The Scottish Parliament
Pàrlamaid na h-Alba

Official Report

HEALTH AND SPORT COMMITTEE

Tuesday 28 February 2012

Session 4

Tuesday 28 February 2012

CONTENTS

HEALTH AND SPORT COMMITTEE
8th Meeting 2012, Session 4

CONVENER

*Duncan McNeil (Greenock and Inverclyde) (Lab)

DEPUTY CONVENER

*Bob Doris (Glasgow) (SNP)

COMMITTEE MEMBERS

*Jackson Carlaw (West Scotland) (Con)
*Jim Eadie (Edinburgh Southern) (SNP)
*Richard Lyle (Central Scotland) (SNP)
Fiona McLeod (Strathkelvin and Bearsden) (SNP)
*Gil Paterson (Clydebank and Milngavie) (SNP)
*Dr Richard Simpson (Mid Scotland and Fife) (Lab)
*Drew Smith (Glasgow) (Lab)

*attended

THE FOLLOWING ALSO PARTICIPATED:

Jackie Baillie (Dumbarton) (Lab)
Sir Harry Burns (Scottish Government)
Dr Sara Davies (Scottish Government)
Bruce High (Nuffield Health Glasgow Hospital)
Adam Ingram (Carrick, Cumnock and Doon Valley) (SNP) (Committee Substitute)
Alison Smith (Scottish Independent Hospitals Association)
Nicola Sturgeon (Deputy First Minister and Cabinet Secretary for Health, Wellbeing and Cities Strategy)
Miriam Watts (Spire Murrayfield Hospital Edinburgh)

CLERK TO THE COMMITTEE

Douglas Wands

LOCATION

Committee Room 1

Scottish Parliament

Health and Sport Committee

Tuesday 28 February 2012

[The Convener *opened the meeting at 09:32*]

Interests

The Convener (Duncan McNeil): Good morning and welcome to the eighth meeting of the Health and Sport Committee in 2012. I remind everyone present that mobile phones and BlackBerrys should be turned off, as they can interfere with the sound system.

Apologies have been received from Fiona McLeod. Jackie Baillie MSP is with us this morning—I welcome her to the meeting.

The first item on the agenda is a declaration of interests by Adam Ingram, as this is the first meeting of the committee that he has attended as a committee substitute. I welcome him to the meeting. In accordance with section 3 of the code of conduct, I invite him to declare any interests that are relevant to the committee's remit, and remind him that any declaration should be brief, but sufficiently detailed to make clear to any listener the nature of the interest.

Adam Ingram (Carrick, Cumnock and Doon Valley) (SNP): I have no relevant interests. I hope that that is brief enough for you, convener.

The Convener: That is very accommodating. Thank you.

PIP Silicone Breast Implants

09:33

The Convener: Agenda item 2 is evidence on PIP silicone breast implants. I welcome Alison Smith, who is chairperson of the Scottish Independent Hospitals Association; Miriam Watts, who is director of nursing at Spire Murrayfield hospital in Edinburgh; and Bruce High, who is director of nursing at Nuffield Health Glasgow hospital. I thank all of you for your attendance.

Richard Lyle (Central Scotland) (SNP): Good morning, ladies and gentlemen. Over the past couple of months, the situation with PIP silicone breast implants has really scared a lot of women and we need to find out what can be done. According to the Scottish Government, more than 4,000 Scottish women have had these implants, although the Scottish Independent Hospitals Association has said that there are only 1,300 such cases in Scotland. How were those figures calculated and how confident is the SIHA in them? Why is there such a significant difference between your figures and the Scottish Government's estimate?

Most worrying of all, although you have said in correspondence that all the SIHA's members have agreed to remove and replace PIP implants free of charge, one of those members, BMI Healthcare, has said that it will not do so in cases in which PIP implants inserted in a BMI hospital have been paid for through a third party or in which patients had surgery in another provider's hospital. There are also continuing reports about women not receiving any support from providers, which I find absolutely outrageous. Can you give us your views on those questions?

Alison Smith (Scottish Independent Hospitals Association): You have raised a number of points. First of all, I have to say that we share your concern about the situation in which we find ourselves. Back in the beginning, these implants were a regulated product and carried the CE mark, which assured us that the product that we were buying and using in our services—or which were being used by any other service—was certified and safe to use. Now that we find we have used a product in which the manufacturer has substituted a clinical-grade silicone with an industrial-grade silicone—which, I should add, was not picked up by any regulatory body—we echo the concerns that you have expressed.

With regard to the discrepancy between the figures that were first given out and the figures that the SIHA has now submitted, I suggest that, when the news broke, there was great panic—I think that that is the appropriate word—among people

who were trying to aggregate the figures and get a feel for the size of the problem. As a result, there was double reporting. I assure the committee that, in the letter sent to Duncan McNeil, the figures for the cases handled by Nuffield Health, BMI Healthcare and Spire Healthcare and the figures from Transform Medical Group are accurate. The 1,300 figure is much closer to the correct figure, give or take one or two on either side, than the 4,000 across the population that was originally mooted.

After listening to what was said at last week's committee meeting and after meeting Dr Sara Davies a couple of weeks ago, I think that another reason for the discrepancy is that certain people who might have been treated in Scotland were not residents of Scotland. Some of the third-party providers have clinics right across the country, and there can be movement of patients to the site where the procedure was undertaken.

As for the point about BMI Healthcare, I should make it clear that, as well as chairing the SIHA, I represent that company in my day job. As with Spire Healthcare and Nuffield Health, BMI Healthcare has said that, for any patient treated in our hospital, we will remove their implants and carry out reaugmentation free of charge if so desired. Over the years, our hospitals have been used by third-party providers; although we have been paid a fee by them, we have not provided the whole episode of care. For that reason, BMI has made an additional statement that it will treat those patients, but for a small fee, which might be paid by either the individual or the third-party provider itself.

Richard Lyle: I take on board those comments. However, with regard to your last point, why should someone who through no fault of their own received an implant made from the wrong silicone have to pay at all?

As far as I am concerned, someone—whether the provider or the people who carried out the operation—has let those people down. Some women have had a health scare that is worse than anything that we could imagine, but we are turning round and saying, "We're going to charge you." We should categorically assure everyone that we will remove the implants, which were the wrong ones in the first place, and ensure that they have the best of health.

Alison Smith: On the tests that the Medicines and Healthcare products Regulatory Agency has done on the implants, there is no record of any chemical toxicity or genotoxicity from the industrial-grade silicone. That does not mean that we were not most disappointed to find that the manufacturer had changed the filler in the implant. However, a Government body has stated that at the present time there is no evidence to suggest that it is creating an immediate or long-term health risk for women.

On the point about payment, I reiterate that BMI in its own right is not charging any woman for any procedure or care for which it was the primary deliverer. However, BMI has levied a cost for doing work on behalf of a third party. If the original procedure was done in the hospital, BMI would have been paid a small fee by the third party, but the bulk of the fee paid by the woman was paid to one of the aesthetic clinics.

Richard Lyle: I know that other members want to get in, convener, but I have a final question.

The Convener: Others are waiting to get in, but okay.

Richard Lyle: If you had the surgery done to you, would you be concerned?

Alison Smith: I think that that question is a little unfair. However, yes—most probably, as a woman with a foreign body in me about which there was any question with regard to the scare that I think has really been hyped up by the media. We have to go back to the scientific and clinical evidence that is on the table and, at this time, there is no evidence that this is causing a threat to the women's health.

Richard Lyle: Would you not—

The Convener: Richard, other members are waiting to come in.

Miriam Watts (Spire Murrayfield Hospital Edinburgh): Can I answer that question, convener?

The Convener: Yes, certainly.

Miriam Watts: In the stance that they have taken, BMI Healthcare, Nuffield Health and Spire Healthcare acknowledge that women are worried, and we are dealing with that worry by offering them free surgery.

The Convener: I suppose that that takes us back to the warnings in the system way back in 2006, when there was some publicity and Spire commented that it was aware of and worried about a developing problem and had notified the authorities. Does Mr High want to comment on that from Spire's point of view?

Bruce High (Nuffield Health Glasgow Hospital): I do not think that I can talk about that on behalf of Spire.

Miriam Watts: I am from Spire Healthcare, convener.

The Convener: I am sorry—I am getting confused.

Miriam Watts: The concerns were raised by a consultant—an independent practitioner who used Spire Healthcare—with the MHRA in 2006. He was quite a high user of the implants, and in his opinion he was seeing a higher-than-average return rate with women. Spire Healthcare never at any point forced a surgeon to use a specific implant. That was a personal choice that was discussed with the patient prior to surgery. When the consultant acknowledged that he had concerns about something, he personally decided to change the implant choice as a first step. There are constant advances in medical technology, so what was the implant of choice in 2004 was perhaps not the implant of choice in 2007, given that other parties had improved their products.

Gil Paterson (Clydebank and Milngavie) (SNP): Can someone give me a steer on the number of PIP appliances that were used in a typical year and how that compared with the use of appliances produced by other manufacturers?

