complications to ensure that women always have a pathway of care. First, women experiencing post-mesh complications are advised to contact either their GP or the consultant who inserted the implant, for a clinical assessment. Next, if specialist care is needed, they can then be referred to the national mesh complications service. This service is delivered across two centres and provides expert specialist care to women requiring mesh removal.

The mesh complications service has a multidisciplinary team in place with a range of medical specialties involved. The two hospitals providing this complications service are recognised urogynaecology centres with subspecialist expertise. These centres have extensive experience in dealing with complex pelvic-floor problems, including mesh complications. An additional HSE investment of €1.3 million was provided specifically for this service in 2021. The consultants involved in the care of patients with mesh complications have specialist and subspecialist training, most of which was done abroad in the UK, US and Australia. In addition to this, an internationally renowned subspecialist training programme in urogynaecology has been established in Ireland.

The national mesh complications service, which is a HSE public service, does not make a distinction between women who had a vaginal mesh implanted in a private or public facility. Information on how to access the national mesh complications service is published on the dedicated HSE web page, and is available from all acute hospitals, GPs and patient representative groups.

Both centres have full diagnostics services available, including translabial scanning. In November 2021, a consultant urogynaecologist from the UK led a translabial and transvaginal teaching day and clinic in the urogynaecology department in Cork. Feedback obtained from the women who attended the clinic was positive. There is an identified lead consultant within each centre for this service. To date, the centre in Cork has seen approximately 40 patients and currently has no waiting list. It has a designated mesh clinic that is held every six weeks. The centre in Dublin has seen approximately 69 patients and has a waiting list of 16. We anticipate that all patients will be seen by October 2022.

The third tier of the pathway is the availability of treatment abroad. For some patients who have defined clinical complexities, access to treatment abroad gives an additional pathway when the level of complexity requires it. An application for treatment abroad can be supported by the HSE national mesh complication service. The care of a patient reverts to the referring consultant upon return to Ireland, through whom all follow-up care is organised.

I will conclude by once again acknowledging the difficult experience of the significant number of women who have and are suffering serious complications from the use of vaginal mesh implants. The HSE hopes that the significant investment made in developing the dedicated services to support women will have a positive impact and outcome for people affected. We take this opportunity to encourage people who may be suffering with mesh complications to contact their GP or the HSE for care and support.

Chairman: I am conscious Dr. O'Sullivan said that she was only available until 11.30 a.m. and it is now nearly 11.20 a.m. Do members want to ask Dr. O'Sullivan about the mesh centres? Deputies Cullinane and Colm Burke have indicated.

Deputy David Cullinane: Dr. O'Sullivan might be able to clarify the extent to which trans-

labial scanners have been used? The Chair indicated earlier and the committee has received correspondence that indicated a specialist from the UK came to Ireland to train staff. We are getting mixed signals in that regard. The HSE statement suggests that both scanners in Cork and Dublin are up and running and are performing, and yet we were told by the women who were before the committee earlier that the scanner in Dublin is not operational, that there were technical issues and issues with the support and transfer of patients who had difficulty getting public transport to centres. If they can, I ask our guests to explain to us what level are we seeing, especially with those two scanners in Cork and Dublin.

Dr. Suzanne O'Sullivan: I thank the Deputy for the question. First, I acknowledge, on my own behalf and on that of my colleagues, the suffering and problems experienced by women who have had complications as a result of mesh procedures and surgery. We sympathise fully with them in the context of their suffering and ongoing problems.

On the translabial scan, I can only speak to our services in Cork. Our machine was bought and during 2021 it was set up in a dedicated space and clinic in November and Dr. Ranee Thakar, a very well-known and world-class urogynaecologist from the UK came over and we scanned nine patients from around the country. Four consultants came from Dublin also attended to learn from this training day and clinical day. The machine is there. We have a dedicated consultant whose appointment is imminent and who will continue with that service. It is important to say that translabial scanning can be helpful but it is by no means the be-all and end-all of assessing patients. Often, it is actually not necessary because we can see clinically, without needing a scanner, where the issue is. If there is a problem, for example, with vaginal mesh erosion into the vagina, we do not always need a translabial scan. I cannot speak to the Dublin services, I am afraid; I can only speak to our own.

Deputy David Cullinane: Okay. I have one quick follow-up question. I am not clear that the scanner is in full use. Dr. O'Sullivan said there was a small number of scans done.

Dr. Suzanne O'Sullivan: Yes.

Deputy David Cullinane: I accept what Dr. O'Sullivan is saying to the effect that it is a judgment that has to be made on whether that is necessary but, obviously, the women will have their view as well. She stated that a dedicated consultant is going to be appointed. Has that person not been appointed already? She also stated that the scanner is in Cork and has its own location. That is fine, but is it in use? Is it operational?

Dr. Suzanne O'Sullivan: We have not done any further translabial scans since November. We have one patient who will benefit from this intervention who is awaiting the appointment of the new consultant who will lead with that service and who will be trained in that.

Chairman: Deputy Burke wishes to speak.

Deputy Colm Burke: On the number of people who are experiencing complications, my understanding from the figures we have been given is that over 750 people have had mesh implants. However, the figures out of Cork and Dublin for people who have attended the treatment centre are quite low. I am wondering whether information is out there with GPs about these two clinics? Is it out there across the board with consultants who might be dealing with women who are having complications? What further work can be done to ensure people are aware there is a specialist clinic dealing with it?

Dr. Suzanne O'Sullivan: Locally, our colleagues in general practice are aware of it, as are

our colleagues in urology. We have worked very hard to set up what we believe to be very good and holistic services, with an aim to be as holistic as possible in the approach to treating the women. This is a very complex situation and it is not a case of one fix answering all problems. We have got two consultant urologists who work as part of our network disability team. We have three subspecialty consultant urogynaecologists and a fourth to be appointed. We have extra physiotherapists and nurse specialists who have been appointed as a result of the investment from the national women and infants health programme into our services in terms of dealing with these patients and trying to address the problem.

This is not a new problem. As a urogynaecologist, I know that we have been using mesh for 20 years in order to treat problems for patients and dealing with complications as they arise. Any surgeon knows there is no intervention that is risk-free or completely safe. That is across the board, no matter how minor the intervention is. However, we have worked really hard in the context of seeking and being able to provide a holistic approach, including in the context of pain support, psychology support, psychiatric support, where required, physiotherapy and surgical interventions. When we carry out procedures and look after patients with seriously complex issues and undertake surgery, there is always a minimum of two consultants on hand. Usually, there are three or four present for the more difficult and complicated cases. We counsel patients extensively beforehand and work together with them to try to address the problems as best and as safely as we possibly can.

