COMMONWEALTH OF AUSTRALIA

Official Committee Hansard

HOUSE OF REPRESENTATIVES

STANDING COMMITTEE ON HEALTH AND AGEING

Reference: Health funding

WEDNESDAY, 6 JULY 2005

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HOUSE OF REPRESENTATIVES

STANDING COMMITTEE ON HEALTH AND AGEING

Wednesday, 6 July 2005

Members: Mr Somlyay *(Chair)*, Ms Hall *(Deputy Chair)*, Mr Cadman, Mrs Elliot, Mrs Elson, Mr Georganas, Mr Johnson, Ms King, Mr Turnbull and Mr Vasta

Members in attendance: Mr Cadman, Mrs Elson, Ms Hall, Mr Georganas, Mr Somlyay, Mr Turnbull and Mr Vasta

Terms of reference for the inquiry:

To inquire into and report on:

How the Commonwealth government can take a leading role in improving the efficient and effective delivery of highest-quality health care to all Australians.

The Committee shall have reference to the unique characteristics of the Australian health system, particularly its strong mix of public and private funding and service delivery.

The Committee shall give particular consideration to:

a) examining the roles and responsibilities of the different levels of government (including local government) for health and related services;

b) simplifying funding arrangements, and better defining roles and responsibilities, between the different levels of government, with a particular emphasis on hospitals;

c) considering how and whether accountability to the Australian community for the quality and delivery of public hospitals and medical services can be improved;

d) how best to ensure that a strong private health sector can be sustained into the future, based on positive relationships between private health funds, private and public hospitals, medical practitioners, other health professionals and agencies in various levels of government; and

e) while accepting the continuation of the Commonwealth commitment to the 30 per cent and Senior's Private Health Insurance Rebates, and Lifetime Health Cover, identify innovative ways to make private health insurance a still more attractive option to Australians who can afford to take some responsibility for their own health cover.

WITNESSES

Committee met at 9.39 am

POPE, Dr Adrianne Kristina, President, Fertility Society of Australia

CHANNON, Ms Susan, Chief Executive Officer, IVF Australia

PORTER, Dr Richard Norman, Director/Clinician, IVF Australia

CHAPMAN, Professor Michael, Chairman, IVF Directors Group

CHAIR (Mr Somlyay)—Welcome. Perhaps you could tell us a little about yourself, Professor Chapman.

Prof. Chapman—I am an IVF doctor and a clinical academic. I have been working as an academic now for 25 years and was a professor at London University. Originally Australian, I spent 15 years in London and learnt about infertility there, and I was there when Louise Brown, the first IVF baby, was born. I came back to Australia 11 years ago and, since then, have been involved in the area of infertility and IVF in Australia. Overall, I have been around for virtually the whole of the life of IVF and seen it grow from something that was, really, an experiment to what is now a clinical procedure available to couples to achieve their pregnancies.

In addition to my general clinical and academic activities, at the moment I am also Chairman of the IVF Directors Group. There are a large number of infertility clinics around Australia and each of those has a medical director. The medical directors get together on a regular basis to discuss issues ranging from regulation and the clinical management of cases through to how the industry or the profession is moving forward and is obviously therefore, in a sense, not the political arm of IVF but certainly the profession's arm in terms of discussing issues with other bodies such as the TGA, who we are in discussion with in relation to the culture medium that we use in our laboratories and the general regulation of our profession.

With all of those hats on, it is great to welcome you here to hopefully give you a little education into what IVF and infertility is about. I suppose the first point I want to make is that infertility is not IVF. When I sit upstairs in my rooms on the third floor in St George Private Hospital and see patients, only about a third of the patients who come and see me for infertility end up having IVF. So when we talk about infertility we are not just talking about IVF. But obviously IVF is the interest of the moment from a financial point of view for the government and the taxpayer. Mr Abbott seems keen on being involved in deciding what is clinically appropriate for our patients through the independent inquiry that he has set up, although I have never had any direct discussions with Mr Abbott about that particular committee or any issue related to this, which I have found somewhat unhelpful.

Mr TURNBULL—Who is on the committee?

Prof. Chapman—The committee is comprised of the chairman, who I think is Professor Ian Fraser, a reproductive endocrinologist who has not had direct involvement with IVF but obviously, as he sees women with endocrine problems, they can end up in the IVF arena; Professor Peter Illingworth, who is an IVF specialist working primarily in the public sector at Westmead, although he has just recently joined one of the private clinics; Bettina Arndt; and two

obstetricians, Dr Macgee, who is an obstetrician who has never been involved in IVF, and Dr Andrew Pesce, the AMA representative, who also has never done any IVF other than as a junior doctor. John Horvath is the chief medical officer. So that is the committee as it stands.

Mr TURNBULL—So you feel it is light on in terms of IVF expertise?

Prof. Chapman—Yes.

Ms HALL—Who is Bettina Arndt?

Prof. Chapman—She'd like you to say that! I do not know how to describe her, actually.

Mr TURNBULL—She is a journalist.

Ms HALL—Oh, a journalist! I was not thinking along those lines.

Prof. Chapman—I think she calls herself a sociologist.

Mrs ELSON—She often deals with issues to do with women.

Ms HALL—I was thinking of doctors.

Prof. Chapman—From the perspective of the profession, in choosing a consumer we would have suggested having a consumer who has been through the process. In selecting the committee, Mr Abbott obviously picked someone who had an interest in feminist issues and would present a woman's view rather than one who has been involved specifically in IVF. There is actually a very strong patient support group: ACCESS, headed by Sandra Dill. This group connects with its members better than any consumer group that I have seen in the medical arena. I think this group even does better than the cancer groups.

CHAIR—Where are they based?

Prof. Chapman—Sydney, but they are Australia wide.

CHAIR—We might meet with them.

Ms Channon—Sandra Dill was invited today but unfortunately she is overseas.

Prof. Chapman—She is recognised internationally as a consumer spokesperson. There is an international body now called iCSi, which will come up again later. She is a member of that group, which includes members from countries all around the world.

Mr CADMAN—What is the Fertility Society?

Prof. Chapman—We will explain to you the structure of the Fertility Society of Australia as we go along. It is the professional body involving everyone from nurses through to clinicians

and laboratory people. People who do not do IVF, such as andrologists and neurologists, are also involved in the Fertility Society.

Mr CADMAN—All professionals.

Prof. Chapman—All of the disciplines involved in fertility. Adrianne is the President of the Fertility Society of Australia, and she will be talking to us later. She is an embryologist. That group has been chaired in the past by doctors, embryologists and counsellors.

Dr Pope—We have had one counsellor.

Prof. Chapman—The other person that is going to be talking this morning is Ric Porter, one of my colleagues in IVF Australia, who is a clinician primarily doing IVF and also general obstetrics and gynaecology.

Let me start with the history of IVF. As I said, in 1979 the first baby from IVF was born with Steptoe and Edwards in the United Kingdom. At that time they were accused of fraud by some of their colleagues because no-one believed that you could create an embryo, put it into a woman's uterus and produce a child. Obviously, subsequent history has proven that they were absolutely right, and the 15 years of research that went into producing that first baby had come to fruition. Now there are millions of babies—it is said to be in the order of two million—around the world born through assisted reproductive technology.

Prior to IVF there were very few treatment options. In the late sixties, for women who did not make eggs, did not ovulate, there was a drug called Clomiphene, which we still use. That was a breakthrough. Prior to that there was nothing that could be done for infertile couples. A couple had to just accept their fertility and go away. Various gynaecological procedures were attempted but none of them did better than doing nothing, because underlying it all there is almost always a chance of conception. Australia was second on the scene. We delivered the second IVF baby in the world, Candice Reid, who was 25 last week. She came out of the Melbourne IVF group with Ian Johnston, who passed away a couple of years ago. She was fit and well when I spoke to her. She is working in London as a journalist and is writing the memoirs of Ian Johnston, which is interesting.

CHAIR—In going through this history, could you mention the funding? Was there any funding involved in this?