Miriam Watts: The figures are not statistically proven, but I would say that, at Spire Murrayfield hospital, the ratio was 50:50. The range was from between 50 per year to slightly more than 100 per year.

09:45

Gil Paterson: Is there a figure for breakdowns of the appliance? Is there a significant difference between PIP and non-PIP appliances over that period?

Alison Smith: The hospital that I represent did not use PIP implants after summer 2005. We used them on behalf of a third-party provider and, in the subsequent years, have not removed any PIP implants for rupture.

The Convener: Are there any figures for the rupture rate in Scotland?

Miriam Watts: No, not at present.

The Convener: Why not?

Miriam Watts: Do you mean for PIP implants?

The Convener: Yes.

Miriam Watts: At the moment, we look at rupture rates in general. The early indication is that the figure is between 5 and 20 per cent but, without medical research being done on the area, we do not know. When we re-operate on patients at Spire Healthcare, we undertake medical research on them. We will have statistical evidence from the 800 patients on whom we have operated to see whether there is a higher rupture rate but, until that work is complete, I cannot possibly put a number to it.

The Convener: Is everyone investing in such medical research? Is it being supported? When do we expect to have a figure on which we can count?

Alison Smith: Spire is undertaking its own project, but the other groups are being guided by the MHRA. We are storing any implants that we remove and awaiting instruction as to whether we should send the implants, photographs, or written feedback from the removal of the implants to the MHRA.

In the years since providers used PIP implants in Scotland, there has been no increased throughput of ruptured PIP implants. Those would be found when women presented with a problem with their implants and sought advice. However, we have not seen a significant number of patients—or any patient, in fact—with a PIP implant coming back and seeking some form of support.

The Convener: Does that mean that there have been no instances of leakage? We cannot draw the other conclusion unless women present with problems.

Alison Smith: If an implant had ruptured, that would usually present in some way—there would be either pain or swelling. The woman would be likely to return to seek advice. However, we have seen no increase in such cases.

It is also worth noting that any implants that were fitted in the early 2000s or earlier were given a guarantee of only 10 years by the manufacturer. Manufacturers of breast implants have started to give lifetime guarantees only in the past year or 18 months. Before that, implants had a limited life. That was part of the information that any woman who sought the procedure was given at the time.

The Convener: I go back to the MHRA guidance. Your description of current procedure—waiting to see whether the MHRA wants the implants or photographs of them—did not give me much confidence. It seems a bit ad hoc. Perhaps that is the wrong term.

How are you responding to and working with the MHRA to establish the scale of the problem and to ensure that it does not happen again? Are you confident that the current arrangements will achieve that, or is it a bit ad hoc at this point?

Alison Smith: I do not think that it is ad hoc. I think that the MHRA is taking time to decide what is the best way forward—whether it wants every implant returned to it or whether it will take a sample group. It even suggested that it might be easier to take a sample group from hospitals that are closer to London.

However, at the present time, we are being asked to photograph the implants, catalogue them

and store them, and when the MHRA has a strategy for managing the situation, we will be instructed on what to do with the implants. No implant that has been removed is being destroyed. They are all being held and catalogued, awaiting an instruction as to how the regulatory body—

The Convener: My concern is that the strategy has not been confirmed yet. Does Miriam Watts want to comment?

Miriam Watts: I believe that the MHRA is working as quickly as it can, given the scale of the problem—the potential 40,000 cases throughout the United Kingdom. As Alison Smith stated, locally, at each hospital, we have quarantined everything and no evidence is being destroyed.

You asked when we will have the medical research to produce some good figures for Scotland. I suggest that it will take, possibly, a year for us to re-operate on everybody, given the numbers that Spire Healthcare has. By the time we put the information together, we could be looking at 18 months. However, we will be working on the statistics as we go along, so we might be able to give you an interim figure in six months' time.

Bob Doris (Glasgow) (SNP): Earlier in our discussions, the terms "appliances" and "products" have been used. That is understandable, but I am reminded that, although we are discussing surgical procedures, we are actually talking about women's bodies, which can be depersonalised during our conversations.

I take it that each independent healthcare provider has a list of all the women who have undergone surgery in their establishments. Have you written to every single woman?

Alison Smith: Yes.

Bob Doris: Have you offered any additional support services and invited them to come for a free consultation to discuss their options?

Alison Smith: Yes.

Bob Doris: What has uptake been like?

The Convener: The questions were a bit rapid. There was nodding of heads, but for the record, could you answer the questions about how you have written to people, and so on?

Alison Smith: Yes. Every woman has been contacted by SIHA and offered a free consultation. If a woman has been scanned and it has been found that there is a problem, or even if it has been found that the prosthesis is intact but she wishes, for peace of mind, to go forward with removal, she will have a consultation with the operating surgeon, who will explain to her the risk that is involved in surgery. She will then be allowed to have the prosthesis removed and have reaugmentation or, if she chooses not to be reaugmented—perhaps because of the scare—a procedure called mastopexy will be offered, which takes the remaining breast tissue and shapes it into a reaugmented breast shape that is acceptable to the woman.

Bob Doris: I thank the convener. That was helpful, as it has put more detail on the record. When I started asking my questions, I saw lots of nodding heads. Do Ms Smith's remarks reflect the experience of the other witnesses? Do they have the same approach to patient care?

Miriam Watts: Spire Healthcare has written to all its patients and offered them a consultation. There is just one slight difference in our approach; women are offered a scan, but if they have already decided that they wish to have surgery, a scan will not change that. If they are undecided about surgery, we will scan them. If the breast implants are intact and they choose not to go forward with surgery, they will be scanned every two years to ensure that there is no deterioration of the implants. We are finding that, in most cases, patients are opting for surgery.

Bob Doris: I will come back to that in a moment. Does Mr High have anything to add?

Bruce High: Nuffield is taking the same approach. We have written to all the women and offered them a free consultation, free surgery and free reaugmentation, if that is what they decide to go for. We have done 25 PIP implants over the years and the uptake rate for our offer has been about 50 per cent—that is the percentage of women that have come in and taken up the offer of a free out-patient consultation and free surgery. All those who have come in for an out-patient consultation have gone on to have removal and reaugmentation.

Bob Doris: I want to—

I am sorry, Ms Smith—I do not want to cut you off. Did you want to add something?

Alison Smith: I was going to say that, although we have discussed the matter in terms of products and procedures, as you said, there have been some highly emotive phone calls and visits to the hospital by women, and I assure the committee that they have been dealt with very sensitively. The staff have put a great deal of time and effort into assuring the women that we will manage their outcome as they wish. There has been a great deal of dialogue and a lot of time has been spent on the issue.

Bob Doris: That raises two further questions. It was mentioned that 50 per cent of the women who have engaged with private healthcare clinics have opted for surgery. Obviously I know far more about men's health than I do about women's health, and

I am well aware that men tend to hide away from potential health issues. Might a number of women who get the letter not respond because they are living in fear and simply do not want to deal with the situation? What percentage of women have not responded? That is what I am more concerned about.

Miriam Watts: Women who choose to undergo cosmetic procedures have taken a long time to think about the matter before they have even their primary surgery, so I do not think that we are dealing with a group of women who would shy away from dealing with problems about their bodies, especially if they thought that they might be at risk of suffering adverse effects on their health in the future. I cannot put a figure on it, but I think that when all this has passed and the figures have settled down we will see that we have had very high—indeed, almost 100 per cent—uptake.

Bob Doris: Is it reasonable for me to ask the independent healthcare providers to write again to women who have not responded to the original contact and to follow that up with a telephone call? We might be talking about a minority, but some women might well not want to face a potential healthcare issue and I want to ensure that everyone is engaging—with their general practitioners as well as yourselves. Might you take that suggestion on board?

Miriam Watts: We have to bear it in mind that many of these women had surgery a number of years ago and might have moved on. One of our principles is the need to protect confidentiality, so phoning up various addresses is not deemed to be the correct approach.

There has been enough media exposure and family interest to prompt people who have not received a letter from us to get in touch. For instance, one lady is travelling the world on a gap year; her sister got in touch with her and she has since been in e-mail contact with me. People's families are finding ways of contacting them and, given the huge media interest, it is unlikely that people do not know that there is a potential problem.

Alison Smith: I echo Miriam Watts's comments. Six or seven years have passed, so we might, if we try to contact a woman at a certain address, find that she is no longer there.

Furthermore, it is not unusual for women who undergo the procedure not to share that information with their families. We have great experience with confidentiality in aesthetic procedures; we need to be sensitive to how that plays in.

Bruce High: I, too, echo those comments. Nuffield is writing to the affected women twice, but that is really as far as we can take it. Given the confidentiality element that Alison Smith highlighted, we simply cannot telephone or hound them.

Bob Doris: It might be useful if, after this meeting, the committee could get some statistics on the number of women who have responded to the letters.

My final question links to Richard Lyle's question about a procedure that might have been carried out by BMI Healthcare or at a BMI Healthcare establishment as host hospital, but which has come through a third-party provider. Does that process in any way dilute your responsibility to these females?