Deputy Colm Burke: Does Dr. O'Sullivan accept that 40 women attending the Cork clinic, which, I assume, covers all of Munster, is quite a small number in view of the overall concerns raised by women across the country? Is there an explanation as to why the numbers attending the clinic are so small?

Dr. Suzanne O'Sullivan: We have two groups, probably. We have patients who have an absolutely clarified mesh complication, such as, for example, where the mesh has eroded into the vagina or where it may have gone into the bladder or the bladder neck. That is a small cohort of patients with absolutely clear problems. We also have a huge cohort of patients who have other issues, for example, relating to recurrent urinary tract infections who also happen to have had a tape or a mesh in the past but those issues may or may not be directly related to their tape. Those patients have always been attending our services and it is only since we set up these services that we have a separate coding for patients with very direct, clear mesh-related complications. I suppose they are not hugely surprising because we have not done any operations in the last four years so we are dealing with women who had surgery prior to the implementation of the pause. While we know many procedures were done in the past, many of them were very successful and were not associated with complications.

Deputy Colm Burke: I thank Dr. O'Sullivan.

Chairman: I want to bring in Deputy Durkan.

Deputy Bernard J. Durkan: I welcome our guests. I just have a couple of questions. It appears to me there is a great deal of contradiction and confusion with the advice and prompt availability of assistance to the women who have been affected. The level of pain and suffering they have endured as a result of the procedure, in particular, and the neglect as they see it of a proper response to the calls for help. Does Dr. O'Sullivan agree with that?

Dr. Suzanne O'Sullivan: As I said, I know there have been problems and I heard the women this morning and have met many of them in my clinic. There is no doubt there have been

problems caused as a result of these operations. There is no doubt about that whatsoever. Again, our door is always open. We prioritise any patient who is referred with a problem related to mesh. We get them into our system as quickly as we possibly can. We prioritise them over other patients and it is a big issue for us because with Covid our waiting lists have really grown but we have dedicated time, we have a dedicated multidisciplinary team, we discuss all the complicated patients and we schedule surgery because some of these operations can be very big. They can last for several hours and we must put aside at least half a day, and often a day, aside to do the really complicated surgical mesh removals when required. Again, I can speak for our service in Cork. We are absolutely cognisant of the issue. We aim to do our very best by the women who come to us. We prioritise referrals. We see them as quickly as possible. We offer them a large range of interventions.

One of the questions that arises relates to total mesh removal. One of the problems is that when we see people, we look at their issues and try to look at causative factors and what is going to make them better. Often total mesh removal, from my clinical perspective or that of our multidisciplinary clinical perspective, may not be, we feel, in the best interests of the patient. It is a difficult dilemma to be trying to say there are other solutions to issues that may or may not be related to the mesh and that we look at trying interventions like physiotherapy, pain management, etc. We definitely will remove the mesh when we are convinced it is the absolute root cause of problems and when we are confident that doing so is going make the woman better. The difficulty or concern is often that full mesh removal can make things an awful lot worse and leave the woman much worse off afterwards. We have looked after women who have come from abroad, including from the UK, after total mesh removal who have had very significant problems and who were really harmed and had dreadful complications as a result of surgery.

Deputy Bernard J. Durkan: Why did these women go abroad?

Dr. Suzanne O'Sullivan: I honestly do not know.

Deputy Bernard J. Durkan: Was there medical evidence or support available for or against their going abroad?

Dr. Suzanne O'Sullivan: I do not understand the Deputy's question.

Deputy Bernard J. Durkan: Did they have medical advice before going abroad as to what they might do in those circumstances?

Dr. Suzanne O'Sullivan: I do not know.

Deputy Bernard J. Durkan: I have a last question. Has the HSE----

Chairman: I thank the Deputy very much.

Senator Martin Conway: I would like to ask Dr. O'Sullivan whether-----

Deputy Bernard J. Durkan: Just a second. Hold on a second. Has the HSE accorded sufficient importance to this particular issue and at such a scale as to be able to respond positively and completely?

Chairman: Deputy Durkan, with respect, that is a question for the HSE.

Deputy Bernard J. Durkan: I know, but I am asking a medical question.

Chairman: Will Deputy Durkan listen?

Senator Martin Conway: I just want to ask a question of the doctor.

Chairman: We have a couple of seconds left. One of the Senators wants to ask a question about the centre in Cork.

Senator Martin Conway: It is a very quick question. We have engaged with the women this morning and we get the impression there seems to be pushback within the medical community towards women who are in horrendous situations exploring options and medical procedures abroad. Is there a certain reluctance or hesitancy among doctors with regard to thinking outside the box in supporting these women?

Dr. Suzanne O'Sullivan: When a woman comes to me with a problem, I will look at all the potential causes and try to treat those issues in the best way possible. One of the problems is some women want the mesh to be completely removed. If, as a clinician, I am fairly confident that doing so may not make their problem any better and has a high chance of making it an awful lot worse, leaving the woman in a much more devastating situation, I am left with a great ethical dilemma. I cannot recommend major and potentially mutilating surgery that I do not believe is in the interests of the patient. I just cannot do that. I have to be honest with women. It is not pushback. We are here to do our best and to try to help our patients and make them better. We have options to do that. As I have said, we offer many different things, including mesh removal where that is absolutely the right thing for the patient. However, it is very difficult when a patient believes total removal of the mesh is a panacea. As I have said, it is difficult when someone tries to push me into doing an operation I genuinely believe may be harmful and in no way good for a woman. I do not mean to push back but I can only be honest about what I believe will help somebody and what I can do to make that person better. Usually, we do not start with total mesh removal as the first step in dealing with issues, whether bladder problems, urinary tract infections, pain or difficulty with intercourse. The variety of symptoms and problems is absolutely enormous. There are, therefore, many options to deal with the issues and to make the woman better. There is no one quick-fix solution. That is where we have to be very careful. As I have said, we aim to provide a holistic multidisciplinary programme.

Senator Martin Conway: I thank Dr. O'Sullivan but we had a lady here this morning who had her mesh removed who said she was a new woman afterwards. I will leave it at that.

Chairman: Can Dr. O'Sullivan take another question?

Dr. Suzanne O'Sullivan: I can.

Chairman: I am conscious we are eating into her time.

Dr. Suzanne O'Sullivan: I am on call at the moment but I can take another question.

Chairman: If Dr. O'Sullivan is sure, I will call Deputy Shortall.