Prof. Chapman—Absolutely. That was our first pregnancy. Australia has had a whole range of firsts in the world—the first donor egg pregnancy, which was also in Melbourne, the first frozen embryo pregnancy, which was in Sydney, and the first multiple pregnancy, which is not so good. That is one that we perhaps would not want to take credit for, but it happened. We were also the first to start the process internationally. We were the first organisation to take up the notion of guidelines for the treatment and practice of IVF in the mid-eighties. We were also the first country in the world, at a state level, to introduce legislation protecting donor gamete pregnancies and ultimately managing the assisted reproductive technology processes. So states—South Australia, Victoria and Western Australia in particular—have their own regulatory authorities in addition to RTAC, which is our regulatory authority.

Ms HALL—Are you going to talk about the impact of legislation at a later stage today?

Prof. Chapman—Yes. The other thing that Australia led the world in—and we are still a leader—is the registration of every IVF cycle and of every baby born from IVF. We were unique for the first five to 10 of years of IVF. Other countries have caught up with us over the last 10 years, but certainly we led the world in being able to present figures on a population basis of how the success rates were going and what the outcomes were. In terms of funding, until 1990-91 IVF did not have any particular item numbers. During a cycle, as you will see when Ric takes you through what an IVF cycle involves, there are blood tests and each of those was billed separately. There were visits to the doctor to have ultrasound scans and they were billed separately. So a patient had a whole page of item numbers, and on top of that a moiety was charged to pay for the infrastructure that went along with an IVF unit.

So it was very messy and there were variations between clinics as to how many visits patients had. It came to the attention of the department of health and the Health Insurance Commission that there were these big variations, so a roundtable consultative process occurred. Geoff Driscoll, who was then chairman of the Fertility Society of Australia, Sandra Dill, who I have mentioned before, and the HIC sat down and over a two-year period hammered out the current item numbers and the costings associated with those. That was in 1990-91. The funding for the particular Medicare item numbers in 1991 was virtually the same as they are in 2005. There has been the small CPI rises that have gone with all Medicare item numbers. In 1998 or 1999 there was a 10 per cent reduction in the IVF item numbers as a result of some politics in the Senate. They went down and then gradually came up again. So the item numbers really are basically the same as they were in 1991.

Not surprisingly, as technology has advanced—and it has advanced greatly, which we will see in a minute—the cost of that technology has increased. There is the R&D that has gone into it and the actual cost of things like culture medium and the catheters that we use. For example, we used something called a ‘tomcat catheter’, which cost 80c and was associated with mediocre pregnancy rates. We changed to the modern catheters, which are softer, made of teflon and very smart, but they cost $26 each. Those costs have all come into the IVF program, so the amount we have had to charge patients on top of the Medicare rebate has risen over the years. Because all those item numbers are outpatient procedures, apart from the collection, when MedicarePlus came along last year, they came into that envelope of MedicarePlus. That is why there was a dramatic rise in the cost: it picked up a large gap that had developed over the years and patients suddenly did not have such a gap. We will come back to that funding issue in more detail.

At the time of the negotiation in relation to the item numbers back in 1991, a limit of six cycles per woman per lifetime was imposed. If a man changes wives, he could have as many cycles as he likes. Our data suggested that only about 1½ per cent of women went beyond, or even got to, six cycles—very few women did. On that basis, Michael Wooldridge, taking advice, lifted the six-cycle limit in 2000. For some women that obviously enabled them to carry on with appropriate treatment until they achieved a pregnancy, and many of them have. Obviously that is the point at issue in relation to what has gone on pre-budget. It is also on the table again as of Saturday, having read Mr Abbott’s comments in the *Australian*. He may have in his mind bringing back the six cycles.

I will talk about the changes over time in this history of the success of assisted reproductive technology. A cycle means a month of a woman's life, but you will see it is actually more than a month. The treatment—the stimulation of the ovaries to produce eggs, the collection of the eggs, the fertilisation of the eggs and replacement of the eggs—takes one menstrual cycle. We look at pregnancy rates per cycle. If a woman is under 35, her rate of conception is around 15 per cent. There is a one in six chance of a woman conceiving in a cycle during natural intercourse when she is making an egg and has normal tubes and he has normal sperm. So it is actually not very high. The human is not a very good reproducer. We are not like rabbits, where the success rate is almost 100 per cent every time the doe ovulates. Until the early nineties, we were not really getting near natural conception rates with IVF. But this is in a group of patients whose chances of success were zero—women with blocked tubes, men with no sperm and women not ovulating at all.

What we have achieved in this last 10 years is this dramatic rise in our ability to produce an excellent embryo which has a higher chance than nature—in fact, twice the chance of nature—of achieving a pregnancy. That is because we are selecting a good embryo. We are capable of doing that; we are capable of growing embryos in the best possible way. Part of this is achieved by a woman in her IVF cycle producing multiple eggs whereas in a normal cycle she gets one and that may be a dud. But because we are producing a number of eggs, we are able to select the best possible egg to produce the best possible embryo. That doubling of the pregnancy rate—I will come back to that later—has an impact on how far taxpayers' money is going in achieving a pregnancy.

What is infertility? Infertility, like all medical things, is determined when you fall outside of the normal range. If you have a cholesterol level that is above 90 per cent of the rest of the population, you have hypercholesterolaemia and therefore you are treated for that. As I said before, for women who are under 35, if you add up their chance of conception every month—that is, 15 per cent plus 15 per cent and so on—by one year something like 90 per cent of women will have conceived. After that, the chances of conceiving are substantially reduced. So we draw the line at one year, in these younger age groups, as being the time that we would investigate why they have not got pregnant and potentially move into treatments to overcome it. As I tell my medical students, infertility is 12 months of trying without success. That is the definition of infertility.

It becomes a little more blurred in the older age groups, because they will never achieve the pregnancy rates that you do when you are younger. This is the brutality of the biological time clock: these women of 40 are starting off not with a 15 per cent chance of becoming pregnant per cycle but with more like somewhere between five per cent and eight per cent per cycle. So their background pregnancy rate is already reduced, and that obviously has implications when we come to doing IVF and the chances of success—another focus of recent debate.

Mr TURNBULL—Professor Chapman, what is it about age that makes older women less likely to conceive?

Prof. Chapman—Will see in a minute some slides that Ric will show you with some more detail about that, but basically it is the quality and the number of the eggs. A woman is born with a large number of eggs; at menopause she has run out of eggs. In that last 10 years it is not only the number but also the quality that is declining. That is what we are fighting against. But IVF

gives us the opportunity to at least pick out the best of those to maximise the chances for those women.

So how common is infertility? One in six couples is the epidemiological data from Australia. In the reproductive years, between the ages of 20 and 50, one in six couples will suffer from infertility—that is, they will be trying for longer than 12 months to conceive. So it is a very broad problem. You would not necessarily realise that for every six people you know one of them is suffering from infertility. People keep it quiet. It still has a stigma to it, although I think it is much less than it has been. It was interesting to read an article yesterday from New Zealand that the rugby player Earl, whose Christian name I cannot remember, has come out of the closet and said he is infertile. He said that he had had IVF some 10 years ago and is doing a bike ride around the 27 provinces of New Zealand to advertise the fact that fertility is an issue for men and that he is basically raising money for research into infertility in New Zealand. It is a common problem but a lot of people do not want to admit to it. It is seen as a failure by both parties. So half a million men and women is what it adds up to.

Mr TURNBULL—Is that in Australia?

Prof. Chapman—Yes.

Ms HALL—We were at Ballarat last week, where we were advised that the infertility rate among males there is higher than throughout the rest of the nation and that it is higher in regional areas than in metropolitan areas.

Prof. Chapman—There is some data relating to men associated with agriculture. It is perhaps what we are spraying on our crops; certainly some chemicals have been definitely shown to be toxic to sperm. It is an issue. Overall, 40 per cent of infertility is related to the man. But I am sure there are pockets of increased male infertility around the country. We are becoming more aware of the environmental issues associated with the male factor, and there seems to be a gradual rise in its prevalence.

Ms HALL—Is research being done in that area at the moment?

Prof. Chapman—Yes, absolutely. Certainly in Europe there is a major follow-through study. It has not happened in Australia. In Newcastle John Aitken is doing some work into environmental agents specifically in relation to sperm. There is work going on.