Alison Smith: You might or might not be aware of this, but at the moment the two BMI hospitals where PIP implants were used were formerly Abbey hospitals and became part of BMI Healthcare only in the past year to 18 months. The procedures at BMI Kings Park and BMI Carrick Glen were carried out by Transform Medical Group as third-party provider using those facilities, and Transform has invited the women involved to phone it back and is managing them itself. The patients who are going back to Transform to have their PIP implants removed are being processed through a number of hospitals, but Transform has asked the women to contact it in the first instance and not BMI or the Abbey hospital, where the original procedure was undertaken.

10:00

Bob Doris: You are an expert on the matter; we are just MSPs asking questions. Is it reasonable for members of the public and MSPs to expect that, if a female presents to you as having had surgery in your institution, the first thing that you should do is go through exactly the same process as you would with every other female irrespective of how she came to present at your healthcare establishment? Would it be reasonable to expect that you not debate with her portions of the cost but carry out the procedures if they are clinically appropriate, and discuss with Transform who will pick up the bill? Would it be reasonable to assume that she will not be involved in any of those financial discussions?

Alison Smith: I assure you that that has happened. There has been a great deal of discussion between the chief executives of both companies to ensure that we manage sensitively the women who come through the door.

Bob Doris: Will you assure the committee that, if a woman who is distressed and wants her implants removed gets in contact with a BMI hospital, you will act first, carry out the procedures whether or not she wants a replacement and worry later about who will pick up the bill? Will you

assure the committee that you will put her health and mental wellbeing first and that she will not have to worry about the price?

Alison Smith: As the executive director of BMI Carrick Glen, I must say to you that that is not the instruction that my chief executive has given me, so I am not in a position to give you that assurance at this moment. However, after the meeting, I can take that concern back to my chief executive and ask for a response from London.

Bob Doris: I appreciate that. I find it worrying and concerning that you have not had such instructions. I am sure that you will take the committee's views back to your chief executive.

Alison Smith: Yes, I will.

Bob Doris: I hope for speedy reflection on the matter and a change of policy.

Jackson Carlaw (West Scotland) (Con): That is Mr Doris's view—not the view of the committee.

Alison Smith referred to scans. Will you clarify for me technically what you mean by a scan?

Alison Smith: The scan could be an ultrasound scan or a magnetic resonance imaging scan, depending what modality it is felt would give the most information judging from the presenting condition of the woman when she comes to consultation. It is more likely to be an ultrasound scan, which would determine whether the skin of the implant had ruptured and the silicone had leaked into the breast.

Dr Richard Simpson (Mid Scotland and Fife) (Lab): The most important thing we have heard this morning is that any woman who desires to have implants changed will be able to do so after the risks of the new operation have been explained to her and that, at that point, she will get a scan. I do not know whether Alison Smith was suggesting that an MRI scan would be done routinely, but MRI is not without concerns.

Is Transform's policy the same as the policy of the three witnesses—that anyone who desires the operation, even for peace of mind, and not only because there is a rupture, will get it? That is welcome, but is Transform following the same procedures? Some press reports have suggested that some of the English providers are saying that the procedure will be carried out only if it is clinically necessary.

Alison Smith: I have spoken to Pat Dunion, the operations director of Transform, who said that Transform is offering free scans and removal to any woman with PIP implants who comes to it. If the woman chooses to be reaugmented, Transform will levy a charge of £2,500, but there is a free consultation, scan and removal.

Dr Simpson: That is quite different from the procedures that the three of you and all other groups in Scotland are following. Is there any other hospital in the Scottish Independent Hospital Association that is not represented here today?

Alison Smith: No: we are the three providers.

Dr Simpson: The Scottish end has got its act together and it is clear that Transform is still a problem. It is clearly of importance that the committee note that.

This brief investigation aims to support the women who have been affected. I am concerned that a clinician's report from 2006 indicated a higher level of rupture—the convener started to mention it—which was reported to the MHRA, but it appears that it took no action. When you are putting in a new device, whether devices such as we are considering or metal hip replacements, for example—there are now problems with the metal-on-metal hip replacements and iron ionisation in people's bodies; I think that that will be the next big problem that we have to deal with—are you required to report from the point at which you take up the newly approved device? I understand that PIP was approved in Germany, although it is a French product, which is quite interesting. Because it was approved in Germany, anyone in Europe can use it. Are you required to report to the German authority on any adverse effects of the device?

Alison Smith: We report to the MHRA and Healthcare Improvement Scotland on problems with any device that we use.

Dr Simpson: That takes us to the next question. Did any of you report to Healthcare Improvement Scotland at any point?

Alison Smith: Do you mean with regard to PIP?

Dr Simpson: Yes. Once the clinician at—I think—Spire had decided in 2006 that the rupture levels were higher than he would have expected, and had made a personal decision not to continue to use PIP because of that and had reported that to MHRA, was that also reported to Healthcare Improvement Scotland?

Alison Smith: No, it was not reported: at that time, it would have been reported to the Scottish Commission for the Regulation of Care. The MHRA report said that there were no concerns, so there was no suggestion that the matter should be reported to the care commission. If the report had expressed concerns, that would have been raised immediately.

Dr Simpson: The report was thought to be eccentric or out of line with the other findings.

Alison Smith: Yes.

Dr Simpson: Do any of you know whether Healthcare Improvement Scotland received any other reports about concerns regarding PIP?

Miriam Watts: Nothing has been raised with us at hospital level by HIS.

Dr Simpson: I take it that none of you was informed of the change between the original registration in the 1990s and the beginning of the previous decade, when the grade of silicone was changed from clinical grade to industrial grade. You are all shaking your heads. None of you was informed.

I do not know the chemical details, but what is the difference between the clinical medical grade and the industrial grade?

Alison Smith: I am sorry, but I am afraid that I cannot talk about the science of that.

Dr Simpson: I know that we will get national reports on that, so I will leave my questioning there.

The Convener: How many scans have taken place?

Alison Smith: I know that SIHA had six patients to whom we gave PIP implants. All six have come forward and are seeking to change the implant. There are still two consultant examinations to happen and, of the four consultations that have taken place, only one patient required to be scanned at the consultant's request.

Miriam Watts: I cannot right now give members the figures for Spire Healthcare, but I will be happy to share them with the committee once I have returned to the hospital. I can say that, since the start of the year, we have done around 130 operations, and that so far 460 women have either had, or are booked in for, consultations.

Bruce High: Nuffield has done 11 ultrasound scans, and 11 women went on to removal and re-augmentation.

The Convener: It would be useful to have an understanding of that and to have information that is similar to the information from down south.

Jim Eadie (Edinburgh Southern) (SNP): I would like to return briefly, if I may, to the issue that my colleagues Richard Lyle and Bob Doris raised, about women who had PIP implants inserted in a BMI hospital that were paid for through a third party, or for which surgery took place in another provider's hospital. For the sake of completeness and in the interests of full transparency, will you tell the committee the number of women in that category? How many have had PIP implants removed and replaced? Finally, will you confirm that the figure that you gave earlier is the figure for removing and replacing implants at a discounted price?

Alison Smith: In the 18 months from 2004 to halfway through 2005 that Transform used PIP, 469 patients received the implants.

Jim Eadie: That is helpful. My second question was about how many women have had the implants removed and replaced.

Alison Smith: I cannot give you an accurate figure for that. However, I can say that at the moment Transform is using BMI Ross Hall and Kings Park hospitals to carry out those procedures, and is doing regular lists of patients. I could ask for the total number of procedures that have been completed or are booked, and provide that information to the committee, but I know that Transform is seeing every woman who has come forward, and that it is acting on their wishes.

Jim Eadie: I am sure that the committee will welcome that additional information.

Finally, is the figure that you gave earlier the one for procedures that have been undertaken at a discounted price?

Alison Smith: Yes. For women who want to be deaugmented, Transform will make no charge for a scan and removal of the implant. If women want to be reaugmented, it will levy a £2,500 charge.

Jim Eadie: I am sure that you will agree that the public needs to have confidence in the regulatory process and that patient safety must be paramount at all times. In that regard, are you satisfied by the terms of reference of both the review by the UK Department of Health and the investigation by the European Scientific Committee on Emerging and Newly Identified Health Risks into the potential health impacts of faulty PIP implants?

Alison Smith: Yes. I have read the papers associated with last week's committee meeting and think that both investigations seem to be taking into account all the concerns that have been identified to date.

Miriam Watts: It is also worth noting that Spire Healthcare—and, I assume, all the other healthcare providers—is regularly communicating with the MHRA on how to proceed. With all the new evidence that is emerging, things are changing, sometimes daily.

Jim Eadie: Has the SIHA made any representations to the MHRA on the terms of reference of the inquiries?

Alison Smith: Meetings have been happening in London with the Department of Health. Because we are all part of a larger hospital group with head offices in England, we have been represented at all of them.

