Citizen Participation and Public Petitions Committee

8th Meeting, 2022 (Session 6), Thursday 12 May 2022

PE1865: Suspend all surgical mesh and fixation devices

Note by the Clerk

Lodged on	17 May 2021
Petitioner	Roseanna Clarkin, Lauren McDougall and Graham Robertson
Petition summary	Calling on the Scottish Parliament to urge the Scottish Government to suspend the use of all surgical mesh and fixation devices while— • a review of all surgical procedures which use polyester, polypropylene or titanium is carried out; and • guidelines for the surgical use of mesh are established.
Webpage	https://petitions.parliament.scot/petitions/PE1865

Introduction

1. The Committee last considered this petition at its meeting on 2 February 2022. At that meeting, the Committee agreed to invite the Minister for Public Health, Women's Health and Sport to give further evidence to the Committee. It also agreed to invite the Chief Medical Officer and Shouldice Hospital to give evidence.
2. The Committee will take evidence from the Chief Surgeon of Shouldice Hospital ats its meeting on 12 May 2022. The Committee then plans to take evidence from the Minister for Public Health, Women's Health and Sport and from the Chief Medical Officer at a future meeting.
3. The petition summary is included in **Annexe A** and the Official Reports of the Committee's consideration of this petition on 6 October 2021 and on 2 February 2022 are at **Annexe B**.

4. The Committee has received new responses from the Minister for Public Heatlh, Women's Health and Sport and Martin O'Neill which are set out in **Annexe C**.

5. Shouldice Hospital submitted written evidence to the Committee on 10 January 2022. A copy of this submission is included at **Annexe D**.

6. Written submissions received prior to the Committee's last consideration can be found on the petition's webpage.

7. Further background information about this petition can be found in the SPICe briefing for this petition.

8. The Scottish Government's initial position on this petition can be found on the petition's webpage.

Action

The Committee is invited to consider what action it wishes to take. Options for action include –

- To consider the evidence heard at a future meeting
- To take any other action the Committee considers appropriate.

Clerk to the Committee

Annexe A
PE1865: Suspend all surgical mesh and fixation devices

Petitioner
Roseanna Clarkin and Lauren McDougall

Date lodged
17/05/2021

Petition summary
Calling on the Scottish Parliament to urge the Scottish Government to suspend the use of all surgical mesh and fixation devices while—

*a review of all surgical procedures which use polyester, polypropylene or titanium is carried out; and
*guidelines for the surgical use of mesh are established.

Previous action
I have been in contact with my MSP, and Scottish Government officials who advised that the concerns of hernia and other mesh survivors would be heard along with those of TVT and pelvic mesh survivors. They never were.

I also met with the Cabinet Secretary for Health and Sport.

Background information
Information on polypropylene and polyester mesh and stitches clearly states the potential complications of their use and titanium protacks carry a cancer warning.

We understand mesh must be used in life or death situations, but we want to ensure that—

*mesh is only used when essential;
*patients have alternatives to mesh; and
*mesh is only used with the fully informed consent of the patient.
We want the use of mesh devices and stitches to be suspended while a review of all surgical procedures which implant any form of polyester,

polypropylene or titanium products – for example hernia mesh, rectomesh, mesh used in hysterectomies – is carried out and guidelines for the use of surgical mesh are established.

We are also calling for suspension of the use of titanium protacks that are used with hernia mesh, as these carry a cancer warning.

While we recognise and support women with TVT or pelvic mesh implants, the mesh that we are talking about is not the same. It is put into the body differently and used for different purposes.

Annexe B

Extract from Official Report of last consideration of PE1865: Suspend all surgical mesh and fixation devices on 6th October 2021

The Convener: Welcome back. This morning we have our first evidence-gathering session, and I am delighted that we have with us Maree Todd, the Minister for Public Health, Women's Health and Sport. Online we have, from the Scottish Government, David Bishop, mesh team leader, and—trying to join us, although he has not yet managed to establish a link—Terry O'Kelly, senior medical adviser.

PE1865 is a continued petition that was lodged by Roseanna Clarkin, Lauren McDougall and Graham Robertson. It calls on the Scottish Parliament to urge the Scottish Government to suspend the use of all surgical mesh and fixation devices while a review of all surgical procedures that use polyester, polypropylene or titanium is carried out and guidelines for the surgical use of mesh are established.

At our last consideration of the petition, on 8 September, we agreed to invite the Cabinet Secretary for Health and Social Care to give evidence at a future meeting. The Scottish Government has advised that the issues raised in the petition are within the portfolio of the Minister for Public Health, Women's Health and Sport.

Having welcomed the minister to the meeting, my first job is to invite her to make a brief opening statement before we open up the floor for questioning.

The Minister for Public Health, Women's Health and Sport (Maree Todd): Thank you. I am grateful to the committee for having me here today. At the outset, I want to acknowledge the efforts of those who have brought forward the petition; I commend them for doing so.

As members know, we have taken decisive action on transvaginal mesh. That action is well documented elsewhere, so it is important today to focus on the use of mesh in other situations.

We are acutely aware that there is concern about the use of mesh in other sites, not least from those who are experiencing complications. I am very sorry to read of the impact that those have had on individuals and their families. I was sorry to read in a submission on this petition that people felt that their symptoms were "dismissed" when they presented for help. Some people did not feel that they were informed of the risks of the procedure that they underwent, and it is only natural to feel let down in those circumstances.

If I may, I will for a moment focus on the use of mesh in hernia repair, which is a very common procedure in NHS Scotland. The Scottish Government asked the Scottish

health technologies group to review available evidence on the use of mesh in hernia repair, first in adult inguinal hernia and secondly in abdominal wall hernia more generally. The group published a report on adult inguinal hernia in January 2020 that concluded that, compared with non-mesh procedures, using mesh resulted in lower rates of recurrence, fewer serious adverse events and similar or lower risk of chronic pain. We await the publication of the second piece of work, which considered the more general use of mesh in hernia repair and is expected imminently.

There are, of course, other gynaecology procedures for which the use of mesh has not been halted. In those circumstances, a high-vigilance protocol is in place across the whole of NHS Scotland. It is important to remember that some of those procedures are complex and long established, with few—if any—viable alternatives. To suspend their use would leave a cohort of people with limited or no treatment options.

I know that this is a very difficult and emotive subject. I welcome being questioned on it and I want to reassure the committee and anyone watching that the Government is absolutely committed to ensuring that everyone with mesh complications gets the care and treatment that they deserve.

The Convener: Thank you, minister. I acknowledge and applaud the Government's forthcoming bill on transvaginal mesh. That is a complete and comprehensive response to an earlier petition that, in the light of the bill, we were able to close at an earlier meeting. That petition was lodged by Elaine Holmes, one of my constituents, and Olive McIlroy. Having spoken to them, I know that they are really pleased. They have had meetings with the Cabinet Secretary for Health and Social Care and have been reassured by the approach that the Government is taking.