The female causes of infertility, as we can see in this slide, relate to tubal problems and to ovulation. Thirty per cent are combined problems, so you unfortunately have a male and female interface where both are having problems. We end up with this group of unexplained infertility which is probably just a roll of the dice. If you think of one in six as the dice and you throw the dice each month, how many times can you throw the dice without getting a six? You could throw it 12 times but, without the dice being loaded in any way whatsoever, on the 15th time you may get a pregnancy. Unfortunately, they are also the facts about IVF. It is a dice that is rolled and each time you try, there is a chance of getting pregnant. So to put artificial limits on the number of times that you can roll the dice is not a valid approach in my view.

Mr TURNBULL—Are there many people—and distinguish between male and female if it is appropriate—who are completely infertile?

Prof. Chapman—Yes, there are. A woman who is born with a chromosomal abnormality called Turner syndrome, where a woman only has one of her two X chromosomes and her ovaries do not have any eggs, is infertile. However, she is capable of carrying a pregnancy, by using an egg donated from another woman with her partner's sperm, and delivering a normal baby. So she is not totally infertile. On the male side, if a male is born without testicles or they have been destroyed by a nasty rugby injury—

Mr VASTA—Very nasty.

Prof. Chapman—Earl says that part of his problem relates to that.

Ms HALL—Or viral?

Prof. Chapman—Or viral. Undescended testes caused by mumps would probably be the commonest.

Mr TURNBULL—But would I be right in thinking that the bulk of infertile people are infertile in the sense that they have a significantly lower than average chance of conceiving?

Prof. Chapman—Correct.

Dr Pope—Or subfertility.

Prof. Chapman—We argue about the semantics of subfertility or infertility at international meetings.

Dr Porter—As opposed to sterility.

Mr TURNBULL—So infertility means that you have not become pregnant in a year.

Prof. Chapman—That is right.

Mr TURNBULL—Having no capacity to get pregnant is what you would call sterility.

Prof. Chapman—Yes. That graph that I showed you before still went up slowly.

Mr TURNBULL—That is important.

Prof. Chapman—Okay, so a bit of anatomy—tell me if I am being too simplistic. This slide shows the vagina and the cervix. The sperm lands here and has to swim into the fallopian tube to produce fertilisation. Fertilisation occurs in the fallopian tube, not in the uterus. The fertilised egg then travels back down the fallopian tube and, some six days after it has been released from the ovary, embeds itself into the lining of the uterus. Sperm has to be put into the right place and it has to be capable of swimming in the order of 12 to 48 hours to find its way down the

fallopian tube. An egg has to be released and the tube has to be capable of nourishing both those processes.

Dr Porter—This is not to scale.

Ms HALL—No kidding!

Mr CADMAN—It does give a false impression.

Dr Porter—Just in case you thought that the ovary was that big.

Prof. Chapman—Relatively, the ovary is the size of the follicle in this slide here. So the first reason that a female might not get pregnant is that the ovary is blocked, which can be caused by infection. At a meeting that Ric and I went to in Europe the week before last, I was amazed to hear that chlamydia—which is one of the very silent sexually transmitted diseases and is prevalent through all classes of society, unlike gonorrhoea and syphilis which tend to be in the lower socioeconomic groups—infection rates have almost doubled in the last five years in women in the 18-to-25 age group in Europe. There is also some data from Australia.

What that means is that in the next 10 to 15 years we will probably be looking at an epidemic of tubal blockages. It is a public health issue that we desperately need to address. The ways of addressing that are logical: you either stop having intercourse—so there is a need for sex education—or use barrier methods of contraception. There was a rising incidence of chlamydia in the seventies and early eighties, but it then had a time out when the HIV scare started. With all the publicity that went with that, all the young people—and older people—used condoms to avoid getting HIV. That scare seems to have waned—or at least the mentality of it has waned—so barrier methods are used less; therefore sexually transmitted diseases are back on the rise. But it is a substantial issue, as chlamydia can damage fallopian tubes. If a pregnancy occurs out here, as we can see on this slide, and the fertilised egg does not go back into the uterus, which happens in about one in 100 pregnancies, and gets caught here, either because the tube is damaged or for reasons we do not understand, the pregnancy grows for between five and eight weeks and then ruptures and causes a bleed—that is called an ectopic pregnancy—and the tube after that is permanently damaged.

Things can also go wrong in the ovary. A woman can just run out of eggs—and that can happen prematurely. While we talk about women of 45 becoming menopausal, there is something in the order of one to two per cent of women who, at 35, run out of all the eggs God gave them just after conception.

As to the failures of ovulation, the process of ovulation involves complex interaction between the hypothalamus in the middle of the brain and the pituitary gland, which is just behind your nose and which releases the specific hormones that make an egg develop. If there are any problems in those two areas it will stop an egg being stimulated, even though the ovary contains eggs. Another hormone imbalance that prevents eggs from being formed properly is called polycystic ovarian syndrome, and that affects somewhere between five and 10 per cent of women. They have irregular periods and tend to be overweight. This problem, in particular, does not need IVF; it can be treated with tablets in about 80 per cent of cases.

A condition called endometriosis is where the lining of the womb—called the endometrium—for reasons we do not totally understand, gets outside the uterus and, as the lining does each month, grows and is then shed. The bleeding that causes the menstrual cycle also causes bleeding internally, which then causes scarring of the ovary and of the tube. There is now evidence that the substances that are released by these cells are also nasty to eggs and stop fertilisation occurring. So endometriosis is another issue we are aware of. It increases with maternal age—the older a woman is and has not had a baby, the more likely it is that she will have endometriosis.

I have written down miscarriage, but that obviously happens after the pregnancy has occurred. Despite achieving a pregnancy, one in six women suffers a miscarriage—that is, they lose it—primarily because it was a bad egg or a bad fertilisation to start with. We will not go into miscarriage today. They are the causes in the female of her contribution to not getting pregnant. I missed fibroids, which are the lumps that occur in the muscle of the uterus. By distorting the cavity of the uterus, they can reduce the chances of an embryo attaching.

This relates to your question about older women. When a woman is born she is already on the slippery slope heading towards menopause. The highest number of eggs a woman has is when she is inside her mother's womb: somewhere around the three to four million mark. By the time she is born they are down to two million and by the time she has her first period there are only 400,000 eggs left. Each month she loses between 100 and 300 eggs, even though she only produces one that would potentially make a baby. With that loss of eggs as time goes along she ultimately ends up with none.

The slope of this curve varies with various external factors. A viral infection, as in the male, can knock out the ovaries. She may genetically, we believe, have fewer eggs at the beginning of her life and therefore will run out earlier. There is a whole range of issues. Ultimately, in a natural situation, she will produce only 400 eggs in her lifetime although she started off with four million. There is a slight oversupply, but that is a bit like men: when we produce a sperm sample the average count is 40 million but we only need one sperm to produce fertilisation.

On the male side we can get failure of sperm production—we have talked about that already—which may be the failure of the testes to come down. They need to hang free. The temperature of the testicle is important in the production line as it is very temperature sensitive. If your testes are up in your groins then the temperature is too high and the production line switches off. There are theories about wearing loose underpants if your sperm count is low to prevent the testicles from warming up. There are some occupations where warm testicles are more common, even if they are swinging in the breeze. Taxi drivers and long-distance truck drivers are said to have reduced sperm counts.

The production line can be working but it may produce abnormal shapes: Friday cars. The production line is working really well but it is producing sperm with small heads, and we will see those in a minute. They also may have poor movement. As I said before, they have to swim for between 12 and 24 hours to find the egg to fertilise, and if they are not capable of swimming and they sit around at the bottom of the cervix you are never going to get pregnant. And obviously the numbers are important.

There is also something called antisperm antibodies which are chemicals that the body produces. Just as when you have a german measles injection your body reacts by producing antibodies so the next time the rubella virus comes along the antibody jumps onto the virus and kills it off. In some men, particularly if they have had a testicular injury or they have had a vasectomy, the body produces antibodies against sperm. These antibodies latch onto the sperm and prevent them from swimming, which is why vasectomy reversal is not very successful.