Deputy Róisín Shortall: I have just one very quick question. Dr. O'Sullivan said she had seen a number of women who had significant problems and who were harmed by having the mesh removed abroad. How many such women has she seen?

Dr. Suzanne O'Sullivan: In our unit, we have seen at least two and perhaps a third. I have personally dealt with one but, as I have said, we have five consultants in our department.

Deputy Róisín Shortall: Over what period did she see two?

Dr. Suzanne O'Sullivan: It was probably over the past five years or so. Again, I cannot be exact with the timelines.

Deputy Róisín Shortall: I presume Dr. O'Sullivan would not have had cause for contact with women who had successful removals.

Dr. Suzanne O'Sullivan: I have not seen any patient who has had full mesh removal successfully done abroad here.

Deputy Róisín Shortall: Okay. So, it is just two so far. Does Dr. O'Sullivan have any idea about the Dublin clinic?

Dr. Suzanne O'Sullivan: No.

Chairman: Before Dr. O'Sullivan goes, for the benefit of people who are unaware of the issues around the mesh itself, will she explain the difficulties in removing it? The skin grows through the mesh, which makes it difficult to remove.

Dr. Suzanne O'Sullivan: There are different types of mesh. It is not a one-size-fits-all product by a long shot. There are tapes for incontinence, which can go in two different places. There are different challenges associated with removal depending on the type of tape. The mesh that is used for vaginal prolapse is different. It has a larger surface area, which results in challenges for full removal. There may be a sequela of scar tissue formation and real issues with vaginal and sexual function after full mesh removal surgery. If mesh is in the wrong place, it must be removed. If it is in the bladder or has come through the vaginal skin, there is no doubt it must be removed. However, it is not always clear that symptoms are directly related to the mesh and that full removal will therefore sort them out.

The problem is we want to deal with the symptoms and make things better as safely as possible while causing as little harm as possible. Nobody is saying total mesh removal is not ultimately going to be the right thing but our approach and best practice everywhere is it should not necessarily be the first port of call. We should look at the issues and at the possible causes excluding mesh, because there can be other causes. We have had several patients referred to us with what were thought to be mesh complications which were actually totally unrelated. We have operated on patients for whom the mesh was not the problem at all and for whom previous procedures had caused the problems. It is a very large area. It is not simple and straightforward. These are complicated procedures and solutions. As I have said, we aim to treat women as holistically as possible and to look at every aspect of their care, including their physical care, their sexual care, their pelvic floor care and care of their mental health. We are working hard to develop these services and to make them as good as they can possibly be to keep women as safe as possible. That is first and foremost in our minds and it is a big concern because there is a narrative out there that total removal-----

Deputy Róisín Shortall: Perhaps Dr. Murphy can answer the clinical questions.

Chairman: I really appreciate Dr. O'Sullivan giving her time this morning. I thank her for eating into her on-call time. We really appreciate her taking part. We will start the speaking rota again. Is Deputy Durkan speaking for Fine Gael?

Deputy Bernard J. Durkan: I was interrupted in mid-flow, which is something I object

to strongly.

Chairman: The Deputy can ask the rest of the panel now. I am sorry.

Deputy Bernard J. Durkan: I am sorry. I just need to record my objection to being interrupted in the course of my question. I never interrupt anyone. I make it a rule not to. I never cut in on anybody else's questioning. However, if it is going to become the norm to do so, I will respond in like kind. I just want to register my protest. Whom can I ask questions of now and for how long?

Chairman: The HSE panel is here.

Deputy Bernard J. Durkan: Can I ask the question the Chairman suggested was for the HSE, which related to the degree to which the HSE has responded to the concerns, pain and suffering, and great isolation of women who have been the victims? Is the HSE satisfied it has responded with sufficient urgency and that there is a high-level alert in respect of the issue within the organisation?

Mr. Robert Kidd: The HSE's response was obviously focused around the CMO's report and the recommendations contained within it. The Deputy will see within the opening statement that the vast majority of those recommendations have been put in place. Our main focus has been the operational response, putting in place the two national units and having communication channels with women, who have suffered pain and suffering, around how they can contact and engage with our services.

Deputy Bernard J. Durkan: Has the HSE compiled a priority list of the patients who have an urgent need of consultation? Has that consultation taken place?

Mr. Robert Kidd: I will ask Dr. Murphy to come in on that.

Dr. Clíona Murphy: A total of 190 patients made contact with the HSE. There were designated emails. Information was put up on the HSE website. All of those contacts were responded to. It then devolved to the individual sites regarding appointments. There is no waiting list in Cork. A number of women are waiting in Dublin, but contacts have been made with anybody who has made contact. There is a slight discrepancy in numbers with regard to what we heard earlier. We are obviously dealing with people who have made contact with the HSE. There are two mesh administrators, one in Dublin and the other in Cork, who have contact and oversight on any of the clinical activity going on. *Pro formas* have been set up to collect data going forward and guidelines have been set up. Considerable work has been done on the ground to address the issues we acknowledge were not dealt with well in the past.

Deputy Bernard J. Durkan: What about the women who went overseas for treatment, which is not highly regarded or regarded to the extent it should be here? What about them? Was any advice available to them as to where they could go most conveniently to receive treatment as a matter of urgency?

Dr. Clíona Murphy: I cannot comment on individual cases, but nobody would ever be blocked from going abroad if that person chose to do so and preferred to go to a different centre. However, the HSE can only administer the treatment abroad scheme and we cannot do so retrospectively. It has always been the case in medicine that, sometimes, people decide they wish to access treatment, in London or elsewhere, that they have heard is good. That goes for fertility and other aspects of medicine. Nobody would stand in someone's way in that, nor would there

be any barrier to anybody coming back from aftercare if that was the case. However, I cannot comment on individual cases in that matter.

Deputy Bernard J. Durkan: Should there not be a system to advise women as to the better service and options available in those circumstances?

Dr. Clíona Murphy: The NHS also has designated approximately seven or eight mesh centres, which are freely available on its website and where it can be seen where there are mesh centres out of which urogynecologists and urologists are working. The NHS has done a similar system to what we have in Ireland. There is obviously a larger population affected, but that information is publicly available.

Deputy Bernard J. Durkan: From the information made available to us already and having listened to the women who were so affected, would it not be fair to conclude that a better organised system is required in terms of dealing with the situation in the first place, and rather than just telling women they can go to whatever service they require, which appears to be the case, referring the women to a reliable, known service, and removal or post-treatment should be dealt with in the same fashion?

Chairman: We can discuss that in private session.

Deputy Bernard J. Durkan: We should have an answer to it in public session.