Drew Smith (Glasgow) (Lab): Do the private clinics in Scotland have sufficient capacity to carry

out procedures for everyone whose primary operation was undertaken at those facilities? What is the waiting time for the procedure? After all, I guess that your business plan did not necessarily take into account the need to carry out these operations.

Alison Smith: We have sufficient capacity, and we expect that the procedures will be undertaken within 12 months. That said, we have to be cognisant of the desires of some of the women involved, who cannot always take time out for surgery. We have to be sympathetic in accommodating people's plans; nevertheless, we expect all procedures to be done within a year to 16 months.

Miriam Watts: We also need to bear in mind that a large number of the consultants work in the NHS. We are co-operating with their job plans to ensure that this work does not impact on the day-to-day operation of their NHS lists and are working with them to provide additional operating time—outwith the normal working week, where necessary.

Drew Smith: You might not have this information with you, but can you tell us the average length of time for undertaking these procedures? I completely take the point that you might have to wait in order to fit around an individual's plans but we would like some idea that it is not taking that length of time to carry out the procedure in every case.

Alison Smith: As an example, one of our ladies was booked in for surgery last Saturday but phoned us two days before the procedure to say that she had just found out that she was pregnant. Obviously, as far as the timeframe is concerned, that patient will be an outlier; she will re-present in 18 months or two years, when we will honour our commitment. We try to manage the situation quickly from consultation when the lady has decided what she wants. The procedures are planned within a fairly limited timeframe after that.

10:15

Drew Smith: When people present to you for consultation, what conditions do you impose should they choose to undergo a procedure?

Alison Smith: None.

Miriam Watts: None.

Drew Smith: Would those people therefore have full recourse to seek compensation at a later stage?

Alison Smith: Yes, they would have the right to do that.

Drew Smith: Do you believe that that is the case for all the independent providers in Scotland?

Alison Smith: Yes.

The Convener: Have I got any other bids? I will return to Richard Lyle, but I am trying to show courtesy to Jackie Baillie. I am trying to establish whether all committee members have had the opportunity to ask a question. Are you content, Jackson?

Jackson Carlaw: I am content that my questions have been asked by colleagues.

The Convener: I invite Jackie Baillie to ask a question, after which I will return for second bids from committee members.

Jackie Baillie (Dumbarton) (Lab): Thank you very much, convener. I am grateful to the committee for allowing me to ask questions.

Before I ask questions, I want clarification on a couple of points, because I am slightly uncertain of the response that you gave. You spoke about there being only 1,300 cases in Scotland; however, a number of the private clinics—including those of the Hospital Group—have their surgeries down south. Have you included in the 1,300 all the women who travelled south for their surgery?

Miriam Watts: I am sorry, but we are not privy to the figures for those healthcare providers.

Jackie Baillie: The number could therefore be more significant, because a number of women have said that they travelled south for the surgery. It is useful to put that on the record.

Miriam Watts: We have no sight, either, of the figures for women who travelled abroad for surgery.

Alison Smith: Transform has submitted the figure of 469 as the number of patients who were operated on in Scotland. At that time, there was an agreement between Transform and Abbey Hospitals that Scottish patients who were seeking aesthetic procedures within Scotland would be operated on in Scotland. As far as I am aware, Transform worked to that principle. Therefore, only if there had been no capacity in Scotland or if a woman wanted her procedure on a specific date would she have gone to one of the facilities in England. I am fairly confident, however, that a Scottish woman seeking an aesthetic procedure would have been treated in Scotland.

Jackie Baillie: I wish to pursue something that Ms Watts said. You spoke about women being given an active choice. Is that a choice between implant A, implant B and implant C or is that a choice that the consultant makes?

Miriam Watts: The choice is made by the consultant and the patient together. There are an awful lot of different implants. For instance, we have anatomical shapes such as the teardrop for

women who want a more natural shape. PIP manufactured only what we call round implants—the classic breast augmentation shape—rather than more natural ones. People would have had that choice.

I do not think that any of our hospital groups has stipulated at any point what implant a woman must have. It is also important to state that no extra charge would have been made had they chosen a different implant. PIP implants were not chosen on the basis of price: it is important to recognise that that was a clinical choice, not a choice of price. There was never a differential in price levy for these patients.

Jackie Baillie: It is helpful to get that on the record. I am drawing from what you have said that the choice was more about shape than about safety or other considerations.

Miriam Watts: The round implants were used predominantly during that timeframe.

Alison Smith: When women consider the procedure, each hospital offers a range of shapes, sizes and manufacturers, as the implants can all feel quite different. It is a very personal choice.

Jackie Baillie: I move to my substantive question, which I will put to all three of the witnesses. How are you regulated?

Alison Smith: We are regulated by Healthcare Improvement Scotland. Before that, we were regulated by the care commission. We have been regulated by HIS since 1 April 2011.

Jackie Baillie: What does that entail?

Alison Smith: It entails our submitting an annual return, which captures governance issues, including all the data that would be collated by an NHS hospital, such as the number of patients that we manage and all our adverse incidents, whether returns to theatre or transfers out. It also takes cognisance of all our inspections, whether by the Health and Safety Executive, the fire department—in our case, Strathclyde Fire and Rescue—and environmental health. It captures all the regulatory data.

We do a further return that asks questions about our environment, which is a much more dialogue-driven return as opposed to one that is driven by statistics. That describes how we collate patient feedback and how we manage that feedback when patients have identified an aspect of our service that they feel we could change. It addresses how we have taken on board what users of the service have identified and how we have modified the service in response.

Jackie Baillie: I want to tease that out. I am interested not in what Strathclyde Fire and Rescue thinks about your fire arrangements or what environmental health might think about your kitchens, but in whether, beyond the issue of satisfaction, there are inspections of the professional service that you provide.

Alison Smith: Yes, there are. There are announced and unannounced inspections.

Jackie Baillie: How frequent are they? When were you last inspected?

Miriam Watts: Spire Murrayfield hospital was last inspected in December 2011. We are subject to an announced inspection at least every two years, and we can have unannounced inspections at any point.

As Alison Smith explained, we complete an annual return. In addition, prior to an announced inspection, we complete what we call a self-assessment, which is highly patient focused and which covers issues such as how we manage our staff, how we interact and our infection rates. When HIS comes in to do an unannounced inspection, the inspectors have the right to look at anything in the hospital. As part of their visit, they interview patients to get feedback on their care and they look at our infection rates. Our surgical site infections have to be logged centrally. That is similar to what is required in the NHS. We are not shown any leniency because we are not NHS hospitals. We are regulated, and the reports on us are published on the HIS website. The report on Spire Murrayfield hospital is the most recent report to have been published—that happened two weeks ago. You will find it on the HIS home page. We are heavily inspected, and we do a lot of self-regulation.

Jackie Baillie: I invite the other two witnesses to say when their institutions were last inspected.

Bruce High: I think that November 2010 was the last time that we were inspected, which was 16 months ago.

Alison Smith: We were last inspected in March 2011.

Jackie Baillie: My final question is whether you carry insurance to cover such eventualities.

The Convener: There was an affirmative nod—it was a yes from all three witnesses.

Richard Lyle: My earlier questions were about the cost. It is not just one member of the committee who is concerned about the cost—several members are. I note that Alison Smith said that she would go back to her chief executive. I hope that she will mention what the committee has said.

I note that Transform is to do free consultations, free scans and free removals. However, if someone needs reaugmentation after removal, surely that, too, should be done at no cost

because, depending on the size that a lady wanted, she will have to go down to a smaller size, so she will automatically need reaugmentation. That should be borne in mind.

The silicone that was used was changed to industrial silicone without anyone's knowledge. I hope that the person responsible gets his full comeuppance, the jail or whatever. Will tests be done in the future on any products that come into your hospitals to ensure that they are what they should be? Do you have any suggestions for further action on the matter that no one else has raised?

Alison Smith: The independent hospitals would be in exactly the same position as the NHS with regard to further testing, in that we must have faith in the regulatory bodies as set up by the Government. None of us had a heads-up about a product that had received the CE mark, which was upheld in this country as an accreditation mark of a safe product. We had no reason not to believe that the product was fit for purpose and safe. None of the hospital groups could set up independent testing centres. We and the NHS are reliant on the national regulatory body for providing us with reassurances.

Richard Lyle: Can any of you suggest any further action that has not been suggested by the newspapers, politicians or the ladies themselves? Given your medical experience, do you think that there is anything more that we should do to get through this terrible situation?

Miriam Watts: I suggest going forward with something that has been raised several times, but which is also worth noting here: we need to look at having a national implant registry as a matter of urgency in order to alleviate fears. I think that it has been proven that the regulation of products by the CE mark means only that products were good on the day when they were inspected. We do not know what companies do outwith that.

From the Scottish Government's point of view, if we had had a national registry that we could have pulled together at a moment's notice when the health scare became public, that would have alleviated the fears of a lot of women in the first instance.