Sperm counts vary. This slide shows the sperm count of one man who produced a sperm sample every week for 120 weeks. There is debate as to who this man was. Somebody said he was a prisoner in jail. I thought it was a lab technician—that was the story I was told. I said that an average count was around 40 million. A fertile level is 20 million. Anything above 20 million, provided they are swimming well and they are normally shaped, will produce a pregnancy. So this shows that he was fertile all the way through, apart from a period of time when he may have had the flu—you get temporary reductions in sperm counts—or it may be because he was stressed; he was in solitary confinement. Men's counts vary a lot from time to time. When we have investigated the individual we then have a range of treatment options. Ric is going to take over at this point, unless you have any questions at this stage.

CHAIR—No.

Dr Porter—I am a clinician, and I have been involved in IVF since 1981. I am involved with the New South Wales clinic, which is the oldest in the state and about the third oldest the country, as a clinician for that many years. I want to present to the committee a fairly practical exposure to the current treatments available to couples who are having trouble falling pregnant. I am going to move through the slide presentation fairly quickly, but please do not hesitate to interrupt me.

Slides were then shown—

Dr Porter—I have things to show you here about what a couple go through in order to achieve a pregnancy. Sometimes all that these people require is advice. As you can see on the top of the slide headed 'ART Treatment Options', they just need to be informed about how to have sex, when to have sex, a little about the menstrual cycle, a bit about when a woman might be fertile and about an ability to keep naturally healthy, and to be given some preconception counselling. Sometimes that is all our job involves. As Michael said, only a small percentage of people might need to go on to higher technical involvement.

We start using some of the three-letter abbreviations when we talk about ovulation induction. I am not going to dwell too much on each of these; suffice it to say that some women, as Michael has already pointed out, do not ovulate—they do not produce an egg every month. We now have drugs available for that. It might be as simple as taking a tablet or as complicated as having injections to stimulate the ovary to produce eggs. That might be the only problem: the couple know how to have sex, the plumbing is all intact and the sperm counts are good. The woman shown here in the slide just needs help to produce her eggs. The eggs are inside the ovary; they are just having trouble being released, which is different to eggs not existing in the first place. Ovulation induction is carried out by a broad spectrum of gynaecologists and by some in general practice around this country, but most of the time we see this procedure carried out at specialist level where the drugs are available only to specialists because of their complexity and the need

for monitoring of the cycle to avoid complications such as overstimulation of the ovary and producing a multiple pregnancy.

We also use the concept of intrauterine insemination, so you will hear the concept in terms of IUI, OI, IUI-IVF and ICSI. We will go through some of them. Intrauterine insemination is essentially a treatment for couples who have unexplained infertility. Michael pointed out that about a third of conception problems are male related, a third are female related, a third are combined and about 10 per cent are unexplained. Here we are talking about the unexplained group—that is, where a woman ovulates normally, she has normal fallopian tubes, she and her partner know how to have sex and he has a normal sperm count, yet conception is not occurring. We find that, if we use a small dose of drug to stimulate the ovary and if, at the required time of the cycle when those eggs are ready, we place a small specimen of prepared concentrated, washed sperm from the husband inside the uterus of the partner, we can achieve reasonable pregnancy rates by that technique alone.

This is different from IVF. We are not talking about taking the eggs out; we are simply talking about putting sperm inside the woman. In the news of late, as you might recall, there was the story of the quads in Queensland—the second group. That was an IUI pregnancy. We have a limited amount of control over how many eggs are released and whether those eggs are any good. We monitor these people carefully—although some slip through the net, as happened in Queensland—through ultrasound so that we can count the number of follicles that are growing in the ovary, and if there are too many we do not inseminate the couple on that particular occasion. We reduce the dose of drugs until we get one or two follicles being produced. That is intrauterine insemination, and I will show you some diagrams of that in a second.

We now move on to in-vitro fertilisation, which essentially means fertilisation under glass or in the laboratory—in test tubes in the old days but now under little plastic dishes. We also go on to even more complicated things such as ICSI, which is injecting the sperm—a single sperm. In IVF we are taking a single egg, putting on top of that egg a large number of sperm and allowing nature to decide which sperm will fertilise the egg, and that is the sperm that enters the surface of the egg.

In intracytoplasmic sperm injection we are leaving that decision about which sperm to use to the scientist, who is picking from a visual inspection of the sperm what is perceived to be the best-looking sperm in its activity and in its normality of appearance and is physically injecting a single sperm into the cytoplasm, which essentially is the guts of the egg. Then we are expecting that sperm to achieve fertilisation. This is really just about putting the sperm inside the egg. Fertilisation is a very active process that nature has to do. Do you understand the difference? One is insemination and one is fertilisation. We can inseminate but nature has to fertilise.

You can see in the diagram of the male genitalia that sometimes we find men have blocked tubes. The factory is working, they are producing sperm but they are not getting out in the ejaculate. That is because they might have been born without the plumbing or because their plumbing may have been blocked off either by surgery or by infection. So we can now go in and put a needle into the testis itself or into the reservoir on the outside of the testis, called the epididymis, where the sperm often collects, and we can aspirate, with a very fine needle, that sperm directly from the male. Then we can use it in very limited quantities to inject into the egg. As a gynaecologist who started off putting needles into women to collect eggs, I have a

newfound respect for the ovary because I now put needles into men's testicles. That is the way IVF has evolved over the years. We now put needles into both ovaries and testicles to get out those gametes. 'Gamete' is the medical word for egg and sperm.

Prof. Chapman—There are no item numbers for ICSI or surgical sperm collection, although we have been asking for them for five years. MSAC has done an inquiry. We do not know what the result of that inquiry was. For some reason it is not being released and no item numbers have been added.

Dr Porter—I will show you some numbers a little bit later. Essentially this used to be the majority of our work in IVF but now, because of the predominance of male factor infertility, we are doing almost 50 per cent of cycles by IVF and 50 per cent by ICSI. This carries an item number but the additional step of actually placing that sperm inside the egg, which uses a sophisticated piece of equipment, as I will show you, and a very well trained scientist to do it, does not carry the additional assistance for these couples.

CHAIR—Who carries the cost?

Dr Porter—The patient does.

Mrs ELSON—What is the cost?

Dr Porter—For a general clinic, ours is about $500. When you are talking about a couple of thousand dollars for IVF, you are adding another $500 for the machine and the expertise to do it.

Prof. Chapman—Obviously that is not picked up by the safety net because that is an in-patient situation. Actually, that is not true. We have been instructed by the HIC that we cannot charge it as part of the moiety in the outpatient area, even though it is not associated with an in-patient procedure because it is happening outside the hospital. But because it is an item number under consideration by HIC we have been told we are not allowed to include it in the safety net.

Dr Porter—I have mentioned surgical sperm collection. I will go on to the use of donor sperm, donor eggs and donor embryos. Malcolm, you spoke a little bit earlier about people being sterile. If you do not produce eggs or you do not produce any sperm, the only option you have as a couple is to make use of somebody else's sperm or eggs. Most fertility clinics around this country offer the services of donor sperm banking or donor eggs from people either known or unknown to the couple, and also embryos. We have embryos in storage that are no longer required by the couple who have helped make them and they will, in an altruistic way, donate those embryos to another couple who may need them. So donor programs are common to fertility clinics in this country.

Prof. Chapman—They account for probably less than five per cent of the total activity of—

Dr Porter—our work.

Mr TURNBULL—How long can an embryo be stored for?

Dr Porter—Decades, but in this country it is legislated. It depends on the state. In Victoria you can keep an embryo for five years.

Dr Pope—Five years is the maximum time frame. Western Australia was three years but it is about to change that. The new NHMRC ethical guidelines are actually now stating around the country that it should be a five-year maximum with the allowance for another five-year extension. Then it is in the hands of an ethics committee to determine what situations may occur.

Dr Porter—There is a difference between what is socially acceptable for how long you can hold an embryo versus what is medically or scientifically possible. The embryo can stay in liquid nitrogen for probably decades without decay but for social, administrative and parental reasons we set these sorts of limits so people are making decisions about what they want done with their embryos.

CHAIR—What about stem cell research?

Dr Porter—At the moment you have to have a specific licence from the NHMRC to do such research. There is a moratorium on those embryos that are currently in storage. We are only allowed to touch embryos that were stored before—

Dr Pope—That has been released.

Dr Porter—I beg your pardon.