My final point in relation to transvaginal mesh is that, at a recent meeting of the Parliament's cross-party group on chronic pain, which I attended, although there was enthusiastic recognition of the bill, one or two women were concerned that some of the problems that had been experienced some years ago, with clinicians suggesting that some of the problems were illusory, were resurfacing and that they were being encouraged to request a mesh option. I point that out to the minister. It would be helpful to ensure that, at all times, we do not lose sight of future concerns of women who might be considered for such an option, given the various actions and prohibitions that the Government has put in place. I know that redress, recovery and restitution will be at the heart of the forthcoming bill.

When we first considered transvaginal mesh, there was a claim that there was a lack of evidence to support the concerns of the original petitioners and an assertion that there was an appropriate level of informed consent. I am struck that those two phrases reappear in the submissions that we have received. There is mention of a lack of evidence of concern about the use of mesh more widely, particularly in males. We know that men can, in general, be less forthcoming about their health concerns. I

know that many men watched with interest the way in which women were able to come together and represent effectively the issues relating to transvaginal mesh.

The cabinet secretary referred to the lack of evidence, and the minister referred to the Scottish Health Technologies Group's report, which says that the advice for NHS Scotland was that "surgical mesh should be used for elective repair of inguinal hernia in adult males, following a process of shared decision making and informed consent."

What process is in place to identify difficulties that have arisen? There was no such process for women in relation to transvaginal mesh. What is the process of giving informed consent? In the case of mesh in women, the process was published, was available in general practitioner surgeries and was very much to the fore of conversations that subsequently took place with patients. With respect to the matter that we are considering today, how are those two issues properly covered and reflected?

Maree Todd: In such situations, it is really important that we work with the evidence that is available. I know that, sometimes, the evidence is limited and the full picture is not clear, but the available evidence points to the benefits outweighing the risks in most cases, as we have said.

As well as working with the evidence, we have to work with the principle of realistic medicine. You will know that that has been an important principle in Scotland for a number of years. It was considered to be almost revolutionary when Catherine Calderwood wrote the first report on realistic medicine, and we have come some way since then. I say that we have come some way but I am confident that we are not at the point at which we can be absolutely 100 per cent sure that every patient in every case and at every time engages in a shared decision-making process. There is ongoing work to ensure that surgeons are confident about raising issues and that they raise them in a manner that enables people to ask questions. There is a power imbalance in medicine that makes it difficult for patients to ask questions of surgeons, so we need to make sure that patients are empowered and that shared decision making takes place.

You mention women being more able than men to get together to create strength through numbers. That is an interesting observation. One of the reasons for the women's health plan is that there is evidence that women face inequalities in access to healthcare, and one of the reasons for those inequalities is the general power imbalance for women and the fact that they are easy to ignore, as are many other groups of people who suffer health inequalities.

We are working on the issues in many different ways. With regard to gynaecological procedures that have not been halted, there is a high-vigilance protocol in place that will systematically gather evidence over time on the issues. It is unfortunate that Terry O'Kelly is not here but, to provide a bit more information, a system of unique

device identification is being worked up, which will mean that a barcode is entered on patients' electronic records to give information about the device that was used, the surgeon who did the operation and other details about the surgery. That will enable NHS Scotland to follow cases through for a number of years, and we will have good quality data available to us.

On the general thrust towards informed decision making—

The Convener: May I interrupt? Terry O'Kelly has now joined us on audio. Given that you have just addressed that point, perhaps he will elaborate on it.

Terry O'Kelly (Scottish Government): I apologise profusely for information technology issues. I am sitting in my office in Aberdeen royal infirmary and I confirm that the NHS Grampian firewall is as robust as you might wish it to be. I am very sorry that I have therefore had to join you by phone rather than by video conference.

There are two parts to the issue. What evidence do we have and how is it shared? We are waiting for the Scottish Health Technologies Group to publish its assessment, which looks again at the use of mesh in not only inguinal hernia but other abdominal hernias. The original report found that the majority of the evidence that we have refers to the use of mesh in men, when what we are looking for is evidence on use of mesh not only in other sites in the abdominal wall but in women with hernias.

My understanding of the evidence is that the use of mesh has benefits but that there are risks. I started my training in the pre-mesh era—we are going back to the 1980s. The introduction of the use of mesh for hernia repair was transformational and made hernia repair much less haphazard, particularly with reference to outcomes. Recurrence is one of the major fears for people with a hernia who are having surgery, and mesh has made a significant difference to that.

For every patient, it is important that they understand what the procedure involves and whether they are going to have mesh implanted. It is for them, with the information that they have, to balance the risks of use of mesh against the benefits, and it is important that they are empowered when meeting their surgeon or clinical team to discuss those risks, look at alternatives and consider what would happen if they had no treatment at all.

As for ensuring that informed consent occurs, I would note that there are two experts involved in such decisions—the surgeon, who informs and advises, and the patient, who is the expert on themselves and on knowing what they want—and we need to ensure as best we can that the culture in our clinical spaces is such that those meaningful discussions are allowed to take place. We need, as far as we can, to flatten hierarchies and adjust attitudes to allow those decisions to be made and those discussions to take place in as equal a fashion as possible.

We also need to collect data, and that need has been spurred by the vaginal mesh issue. Coupled with that is a unique device identification project that will allow information about the individual device—for example, the barcode associated with the products—to be captured at the time of insertion, and it will be associated with the electronic patient record. That will allow us to know who the patient was, who the surgeon was, the place where it happened, the time it happened and what the product was so that surgical and product performance can be followed over time.

The Convener: I have two brief supplementary questions, after which I will go back to the minister and then to other colleagues.

First, what is the timeline for introducing the pathway for recording information? Secondly, you referred to the transformational advance that you felt was made by the introduction of mesh. Do the skills still exist for a non-mesh surgical option to be offered?

Terry O'Kelly: Taking your second question first, I would say that, when I talk about a transformational advance, I mean that anyone who trained in the pre-mesh era would, I think, recognise—as I did and as others have—what happened with the introduction of the use of mesh, which in these circumstances is non-tension and provides a synthetic network for in-growth connective tissue to create a robust scar and hernia repair. Before mesh, native tissue was used, as it still can be in certain circumstances; however, we know that, in a number of circumstances, such tissue is not normal and therefore generates disordered connective tissue formation and weak repair. That was augmented by a lattice or framework of non-absorbable polypropylene sutures that it was hoped would strengthen the initial process of repair and also stimulate in-growth tissue. However, the creation of those lattices was not uniform, and the resulting outcome was not predictable. The use of mesh reduced recurrence substantially which, as I have said, has been transformational and an important outcome for many patients.

As for non-mesh skills, it will be necessary for individual boards to look at that matter. We are expecting, with the publication of the Scottish Health Technologies Group report, to write to medical directors and potentially chief executives and governance and medicine leads and ask what provision boards have made for non-mesh surgery, if that happens to be one of the recommendations, whether there is a skills gap in that respect and, if so, how it might be addressed. I do not think that every patient will want hernia repair without mesh, but for those who do not want mesh to be used, we need to ensure that they are provided with a service. We will need to look at that.

As for the UDI project, that work is on-going. There is a programme board, and a paper on funding is being submitted to the Government. As you will appreciate, none of this comes free of charge; indeed, we are looking at funding of a number of millions of pounds to do this work.