Alison Smith: I think that the benefit of such a suggestion can be seen in the situation with metal-on-metal hip replacements, to which Dr Simpson referred. The Scottish arthroplasty project collates robust evidence from both independent and NHS providers on all joint replacements; when a problem is identified with MOM replacements, robust information can be collated quickly from a reliable source.

Bruce High: Nuffield as a group has written to Lord Howe, Parliamentary Under Secretary of State for Quality, and Professor Sir Bruce Keogh, the NHS medical director, suggesting a 12-point cosmetic safety plan. That is a considered document with 12 proposed safety points, which I can let you have, too, if you would like.

Richard Lyle: I would certainly welcome seeing the plan, through the convener. Who would set up a national registry, who would run it and who would pay for it?

Miriam Watts: The Scottish arthroplasty project, for example, is funded from the Scottish purse to look at the issue. It consists of a committee, on which I sit as a representative of the Scottish Independent Hospitals Association, and is run in conjunction with the Information Services Division team at the Gyle. The project undertakes statistical analysis and looks at outcomes. It also allows us to look at outliers for complication rates.

To answer Mr Lyle's question, I suggest that a first port of call would be to look at the process that the Scottish arthroplasty project went through.

Alison Smith: There is another model. The English joint registry is funded by a £25 levy by the manufacturer on each joint prosthesis that is sold. A levy for each implant that is bought could fund a national register. That would work; that model is sitting in the environment at present.

The Convener: That is interesting. Thank you. Adam Ingram has the final question.

10:30

Adam Ingram: There have been some media reports that women are not receiving from other private providers the level of support that you have provided to your clients and patients. Why might those private providers not be providing such support? What steps do you take to police your own sector, as it were? Are you aware of providers of that ilk?

Alison Smith: As I said, I spoke to Transform's operations director. It has received 25,000 phone calls in the past four weeks. We managed 96 Transform patients in the period of the PIP implants. We have an electronic record of all those patients, including all the data regarding the implant, the batch number and so on, so Transform refers the patients on to us and we can give that information to the women over the telephone.

It is interesting to note that, at the point of discharge, every woman who has an implant fitted is given a little card with all her implant details on it. The patients would therefore have known whether they had a PIP implant. A lot of the phone calls were from people who were asking what kind of implant they had, because they had not retained

the information that they were given at the point of discharge.

If Transform cannot manage the volume of calls, we are happy to take up the call and provide the information, as we have it all stored on file.

Adam Ingram: Would anyone else like to comment on reports of women not being supported?

Miriam Watts: I cannot comment. We have never used any third-party providers. I can say only that Spire Healthcare has offered full support to its patients. Our feedback is that the patients have been quite appreciative of the level of support that we have given them.

Adam Ingram: Are you aware of any providers that have gone out of business and have not passed on information on patients to other providers in the sector?

Miriam Watts: No. Two of our consultants have retired, but the patients are being treated by other consultants. All their medical notes have been handed over. I cannot comment outwith our area.

Adam Ingram: Are you satisfied, as far as Scotland is concerned, that any woman who requires support of the nature that we have discussed is having that support made available to her?

Miriam Watts: I think that the three providers represented on the panel today are doing all that we can to provide support, but I am not in a position to comment for providers of which I have no knowledge, other than from press reports.

Adam Ingram: I am a little bit disappointed about that. Are you aware of other private providers in Scotland that have provided this form of procedure?

Miriam Watts: No, I am not.

Adam Ingram: Would anyone else care to comment?

Alison Smith: I commented on Transform, which had 469 cases, and described how it is managing them. One of the other third-party providers is the Harley Medical Group, which has not used any PIP implants, so the issue does not concern it.

Bruce High: We have seen both Surgicare and Transform patients through the Nuffield hospital. We have treated them as we would any other Nuffield patient, so we have given them all the support that would be due to a Nuffield patient.

The Convener: I thank the witnesses for the evidence that they have provided, which is appreciated by the committee. I suspend the meeting while the witnesses change over.

10:33

Meeting suspended.

10:36

On resuming—

The Convener: I welcome to the meeting our second panel of witnesses: Nicola Sturgeon, the Cabinet Secretary for Health, Wellbeing and Cities Strategy; Sir Harry Burns, chief medical officer; Dr Sara Davies, consultant in public health medicine; and James White, policy officer with the Scottish Government. I invite the cabinet secretary to make a short opening statement.

The Deputy First Minister and Cabinet Secretary for Health, Wellbeing and Cities Strategy (Nicola Sturgeon): Thank you, convener. I will keep my remarks fairly brief because I know that committee members want to ask about a number of points.

The most appropriate opening remark that I can make is that the Government takes this issue very seriously. We—indeed, everyone—can understand and appreciate the stress and anxiety that has been caused to women because of the recent news about PIP implants. Last week, I met a group of women to discuss the matter and some of them are listening to the evidence today.

Committee members might already be aware of this, but I point out that through a rigorous checking procedure we have been able to establish that no patients in Scotland were given PIP implants on the NHS. The Scottish Government cannot be definitive about the number of patients who have received PIP implants from private providers, but the committee has already had a very helpful discussion of the independent healthcare sector's estimates. In our initial estimate, we took a pro rata share of figures that had been used for the UK to get the best estimate that we could; indeed, we almost deliberately pitched that at the higher end to ensure that we did not inadvertently underestimate the numbers. However, the information that we have received from the independent healthcare sector and which you have discussed this morning suggests that the actual number of women involved might be significantly lower than our initial estimate of between 2,500 and 4,000. The figure that has been cited is in the region of 1,300, the vast majority of which were treated by Spire Healthcare and Transform.

Very early on, we clearly set out our expectations of private providers and you have heard this morning how some of those providers have gone about meeting those obligations. We also said that if a patient was unable to get the level of service that we would have expected from the private provider because the provider did not

exist, could not be contacted or was unwilling to provide that service, the NHS would step in and provide consultations, carry out scans where appropriate and remove implants. The NHS will not routinely replace implants, although it will do so if there is a clinical requirement. Members will appreciate that the reason that the NHS does not routinely carry out replacement surgery is that it does not carry out purely cosmetic surgery. Therefore, any decisions on replacement would be driven by clinical considerations.

We have some information on the number of women who have been referred to the four NHS plastic surgery centres in Scotland. At this stage, the numbers are very small: we know of 23 women who have been referred and one case of surgery that has been carried out. Members may want to come back to that later, and I will talk about it in as much detail as I have.

The chief medical officer wrote to the NHS on 10 January and intends to write again to the service and GPs over the next period to reinforce the guidance that he has given.

Medical devices regulation is a reserved matter, as members are aware; it is not devolved to this Parliament. However, the Scottish Government played its part in the expert group work and, as a follow-up to that work, two further reviews are under way, as members will be aware. One—conducted by Lord Howe—looks back at the actions that the MHRA took in light of the information that was available. That review is expected to report by round about the end of March this year.

The second review, which is being undertaken by Professor Sir Bruce Keogh, is looking ahead at what arrangements it may be appropriate to put in place to regulate and govern cosmetic surgery in the future. That review will take longer. It has been estimated that it will take round about one year.

Although the matters are, by and large, reserved, the Scottish Government is playing as full a part as it can in those reviews, as members would expect.

That is a brief overview of where things stand, the Scottish Government's actions to date and what we consider to be the national health service's responsibility. I expect the NHS to be there for women who need support and advice but, as I have said repeatedly, I also expect the private healthcare providers to carry out their responsibilities. We heard some helpful information this morning about how private providers are meeting those responsibilities.

I and my colleagues are more than happy to answer members' questions.

The Convener: I thank the cabinet secretary for those opening remarks. We move to questions.

Dr Simpson: We have heard that PIP implants were not used in the NHS. Was that by chance or a specific decision? Were there concerns about them? How did that happen?

Nicola Sturgeon: As far as I can tell, it was more chance than anything else. Obviously, it is for individual health boards that might carry out the procedure to decide what implants to procure, but I can certainly say that it was not as a result of any guidance or instruction given to health boards.

Dr Simpson: From the evidence that we heard this morning, there seem to be two groups of patients in Scotland. The first is those to whom the providers from whom we took evidence are providing a full service on the basis of the patients' desire rather than specifically on clinical need, although they have, of course, discussed with every patient the risks and benefits of proceeding beyond removal to replacement. We have heard a clear position from the purely Scottish providers.

There is also a substantial group of patients who are related to Transform, directly or indirectly, for whom removal and reaugmentation appears to be based not purely on desire but, at least for the last stage, on need. Have you, or has your department, had any discussions with Transform about why it is adopting a different line from that which the providers from whom we took evidence are adopting? I cannot speak for the committee, but I think that it would feel that the actions that those providers have taken are good.

10:45

Nicola Sturgeon: My officials met Transform and I will be happy to ask Dr Davies to say a word or two about that in a moment.

We outlined, as did the Department of Health in England, the level of service that the NHS would provide for patients who had received PIP implants on the national health service. As it turned out, that did not apply to anybody in Scotland, but that level of service would have included replacement. The reason is that, if somebody received their initial implant on the national health service, it is likely to have been for clinical reasons, as opposed to just for cosmetic reasons. We said clearly that that is the level of service that we expect from private providers as well. The committee heard this morning from various representatives of private health care providers about the level of service that they are providing. Based on what I have heard and what I know, I can say that the majority of private providers are providing that level of service and meeting their obligations.