Dr Pope—The sunset clause came in in April this year and it is now possible for people with embryos frozen to now declare them as excess embryos with facilities that have a licence to allow donation to stem cell research.

Prof. Chapman—There are emotive words like 'excess' and 'spare', which just cloud the discussions.

Dr Pope—Yes, unfortunately, that is how it must be declared.

Prof. Chapman—'Excess' means that, in the process of producing—as we will see a minute—your best embryo, there are also potentially a number of other embryos being produced. If you get pregnant in that cycle and you get pregnant again perhaps with some of those frozen embryos and you only want two children, there are embryos then still available. They are not created for the sake of creating excess embryos or they are not there 'spare' on the basis that something might go wrong in the future; they are the outfall of the process of IVF. They are a dilemma—particularly for the patients, obviously. The patients in most clinics are charged on a six-monthly basis, which is how we keep in contact with them so they are not losing contact with their embryos. They are paying for the storage of those embryos, they are aware that they are there and they make decisions about the three options for them, which are: ongoing storage, donating them to research or donating them to others. Another option, obviously, is to allow us to thaw them and not foster them with culture medium. In that case the cells break up and that is the end of the embryo.

Mr CADMAN—Isn't the other alternative that they could all be used in the donors—I mean by the parents themselves?

Prof. Chapman—They certainly can use them. In Australia four children is the most that has been produced from one cycle of IVF. Most couples want one or two or three, so sometimes they will still have embryos remaining after that.

Mr CADMAN—So there is probably five options.

Prof. Chapman—Yes, five. We could legislate that you have to use all your embryos!

Dr Porter—I missed the five—you have made up one? What were your five?

Dr Pope—Just their own use of them.

Dr Porter—But there is only four: you can put them back into yourself—

Dr Pope—But that is the storage at the moment.

Dr Porter—That is the storage, that is what you are talking about—continued storage for your own use? I beg your pardon. I thought: 'Gee, for years, I have only told people that there are four options.' It is very emotive. You sit across the desk from a couple and you say what can happen. They say: 'We have actually got the two children we wanted and we have ended up with a spare embryo in the freezer. Doctor, what can we do with it?' 'You can still have it transferred.' 'No, no, we do not want any more children.' 'Well, you can donate it to research, donate it to another couple or you can thaw it out and allow it succumb.' You can imagine how very polarised the views are about those outcomes. Some people say, 'I could never do that, but I could consider that.' The next couple that comes in would say, 'No, I would do the opposite.' Those alternatives are so emotionally charged. We do rely on the altruistic nature of people to give embryos to other couples. We rely on the altruistic nature of couples to donate for ongoing research. Some people feel more comfortable about that. They do not like the concept of their own embryos being used or donated and knowing that there is a full sibling walking around that is related to them but who they will never see again. So there is a whole lot of emotion charged to frozen embryos.

If you add up the total number of babies born in this country from fresh embryos versus frozen embryos, it is fifty-fifty. I can explain that statistic to you. If you look at the pregnancy rate of putting fresh embryos back and you add in the stored embryos that are there for those couples—you add up, therefore, the total number of IVF babies born in Australia—you find that half of them have come from fresh embryos and half have come from the frozen embryos that have been transferred back. So they are a really important biological material that these couples make use of.

Mr TURNBULL—Is there any difference between the success rate and the subsequent health of fresh and frozen?

Dr Pope—Yes.

Dr Porter—Yes, there is, and we can address that. Yes, in general terms, the implantation rate of a frozen and thawed embryo is less than that of a fresh embryo. There are whole number of reasons why, when you have a batch of embryos, you are going to put back one in today fresh because it was only made a couple of days ago and the ones you are going to put in the freezer for later. If the woman does not get pregnant on this cycle she can come back in a month or two and have those frozen ones put back in. Or, if she does get pregnant, she has the baby, she breast-feeds it and she comes back in two years time and says, 'Instead of going through the whole process again, could I please have that frozen embryo put back in.' How you decide which embryos go which direction is all to do with the science and the morphology of the embryos, which we will go on to.

Mr VASTA—There is no difference in the quality of the babies?

Dr Porter—Research data around the world compares ICSI babies, IVF babies, frozen embryo babies and naturally conceived babies. The studies correct for two things. One is age. The average age of a patient going through assisted reproductive technology is older than the general population and therefore carries higher abnormality rates. That is purely nature. It is not related to the technology as to how they got pregnant; it is simply because they are in an older age group. The studies also correct for multiple pregnancies because in this technology we have a higher multiple pregnancy rate than in the general population. If you compare apples with apples and correct for age and single pregnancies across ICSI, IVF, frozen and naturally conceived there is no difference in the abnormality rates, the miscarriage rates or the development of those children. The studies are now up to about 15 years, but they are ongoing.

Ms HALL—What is the percentage of multiple pregnancies?

Dr Porter—It very much depends on the age of the patient. In general our multiple pregnancy rate runs at around 15 per cent. We are desperately trying to bring that down.

Prof. Chapman—I will talk a little about that later.

Dr Porter—That is across the board. Michael might be able to modify that figure for you.

Prof. Chapman—If we could reduce multiple pregnancy rates there would be no financial debate. The overall costs to the health of the country of the twin pregnancies we have created far outweigh the cost of IVF treatment itself.

Dr Porter—One of the newer technologies I want to mention is PGD, preimplantation genetic diagnosis. Before the embryo goes back into the woman we can now look at the specific cells of the embryo, looking for specific genetic disease. It is not a panacea to say whether an embryo is going to make a baby or whether it is a normal embryo. At the present time we are looking for specific genetic disease in a particular family where that disease might be prevalent. It is very early days for PGD but it is certainly a technology that is advancing at the rate of knots.

I will whip through the rest of this. Before any patient comes in for something like IVF or even ovulation induction or uterine insemination a degree of counselling goes on. It is information counselling, it is sometimes crisis counselling and it is grief counselling. It is very important that our couples be exposed to this type of counselling. It comes from clinicians,

dedicated counsellors, our nursing staff and our scientists. Everybody in the fertility clinic is trained at some level to counsel patients.

Ms HALL—Is there a set counselling procedure?

Dr Porter—In some states there is mandatory counselling.

Dr Pope—There is indeed through RTAC. The counsellors have determined the processes that should be in place and what areas they should be addressing. You need to be a counsellor trained in infertility to work in this field.

Dr Porter—Counselling is almost mandatory in couples that are using donated gametes. They need screening blood tests. We tend to screen our patients for a number of communicable diseases such as HIV and hepatitis B and C and make sure they are immune to rubella before they start out on this. Often they will require semen analysis to make sure we know exactly what type of sperm we are dealing with to differentiate between IVF and ICSI.

We give out large amounts of information. We have booklets, information evenings, material in printed and oral form and on our web sites. All fertility clinics around Australia do so because it is all about informed consent. Whenever you have a technology that is not 100 per cent guaranteed you have to inform your patients about the likely success rates and the side effects so that you can have informed consent and they know what they are doing. These are clinical in terms of what might happen to them and what should happen to them. We go into the financial costs as well, so nobody goes in with their eyes closed.

Then we talk about commencing a treatment cycle. This is a diagrammatic representation of what I was talking about. Here is the anatomy again: vagina, cervix, through the cervix into the uterine cavity, then the fallopian tubes and ovaries, from where the eggs arrive. So in each uterine insemination the woman herself is actually ovulating. We are relying on her egg to be released, to be caught by the end of the tube to travel down here. At that required day of the cycle, we prepare our sample of sperm from the husband and we inseminate her. This is very similar to having a pap smear—it is that simple, and it is not that uncomfortable. We pass the catheter through the cervix and deposit in the uterus a set number of the best and most concentrated and clean sperm that we can manage. We rely on nature to do the rest. So it is a little more natural if you accept that there is some degree of intervention involved already. That is intrauterine insemination. We often try that with a couple for several cycles before going on to the more sophisticated techniques such as IVF or ICSI, as I have explained. We are using fairly high-tech instruments in the laboratory, and we will go through that in a little more detail now.

Prof. Chapman—You will be seeing that this afternoon as well.