The Convener: Returning to the minister, I will have to put her on the spot by asking whether the funding will indeed be available for recording that information.

Maree Todd: I cannot make a decision on funding until I see the full proposal, but the committee should rest assured that the Government is willing to look very closely at any information that comes forward. We are well aware of the need for a good, solid evidence base in this area.

The Convener: I interrupted you earlier to go to Mr O'Kelly, minister. Was there anything more that you wanted to say?

Maree Todd: To be fair, I cannot recall where I left things, convener. However, I will say that, with regard to the second report that is coming, I am more than happy to offer to come back to the committee to discuss that, if required. We will certainly inform the committee when that report is published and available.

The Convener: I am aware that I have not invited the mesh team leader, Mr Bishop, to comment. Is there anything that you wish to comment on before I bring in my committee colleagues, Mr Bishop?

David Bishop (Scottish Government): No, convener. I completely agree with everything that has been said already, so that is all good.

The Convener: Thank you. I call David Torrance.

David Torrance: Good morning. My questions are about hernia and abdominal mesh, and I should put on record that I am one of the lucky ones who has had success with that procedure. On the issue of data, which has just been mentioned, do we have information on the number of procedures that are carried out and the number of complications that have been recorded in this area?

Maree Todd: I think that we do. Perhaps Terry O'Kelly can confirm this, but my understanding is that more than 5,000 procedures a year are carried out in NHS Scotland, and I think that the rate of complications is somewhere between 0 and 5 per cent. I will ask my clinical colleague to confirm that to ensure that the committee gets the correct information.

Terry O'Kelly: The Scottish Health Technologies Group has looked at the issue and will obviously draw some conclusions on it in its report. However, my understanding of the information is that between 5,000 and 6,000 mesh hernia repairs and 20 to 30 mesh removals are performed per year. Not many meshes need to be removed, and those that are removed form a small proportion of the total number. Of course, that is still very significant for the patients involved.

As for other complications such as chronic pain and bleeding, I cannot give you a precise number per year, because that is not recorded. However, with regard to chronic pain—which we know for the individuals concerned is a devastating

experience—the evidence overall suggests that that is less likely or at least no more likely to occur with the use of mesh.

David Torrance: You mentioned mesh removal, but how easy is that procedure for someone who has complications after being treated for hernia in the abdominal area?

Maree Todd: I will pass to Terry O'Kelly to go into the issue in detail, but we are certainly aware that, when women came forward with concerns about transvaginal mesh, they had to go through a long process of feeling that they were not being listened to and that their concerns were being dismissed. Again, that partly reflects the power imbalance that operates throughout healthcare, but there was a feeling that it was difficult to raise concerns.

I am sure that every MSP around the table will have received mail from constituents who feel worried about raising concerns about their medical treatment and who worry that, if they do, they will somehow suffer in their passage through healthcare. Some of the experiences that we have heard about with regard to women who had transvaginal mesh implanted will be common to that situation, but I would like to think that, since 2018, we have put procedures in place and communicated well with healthcare professionals to ensure that that is not the case any more. Moreover, as I have said, the general thrust in NHS Scotland for a number of years now has been towards realistic medicine and holistic and patient-centred care. I would like to think, therefore, that that sort of thing will be less problematic than it might have been in the past.

I will ask Mr O'Kelly to talk you through the process of presenting with complications and then accessing surgery to remove mesh.

Terry O'Kelly: The question with mesh complications when they occur is whether the complication has been caused by the mesh itself or whether the mesh is caught up in some other condition that is causing the complication. As for mesh removal, it all depends on when the mesh was put in and how soon after surgery we are talking about. If the mesh has been in for a while, there will be associated connective tissue fibrosis; indeed, that is why it is there.

The impact of removal on a patient is determined by what the problem is and what other structures are adjacent to it. Unfortunately, because a hernia is caused by protrusion of the intestine through the abdominal wall, it is possible that the bowel can be in close contact with the mesh. In such circumstances, one would probably remove the mesh from tissues instead of removing tissues from the mesh, with the intention of preserving other structures intact, if at all possible. Once the mesh is removed, the patient will potentially be left with a defect that will need to be dealt with, and what happens will be determined by the circumstances that pertain at the time.

Locally in my own centre and in a number of others, colleagues with a specific interest in mesh surgery have, following the acquisition of training certification, formed multidisciplinary teams or clinical networks. The patients involved will be discussed and a strategy will be devised prior to surgery with regard to what is going to happen and how best to achieve an outcome that ensures not only that mesh is removed, if that is necessary, but that any residual defect that is left behind is managed.

If the bowel is involved, that is a major problem. It is not common, given the total number of meshes used, but for every patient involved, the situation is very challenging. The issue will need to be discussed in the way that I have highlighted, with a focus on the intention behind the procedure, what will be required and what the risks and benefits will be, and the patient, sadly, will have to look at all of that in what are very difficult circumstances.

David Torrance: When an individual presents with complications, they will go to their GP first. How aware are GPs of the issue? How much information is the Scottish Government giving them in that regard?

Terry O'Kelly: Most GPs will have worked in the era of mesh being used for hernia repair, and if there are any issues, they will refer the patient on or make contact with clinical colleagues.

As I have said, the question is whether the complication is a mesh problem or whether there is a problem with the surgery and the mesh has been incorporated into it. If someone who has had a hernia repair has, say, an infected wound, is the mesh the cause of the infection, or has the patient simply got a wound infection but there is mesh involved? GPs are pretty quick to refer patients back. Moreover, I should make it clear that, when patients have problems, it is incumbent on my colleagues to ensure that every one of them is welcomed with sympathy and empathy every time and dealt with in the holistic way that has been discussed.

The Convener: Did you want to add anything, minister?

Maree Todd: No. That was perfect.

The Convener: I have just one follow-up question. One of the scandals that arose with transvaginal mesh related to the quality of the mesh itself. It turned out that the regime that was in place to ensure the highest standard of mesh material was really not robust and, to our shock and dismay, some of the mesh that had been fitted in some women was no different from the mesh that is found wrapped around packages that come through the post. Is a strong regime in place for the mesh procedures that we are talking about to ensure the quality of the product that is fitted in any operation?

Maree Todd: As I understand it, it is the Medicines and Healthcare products Regulatory Agency that grants licences for those products on a United Kingdom-

wide basis. David Bishop might want to come in on this but, as I understand it, the transvaginal mesh situation prompted a review of all those processes. I think that on-going work is still being done on that.

Our feeling in the Scottish Government is that the MHRA's procedures should be absolutely robust and that there were lessons to be learned from that situation. We are keen to ensure that those lessons are learned.

I invite David Bishop to give some more information on that front.

The Convener: I can say to Mr Bishop that, if we were relying on the MHRA at the time, it was woefully inadequate in its explanation of its procedures and in respect of the subsequent regulation to ensure that only proper materials were used. It is clear that some products bypassed that. Can patients now proceed with greater confidence?