Deputy David Cullinane: A number of women and two groups were in earlier. They raised a number of issues with regard to medical card access, accountability, supports in terms of attending clinics in Cork and Dublin, aftercare and support issues, the use of translabial scanners and the extent to which they are available, issues around access to treatment abroad, and many other issues. It strikes me there is a poor lack of engagement between those women and advocate groups and the HSE. I do not know if there a point of contact or somebody in the HSE who engages with these women, but it strikes me that it is quite poor.

If women, who are survivors, are coming before this committee to tell us their experience was not a good one, that is a problem for the HSE. I suggest that the first thing the HSE needs to do, notwithstanding Mr. Kidd's opening statement about the implementation of the CMO's report and the supports and services he says are available, is that the HSE needs to examine that in the first instance, because women obviously have a different view which needs to be listened to.

I want to ask questions about the different treatment options and the clinical, so perhaps I can come to Dr. Murphy. I understand a clinician has to make a clinical judgement as to what treatment he or she feels is best, whether that is a partial or a full removal. A surgeon or specialist will have to decide, from his or her perspective, what is best and safe. However, the women obviously have their own choice and view. It seems to me that either there is a bias within the system towards partial removal, on the one hand, which might be based on the fact that clinicians see it as the best option, or there is a lack of skills and expertise in performing full removals in this State. Which is it? Is there are lack of expertise in being able to perform full removals? Is that one of the reasons there seems to be - I will not say "push" but a view - from clinicians that a partial removal is best?

Dr. Clíona Murphy: When describing options for complications of procedures, one has to give all of them, including conservative, interventional and so on. The types of procedures that can be done after a complication are, covering or division of the mesh, partial or full excision and complete removal. They are all options, if one reads any of the papers. With regard to

pain, there is good evidence to say that if there is no mesh abnormality found, in that the mesh is not extruding and it is not in the wrong place, in fact, removal of the mesh can even have persistence of pain in up to 42% of people. It can depend on the presenting complaint and the best option. I would not say it is the fact the expertise is not there but it is along the lines that we know that anywhere between 15% and 20% of people can have further complications after removal of mesh. There is a duty of care, in the first instance, when one is doing a primary procedure in medicine, to offer all of the options and to counsel appropriately. There is also a duty of care not to make a situation worse or to offer-----

Deputy David Cullinane: I get that. My time is very tight. I am very sorry. I have one and a half minutes left and I want to come back on that point. If a woman believes a full removal is best for her, it seems that one of the few options, or maybe the only option, is to travel abroad to have it removed. The HSE is saying it fully supports that and will support her through the reimbursement scheme or the treatment abroad scheme. However, this is what one of the women said today in her opening statement, and I will address to Mr. Kidd and Dr. Murphy. She wrote that, "for HSE healthcare patients the treatment abroad scheme is illusory" and that "the system is stacked against them". In the view of Mesh Ireland, "patients who reject the HSE surgical preferences will only receive ... lip-service support when they ask HSE consultants to provide necessary documentation to support their application for the public healthcare treatment abroad scheme" and that the approach is "like it or lump it" and "partial removals or nothing". I will read the last paragraph of the statement, which is important:

> ...the HSE's official position that there is not just one but many surgeons who perform this operation locally means that the treatment abroad scheme pathway is a fool's errand. The door was never really open. The HSE conducts an automated appeal. Rejection follows. The door is bolted. From the inside.

That does not suggest to me that this is an option for many women. They feel that it is very restrictive and that they do not get supported if they want to get treatment abroad.

Dr. Clíona Murphy: On availability, it certainly is available and there are people with the skills to do total mesh removal here. I ask Ms Donohoe to describe access to the treatment abroad scheme and experience so far.

Ms Catherine Donohoe: The treatment abroad scheme is governed by legislation, rules and criteria that are set down by Europe. Under the criteria, the patient needs a referral letter and an application form that has been fully completed in conjunction with the referring consultant.

We recognised that women were experiencing difficulty and we developed a protocol so that they would get automatic approval. What that protocol allows for is that in situations where a case is complex, and outside the competencies of the specialist service in Dublin or Cork, the patient is referred either from Dublin to Cork or from Cork to Dublin for a second opinion, in the first instance. Once the patient has those two examinations, and they have their referral, then they are automatically approved by the treatment abroad scheme.

Deputy David Cullinane: That is not the women's experience. We will have to come back to this issue because it is not what we have been told by two different sets of groups who represent hundreds of women. Clearly, the scheme has not worked for many women. It seems that if a consultant does not sign off then the person cannot avail of the scheme. While the HSE says the scheme is available what women have told us is that in reality it is not and is an illusion because there are problems with sign-offs.

Ms Catherine Donohoe: The Deputy is absolutely right. If the consultant does not sign off on it, the women need that referral in order to get through, yes.

Chairman: Where a person needs more than one operation, maybe a follow-up is needed for reconstruction, it was not covered under the scheme which was one of the points that were made to us this morning. Is that the case?

Ms Catherine Donohoe: Again, that is not completely accurate. Each application is an individual application. When one applies for surgery it is either approved or declined. One can apply for further surgery, if that is deemed necessary. If one applies for follow-up care or to transfer one's care to another jurisdiction then that would not happen. One would have to have a very good reason follow-up care could not be provided in Ireland. If the follow-up care, being surgery, could not be provided in Ireland then, yes, of course one would be approved but one must have a new application.

In the initial application one could specify two or three surgeries or whatever but that information is required to be included in the first application. We can only approve what is applied for. We cannot approve what we do not know. If there is something that is required later on that was not known when making the first application then just re-apply.

Chairman: Is it not the case that removal necessitates construction but, again, depending on the individual case?

Ms Catherine Donohoe: Normally, when a patient goes abroad for surgery, regardless of whether it is paediatric heart transplant, mesh removal or whatever the surgery is, at discharge the treating consultant abroad gives an up to date medical report, and a care plan, to the referring consultant in Ireland, and the referring consultant in Ireland implements the care plan.

Deputy Róisín Shortall: Who is the senior person responsible for service provision and policy regarding this issue?

Mr. Robert Kidd: In terms of the operational implementation of the recommendations of the report, and the oversight of services, it falls to acute operations in the HSE.

Deputy Róisín Shortall: Who sets the policy?

Mr. Robert Kidd: Policy is a departmental issue and is outside.

Deputy Róisín Shortall: From a clinical perspective, who is it?

Mr. Robert Kidd: Again, we would have worked closely with the national women and infants health programme to put in place the response from the recommendations.