My responsibility is principally to ensure that the NHS is fulfilling its responsibility, and I have set out what I consider that responsibility to be. As I said, we know that very small numbers of women have been referred to the NHS as a result of concerns about breast implants. We will continue to update the information, so it is possible that the numbers will increase, but as of the 27th of this month, which was yesterday, the numbers are very small.

One issue that arose from my meeting with some women last week was their desire for the advice that we are giving the health service, and GPs in particular, to be reinforced in order to ensure that GPs' awareness of what is expected of them in these circumstances is as high as it can be. That is why we gave an undertaking, which Sir Harry Burns will fulfil over the coming days, to reissue and reinforce the guidance to GPs.

Sara, do you want to say anything about your discussions with Transform?

Dr Sara Davies (Scottish Government): We met Transform and heard its experiences to date. It explained to us that it has implanted about 5,000 women in the UK, including about 500, it assumes, in Scotland. It has taken 20,000 calls. It has employed a lot more staff to manage its medical records, its contacting of women and its scanning procedures, and it has developed guidance for those procedures. We listened to what it had to say and, as the cabinet secretary said, we encouraged it towards providing the best service that it can provide and towards meeting its obligations as we would expect.

Dr Simpson: It looks as if these women will be left with a different service because they will be charged £2,500. If any of them has a requirement for reaugmentation that is clinically led, be it related to physical need or psychological need, the NHS will pick that up, as I understand it.

Nicola Sturgeon: Yes. As Dr Simpson will understand probably better than many people, it is not for me, as a non-medically-qualified person, to assess clinical need, but clinical need can stem from physical or psychological requirements. I am clear that, where a woman has a clinical need for replacement of breast implants and we are clear that it is a clinical need, the NHS could step in.

Dr Simpson: Will you then bill Transform?

Nicola Sturgeon: That is not a decision that we have come to, because we are dealing with very small numbers at the moment, but in the current climate in particular, you can be sure that we will have an eye on the interests of the public purse.

Dr Simpson: Thank you.

Richard Lyle: Good morning, cabinet secretary. I welcome your comments on the matter. Right from the start, the Scottish Government has been behind women who have faced this situation.

We have heard excellent evidence this morning, but we also heard that charges will be made. I return to one of Richard Simpson's points. Transform will do free consultations, free scans and free removals, but if there is a removal and reaugmentation, it wants a non-profit fee of £2,500. What happened was no fault of Transform's, but it was also no fault of the women. Can we put pressure on providers to ensure that they look again at their charges?

Perhaps Sir Harry Burns can answer this question, but is it possible to test products coming into this country to ensure that they meet full medical standards? What further action should be taken on the matter? For example, at the end of the evidence session with the previous panel, there was an excellent suggestion about the establishment of a national register.

Nicola Sturgeon: I will hand over to Sir Harry Burns in a moment to talk about testing. I know that he will also want to comment on the proposal for a national register, but I, too, will comment briefly on that.

As far as charging is concerned, there are different circumstances at play. As I understand it, any charges made by certain private providers relate to cases in which a procedure was carried out in their hospital, but by a third-party provider. My view is that, in such circumstances, the third-party provider rather than the patient should pay the charge. The situation with Transform is slightly different and I think that I have made my views about that known. Based on experience to date and what we now know about private sector provider policies, I am happy for my officials and me to continue discussions with private sector providers to find out whether a case can be made for any of them to go further. Given the comments that have been made during the meeting, I am happy to take the matter away.

I am open-minded about the proposal for a national register. There was, to a lesser extent, a form of register in existence until about 2006; however, the Department of Health decided to discontinue it because of incompleteness. As a result of data protection, it was down to individual women to choose whether they wanted their details to be registered. It is not for me to comment on the rights and wrongs of the decision to discontinue—after all, I was not in office at the time.

I know that there are complications and complexities around it, but the case for looking at something like a national register in future is strong and I am sure that Sir Bruce Keogh's review will consider the proposal. We will certainly

be guided by any recommendations in that respect.

Sir Harry Burns (Scottish Government): As far as testing is concerned, medical devices are governed by European Union law. Under the EU registration process, a device that is approved by a recognised agency can be used across the whole EU. Because the UK is a member of the EU, MHRA decisions on such matters are reserved to the Westminster Government.

Legally, devices can be approved after being tested and having gone through an assurance process. Of course, as we have been told, when PIP implants were first registered and approved, they contained medical-grade silicone. However, that changed because a different process was used. Not only would it be legally difficult for us to stand up and say that on the basis of our testing we were not going to use a device that had been approved elsewhere in the EU—indeed, I think that such a move would be subject to legal challenge by the manufacturers—it would be technically difficult to do so, as it would mean setting up a very big and complex system to test all the different products that might come into Scotland. It would have to be a very unusual case for us to turn round and say that the process that the European regulatory authorities had gone through was not up to scratch. In this case, we would have tested PIP implants when they first came into Scotland but we would not have seen the undeclared change in the product that the manufacturers made and which I understand is the subject of significant legal action.

As for the register, I am very much inclined to support the idea that not just breast implants but the implanting of any foreign material should be recorded on patients' notes. However, given that a whole range of things—one thinks of stents, plates, pins, wires and so on—has been going into patients for decades without any problems being identified, we will have to give quite a lot of thought to where we draw the line.

Secondly, it is probably not sensible to put in place a register on our own. Statistically speaking, if we put in 100 implants and one or two of them failed, it would not mean anything. However, if we were monitoring 10,000 across the UK or Europe and 200 of them failed, that would tell us something. There is something about large population registers that is important.

With regard to how things are registered, there are issues around data collection. As the cabinet secretary said, the discontinuation of the register in 2006 was due to the fact that folk were not filling in the details and that there were data protection issues and so on.

At the moment, we have been talking about the need for every device to have a bar code with a number on it, which tells you its production number. That number can just be scanned into a machine and recorded. Your mobile phone can do that now. There must be technology that we can use to do that.

I would want to discuss with colleagues in England how we can get UK national registers of major joint prostheses and significant implants that we can follow up on. I am in favour of that approach, but the difficulties of implementing it are not trivial.

Drew Smith: I will follow up a couple of points that I made in the earlier session and give the cabinet secretary the opportunity to comment on them.

The previous panel was confident that there was sufficient capacity in the independent sector to deal with the problem that they are now facing of people coming back to them. One of the issues that was mentioned in that regard was that some of the consultants are shared. I want to give you an opportunity to say whether you are satisfied that there will not be an impact on the NHS, whether you believe that that capacity is there and to talk about the impact that there will be in terms of consultants and agency nurses as a result of the number of people coming forward.

Nicola Sturgeon: One of the reasons why we are collecting the data that I have mentioned already is to help in the process of giving reassurance that the NHS can provide a certain level of service, should it be required. Another reason is to enable us to assess capacity issues on an on-going basis and ensure that any consequences of the PIP situation will not have a knock-on effect on our other waiting times.

At the moment, given the very small numbers that I have cited today, there are no concerns about that. However, gathering that information on an on-going basis will enable us to be well positioned to deal with any issues that arise.

Drew Smith: The independent sector mentioned that a waiting period of a year to 16 months might be the case for some patients. Obviously, we all want the procedures to happen as soon as possible. Do you have any view about how quickly the operations should be happening?

Nicola Sturgeon: I can speak for the health service. Where procedures are required for the clinical reasons that I have been speaking about, we would expect them to be carried out within the guaranteed national waiting times.

Drew Smith: I asked the private sector witnesses whether, when someone presented to a consultant at the consultation stage and then went

on to have a procedure carried out, any conditionality was being applied that might affect their legal rights or rights to compensation. I believe that you indicated to some of the women who are affected that you would take a dim view of any conditionality and that the NHS would step in if conditions were being imposed. Would you be prepared to put that on the record?

11:00

Nicola Sturgeon: I will provide a bit of context first. I understand, from the information that I have seen, that most of the private providers are not imposing that kind of conditionality. The issue that I discussed in my meeting with the women last week concerned women being asked to sign particular legal waivers. As far as I am aware—I stress that it is only as far as I am aware—only one provider has made that suggestion.

As I said in the meeting that I had last week—I am happy to repeat this on the record—I do not expect private providers to attach unreasonable conditionality to legitimate treatment. Should any provider—we are talking to some extent hypothetically—do so and the conditionality was unreasonable, I would consider that to be tantamount to not offering the treatment in the first place and would therefore consider that to be a circumstance in which the NHS would provide the levels of service that I have spoken about.

The Convener: I was having a discussion with the clerks during your previous response. I might be displaying my ignorance, but can you clarify your response to Drew Smith's question about the 16-month wait, in particular your reference to the national waiting times?