David Bishop: Terry O'Kelly might want to comment further on that, as he perhaps knows more about it than I do. That was taken up with the MHRA at the time of the transvaginal mesh issue. Our ministers at the time and the then chief medical officer wrote to it about that issue to query it. As the minister said, we raised concerns. My understanding is that the MHRA is reviewing procedures. It is also taking forward new medical device regulations as a result of Brexit and so on. That is all being looked at.

The Convener: In the interests of time, we will leave that question.

Bill Kidd: Is there any plan to ensure that everyone who has had a mesh procedure over a period of time to be decided is contacted to ask them about their experience since they had the treatment? I know that there are people who have been uncertain about how they can complain, who they can complain to, and whether they are wasting people's time. However, they are in discomfort, and having that material inside them is affecting their lives.

Maree Todd: That would be a challenging undertaking retrospectively. However, on the use of mesh in other sites for gynaecological procedures that was not subject to the halt, the high-vigilance protocol has a number of procedures in place that ensure that that is perfectly possible. There is documentation of all the procedures and complications and on the reporting of complications on an agreed database. Crucially, documentation is given to every single patient who is treated with mesh that details their procedure and the mesh product used, along with the name of the patient. Therefore, in future, the precise situation that you have outlined will be less likely to arise in gynaecological procedures in which mesh is used.

Bill Kidd: That is very important. I recently spoke to a man who had an abdominal hernia repair that involved mesh and who has suffered great pain and almost disability as a result. The issue has not been covered widely in the media, but there are men who do not know what to do next. They do not know who to complain to and

whether they should just go back to their GP or somewhere else. There are people who have problems but who do not know what to do about them. I wonder whether everyone who has had the procedure could be contacted, because issues might then be raised that are being ignored at the moment.

Maree Todd: I am not sure how that would happen, given the scale of the procedures, with 5,000 to 6,000 per year being carried out since the 1980s. However, as Mr O'Kelly outlined, patients should first present at their GP.

People must be listened to, because the key point that has come out through all the testimonies is that people do not feel listened to. We must learn from the transvaginal mesh incident— people's concerns have to be taken seriously and acted on appropriately. In many areas, there will be a multidisciplinary team in place, as Mr O'Kelly outlined. There is a complexity in dealing with mesh complications, and the multidisciplinary team and clinical networks will together look at each individual case. However, it must be straightforward for patients to access that level of expertise when they find themselves in the situation that Mr Kidd describes.

Alexander Stewart: In your opening statement, you acknowledged that individuals have been let down and dismissed, and you talked about the risks that are associated with the complicated situation that many individuals find themselves in. You have talked about lessons being learned, which is vital. What you have said is helping me to think that that is happening as a result of this process.

Where are we with longer-term research on hernia? We have learned from the transvaginal mesh issues and gone through those, but is longer-term research being done when it comes to hernia? If there is no research, how are you taking forward some of the issues that have been raised by individuals who have suffered?

Maree Todd: Research will be on-going all the time. The Scottish Government has asked for a review of the evidence. The Scottish Health Technologies Group has already published a report of a review of evidence on primary inguinal hernia repair in men. Following that, we asked the group to examine hernia more broadly, to include men and women and to review the outcome of mesh versus non-mesh surgery in a variety of abdominal wall hernias. We have asked the group to look at the published evidence on that and to come back to us, and we are waiting for publication of that report. We expected it at the end of summer this year. That is quite a broad term, but we are hopeful that it will be published very soon and that it will give good-quality evidence. Without high-quality and well-reviewed evidence, it is not possible for patients to make an informed decision.

Alexander Stewart: Obviously, the pandemic has had huge implications for the NHS, with individuals not having the opportunity to have operations. What is the Government doing to ensure that people do not have to seek private treatment? With the mesh situation, individuals had to seek private help. Due to the waiting times and

lists, they could not get an opportunity, and they felt that they had no option other than to go private to ensure that they received the care that they required.

Maree Todd: You are absolutely right—the pandemic has placed immense pressure on the NHS. We talk about that in almost every parliamentary committee and regularly in the chamber. Undoubtedly, after 18 months of impact on NHS capacity and how we work, there is pent-up demand for surgery in a number of clinical areas such as orthopaedics. Cancer surgery has been prioritised throughout the pandemic.

An NHS recovery plan is in place. Work is being done to ensure that we can tackle the pandemic and keep the number of hospitalisations at a level at which the NHS can function. There are plans in place for the NHS to recover from the pandemic. National treatment centres are being developed where surgery can take place. The process will not be instant or overnight, but there is a recovery plan in place that will benefit everyone who is waiting for treatment, not just the people whom you mentioned.

Paul Sweeney: Following on from those points, I noted that the petitioner highlighted the work of surgeons at the Shouldice hospital, who are pioneering alternative treatments in natural tissue repair. There have been interesting outcomes from that technique and the study of the technique. What is your view of it? What are we doing to train surgeons in Scotland in it? Are we developing a critical mass of knowledge, so that we can use it as an alternative means of treatment?

I am conscious of the significant inertia in the medical profession in relation to the use of mesh. The technique is long established and has been normalised in Scotland, so trying to move away from it is bound to meet with some resistance. Are there better ways to embed and build up alternative, pioneering techniques?

Maree Todd: That is a clinical decision, on which I will defer to Mr O'Kelly. Comparing the two techniques is way beyond my level of expertise. I ask Mr O'Kelly to give you some information about whether a process is under way to gather evidence on pioneering techniques and to compare them with existing techniques.

Medicine is slow to change practice. You will know that, in my past life, I was a clinical pharmacist. When I first started out in my practice, there was a gap of about 15 years between evidence and practice. The internet has speeded up the ability to obtain and review evidence from all over the world. We are faster at gathering evidence.

We have seen a brand-new virus that nothing was known about. During the pandemic, scientists and clinicians from all over the world collaborated to find a way forward in the emergency in which we found ourselves. I am very hopeful that some of that collaborative effort will survive into future practice and mean that we will solve some of the big questions. I also hope that, at the heart of that, there will be fewer

commercial concerns and more altruism when it comes to solving some of the medical problems.

That was a bit of a philosophical answer. I will let Mr O'Kelly give you the clinical answer.

Terry O'Kelly: Shouldice repair, which has been popularised by the Shouldice hospital, is a non-mesh tissue repair for inguinal hernia. I think that that will be one of the treatments that one would look to if patients did not want mesh to be used. There are other non-mesh techniques.

Shouldice repair is not something that every surgeon undertaking hernia repair in Scotland would be familiar with, but there will be those who are skilled in it. We would need to do a skills assessment and address any skills gap, if one exists. However, the technique will not be applicable to non-inguinal hernias; it might also not be appropriate for patients with larger defects, or for very degenerative tissues. It is certainly a technique that we would look at.

The Convener: Thank you. Are you content, Paul? Paul Sweeney: I think so. I just note that it is interesting that the onus seems to be on the patient to demand an alternative. That goes back to the issue about the power imbalance when it comes to knowledge and the need for people to be quite robust in their challenges. I wonder whether that is a potential concern.

Maree Todd: To be absolutely clear, the process of informed decision making is about the patient and the clinician sitting down together, understanding the condition that the patient presents with and talking over the options. It involves consideration of the elements of the acronym that is gaining popularity in realistic medicine circles, which is BRAN—the benefits, the risks, the alternatives and the effect of doing nothing. Alternatives are absolutely part of that process.