Dr Porter—This slide is a little complicated. It is in front of you, and you might like to refer to it. It is a time line that we use a lot with our patients, because I want you to keep in perspective what a couple are going through when they come through IVF. This red represents a period and this red represents another period. So that is a month from there to there, and this is another month from here to here. This is where it all happens—between this period and this period. This is where all the action is—and we will refer to that a bit—but you can see with this particular way of administering IVF that we actually start in the cycle before. You can see that

on day 22 a typical patient may ring in when she gets her period but about three weeks later—so one week back from the next cycle—she commences a particular drug.

These drugs are here. This is in the form of a nasal spray. Our patient would pick up that spray—and that contains one of the drugs we are talking about—put it up their nose and squirt. That particular drug is to do with turning off the pituitary gland. There are lots of samples here that you might like to play with. This what the patients have to get used to. Some people do not like putting things up their noses.

Mr VASTA—I will not take any!

Dr Porter—It is not for getting pregnant. This first drug turns off the pituitary gland, because we do not want the eggs to be released. That is called ovulation. It is hard enough to find a microscopic egg inside a follicle; it is almost impossible to find it if it has been released. So we have to turn off the normal female ovulation, and to do that we use this drug here on a daily basis. It comes in two forms—either as the nasal spray that you have in front of your or as an injection. The drugs are exactly the same. It is just personal preference by the patients as to which one they would like to have administered. So this is going on on a daily basis.

Prof. Chapman—The cost of the Synarel is about $180 for one of those.

Dr Porter—It is sometimes covered by a private health fund but not covered by Medicare—and as I said, it comes in two forms.

Ms HALL—Why only sometimes?

Dr Porter—It depends on the health funds. It depends on what level of health cover the member has and how much rebate the health fund will give for pharmaceuticals.

Mr VASTA—And it is one of those injections instead of taking the nasal spray daily?

Dr Porter—No, daily.

Mr VASTA—You do not get it injected daily, do you?

Dr Porter—Yes. I am showing you one style of treatment. There are a number of ways of giving it, but this is a fairly common one around this country. This drug here is given on a daily basis. You either sniff daily or inject daily. Some people do not like shoving this up their nose, so they prefer to inject. Other people do not like injecting and prefer to sniff. It is very personal and you can never pick who likes what, trust me.

So they take this drug to turn off their pituitary gland. It sounds paradoxical, because, as Michael told you, it is the pituitary that turns on the ovary. But it is also responsible for that surge of hormone midcycle that allows the eggs to be released. We do not want that. We have to go in and get those eggs out before they are released by the ovary. Once they are released from the ovary, they are floating around in the abdomen and you cannot find them. It is a needle in a haystack scenario. So we turn off the pituitary gland.

Once you turn off the pituitary gland you still have to turn on the ovary, because the pituitary gland is responsible for stimulating the follicles. One thing is to turn off the pituitary gland and the next thing is to turn on the ovary. That is when we get to this next set of drugs—another injection daily. A lot of these people would cut off their right arm to fall pregnant, so they do not mind having a daily injection like this. It is relatively new. These two pens are now available. Just as diabetics give themselves injections with insulin pens, these are now the latest things for fertility treatment.

Mr GEORGANAS—There is no choice of spray or injection at this period—

Dr Porter—No. This one here is just an injection.

Ms HALL—What is the cost of these?

Dr Porter—That is actually covered by the schedule—

Prof. Chapman—Section 100 covers the FSH. The cost to the PBS is 48c for every unit, and each patient uses something in the order of 3,000 units per treatment cycle. There is about $1,500 of taxpayers' money per cycle on the medications, and that is covered by section 100 within the PBS.

Mr TURNBULL—How much per medication is not covered by—

Prof. Chapman—The nasal spray—

Mr TURNBULL—So for medication, $1,500 is covered by PBS and $500 is not covered by PBS.

Prof. Chapman—It is $180, unless the cycle becomes prolonged.

Ms HALL—Sometimes you can get it from health insurance.

Dr Porter—There are later drugs in the cycle that we have not got to yet. There are more costs to come.

Ms HALL—That is important to us.

Dr Porter—This drug here that they are sniffing or injecting is paid for by the patient; this drug here is paid for by the government.

Mr TURNBULL—What does the second drug do?

Dr Porter—It is to stimulate the ovaries. The first drug stops you ovulating and the second one stimulates the ovaries. We have actually taken over control of the ovaries now. We are now giving FSH, follicle stimulating hormone. Historically it used to be a urinary product, but Australia leads the world again because we are now using recombinant DNA technology. What you have got in front of you with these pens is recombinant DNA. It has done away with the

whole problem of urinary based products—prions, Creutzfeldt-Jacobs disease, mad cow disease. Very precise doses are now given.

You dial up the dose. You will see that it depends on your age and your size as to what dosage is appropriate. You will dial up the dose on the end—and if you are like me you will find a roll of fat just here—and you will just go straight in like that and inject. It takes seconds. In over 20 years of IVF this is the greatest thing since sliced bread. Patients who have been so anti-injection love these pens because they are now flexible and mobile. They take them in their purse to work. They could give themselves an injection without having to run to the loo, or drawing up drugs and looking like somebody who is injecting, or having their husbands drawing targets on them and running across the room and injecting. I kid you not, that is what happens. It makes these women very independent because they are now looking after their own medication.

So there is a suppressing drug and the stimulating drug, with monitoring along the way. We need to know how the drugs are working, and we do that by doing blood tests to watch oestrogen levels and other hormone changes through the cycle. We are doing ultrasound scans. They are done internally through the vagina so that we can watch the follicles, which appear as black circles—and I will show you a picture in a minute. These are the fluid filled spaces on the ovary that, hopefully, will contain an egg. Remember, a woman who is not being stimulated at all by drugs produces and releases one egg a month. We are hoping to release about 10 eggs per cycle.

So there are injections and monitoring until we get to this stage in the middle here. This is one of the examples: Synarel, the nasal spray. These are the injections. These are the pens you have now got in front of you. This is the stimulation phase, if you like. They are produced by two drug companies in Australia. We are now up to the stage where we think there is good follicle growth and the oestrogen levels are rising nicely, so from a clinical perspective we think everything is getting ready for us to go in and collect those eggs. You cannot collect a woman's eggs any day of the week. You can collect a man's sperm any hour of the day because his sperm is always ready to go. But a woman's eggs must be matured and that is why we have this complex growing of the eggs inside the woman's ovaries and monitoring to indicate when those eggs are mature. There is only one day in which we can actually get those eggs out and that is why it is all timed as accurately as it is.

This is what the ovary looks like on ultrasound. This is a transvaginal ultrasound. A probe a little larger than your finger goes into the vagina and gently up into the side. You can actually see these black circles showing up on the ovaries. This is the ovary all the way round here and these are fluid filled sacs. They get to the stage of being about two centimetres in size—about the size of 20c coin or maybe a little bit bigger—which is the average size of a follicle. A woman is producing one of those every single month. Some will complain of pain when they ovulate, because they are actually bursting a little follicle that is about an inch in diameter. This woman has between two and five of these on each ovary so she feels a little bit more bloated because of the eggs being produced.

On this slide you can see a diagrammatic representation of the ultrasound probe going into the vagina. The needle on top of the probe goes in through the follicles. Adrianne is opening up the packet of one of the needles which we use. Under a TV screen sitting beside us in the operating theatre, we can identify the black circles that you saw on the previous slide. Under ultrasound control we can direct that needle into the follicle. It is much bigger in this diagram than it is in

real life, but we try to suck that egg down that tube. It goes down the tube, around here and into a test tube sitting next to the patient. That test tube full of fluid is then given to a scientist in the operating theatre. Under a microscope the scientist will sift through that fluid, looking for the microscopic egg. If you take a normal household pin, stab it through a piece paper and hold it up to the light, you can get five human eggs across that hole. That is how small we are talking; that is how small a human egg is. It is not the chicken's egg that you and I are used to.

Mr TURNBULL—You are identifying the egg through the ultrasound?

Dr Porter—No. We are identifying the follicle. Ultrasound is nothing like that sophisticated. All it can do is look at the target.

Mr TURNBULL—How do you know you are picking up an egg?