Deputy Róisín Shortall: Am I right to say that it is Dr. Murphy?

Mr. Robert Kidd: Dr. Murphy is currently the clinical lead of the unit but ultimately clinical responsibility falls to acute operations.

Deputy Róisín Shortall: Who is the clinical lead for vaginal mesh issues?

Mr. Robert Kidd: Locally, within the two national mesh complications centres there are lead clinicians in place and I ask Dr. Murphy to comment.

Dr. Clíona Murphy: With regard to developmental things, like the national clinical guide-

lines, that comes under the remit of the national women's and infants programme, of which I am the clinical director since April.

With regard to engagement with the clinical leads, that would be in our remit. An awful lot of work has been done to set up mesh administrators with engagement with those two sites.

Deputy Róisín Shortall: There is a group of women here who clearly have been harmed and whose lives have been very negatively impacted by the treatment they received within the Irish health service. They need to be able to engage with somebody at a senior level within the HSE and there has not been that engagement. I ask the witnesses to meet them. Dr. Murphy is the most obvious person to meet them. I ask her to undertake to meet these two groups of women to address some of the issues that they have raised.

Dr. Clíona Murphy: I have no problem with engaging with patients in any capacity. Patient engagement was part of the original steering group that kicked off this process.

Deputy Róisín Shortall: I thank Dr. Murphy. It is very important that she would meet each of the two groups and soon. How many women have been fitted with a vaginal mesh in Ireland over the last 20 years?

Dr. Clíona Murphy: We cannot give those numbers. In fact, it has been difficult in many jurisdictions to give those numbers. The reason is that the coding for stress incontinence procedures, for example, would not have specifically said mesh and the same for a prolapse operation, as it would be described; it would not necessarily include mesh. Added to that is the fact that for many years we have paper-based services here. This is not necessarily unique to Ireland and we heard earlier-----

Deputy Róisín Shortall: Presumably, the mesh is regarded as a medical appliance.

Dr. Clíona Murphy: Yes but there is a number-----

Deputy Róisín Shortall: Dr. Murphy should know how many meshes have been used?

Dr. Clíona Murphy: A number of different companies supplied them so there is a potential that each company would know. To be perfectly honest, it is hard to be absolutely accurate about those figures.

Deputy Róisín Shortall: Surely that data would have been identified for the CMO's report.

Dr. Clíona Murphy: It is still very difficult to do retrospectively. What we able to do is prospectively tell people going forward exactly how many will have been used.

Deputy Róisín Shortall: The retrospective figures are the relevant ones.

Dr. Clíona Murphy: Yes but we do not have the full figure for that.

Deputy Róisín Shortall: Can the figures be accessed?

Dr. Clíona Murphy: It will be extremely difficult unless one does a hand trawl.

Deputy Róisín Shortall: Why can that not be done? The number are not massive.

Dr. Clíona Murphy: The number of affected women is not large but it has been estimated that it is 10,000 meshes because we know that the complication rate is between 1% and 3%. For

example, when the UK reviewed it was found that there were 95,000 women.

Deputy Róisín Shortall: Is Dr. Murphy saying that there is a complication rate of between 1% and 3%?

Dr. Clíona Murphy: A complication requiring removal rate.

Deputy Róisín Shortall: What is the complication rate?

Dr. Clíona Murphy: Depending on which paper one reads, the rate can be 10% or 12%.

Deputy Róisín Shortall: What is international best practice?

Dr. Clíona Murphy: It is 10% or 12%.

Deputy Róisín Shortall: How many people with complications have come to the attention of the HSE?

Dr. Clíona Murphy: With regard to numbers contacting us, specifically, that would be 190 people. However, there may be people with side effects which were not as significant that would have been treated at urogynaecological or gynaecological clinics and have their symptoms resolved or treated. We are aware that those who contacted us as mesh injured patients would be a small subset of those with symptoms. There is an acknowledgement in the CMO's report that there was under-reporting.

Deputy Róisín Shortall: How many people had partial removal?

Dr. Clíona Murphy: Again, it is hard to know because some of that partial removal would have even been done prior to the CMO's report. Partial removal is not that difficult to do, for example, if it is mesh erosion and was often done in a timely fashion.

Deputy Róisín Shortall: This whole thing displays an extraordinary dearth of data. These are procedures that have been carried out on people in this country in the HSE and Dr. Murphy cannot tell us the number plus an expert report was compiled in 2018. It is extraordinary that Dr. Murphy cannot produce those figures for us.

Dr. Clíona Murphy: As the Deputy will know, we are in the process of developing electronic health records. The health records in this country have been behind for a number of years and matters are being addressed in that regard. We must address that.

Deputy Róisín Shortall: Okay, but there must be manual records of the number of procedures that took place. Presumably they did not happen in every hospital.

Dr. Clíona Murphy: There are 19 units that have gynaecology units. There are more in the private sector as well. Many of them were in the private sector. It spread-----

Deputy Róisín Shortall: Was there any attempt made to request those 19 units to produce figures?

Mr. Robert Kidd: There was a top-level assessment. Dr. Murphy referred to it earlier. It relates to the figure of 10,000, which was referred to. On the registered medical device issue, that is something we have engaged on with Health Products Regulatory Authority, HPRA, since the recommendations were made. That is something new going forward that-----

Deputy Róisín Shortall: Surely, there is a record of the number of those devices that were used.

Mr. Robert Kidd: It was not a registered medical device prior to this. It is only after this. That is the issue. However, the figure of 10,000 is that top-level assessment.

Deputy Róisín Shortall: Does Mr. Kidd have a figure on the number of people who had a full removal, if any?

Dr. Clíona Murphy: We estimate that seven have been done in Cork. Some partial removals have been done in Dublin.

Deputy Róisín Shortall: Is it the case that there have been no full removals in Dublin?

Dr. Clíona Murphy: I am not entirely sure of the Dublin figure.

Deputy Róisín Shortall: Can Dr. Murphy get that information for us please?

Dr. Clíona Murphy: Sure.

Deputy Róisín Shortall: That is okay. How many people applied for the treatment abroad scheme?

Mr. Robert Kidd: I might ask Ms Donohoe to answer that.

Ms Catherine Donohoe: Since 2018, seven people applied.

Deputy Róisín Shortall: Seven people. How many of those were approved?

Ms Catherine Donohoe: I will give Deputy Shortall the exact details. One person was approved in 2018. One person was approved in 2021 or 2022. There is another application that is in the process of being approved. We are waiting on the multidisciplinary team, MDT, from the second specialist unit. Once that is in, that patient will get approved.