That approach is becoming ingrained in medical practice—for example, the acronym appears in advertising campaigns in the virtual waiting room for NHS services in my area. The intention is to normalise that process. The clinician should be sitting with someone and discussing alternatives. They should say, "Here's what you've got and this is my understanding of the factors that are significant for you as an individual. What do you need me to understand about you as an individual? Let's see what alternatives are on the table and make a decision together." That is how it should be. The onus should not be on the patient to ask questions. We intend to create an atmosphere in which it is normal for the patient to ask questions. It is their body that is the subject of the process, and it is altogether more satisfactory if the patient is empowered to make a decision in such situations.

The Convener: Thank you, minister. I also thank David Bishop for his contribution and Terry O'Kelly for his audio participation. I would like to reflect on what we have heard. I suggest that we take time to read the Official Report of this discussion and

return to the petition at a subsequent meeting. Do members agree with that suggestion?

[Members indicated agreement.]

Extract from Official Report of last consideration of PE1865: Suspend all surgical mesh and fixation devices on 2nd February 2022

The Convener: PE1865, by Roseanna Clarkin, Lauren McDougall and Graham Robertson, calls on the Scottish Parliament to urge the Scottish Government to suspend the use of all surgical mesh and fixation devices. I apologise for the fairly long preamble. The petition has had something of an airing in the Parliament in connection with the bill on compensation for transvaginal mesh surgery that was recently passed. The petition calls on the Parliament to suspend the use of surgical mesh and fixation devices while a review of all surgical procedures that use polyester, polypropylene or titanium is carried out and guidelines for the surgical use of mesh are established.

The petition was last considered on 17 November 2021 and at that meeting the committee agreed to write to the Minister for Public Health, Women's Health and Sport and to the Shouldice hospital in Canada. Responses have been received from the minister, the Shouldice hospital, Sling the Mesh campaign and the petitioners.

I am delighted that Jackie Baillie is still with us this morning and I welcome Carol Mochan MSP, who joins us online; both members wish to speak to the petition. Before I bring in my colleagues, I will provide a little bit more of the background, which I apologised for the length of a moment ago.

In 2019, the Scottish Health Technologies Group carried out a review into the use of mesh in primary inguinal hernia repair in men. The review concluded that, compared to non-mesh procedures, using mesh resulted in lower rates of recurrence, lower rates of serious adverse events, and similar or lower risk of chronic pain. The advice for NHS Scotland was, therefore, that surgical mesh should be used in elective repairs in inguinal hernia in adult males.

The SHTG review was subsequently expanded to include women, examining the outcome of mesh versus non-mesh surgery in a variety of groin or abdominal wall hernias. The Scottish Health Technologies Group concluded that current evidence supports the continued availability of surgical mesh for elective repair of primary ventral hernias, incisional hernias, and primary inguinal hernias in adults in Scotland. The group recommends, however, that consideration should be given to patient preference and that patients should also have access to alternative hernia treatment options such as non-mesh—suture and natural tissue—repair.

The chief medical officer has also undertaken a number of activities relevant to the petition, including: writing to the board chief executives and medical directors to draw their attention to the SHTG report's findings; asking health boards to consider the

availability of non-mesh surgery within their health board, and how any skills gaps can be addressed; asking health boards to consider the development of local clinical groups and broader clinical networks for the management of complex cases; and asking medical directors to remind clinicians of their obligations under the principle of realistic medicine, of informed consent and of the importance of recording both the content and outcome of such discussions.

With regard to the issues raised about the quality and authenticity of certain materials being used, the minister states that the Scottish Government contacted the Medicines and Healthcare Regulatory Agency in 2018, which confirmed that there was no new evidence to prompt regulatory action and that the products in question remained acceptably safe when used as intended.

The committee also wrote to the Shouldice hospital in Canada, as the leading experts in natural tissue repair. In what I thought was a fascinating submission, Shouldice states that in its own practice, surgical mesh is not used unless absolutely necessary and that has led to it being used in less than 2 per cent of cases. The hospital specialises exclusively in abdominal wall hernia repair. It states that where the body's natural tissue is strong enough to support the surgical repair, natural tissue repair should always be used and where underlying patient tissue is poor, surgical mesh may be necessary in some femoral and large incisional hernia repairs. All the hospital's surgeons are trained to do a natural tissue repair as their first choice; natural tissue repair should be the first choice for all primary inguinal hernias, most recurrent inguinal hernias, most femoral hernias, most epigastric and umbilical hernias, and small incisional hernias.

Shouldice also notes that since mesh was introduced in the 1980s, the recurrence rate for inguinal hernia repair—more than 85 per cent of most of its hernia repair—has not improved. There has been a staggering increase in post-operative complications not seen prior to mesh. Chronic and debilitating pain and other severe complications such as mesh shrinkage, mesh migration, and related nerve entrapment are widespread. There are no side effects of tissue repair if it is done correctly. Training for surgeons on the natural tissue technique ranges from three months for an experienced fellowship general surgeon to six to nine months for an inexperienced general surgeon.

The Sling the Mesh campaign shared the results of its recent survey of its 9,300 members with experience of vaginal, abdominal, pelvic, rectal, hernia mesh and mesh following mastectomy. It notes that one in four have considered taking their life, six in 10 suffer depression, one third have been forced to give up their work, one in four now need a stick to walk, and one in 14 now need a mobility scooter or wheelchair.

In their submissions, the petitioners welcome the information contained in the Shouldice hospital submission and ask for further information to be sought on the use of protacks, which are devices used to fix mesh to soft tissue. The petitioners believe that there is evidence to suggest that a considerable sum of money has been spent recently procuring hernia mesh and other fixation devices and they feel that that money could have been spent on investigating and teaching natural tissue repair. The petitioners also query why mesh is still being bought and why clinicians

are not yet accurately and systematically recording the effects of such material on patients.

We have gathered quite a lot of evidence since we last considered the petition. I invite both Jackie Baillie and Carol Mochan to contribute ahead of comments from committee members.

Jackie Baillie: Many thanks to you, convener, and to the committee for allowing me to speak to the petition. Given your detailed knowledge and interest in the area, I feel as though I am pushing an open door.

I have been contacted by one of the petitioners, Roseanna Clarkin, and she shared with me the evidence from the Shouldice hospital in Canada. I know that the committee has seen that evidence.

In the past week, I have also been emailed by a number of men and women across Scotland who have experienced post-operative complications after the use of mesh. Their stories are heartbreaking. They are living in excruciating pain. Many of them have had to give up work. Their fears are somehow being dismissed as psychological and not physical. Some have had to go private because the national health service is refusing to help them. Some have been so low they have considered taking their own life. You will appreciate, convener, that those stories are remarkably similar to the stories that we heard from women who experienced difficulties as a consequence of transvaginal mesh. The evidence of problems with mesh appears to be increasing, not just in this country but in other countries around the world.