Dr Porter—Because you are sucking out all the fluid and in that fluid comes a tiny little speck of dust. You hand that fluid across to someone much cleverer than me—an embryologist such as Adrianne—who has a high-powered microscope and can sift through that fluid. It is not that difficult because the egg is actually surrounded by cumulus cells. They are like fluffy, cotton wool cells, so a good embryologist can identify it with the naked eye. But they use a microscope to confirm it. They then have to wash it to get it out of the fluid and transfer it into a small dish. There are some numbers that I need you to understand. Not every egg makes a baby. You heard Michael say that, as a woman gets older, her eggs age. There are two important parts of the egg. One is the nucleus, where the DNA material is that tells us what hair colour, eye colour and build the person will have and whether they will get breast or prostate cancer—all those things. All the genetic material is in the nucleus. There are also the mitochondria, which are outside the nucleus. These are the energy packets of the cell.

We think there are probably two things going on. As a woman gets older, her eggs are ageing, so the egg she produces at age 40 is already 40½ years old. By that time some of the nuclear material inside the egg is probably breaking down a little bit, and certainly some of the energy packets that the cell relies on are also degenerating. It is running out of oomph. When the sperm gets inside the egg, the egg does most of the work and therefore it relies on its own energy packets for fertilisation. That is a very energy-zapping thing to happen. This is life beginning. This is a huge, ongoing saga of the DNA from the sperm meeting the DNA of the egg and fusing together to make a whole complex. That takes energy, and that energy has to come from the egg. The older the egg is, the more likely it is to have DNA damage or to have a lack of energy from mitochondria. So that is what we are after, and every egg is variable in its quality. If we look at it statistically—these are averages—if we look across all the patients we treat in one year and ask how many eggs we normally produce from each, the answer is about nine.

Mr CADMAN—Is that from both ovaries?

Dr Porter—Yes, you might get four from one and five from the other. Do not forget that there are some patients who produce no eggs. It is very rare. They come into the operating theatre because they are 41 or 42 years old and have only got one or two follicles. Occasionally in a year we may not be able to get an egg from somebody; it happens. On the other end of the scale, we have women who produce massive numbers of eggs. Instead of producing the average of nine, they might produce 15 or, very occasionally, 20. I am purely giving you the mean across a year's

work of IVF. On average we would collect nine eggs from our patients, but it is very dependent on age and on dosage of the drugs we are using. Of those nine that we collect, not all of them are going to be mature because there is a wave of eggs coming through from which we are trying to pick out the most mature ones. Not all of them mature. In fact, on average, we would expect seven to be mature.

We put the sperm with them and we find that not every egg will fertilise. While we can put sperm with them, either on top of the egg or into the egg, we still rely on nature to go through the active process of combining that DNA. We have no control over that. We find that only about six out of nine eggs collected—so in the order of 70 per cent—will actually get fertilised, because some just do not fertilise even when they are mature and some eggs are immature—so we have already lost three. So now we have got fertilised embryos. We have identified that sperm has actually triggered fertilisation inside the egg, but not all the embryos will then go on to the next stage, which is to divide from a single cell into two cells or four cells—and away they go. You can see here two-cell embryos in diagrammatic form. You can see that not all of them have gone and divided. Not all the ones that divide will keep growing. So we might end up at the end of the cycle with one or two embryos. Remember that I said that most of the time these days we are only putting one back and that might leave us with one or two spare ones to go in the freezer for later. So out of nine or 10 eggs we have ended up with only one or two decent embryos. That is nature. That is the fall-off. That is why when couples have sex at home there is only a small chance that the woman will end up pregnant, as Michael said, because there is this huge fall-off due to natural selection. We are now identifying, through years of IVF experience, that it happens in our laboratory as well.

So we have actually used these two drugs, we have suppressed the pituitary, we have stimulated the ovary, we have triggered ovulation and, a certain number of hours after triggering ovulation to occur, we have gone in and collected the eggs. So we should now have mature eggs in our dishes and we then add the sperm by whatever technique we are going to use. If it is by IVF, on top of the egg we are putting a dollop—an unscientific term, I am sorry—of usually 80,000 to 100,000 sperm that have been washed and prepared. In ICSI, we take one single sperm and physically microinject it into the egg, and then we see how the embryos grow.

Mrs ELSON—Why do you have to wash the sperm?

Dr Pope—Seminal plasma in an ejaculate has a whole lot of other products that would normally be filtered out by the cervical mucous. That is what the cervix is for: it acts as a filter so only the motile sperm get into the uterus and then get to the eggs. Otherwise, you can transfer bacteria, prostaglandins—which are chemicals that create all kinds of contractions within the uterus—and a lot of things that you do not necessarily want to be in the uterus. So we have to repeat that as well. We literally have to get rid of those products and concentrate the motile sperm and make sure that they are the only things that go into the uterus or get in contact with the eggs.

Mr TURNBULL—How do you wash the sperm?

Dr Pope—It is done in a centrifuge. It is a bit like a washing machine, in all honesty. We use some substances that are quite viscous. We layer them and then put a layer of raw semen on the top of them. With high levels of centrifugation, the speed will actually force the motile sperm

through these viscous solutions and down to the bottom of the tube that you have them in. What you literally do then is go in, remove the motile sperm off the bottom of this column and then wash it in a fresh culture medium, so you literally use a filtration system to do it.

Mr TURNBULL—So it is survival of the fittest?

Dr Pope—Yes.

Ms HALL—What are the success rates when you are doing a comparison between IVF and ICSI?

Dr Porter—They are very similar. As for success rates, there is very little difference between IVF and ICSI in terms of outcome. They are different groups of patients you are using it for, so once you overcome that hurdle—remember that the ICSI group have usually got major sperm problems—and you achieve fertilisation, the outcome is the same. Once we have got a multicelled embryo that has started to divide and we feel confident that it might make a baby, we then transfer it back into the uterus. It is a procedure very similar to the IUI you saw earlier. It uses a little catheter. We have catheters here for you to see. They are very thin and floppy. They are very malleable and very soft. They are passed up through the cervix and that single embryo is placed high up into the uterus. That is called an embryo transfer. The egg collection is usually done under light anaesthetic. The embryo transfer is done without anaesthetic, because it is similar to having a pap smear done.

I will not dwell too much on success rates, except to say that the biggest thing you can take away from this is that age is the enemy. As you get older, it is harder to get pregnant; the same occurs in IVF. The best chance of getting people pregnant is when they are at an earlier stage, but that is not the group that fronts for IVF. The bulk of our population is between 30 and 40 years of age. If you look at the fresh embryo transfers on the slide where it is broken into dark blue and light blue, we have about a one-in-two chance of getting a young couple pregnant by putting back a single embryo. If we then put those spare embryos into the freezer and she comes back and has the one or two spare ones put back in—in other words, picks up another pregnancy—then that will boost it. This slide shows the frozen embryos.

You asked about the success rates between fresh and frozen. In this slide, you can see the difference between singling out what we think might be the best embryo—and we are going to put that one back in fresh—and the other ones that should be okay. That is already biasing the results because we might have put what we think is the best embryo back in and the other ones go into the freezer. If you add in the frozen ones, then you have well over a 70 per cent chance of getting a young patient pregnant after one egg collection, but maybe after a couple of embryo transfers. By the time you have used up that biological material you have from one cycle, she has a two-thirds or more chance of being pregnant.

The thing I want to draw your attention to on the slide is that the graph goes down; it is age dependent. Our success rate with people in their 30s is around 30 per cent—like a one-in-three chance of getting pregnant. But if you add in the frozens, which are like an insurance policy—an extra go, an extra ticket in the lottery, if you like—that will boost the success rates again, as shown here on this slide. In the ‘41 and above’ age group, we are talking about 15 per cent fresh and about the same frozen. The success rate we were getting 20 years ago in IVF is shown on the

slide. That has been the change that we have all seen as IVF clinicians. In the 20 years of IVF, the scale has gone as shown on the graph. We are getting these people pregnant much more frequently and the older women the same way. The whole graph is lifting up. We were patting ourselves on the back 20 years ago for the success rates of the group shown on the graph.