Deputy Róisín Shortall: What are those criteria that have enabled two people to access that scheme when others were refused?

Ms Catherine Donohoe: The criteria for the scheme are-----

Deputy Róisín Shortall: I know. What were the criteria that were met by those two people who got approval?

Ms Catherine Donohoe: I genuinely do not know. I do not have access to the patients' applications if they are approved. I only see them if they come to appeal. In the second application, she was approved because she had been seen by both the Cork and the Dublin clinical services. They both recommended the treatment.

Deputy Róisín Shortall: Is it a requirement that you must go to two clinics?

Ms Catherine Donohoe: Yes. You must have been seen in one of the specialist clinics and a second opinion must be sought and received from the second clinic. You must be able to demonstrate that you have exhausted all the services, as well as a second opinion in Ireland. Then you are automatically approved.

Deputy Róisín Shortall: We heard earlier of the distressing experience of going through

the hoops in order to qualify for treatment abroad. Can the HSE outline to us exactly what is the procedure if a woman has serious difficulties with the mesh and she wants to go abroad?

Ms Catherine Donohoe: An application to the treatment abroad scheme comes in two parts. Part A is completed by the patient and is on general information. Part B is completed by the treating consultant and referring consultant. The referring consultant must recommend the treatment and must provide a copy of the referral letter. In the case of mesh, they must have been seen in either the Dublin or Cork unit, and then have a second opinion from the other service. They must be a public patient. They must apply and receive prior authoritisation before they travel. They must be attending a service in the EU, the EEA, UK or Switzerland as a public patient.

Deputy Róisín Shortall: In Ms Donohoe's experience------

Chairman: Deputy.

Deputy Róisín Shortall: -----sorry, this is my final question. In the cases of people who did not qualify for this scheme, what was the reason for that in main?

Ms Catherine Donohoe: I am conscious that the numbers are small. Accessing healthcare outside of the EU or EEA is a disqualifying criteria. Accessing healthcare in the private sector in any country is disqualifying criteria. Accessing healthcare without receiving prior authorisation is a disqualifying criteria. On that last issue, we use some discretion, but only where all the other criteria are filled.

Chairman: Deputy Gino Kenny is next.

Deputy Gino Kenny: I thank the Chair and good morning to all our guests. I want to focus most of my questions on the CMO's report of 2018, in relation to its 19 recommendations. The HSE has said that 11 of those have been completed. Could they name a number of the recommendations that have been completed in that category?

Mr. Robert Kidd: Yes, and I might also ask Dr. Murphy to come in. There have been a number of recommendations. I will start on those that have been completed. One is, "Working in conjunction with other stakeholders as appropriate, should develop comprehensive evidence-based information resources about mesh devices and the services in place". I do not know whether the Deputy wants me to read them all out. I can provide a report to the committee on each one because they are quite lengthy in detail.

Chairman: Can Deputy Gino Kenny accept that we will get that full report?

Deputy Gino Kenny: Yes. Could the HSE elaborate on the five ongoing recommendations?

Mr. Robert Kidd: For ease of reference, four of those are ongoing. They relate to professional training requirements and to mesh surgical unit facilities. For ease of reference, and I will not go through them all again because they are quite lengthy, recommendations 8 to 11 have been mainly comprehended by recommendation 12, which is around national clinical guidance. They refer to when the pause is lifted. They will only come into being when the pause is lifted. They require that pause to be lifted. Those are four of the recommendations. The other ongoing recommendation is recommendation 1, which is under the heading of "Patient Information and Consent Recommendations". That is in draft. It needs to be updated in

line with new research and with best practice, when the system is on notice that the pause is to be lifted. Again, it relates to the lifting of the pause.

Deputy Gino Kenny: Could the HSE elaborate on the three recommendations that are no longer deemed clinically appropriate?

Mr. Robert Kidd: Yes. I might ask Dr. Murphy to come in on that.

Dr. Clíona Murphy: Those relate to mesh for prolapse surgery. It will now not be a recommendation that mesh would be used in prolapse surgery. The clinicians will advise that going forward. In that case, it makes them moot. We have guidance going forward to deal with that.

Deputy Gino Kenny: My final question relates to the overall programme itself. Four years ago it was paused. Does the HSE envisage that the programme could recommence under the recommendations if they are fulfilled and carried out, and with the consent of medical professionals and the women who have suffered terribly in relation to this? Is it envisaged that the programme could recommence in the future?

Mr. Robert Kidd: I will come in first and I will bring in Dr. Murphy second. One of the issues for us, and we have heard the testimony by the women affected through a number of the members here, is the significant learnings from the response to the recommendations that we have put in place across a number of headings. That is recognised and we need to hear that. I have heard that from a number of the members and from the women affected. That is something we need to take on board. It has always been our intention that after the set up of the service and that operational response we would have a national oversight group in place to look at the service in terms of what we have put in place and what learnings we can take from that, as well as the learning from today and from our engagements with the groups. On the specific question around lifting the pause, the intention around that oversight group was to look at whether that would be appropriate. I might ask Dr. Murphy to come in on the mechanics of that.

Dr. Clíona Murphy: It would not be our role to lift the pause. The CMO called for the pause in the first place for good reasons. Should the pause be lifted, we would be talking about a different landscape. We would be talking about tighter guidelines, designated people who would be approved to insert mesh under strict controls. It would involve a database of those mesh. As a clinician group, we are aware that there is a large number of people who are suffering from stress urinary incontinence, SUI, symptoms, for whom conservative measures have failed. Mesh is recommended by a number of professional groups as an appropriate management for stress urinary incontinence, so there is that other competing interest of large numbers of women also in clinics suffering from incontinence. The landscape, controls, oversight and data collection would be different.

Deputy Gino Kenny: What I am taking from that is that the programme could be recommenced in the future. How prevalent is this procedure in Britain or mainland Europe?

Dr. Clíona Murphy: There are different approaches in different countries. For example, in Germany I do not believe there was or is a pause. Mesh itself was not taken off the market in any place. In the Netherlands, the response was along the lines of clinical governance and tightening regulations and guidelines. In New Zealand and Australia there were slightly tighter controls as well in that area. It is fair to say that mesh is being used in many other countries.

Deputy Gino Kenny: In Dr. Murphy's experience, has the procedure been banned in any country around the world by a government or health authority?

Dr. Clíona Murphy: It has been paused as opposed to being banned. The HPRA would say there was no report of a particular device, for example, being taken off the market or deemed unsuitable to use in that way.