I am astonished that on 25 January, the Scottish Government signed a deal with mesh providers to provide more mesh for more mesh surgeries for the next 24 months at a cost of £3.5 million. Equally, I am not aware whether it is a matter of routine for alternative surgeries to be offered and I wonder whether that is something that the committee would consider exploring.

Given the experience of the transvaginal mesh campaigners, I ask the committee to ask for an independent review—not an internal review—and get the data to understand the scale of the problem that is starting to emerge here. The committee should also consider asking the Scottish Government for mesh removal and other mitigations for those affected.

Carol Mochan (South Scotland) (Lab): I am quite new to the subject matter and I want to put on record that I am interested in the way the matter has progressed. Similar to other members, I have been involved in the mesh debate with women in relation to transvaginal mesh. It is important that we use the evidence that we have from other areas.

I support the overall sentiment of the petition: it is a perfectly reasonable request that a review is held and that guidelines around the surgical use of mesh are established. The petitioners have brought evidence to the minister and the committee has gone over other evidence. It is incumbent on us to ensure that reasonable requests are respected; it seems reasonable for the Citizens Participation and Public Petitions

Committee to take action and at least further scrutinise what can be done to support the petition.

Thank you very much for the opportunity to speak today. I hope to keep an eye on what is happening around mesh for those people.

The Convener: I am grateful for that. Do any members of the committee wish to comment?

Alexander Stewart: I am amazed at what has already been achieved through the campaigns in the past, but looking at the current situation, it would appear that lessons have not been learned. There is a real similarity between what happened to the women and what is now happening to the men. The Shouldice hospital report is eye-opening; it is important for us to have that information and to collate some of the issues that have been raised.

We need to seek more clarity on all of it. We should at least be writing to the chief medical officer in Scotland to ask what is happening with the process. Ms Baillie has some very strong views about what is taking place and the funding that has been provided. If we do not take some action, are we just saving up more problems for individuals in the future? I want us to write to the chief medical officer and also to ensure that the minister for public health comes back to the committee and gives us more updates on what is taking place.

I would have hoped that, following the whole debate and debacle with transvaginal mesh, we would have learned some lessons, but it would appear that we are repeating some of the failures and we are putting individuals through the trauma that some women experienced in the past. We need to get real clarity on all of that and we should continue the petition on those grounds.

Paul Sweeney: I support what Jackie Baillie said about the submission from Roseanna Clarkin. It was quite shocking to learn that the vendor, Covidien UK, was supplying Parietex mesh, which has been subject to Food and Drug Administration restrictions in the United States because it has been directly linked to postoperative complications and adverse effects in patients. Perversely, we are in a position in Scotland where we have fewer medical clinical protections for patients than in the United States. I am sure that if you asked the average person in the street which jurisdiction they think offers more protections to patients, they would say Scotland, when as a result of the Government's decision, that is not the case.

It is critical that we pursue the issue. The submission from the Shouldice hospital offers an insight into an alternative model that is quite compelling. In light of that remarkable evidence, it would be worth asking the health secretary to engage with it directly and perhaps look at the opportunity to set up a pilot project in Scotland with a particular hospital or surgical centre, to seewhether we can adopt those methods. We could use the pilot as a control against standard procedures and see whether it produces demonstrable effects that could improve patient care.

Ruth Maguire: I am thankful for the evidence that we have been given. It has certainly been eye-opening. I think that one person in pain and distress and not being believed is one too many. That said, it is important that we understand the

scale. Based on what has happened previously and our experience of what happened to the women, I would like to invite the minister to come and give evidence. It is important to start that dialogue. It is almost too big to just write and ask for some information. We should have an evidence session in the first instance.

The Convener: We took evidence from the minister prior to your joining the committee, but there is every reason to suggest that we might wish to have the minister back.

David Torrance: I am like my colleagues in that I am very interested in the petition as somebody who has been there from the very start in relation to the mesh cases. It is important that we get to the bottom of the matter. Rather than write to the chief medical officer, could we ask him to give evidence? We could invite somebody from the hospital in Canada to give evidence to the committee, too, so that we could ask questions. Let us just push the petition on and make progress on it.

The Convener: The associated concern of hernia mesh was referred to from time to time during the progress of the committee's dealings with the mesh petition previously. There was an immediately united, informed body of women who drove the transvaginal mesh petition forward. The issue of hernia mesh was understood to be there but did not have the same profile.

What is depressing is that the pathway seems to be exactly the same: a lack of any subsequent follow-up to establish whether issues have arisen, a denial of the association of any issues with the mesh that has been fitted, and the calling into question of the motivations or understanding of those who are themselves feeling pain and that pain being dismissed as not real but imagined. Even during the debates on recent legislation, I was reluctant to conflate the two issues because I felt that we did not have the same body of evidence. As a consequence of our pursuit of this petition, the wider body of evidence is beginning to emerge. Therefore, I think that it is very much an issue that the committee should pursue further and that we should leave the petition open.

I would very much like to welcome the minister back to the committee. The minister should have the opportunity to properly consider the evidence that we have received from the Shouldice hospital. Taking evidence from representatives of the Shouldice hospital would be slightly problematic in terms of timing because they will not be working to the same clock as our committee—I imagine that they are all fast asleep at the moment—but we could think about that.

I would like to hear from the chief medical officer and the minister. I would certainly like to understand that evidence and flag up in advance the procurement of the particular mesh material because I do not understand why that has happened. All the issues look broadly similar. When we heard from the minister previously, the Government was working on informed consent procedures. That seemed fair enough, but we have been here before.

We can assume that there is now a broader body of men who have concerns. However, a number of men have contacted me to say that they have had perfectly successful mesh procedures and it has made a huge difference. I want to understand the volume and the relationship between those who feel that they have

had successful mesh procedures and those who have had unsuccessful mesh procedures. In the case of transvaginal mesh, the balance was fundamentally on the side of those who had experienced serious health consequences. That may have to form the basis of any informed consent in the event that there is an argument for the mesh process proceeding.

Are we content to take and consider further evidence from those parties that have been suggested?

[Members indicated agreement.]

Annexe C

Minister for Public Health, Women's Health and Sport submission of 7 March 2022

PE1865/FFFF – Suspend all surgical mesh and fixation devices

Thank you for your letter of 16 February 2022 concerning the above petition. Firstly, I am grateful to you for bringing the submission from the Shouldice Hospital to my attention. This provides a perspective from a well-respected institution and the views provided on hernia repair clearly require consideration.

As the Committee is aware, the Scottish Government commissioned the Scottish Health Technologies Group (SHTG) to review published evidence on the use of surgical mesh in hernia repair (Surgical mesh repair of primary inguinal hernia in men (shtg.scot) and Elective surgery using mesh to repair primary or incisional hernias in adults (shtg.scot)). In order to reach conclusions and to make recommendations applicable to the NHS in Scotland, SHTG focused principally on high-level evidence derived from randomised controlled trials (RCTs) in the form of meta-analysis and network meta-analysis. This differs from the data sources quoted by Shouldice Hospital (observational studies based on retrospective review or registry data) and helps explain the difference in the conclusions reached.