Nicola Sturgeon: I am responsible for the NHS. I believe that the 16-month wait is something that a representative of a private provider mentioned. I was engaged in other business when the first evidence session took place, so I had only one ear on it, but I think that the representatives of the private providers are sitting behind me in the public gallery, so I am sure that they can correct what I say if it is wrong.

I think that they said that they thought that 16 months was the period that it would potentially take for them to treat all the women who might come forward. I might be wrong, but I did not understand them to be saying that 16 months would be a waiting time for an individual patient.

I cannot talk about waiting times for the private sector. I am responsible for health service waiting times. I digress, but I see from statistics published this morning that health service waiting times are doing rather well and I expect them to continue to do so.

As I say, I might be wrong, but I did not think that what I heard members of the previous panel say meant that there was a waiting time of 16 months for an individual patient.

The Convener: The committee might seek clarification and it might bear in mind the waiting time compared to NHS waiting times when it assesses the evidence that we have heard. I suppose that we will discuss the matter at some future date.

Bob Doris: I acknowledge the reassurances that the Scottish Government has given on the matter where possible. I also know that hindsight is a wonderful thing. I note Professor Sir Bruce Keogh's on-going review into the regulation and the reserved or European-wide nature of much of the regulation.

With hindsight, is it a bit odd that a private patient in Scotland can pay several thousand pounds for a breast implant and be told that in 10 years' time it might need to be replaced, without any assurances that they would be able to have that replacement in 10 years' time, because they do not know the financial situation that they will be in, and that no responsibility is placed on the private healthcare providers? That was the case before PIP became an issue. I know that hindsight is a wonderful thing, but is that not an odd situation in the regulation of any cosmetic surgery market?

Nicola Sturgeon: Some, although not all, of the points that you raise will be covered in one or both of the reviews that are under way, so I will not say anything to pre-empt what the outcomes of those might be.

I will hand over to Harry Burns shortly, because he is more qualified to speak about some of these issues than I am but, from a layperson's point of view, any implant that is implanted into somebody's body is bound to have a life cycle. We know that most implants have a life expectancy—if I can use that term—of around 10 years before they may require to be removed and replaced. I would expect that to be fully explained to a woman before she consents to a procedure and, in the case of private medicine, pays for it.

Sir Harry Burns: It is absolutely right that you cannot give any guarantees on the longevity of just about any surgical procedure. That applies to anything from implanted teeth to hip implants and so on. Some of those implants are made from, for example, titanium, which archaeologists will find when they dig us up thousands of years from now, because those implants are very long lasting. However, they are implanted into bone and tissue that itself can fail; therefore, 10 or 15 years down the line, we may find out that an operation has failed not because of a problem with the implant,

but because the supporting tissues have deteriorated in some way. In the case of a hip replacement, for example, the surrounding bone can shrink and become loose. We can never give guarantees around these things.

While we are on the subject, I will address the question of waiting times for operations. It is important to say that, when a breast implant has not ruptured and there is no evidence of the silicone having leaked out, there is no urgency to have the implant replaced—it is not an emergency procedure, but something that needs to be done after the woman has had the opportunity to think about it and consider the risks of the operation. Therefore, it is reasonable to take some time, unless there are psychological issues that mean that the woman wants it taken out as quickly as possible. That would clearly influence decisions.

Bob Doris: Those reassurances will be useful to people watching the activities of the committee. I will not push the point much further. I merely wanted to put on record that there must surely be a better way of doing this. I understand that no lifetime guarantee can be given for a foreign body that is in someone, but if 10 years is the natural lifespan of certain products, in 10 years' time there will be a clinical need to have them removed irrespective of the financial means of the patients who initially had the surgery done. I imagine that there would be significant mental health issues for patients if, in 10 years' time, their implants were removed and they were not able to have replacement products put in.

Mapping forward, can we get reassurances from the Scottish Government that such issues will be raised with the UK inquiry that is taking place, so that the matter can be better regulated? Many people have asked me about the issue in my day-to-day life, as there is a high degree of public interest in it. Can these ideas be put forward at a UK level to see whether we can do something constructive to ensure that the situation does not arise again?

Nicola Sturgeon: That is potentially the stuff of the second of the two inquiries that I spoke about. We play into those inquiries and I am happy to get officials to reflect those comments. I am sure that a number of issues arise. For me, the most important is the need, when any woman makes the decision to have cosmetic surgery, to have all the information and the risks properly explained at the time so that absolute informed consent is given.

Jim Eadie: I seek further clarification on the numbers. At the outset, you provided a useful clarification of the most recent position. How many women who are resident in Scotland may have received their PIP implants in other parts of the UK or abroad? What action can the Scottish Government take to establish how many women might be in either of those categories?

Nicola Sturgeon: I am unable to give you the answer to that. As I said earlier, the numbers that we were working with were estimates of the number of Scottish women in Scotland who had received PIP implants. We now have more detailed and probably more accurate information from private providers, but we do not have the records that you ask about. I do not know whether the private providers can give that information, but we do not have records of the number of Scottish women who have had surgery in England or in other countries. That may be a question that we need to ask, as it relates to the idea of a register that we talked about earlier and the need to ensure that we have much more reliable data in the future.

Jim Eadie: We have heard reference to the UK expert review group and the European scientific committee that are investigating PIP implants. This question might be more for Sir Harry Burns than for the cabinet secretary. What confidence does the Scottish Government have in the ability of the existing regulatory process to pick up such problems when they arise? What representation does the Scottish Government have on those reviews and what formal representations is it able to make to them?

Nicola Sturgeon: I will hand over to Harry Burns on that, but I will say a couple of sentences first. Those are the regulatory authorities with which we work. They are reserved or, as Harry Burns said earlier, European in terms of their governance. There is no doubt that PIP implants raise questions about the efficacy of the regulation involved that must fully explored and fully answered. It would be wrong for me, this side of Lord Howe's review reporting, to say that the answers to those questions necessarily lead us to say that there are deficiencies in the regulatory regimes. However, questions have certainly been raised, which is why the review is under way.

Sir Harry Burns: It is important to remember that the fundamental problem with the implants—the switch from medical-grade to industrial-grade silicone—would have automatically invalidated their approval if the regulatory agencies had been informed. Manufacturers have to play the game; they are legally required to do so. Legal proceedings are under way and I understand that the PIP company has gone into liquidation. We are reliant on people sticking to the rules. Thankfully, in 9,999 cases out of 10,000, that is what happens.

Jim Eadie: Does the fact that a provider was able to make that switch without being subject to approval point to a deficiency in the regulatory process?

Sir Harry Burns: The company was able to do it because it did not tell anyone. There is no reason to go back and retest products if people do not tell us that their manufacturing methods have changed. There is no question but that the due diligence that is done by organisations such as MHRA in relation to the underpinning science is very intensive. It is very difficult to get a drug or a device registered without clear, convincing evidence.

The type of incident that we are discussing will lead to further thought on how we deal with a rogue manufacturer. However, in the vast majority of cases, companies doing their best for their shareholders and for the patients they serve will obey the rules.

Nicola Sturgeon: Everything that Harry Burns said there is absolutely correct. What we had at the centre of this incident was a company that had changed the content of its implants without telling anybody. That said, one of the questions for the regulatory authorities is whether they were acting as would have been expected on any information that they were getting, if they were getting information from adverse reporting or from external sources. That is exactly what the first of the reviews that I spoke about is looking at.

Sir Harry Burns: When the question of rupture rates was raised in 2006, it was pursued with the licensing authority in Germany. The conclusion that was reached was that more ruptures were being reported because reporting systems had improved and more implants were being used. There was an investigation and reasons were given. If we had had a register, particularly a register across the whole of Europe, we would have had lots and lots of data with which to check the validity of the claims. That is why I would support moving in that direction.

An investigation was carried out in 2006 and, apparently explanations were provided.

Nicola Sturgeon: In short, to sum up our answers, there may well be questions for the regulatory authorities and the regulatory regime that is in place. If there are questions and deficiencies are identified, they have to be addressed. However, it is not necessarily the case that the regulatory regime has failed in this instance. It may just be that we are dealing with a rogue company. However, those are the questions for which we need answers.

Gil Paterson: Just to add to Jim Eadie's line of questioning, are straightforward medicines such as cough mixture quality checked by the regulatory authority before people are able to take them? In other words, if a manufacturer made a medicine and registered it, would it never be checked again?

11:15

Sir Harry Burns: Drug approval processes are extremely rigorous. When I was a surgeon, I did studies of new products, which were then used to approve drugs. The regulators go as far as coming to see your original records, and they expect to find crossings out. They look at the records in great detail, and if everything appears hunky-dory, they are suspicious. On the internet, people can buy drugs that are not registered and not approved by the regulatory authorities, but they do so at their own risk. People are advised always to use proprietary drugs prescribed by their GPs, or off-the-shelf medicines, such as cough mixture, which have a quality standard applied to them.

Gil Paterson: Are approved products that are prescribed checked every so often, or only at the time of manufacture?

Sir Harry Burns: On-going manufacturing is subject to continuing quality assurance by the company concerned.