Deputy Gino Kenny: Does it cause Dr. Murphy concern that various countries have paused the programme? There are obviously concerns not only in this country but elsewhere that a medical procedure could be detrimental to somebody's health.

Dr. Clíona Murphy: In retrospect, what was possibly the problem is not so much the medical device in itself but its widespread use, what indications there were and the counselling and other options that were given to people, as opposed to a particular device being unsafe in itself. I think that would be fair to say. The responses in the different countries would seem to indicate that the safety measures put in place involved tightening the controls and the indications for that, as opposed to being more indiscriminate.

Deputy Gino Kenny: Does Dr. Murphy expect the programme to recommence in the future in Ireland? I accept it is difficult to say.

Dr. Clíona Murphy: It is not for anyone in the HSE to lift the pause. We will await developments.

Deputy Gino Kenny: Who would make that decision?

Dr. Clíona Murphy: The CMO. We have been working to complete the CMO's recommendations. That would be the first step.

Deputy Gino Kenny: I thank Dr. Murphy.

Deputy Colm Burke: Could I deal with the issue of numbers? I was a little concerned when I heard Dr. Murphy say that up to 10,000 women may have had mesh used and that procedure followed, yet only slightly more than 100 people have attended specialist clinics. We heard earlier this morning that there is concern that a large number of women have gone through the procedure who feel that they have not received the required follow-up care. Does Dr. Murphy not think that there is evidently something missing? She referred to 190 people making initial contact. She also referred to various figures, including that approximately 10% have had adverse outcomes as a result of the procedure. I calculate that 10% of 10,000 is 1,000, yet only 100 people have attended the clinics.

Dr. Clíona Murphy: Almost 200 made contact. What I think we can infer is that a number of other people would have been seen at general gynaecology clinics in recent years. The complications people can have after mesh can vary from more minor to more serious. I expect that those who made contact were those at the most serious end of the scale. For example, somebody might have voiding dysfunction or difficulty in passing urine after a tape was put in. That might occur in the first two or three weeks after surgery. That would be addressed by the clinician and a woman may not have any complications going forward. We would not have captured those types of instances. There are so many different gynaecology clinics where women would have been seen and potentially had any issues addressed.

Deputy Colm Burke: People are looking to get treatment abroad because they are not happy with the service in Ireland. Does Dr. Murphy accept that there may be a scenario where people who have been reviewed in Cork or Dublin are not happy with the outcome, and that there is a need for a better approach on this? People are going off and trying to get assistance

from elsewhere without any support from the health service here.

Dr. Clíona Murphy: I do not think any clinician wishes to put barriers in front of women. I have dealt with patients in different spheres where we have engaged with the treatment abroad scheme for other conditions. That has been part and parcel of the health service. People have a professional obligation to engage. The treatment abroad scheme is not just for this area; it is also for other areas. I do not see that clinicians-----

Deputy Colm Burke: For instance, I came across a scenario that is nothing to do with gynaecology or obstetrics where a consultant here refused point-blank to allow a person to get treatment in a particular area. The consultant required him to undergo an operation, while in fact he could get treatment abroad that did not require an operation and there was a stand-off between the patient and the consultant. The patient did go abroad and got the treatment and then there was a scenario where I was involved in a legal capacity in trying to recover the money from the insurance company. We eventually recovered it through the legal process. There is sometimes a difference of opinion with consultants. Sometimes, it may be that the best outcome for a patient is to get that care abroad because that is the belief they have.

Dr. Clíona Murphy: The reason there are two centres is so that there is recourse to more than one consultant. That is fair to say. As much as possible, we feel that people should be able to receive care in this country. We are doing our best in that regard. We are conscious that travelling abroad is not an easy option for anybody. None of this is going to hinge on one consultant or the opinion of one consultant.

Deputy Colm Burke: Does Dr. Murphy not accept that there are people here in Ireland who lack trust in the system because of what has happened to them, regardless of what advice is provided, and sometimes it might be a better option to allow the person to avail of options abroad? Obviously, I am talking about staying within the European Union because the cross-border healthcare directive provides for that. Does Dr. Murphy not accept that there should be a process put in place to accommodate persons who have lost trust in the system here?

Mr. Robert Kidd: I might let Ms Donohoe come in on that.

Ms Catherine Donohoe: Deputy Burke is absolutely correct. We come across that situation not often but regularly. That is probably the biggest advantage to the cross-border directive because the patient does not require a consultant to sign off on a referral like the treatment abroad scheme does. He is correct in what he says about the cross-border directive. It refers to the EU and the EEA. If a patient has a GP referral, he or she can use it to access healthcare under the cross-border directive. They do not require prior authorisation or notification. With their properly executed GP referral they can simply opt to access healthcare in another country in the EU or the EEA.

Deputy Colm Burke: Ms Donohoe is talking about access within the EU. Does that now exclude access to treatment in the UK because of Brexit?

Ms Catherine Donohoe: It excludes access to the UK and Switzerland because neither of those countries has transposed that directive.

Deputy Colm Burke: Whereas previously they would have been able to go to the UK.

Ms Catherine Donohoe: The Northern Ireland planned healthcare scheme was put in place by the Department of Health and is continuing on an administrative basis. People can access

healthcare in Northern Ireland in the very same way as the cross-border directive in the private sector.

Deputy Colm Burke: Some people have lost trust in the system here, which is not a criticism of medical professionals. It happens in all areas, including the legal world. It happens in every sphere of Irish life. If a GP is satisfied that a person requires an opinion and perhaps treatment, there is nothing preventing that GP from giving a person a referral letter in order to travel. The disadvantage with the treatment abroad scheme is that the person has to pay in advance and then try to recoup the costs afterwards.

Ms Catherine Donohoe: The Deputy is absolutely correct. That is the big disadvantage. The cross-border directive-----

Deputy Colm Burke: It is not a scheme that is open to everyone.

Ms Catherine Donohoe: The cross-border directive is open to everybody.

Deputy Colm Burke: Due to the cost issue, it is not open-----

Ms Catherine Donohoe: Finances can be a barrier, but we are doing all we can. We are meeting the Irish League of Credit Unions later today to try to put in place a scheme to allow patients to have access to funding because it is the patients who do not have private health insurance who are using the cross-border directive. It is very important that they have access to financing.

Deputy Colm Burke: I want to come back to Dr. Murphy. The number of consultants who would have provided this care is quite small in real terms; my understanding is that the figure may be lower than 20. The collection of data is not easy because people have to go through records. We have a crazy system whereby we do not have an up-to-date data collection service in real terms. Our medical records are still paper files. Is it still not possible to collect that data due to the small number of consultants providing this type of care?