This notwithstanding, the results reported by the Shouldice Hospital are notable. They do however illustrate outcomes achieved in a centre dedicated to a single condition (hernia) and in a healthcare system different from our own. In the NHS in Scotland, the model for delivering surgical treatment is different and having examined available evidence as described, SHTG supported the continued use of mesh in hernia repair. Significantly, SHTG also signalled the importance of patient preference and the need for alternative treatments to be available, such as natural tissue repair. I believe these latter issues do require further

consideration in order to ensure that NHS Scotland can and does offer a range of treatment options and patient choice. Accordingly, the Chief Medical Officer wrote to Scottish Health Boards on 7 December 2021 and hernia repair will be discussed at a future meeting of the Scottish Association of Medical Directors.

Secondly, I understand the Committee also discussed the procurement of hernia mesh, for which NHS National Services Scotland published details on 25 January 2022. It may be helpful if I explain that this was a modification notice that sets out the terms of a short extension to an existing framework for the supply of hernia mesh products. The framework was extended, early last year, by three months due to Covid-19, but this has now ended and was replaced by a new framework on 1 April 2021 which will run until 31 March 2025. The £3.5 million referenced covered the five-year period from 1 January 2016 to 31 December 2020.

Martin O'Neill submission of 8 May 2022 PE1865/GGGG - Suspend all surgical mesh and fixation devices

I have the following suggested questions for the Surgeon from Shouldice Hospital:

- What is the comparative % for males vs females that have inguinal herniations?
- What are the differences of any possible harm between the sexes within this specific region of herniation?
- Is there any documented evidence that can show a comparison of harm or natural Shouldice method vs a mesh repair?
- Within that, what % of patients have lost bodily parts, or have suffered adhesions to bodily parts, and damage to nerves with a Shouldice repair method?
- Have the Shouldice centre had to remove a males testy or testis after a "failed" Shouldice repair?

- Have the Shouldice had to remove anything after any failed herniation anywhere within anybody whom has ever been worked on at the Shouldice hospital in its 75 year history?

- Have any persons reported to the Shouldice hospital any harm caused by the consistency of issues after a natural repair due to any of the following ailments;

    - infections (urine/testicular or vaginal infections)
    - Skin problems
    - Fungal problems
    - Strange smells coming from mesh site
    - symptoms of chronic fatigue tiredness
    - symptoms of brain fog
    - symptoms of microbial anomalies that cannot otherwise be explained

- Has any person ever been left disabled by the Shouldice centre after any repair, or “failed” repair of a patient has had to come back for revision surgery within its 75 year history?

- Has the Shouldice had to “remove” any of its natural tissue repair methods?

- Has any patient complained that the repair method has left them in chronic debilitating pain, and that they can feel the “natural repair” poke into their body causing pain?

- Has any patient ever suffered muscular spasms after any natural tissue repair?

- Has any patient ever presented with sexual dysfunction or loss of sexual function due to pain, nerve or similar damage or a combination of both?

- Has the Shouldice centre ever had any of its patients tell them that they are suicidally depressed due to the chronic debilitating pain that their natural repair method has left them in?

Annexe D

Shouldice Hospital submission of 10 January 2022

PE1865/XXX – Suspend all surgical mesh and fixation devices

Thank you for the opportunity to participate in this very important initiative. As you know Shouldice Hospital has been a steadfast supporter of our natural tissue hernia repair for over 76 years. Few know that we were a pioneer in the investigation of using Surgical Mesh back in the 1980's, and we choose not to pursue its use unless it was absolutely necessary to do so. To this day we use mesh in less than 2% of all our cases and our surgical outcomes remain the gold-standard in abdominal wall hernia repair.

As requested, here are our views on the questions posed in your letter of November 24, 2021. For context, Shouldice Hospital specializes exclusively on abdominal wall hernia repair and our responses should be interpreted based on that surgical focus. This means that the responses given may not be relevant, or fair, to other surgical procedures where Surgical Mesh may have a different risk profile.

For the record the following responses are a compilation of answers from Shouldice surgeons, including Dr. E. B. Shouldice:

What types of surgery natural tissue repair is best suited to? (hereafter "Tissue Repair")

Generally speaking, where the body's natural tissue is strong enough to support the surgical repair, it should always be used. This is in lieu of introducing a "foreign body" (Surgical Mesh)

that may cause unwanted, and needless, post-operative complications.

Specific to abdominal wall hernia repair, it is important to understand that this comprises “Groin” hernias (Inguinal and Femoral) and “Ventral” hernias (Incisional, Epigastric and Umbilical).

Tissue Repair should be the first choice for all primary Inguinal hernias, most recurrent Inguinal hernias, most Femoral hernias, most Epigastric and Umbilical hernias, and small Incisional hernias. Where the underlying patient tissue is poor or minimal, Surgical Mesh may be necessary in some Femoral and large Incisional hernia repairs. Even then it should be used as a last resort, not a default.

At Shouldice Hospital all Surgeons are trained to do a Tissue Repair as their first choice.

What are the benefits of using natural tissue repair versus mesh devices?

Surgical Mesh was introduced into hernia surgery in the 1980’s to reduce the number of recurrent hernias, and over the next two decades it became the default method of hernia surgery. Five decades later, if one reviews the literature, the recurrence rate for inguinal hernia repair (over 85% of most hernia surgery) has not improved. Compounding this failure, the use of Surgical Mesh has resulted in a staggering increase in post-operative complications that were not generally seen prior to its introduction.

Consider the following:

Hernia Recurrence – there is a plethora of published papers on hernia recurrence rates, many of which are unreliable given poor patient follow up and an unrealistic definition of “recurrence”. Some define a recurrence as a hernia that

reappears within 2 years, and we believe that is self serving as a hernia repair should last a life-time.

Even within acceptable research the rate of recurrence is wide ranging, from 5% to over 15% in most Hospitals. Within this range it is generally accepted that the recurrence rate has not declined with the introduction of Surgical Mesh (cited on page 9 of the "**Trends of Inguinal Hernia Repairs Performed In the United States**". This paper covers a massive sample size and includes three nationally recognized institutions that concluded:

"The proportion of inguinal hernia repairs performed in the United States has remained relatively constant from 2005 to 2015. Based of these larger evaluations of recurrent hernia surgery, the current surgical literature on IHR is skewed and overly optimistic."

Further to this, Shouldice's recurrence rate for Inguinal Hernia Repair rate is less than 2%. This is a life- time rate, as we have the luxury of having the largest single, updated database of hernia patients in the world. To validate this, see the "**Recurrence of Inguinal Hernias Repaired in a Large Hernia Surgical Specialty Hospital and General Hospitals in Ontario, Canada**."

This paper was entirely independent (in fact we never knew it was being published) and includes a large patient population, over a long period of time, when Surgical Mesh was being introduced as the default repair. It is fair to say that of the surgeries done in these public hospitals well over 95% were done using Surgical Mesh.

It concludes *"Inguinal hernia repair at Shouldice Hospital was associated with a significantly lower risk for recurrence than repair at a general hospital".*

It is reasonable to conclude that hernia recurrence has not improved with the advent of mesh. You will note later, the

importance of specialization through comparing our results to Ontario General Hospitals, where General Surgeons, who are all competent, do not typically specialize in hernia surgery.