Gil Paterson: But not by the regulator.

Sir Harry Burns: I do not think that the regulator regularly goes into factories to check products.

Nicola Sturgeon: I think that that is the case. Harry Burns has already said that the drug processes are extremely rigorous, but there are differences between the regulatory regimes for devices and for drugs. We could set out the different steps if that would help the committee.

Gil Paterson: This building is full of silicone—in the seals, and so on. It is an everyday product. I am involved in the motor industry and, even in that industry, there are enormous differences between the prices of products, because the chemicals in those products act differently. If the regulator has checked something and declared it fit to be put in the body but it then ends up with a chemical in it that is for an industrial process—

Nicola Sturgeon: That is what happened here.

Gil Paterson: Yes, and that looks to me like fraud. Is the procedure wrong? Rather than the manufacturer having to provide notification, should this not have been captured by a quality control check before the product reached the market?

Sir Harry Burns: If a company decides to change the composition of a drug, it has to go through the regulatory process again. It must inform the regulator, who checks whether the drug is doing what it used to do.

The Convener: It would be helpful if the cabinet secretary could offer us some of that information, to clarify the matter.

Jackie Baillie: There are very different regimes for the testing of drugs—which, as has been said, is more rigorous—and the testing of medical devices, and therein might lie some of the solutions.

Cabinet secretary, may I take you further into the regulation of services? From the previous witnesses, I understand that, since 1 April 2011, regulation of services provided by independent healthcare providers, hospices and clinics has been devolved to the Scottish Parliament through Healthcare Improvement Scotland, but my confusion and desire for clarification come from the cabinet secretary's answer to a parliamentary question that I lodged:

"The independent healthcare services regulated by HIS do not include private health clinics, so there is no requirement for them to register."—[*Official Report, Written Answers*, 7 February 2012; S4W-05218.]

Nicola Sturgeon: The power is devolved, but HIS does not yet inspect clinics; it only inspects hospitals. That is, as we speak, under consideration, and may change in the future.

Jackie Baillie: It is helpful to know that that is under consideration. We heard from the earlier witnesses about the nature of inspection at some of the hospitals. Do you see inspection as going beyond infection control issues, to governance, to whether insurance is required and to all the issues that clearly relate to where we are today?

Nicola Sturgeon: By and large, Healthcare Improvement Scotland would inspect a private hospital on the same basis that it would inspect an NHS hospital. However, it does not get into some of the regulatory issues that we have been discussing this morning with regard to the medical devices that are used in those hospitals.

Jackie Baillie: But I take it that, as with NHS hospitals, it will not necessarily get into the governance arrangements of private sector hospitals.

Nicola Sturgeon: It depends on what aspect of governance you are talking about. I am more than happy to set out the process in writing. HIS reports of private hospital inspections are published in the same way as reports on NHS hospitals and, although those reports are publicly available, we can certainly make some of them available to the committee. It might be most helpful in getting a sense of the scope of an HIS inspection.

Jackie Baillie: That would indeed be helpful.

There is quite a difference in what the providers are prepared to do. At their best, they are offering free scans, free removal and free reaugmentation. However, Transform and perhaps the Hospital Group and others are either levying charges or not being public about their position. Apart from Transform, how many private sector medical companies have you or your officials met since the scandal broke and what pressure has your office been able to apply?

Nicola Sturgeon: We have had direct discussions only with Transform. As the earlier evidence made clear, the majority of what we know to be privately provided implant procedures have been carried out by Spire and Transform.

We now know a lot more than we previously did not only about the numbers that are likely to come forward but about the position of private providers and I am certainly happy for my officials—and, if appropriate, for me—to have further discussions with those providers to find out whether aspects of the service that they are offering could or should be enhanced.

Jackie Baillie: I have a couple more questions, but I will be brief.

I understand that, in England, something like 3,500 women who had their implants inserted in private clinics have been referred to and subsequently treated by the NHS, and the Department of Health has said that it will bill the private clinics concerned for the work. I accept that the numbers affected in Scotland are smaller but, in the event that they rise, what process is open to the cabinet secretary to reclaim the money from private clinics?

Nicola Sturgeon: The same processes that are available to the Department of Health are open to us. However, the reason why I am not being definitive about what we might or might not do is that, right now, we are dealing with extremely small numbers. According to figures that I gave earlier, we have had to date one instance of surgery. We will have to make judgments about the efficacy of and value for money in seeking to recoup any money, and I will keep that judgment under review as we continue to look at the figures. If the figures were to increase dramatically, the balance of judgment might change.

Jackie Baillie: Does the cabinet secretary not agree that it might be instructive to, say, Transform or the Hospital Group if you were to make it clear that you would pursue costs? It might encourage them to follow the example of some of their Scottish colleagues and do this work for free.

Nicola Sturgeon: I will give further consideration to doing that in further discussions that we might have with a private provider such as Transform. I am not naive about some of the driving forces behind these decisions but, as I have said before, I think that private providers have a moral obligation as well as a pecuniary imperative. I would expect providers to meet those obligations and, from what I have heard this morning, I think that most of them are doing so.

Private companies carried out these operations and, although I absolutely take the point that they acted in good faith based on regulatory decisions, they still charged women for the work and I think that they have a moral obligation to do the right thing.

Jackie Baillie: The women themselves and their representatives have demanded a public inquiry—I know that the women whom the cabinet secretary met raised the issue. Will you talk about your reasons for considering their demand?

Nicola Sturgeon: I will say what I said to the women whom I met last week, and I will be as frank with you as I was with them. I am not in the business of falsely raising expectations or misleading people. I made two points. First, until we have Lord Howe's review, I will not come to a view about—because I will not know—whether any further process is required to answer questions that remain to be answered. When we get to that point, I, on behalf of Scottish interests, will consider whether questions remain to be answered, whether a further process might be required and what such a further process might be. I said to the women whom I met last week that I will consider their understandable request for a public inquiry at that stage and in that context.

It is vital that I am frank, open and up front with people. Regulation of medical devices and the issues that we are talking about are reserved matters—I am not trying to pass the buck to anyone when I say that; it is a statement of fact. My ability as Scottish health secretary would be to order a public inquiry into Scottish matters. I seriously struggle to see how a Scotland-only public inquiry could get anywhere near the issues and the answers that the women whom I spoke to understandably want. I will be as open and honest with the committee about that as I was with the women last week, as you would expect me to be; I will not sit here and mislead people or falsely raise expectations.

The Convener: Richard Simpson has a brief supplementary question.

Dr Simpson: It is very brief. Cabinet secretary, you said that the inspection regime in Scotland covers independent hospitals but not clinics. In our discussions about the reform of the regime and the transfer of responsibilities from the care commission to its successor body and HIS, I had understood that high street clinics that do refractive eye work, for example, would be inspected, as happens in England through the Care Quality Commission.

Nicola Sturgeon: The current position is not the definitive, end-of-the-line position; it is just that we have not yet brought such clinics into the inspection regime. As I said to Jackie Baillie, the issue is under consideration.

Dr Simpson: Significant procedures are now being done out in clinics. In the context of what happened with PIP, such procedures could have been done in clinics.

Sir Harry Burns: The clinic end of things is basically the out-patient consultation. If, for example, a consortium of doctors opens up a consulting room in a house somewhere, it is difficult for us to inspect the process. That very much out-patient part of the process is least likely to come into the regime soon. You are right to say that, where interventions are being carried out, a separate set of issues is raised that clearly needs to be considered.

Nicola Sturgeon: I agree with the thrust of Richard Simpson's question and take seriously the reasons why people think that clinics—even out-patient clinics—should fall within the ambit of regulation. The argument stands on its own. However, it is important to say that there is no suggestion—and no one who is here today is suggesting—that such regulation and inspection would have picked up the problem with PIP implants. It is important to have clarity on that.

Dr Simpson: I was anticipating the need for adequate regulation and control of interventions that are carried out in high street clinics, given that such interventions are becoming much more prevalent.

The Convener: Thank you for asking that very brief supplementary question, Richard—it was interesting. I thank the cabinet secretary and her colleagues for attending and giving evidence.

As we agreed, we will move into private session for item 3, which is consideration of our approach to the proposed social care (self-directed support) Scotland bill.

11:29

Meeting continued in private until 13:25.

Members who would like a printed copy of the *Official Report* to be forwarded to them should give notice to SPICe.

Available in e-format only. Printed Scottish Parliament documentation is published in Edinburgh by APS Group Scotland.

All documents are available on
the Scottish Parliament website at:

www.scottish.parliament.uk

For details of documents available to
order in hard copy format, please contact:
APS Scottish Parliament Publications on 0131 629 9941.

For information on the Scottish Parliament contact
Public Information on:

Telephone: 0131 348 5000
Textphone: 0800 092 7100
Email: sp.info@scottish.parliament.uk

e-format first available
ISBN 978-1-4061-8412-9

Revised e-format available
ISBN 978-1-4061-8423-5

Printed in Scotland by APS Group Scotland