Dr. Clíona Murphy: Individual consultants can do so. Some have gone through their own files. Some of the difficulty can arise when people have retired. Information is spread across maternity units with gynaecology services, but there are also some stand-alone gynaecology units within HSE hospitals and private centres. The data covers a large number of units and some have better data collection systems than others. I accept it would be great to get more granular data in order to know the exact numbers and have a better denominator as to how many people had good as well as poor outcomes.

Deputy Colm Burke: I refer to the pausing of a particular medical procedure, which in this case has been paused since 2018. If a medical procedure is identified at some stage, no matter what area of medicine is involved, how long does it take us to take action to make sure we act on what is international best practice on pausing a particular type of treatment? Is there a mechanism in place for doing that?

Mr. Robert Kidd: I might come in on that and will bring Dr. Murphy in afterwards. That can vary depending on the type of notification we receive. It could be through the HPRA around a particular implant or product that we use in respect of an intervention with the patient. That can be immediate, whereby it notifies a pause to us and advises us to please not use a product, or it can vary with emerging evidence on the use of the product and the type of complications that result. That can happen over time and can have an impact. It depends on a given situation.

Dr. Clíona Murphy: In the CMO's report it was not envisaged as being as long as it has been. Obviously, a lot of things have happened in the health service in the past two years that have impacted on the situation. There may well be changes in other jurisdictions which may impact on us. A pause would not normally have been as long as that.

Deputy Colm Burke: What are the indicators that need to be in place before we decide to pause a medical procedure? Is it at European, UK or US level?

Dr. Clíona Murphy: In Ireland, we often respond to signals in the UK. We had examples of that in vaccination, where there was a pause in the use of a particular vaccine until more evidence was available and then the pause was lifted. We often follow trends in the UK, our nearest neighbour. There is close communication between clinicians and CMOs in Ireland and Scotland on those matters.

Deputy Colm Burke: I thank the witnesses.

Chairman: Today we got a sense of the scale of the challenge, yet the figures on those who go to Cork and Dublin do not seem to reflect that. Women out there are suffering. In one of the opening statements we were told there were advertisements and so on and that 70 women came forward. I am surprised that more women are not coming forward. I do not know if that is down to a lack of confidence in the service. I have listened to what the witnesses have said. I welcome the fact they are engaging with organisations such as the Irish League of Credit Unions.

The witnesses have said they will follow the evidence that was given today. I mentioned the Cumberlege report to some women earlier today. I said that if I was examining this area, I would go through that report and examine whether there was anything we could adopt in terms of an Irish perspective. A lot of the information is common sense. It could certainly be a way forward. Is there a particular timeframe in respect of the CMO's recommendations?

Mr. Robert Kidd: I gave an update earlier on what we have implemented to date. The next step for us is the oversight group and addressing the remainder of the recommendations. Our intention is to put the group in place. In fact, we have identified a chair. We will want patient representation as part of that process, which is important following the evidence today. As part of that, it is to be hoped we will feed in to the improvements we can make and address the communications piece. We would be happy to bring back a report to the committee in the third quarter, that is, late autumn, if that is okay. That is a reasonable timeframe.

Deputy Burke has left the meeting. He commented on data. It is important to distinguish between two things. We have acknowledged the difficulties in the retrospective piece. What we have put in place is a programme of work to deal with the prospective piece more effectively. We will have clear data, and we can include that in the report we will bring back to the committee, if that is reasonable.

Chairman: Women referred to difficulties with transport to clinics. The Cork clinic serves all of Munster. We also need to examine other issues, such as the length of time people are in a clinic. I am conscious that people may not be able to sit for a long period. There are other services and a bigger picture. Treatment does not just involve sitting down and seeing a clinician. Other supports could be provided to make things easier for people in terms of access for women who want to come forward. That is something that could be looked at.

The communications strategy is useful. We gave a commitment that we would return to

this issue. I am conscious that there are men who have had problems. We will examine other areas outside of the general mesh implants. I refer to the governance structures around the mesh devices. Will changes come about in respect of that? What is the structure moving forward on foot of the CMO's recommendations?

Mr. Robbie Kidd: If I understand him correctly, the Chair is referring to the governance around their use. I will bring Ms Murphy back in.

Chairman: I am conscious that there is a pause. That was referenced in some of the questions people asked. Mr. Kidd spoke about Germany and how this stuff went ahead in some other jurisdictions. It may work for some but we are walking a delicate line.

Dr. Clíona Murphy: To answer that question, the HPRA has classified mesh differently. More communication has been sent out to people as regards reporting instances. There was an acknowledgement that there was maybe an under-reporting of complications in the past. A *pro forma* mechanism has been set up in order that any mesh that is put in and results in complications will be identified and clearly tagged. We also put up very detailed guidelines regarding the diagnosis and management of complications with mesh, as well as management of stress urinary incontinence going forward. Much work has been done in respect of clinical governance.

In the future, should the use of mesh be allowed in the country again, a strict number of people would have the authorisation to use it on their lists and there would be a clear line of governance. There would also be multidisciplinary teams in order that there would be good decision-making behind any insertions of mesh. There are a number of things in place that will improve the quality and safety of care given to women.

Obviously, I will say again that we would welcome contact from any women who have not contacted us previously. We want to do our best for women. We acknowledge that people may be embarrassed to come forward or maybe do not want to go again to the same unit they were in. That can be an issue but the services are there. We want to provide services for people who feel they have lost out or who maybe did not come forward in the past.

Chairman: I am getting the nod that we have gone over time. I really appreciate the witnesses coming in.

Deputy Bernard J. Durkan: May I make a suggestion before we close?

Chairman: Yes.

Deputy Bernard J. Durkan: As we will be returning to this subject again, would it be unreasonable to ask the HSE to carry out whatever is required of it in order to reassure the women from whom we have all heard and restore their confidence with regard to the methodology, manner and treatment and also to ascertain that where pauses have taken place in other countries, they have not been without some reason? Could the HSE perhaps enlighten us at the next meeting as to the reasons for those pauses in order that if particular procedures are a cause for concern, which is what the issue is, of course, we will know about it?

Chairman: Mr. Kidd might give us a written reply regarding what he mentioned earlier about gynaecologists from Britain who came over for a teaching day. It seems strange that it was just one day in Cork. He might give us the background to that.

I appreciate the witnesses coming in and thank the group that came in previously. I thank

everyone for their involvement in this comprehensive discussion with the committee today.

The joint committee adjourned at 12.34 p.m. until 9.30 a.m. on Wednesday, 6 July 2022.