Post-Operative Complications:

Prior to the introduction of Surgical Mesh there was virtually no mention of post-operative pain after hernia surgery in any medical literature. Now, chronic and debilitating pain, along with other severe complications, associated with mesh use such as mesh shrinkage, mesh migration, and related nerve entrapment, are rampant.

Again, studies vary on the incidence of these significant mesh related complications, however the paper "**Pure Tissue Repairs: A Timely and Critical Revival**" produces a reasonable summary of these issues and concludes:

"If we are to believe our colleagues, our registries, our guidelines as well as giant studies of The Mayo Clinic and the University of Toronto, we would be looking at a mesh complication rate of dysejaculation of 3.1%, of sexual pain of 10.9%, a recurrence rate of 10% and a rate of chronic post-inguinal herniorrhaphy pain of 13%! A combined minimal rate of 37%! These are minimum values presented in their publications."

Using information from the Shouldice Hospital's data bank our post-operative complication rates are around 2% for chronic pain, 0.37% for other issues including seroma, cellulitis, and hematoma, and 0.57% for wound infections.

Costs to the Healthcare System and Post-Operative Mesh Removal:

To date, and to the best of our knowledge, there are no published studies quantifying the cost of mesh related recurrence surgery, or treating the complications associated with its use. The costs of using Surgical Mesh can range

widely, but include simple discomfort, visits to emergency rooms and pain clinics, additional surgery to redo the failed hernia repair, the high cost and significant risks of mesh removal surgery, to documented cases of suicide where the pain, caused by mesh's entrapment of nerves and adherence to organs, becomes intolerable.

When you consider there are 20 million hernia surgeries done in the world each year, any reasonable estimate of these costs is astonishing considering the lack of documented benefits.

How many natural tissue surgeries are performed at Shouldice every year and what is the complication rate?

Shouldice Hospital has been in operation for over 76 years (founded in 1945 by Dr. E.E. Shouldice) and has to date performed over 407,000 abdominal wall hernia repairs. Of these repairs approximately 85% are Groin hernias, and the remainder Ventral hernias, of which the vast majority are Umbilical hernias.

The number of surgeries performed each year depends on our surgical complement, which over the past 10 years has averaged 10 full-time employed Surgeons, performing approximately 6,800 surgeries per year.

One critical factor to our success is due to specialization. Each of our Surgeons perform between 600-700 hernia surgeries per year, which is more than a typical General Surgeon would do in a lifetime. Quite simply "the more you do of anything the better you are at it".

Our comparative recurrence and complication rates are summarized above.

What are the most commonly reported side effects?

All invasive surgery (whether "open" or "Laparoscopic") has inherent risks, but in terms of "side effects" a huge advantage

of Tissue Repair, done right, is that there are none. This is essentially because you use the body's natural tissue as the basis for the hernia repair. This means the well known "foreign body reaction" in response to the implanted Surgical Mesh is avoided.

How many surgeries have been reported as unsuccessful and the reason why?

If we define "unsuccessful" as hernia recurrence and post-operative surgical complications and adverse symptoms, the comparative numbers between Tissue Repair and repairs using Surgical Mesh, have been summarized above.

In principle a proper Shouldice Tissue Repair (Groin) should always be successful when done correctly, however surgery is never perfect. Reasons why a Tissue Repair is unsuccessful include:

- Surgeon experience and competence – for a Tissue Repair to be successful it requires a thoughtful and complete dissection of the groin area. Most General Surgeons have a poor understanding of the complexity of the human groin because typical surgical training does not focus on this area. As a result, inexperienced Surgeons who opt to use any Tissue Repair (the Shouldice Repair is one of 2 or 3 most currently performed in the world) often do not perform the dissection or hernia repair technique correctly. As outlined, this is why Shouldice Hospital has superior surgical outcomes, not only over Surgical Mesh, but also over those other Surgeons performing any Tissue Repair. When done incorrectly the following can result;
- Recurrence of the hernia; and
- Post-operative complications such as infection (poor sterile field), pain (nerve and vas 'deferens' entrapment)

and testicular atrophy (rarely, but can result through carelessness or from sources that remain uncertain).

- Post-operative issues such as smoking, obesity (both pre and post), diabetes, use of steroids, connective tissue disease, and wound infections.

What aftercare is required following natural tissue repair surgery?

As all Tissue Repair is done using the “Open” approach (versus “Laparoscopic”) the aftercare is simple and involves non - narcotic pain control, exercise, rehabilitation, and routine wound care. This would be comparable to when Surgical Mesh is implanted using an Open Repair (85-90% of cases), but is different than when Laparoscopy is used. In this case it is argued that there is less incisional area and resulting wound care, but there is a minimal 1–2-day issue as Tissue Repair wounds heal very quickly.

Why do you not use mesh devices in your surgery?

As outlined above we do use Surgical Mesh when it is required due to the state of the underlying tissue being unable to support the hernia defect’s repair. In our experience this is in less that 1 % of all Groin repairs and up to 5% in large Femoral and Ventral hernias (less than 2% on average).

Simply put, the virtually universal use of mesh in abdominal wall hernia repair is not supported by the facts, and in our case NO technique, even other Tissue Repairs, can match the surgical outcomes of the Shouldice Natural Tissue Repair done by an experienced Shouldice Surgeon.

Furthermore, as today’s healthcare costs are skyrocketing the use of Surgical Mesh, and a Laparoscope, contribute needlessly. Individual Surgical Meshes can range from C$35 to over CS1,000 for complex organic versions, and Laparoscopes costs well over C$100,000 per machine. Natural-tissue Repairs

“may” take slightly longer in the operating room, but this cost pales in insignificance given the other negative issues with using Surgical Mesh as noted.

How long it takes for a surgeon to be trained in natural tissue repair and cost?

The duration of training depends on the experience of the Surgeon, and ranges from 3 months for an experienced Fellowship General Surgeon, to 6 to 9 months for an inexperienced General Surgeon. The cost of this is difficult to determine given variances in healthcare systems. In Canada, this is a paid position whose services are then billable to the provincial healthcare system where the dollars equal out. In our case the real cost is “soft”, where the in-person training slows down the Operating Room’s normal rhythm and throughput by 15-20%.

On a comparative basis there is little doubt that it is simpler, and quicker, to train a General Surgeon to do a Mesh based hernia repair using the Open technique. However, this comes with all the above- mentioned costs of complications and poorer surgical outcomes, therefore it should not be the reason why Surgical Mesh is used as much as it is.

Conversely, training a General Surgeon to implant Mesh Laparoscopically can take equal or more time, as instead of learning to do a Groin dissection, they must train to do the procedures mechanically. Studies have shown that it takes between 200-300 cases to become totally proficient with a laparoscope, whereas a typical Open technique will take 20-30 cases when Mesh is used, and up to 100-150 when the Open repair is done using a Tissue Repair.

Thank you again for allowing Shouldice Hospital to introduce our views on these important questions. If you require clarification on our responses, or have any follow-up questions, please contact me anytime.