I do not know how far we can get this group to go up with more years of research. The thing that makes us always hit the ceiling is the age of the egg. We cannot change that. The graph will probably go up a small amount. That is where it boils down to the individual decision between doctor and patient as to what is an acceptable success rate and whether they should have a go at IVF. I believe strongly that that is a decision between doctor and patient. With informed consent, the patient and the doctor can decide whether it is worthwhile being treated at 41, 42, 43 or 44. I am not sure that you can or should legislate for that.

Mr VASTA—You were talking about the power pack on the embryos and that older embryos do not have that power pack. Does that make a child less resistant to—

Dr Porter—No, nature is very good about that. It really almost is an all or nothing procedure. In other words, if that embryo is good, you can end up with a baby. If it is not good, the woman does not even get pregnant or she miscarries early. In the general population you do not see an older mother with a young child where that child is any less normal than anybody else.

Mr CADMAN—Is there a sensible limit? You say that the patient and the doctor decide. Where is the public interest? Should the public support how ever many times the doctor and the patient decide that they should have a go? Where is the ethical cut-off point?

Dr Porter—Do you want me to get into ethics like that?

Mr CADMAN—We are required to make those sorts of decisions and we need expert advice.

Dr Porter—I could not agree more. I have a couple at the moment aged 30 who I believe have almost a zero chance of getting pregnant. My role as a doctor is to say, 'I think you should stop treatment because you are not going to get pregnant.' I have women at 42 and 43 whom I believe have a reasonable chance.

Mr CADMAN—The probability factors change, don't they?

Dr Porter—Yes.

Ms HALL—It is individual—that is what you are saying.

Dr Porter—It is very individual.

Mr CADMAN—Whatever measure you apply, as age increases—and you have already talked about treatment at 41, 42, 43 and 44—there has to be a diminished prospect.

Dr Porter—Yes, just as there is at your age if I decide I want to put you into intensive care because you have a heart attack today. You are a very productive man at your age in this community and I would move heaven and earth to put you into intensive care, whereas—and I

will have to be careful about how I say this—there must be other people with other medical diseases and for other factors involved in their quality of life perhaps should not go to intensive care.

It boils down to a decision about whether you believe this woman at age 42 or 43 has the right to access treatment because she will make just as good or healthy a mother. What are those ethical dilemmas we face? Should she have the right because she is going to make a better mother or a better parent than this person back here in the 25-30 age group? Your question is: how much should we as taxpayers fund this level of fertility versus this level? That is a huge argument, but that is what you have this committee for. It boils back down to the same arguments as those about funding intensive care or chemotherapy or radiotherapy. In terms of longevity and productivity of this person that is born here in the community in Australia, I believe it is a better spend of the Australian dollar than it is to put my grandfather on chemotherapy. That is my ethic; that is just Ric Porter speaking. I am not speaking for anybody else.

Mrs ELSON—How many woman over the age of 40 would you treat per year?

Prof. Chapman—About 15 per cent of the total population of the cycle. That is 15 per cent of 25,000.

Dr Porter—When you put this data in front of most couples, they will say: 'I didn't realise that was so low. Thank you for giving me information. I can now make an informed decision. I do not want to go ahead, because I thought my chances were something like 30 per cent and you are telling me only 10 per cent are take-home babies.' They say, 'Thank you. All I needed was the information.' We have a small group who say: 'I thought you were going to say my chances were zero, and you have told me they are five per cent. I want to take that chance.'

Mrs ELSON—That 15 per cent of your 25,000 are the ones that are taking the chance?

Prof. Chapman—Everyone takes a chance. They back a horse on longer odds.

Mrs ELSON—The leftovers are the 15 per cent that you are treating.

Prof. Chapman—My personal and anecdotal experience would be that more than half of the women who come to us are over 42. Up to age 42, the pregnancy rates are reasonable. As Ric said, we were treating 25-year-olds with the same odds 15 years ago. We were encouraged to treat them, and science moves on with them. Of the woman I see over 42, the majority will say, 'I won't have a go. I just wanted the information.' The next group, which is probably another third, will say: 'I want one go so that, when I am 60 and I look back, I know I did everything I could to have a baby, which was the thing that I wanted to do more than anything else in the world at that moment in time and it will be with me for the rest of my life that I am childless. I want to have one go so that I can't say to myself that I didn't try enough.'

Mrs ELSON—I do not have any problems with that. I think everyone should be given a go, but I am just verifying that the 15 per cent are the ones that go ahead with the treatment.

Prof. Chapman—As you come down, the remaining group will be tryers, who will try again and again on the basis of only a two or three per cent chance of success.

Ms HALL—What Kay wants to know is whether the 15 per cent is out of the total of everybody in all age groups.

Prof. Chapman—Yes. It is out of the total of all the IVF group.

CHAIR—If someone has a frozen embryo that was taken out when they were under age 30 and they do not use it until they are 40, what does that do to the success rate?

Dr Porter—The success rate relates to the age of the mother when the embryo was formed.

CHAIR—So there could be one approach that you might adopt that all girls at 20 have an IVF cycle and put them away in the fridge.

Mr CADMAN—That is a great idea.

Dr Porter—Don't knock it. There is a small group in the community who push for that. The trouble at the moment is that we are not good at freezing eggs that have not been fertilised. We are working towards that.

Mr CADMAN—Therefore, you need a partner.

Dr Porter—If you come in to us at 20 years of age and say, 'I want to put my embryos away because I have met the man of my dreams but we just do not want to have children for another 10 years as we are career minded,' I can put the embryos away—but you need a partner. I cannot put your eggs away with any degree of certainty in the year 2005. It is coming, but it is not here yet.

Dr Pope—The other group of people that falls into that are those who are going to undergo chemotherapy or oncology treatment who may choose to undergo these treatments to preserve their fertility for a later stage.

Dr Porter—At the European meeting we were just at—

Mr CADMAN—Isn't the five-year barrier a problem there, though?

Dr Pope—No. That is where the ethics committees can give approval for extension. That is what happens in Victoria.

Mr CADMAN—The way you described it earlier was that it is mandatory at five years.

Dr Pope—No. It is mandatory that you make a decision at that time, but I am in Victoria these days and the Infertility Treatment Authority can make decisions to extend those based on the reasons why they have been frozen. It is the same as if you have put semen away because you are going to have oncology treatment. They have an option. You could be 16. We see 16-year-old boys coming in who are about to undergo chemotherapy and they may store semen for 20 years.

Mr GEORGANAS—In most cases, they override the legislation—

Dr Pope—They do, because it is based on the individual's reasons for having that frozen. If you are 43 years old, they are not going to say, 'We'll extend it for another five years,' because the age is getting away from you. But if you are 16 or 17 and undergo a treatment like this, they may say that that may be an acceptable reason for 20 years of storage because you are still within your fertile or reproductive age.

Mr GEORGANAS—You are using the ages of 16 or 17.

Dr Pope—For the semen.

Mr GEORGANAS—But if you are 20 or 25 or 30 and you are going for chemotherapy—

Dr Pope—You may hold it for 10 years or more. It is 10 years for gametes, for semen. I know of cases in Victoria where people have frozen their semen for medical reasons and it has been held for much longer than that, purely because they were very young when they had it frozen.

Dr Porter—One of the anomalies that you need to be aware of is that it is state by state. Adrianne works under a different set of legislation than I do. I can freeze sperm for 10 years as long as my ethics committee is happy. There is no legislation in New South Wales that says I can only store sperm for a certain period. There is state-by-state legislation. People jump states for the best deal.

Mr GEORGANAS—Do you appear before this ethics committee when you have a case?

Dr Porter—Yes.

Mr GEORGANAS—Is that on a regular basis or whenever you—

Dr Porter—Whenever we have a case. In New South Wales, we are governed by the regulations and guidelines of the National Health and Medical Research Council and our own institutional ethics committee, because there is minimal legislation in New South Wales. Other states have formal legislation.

Mr CADMAN—Queensland is the same.

Dr Porter—They have some legislation to do with surrogacy that we do not have in New South Wales and they have some legislation to do with donor gametes as well. In general, New South Wales has taken the fairly laissez-faire approach of self-regulation in a local environment, rather than legislating across the state. We are very happy with that because it works. This technology—and this is another thing—keeps changing year by year. If you legislate, you get out of step quite quickly.

Ms HALL—Are you happy with the state-by-state legislation? Would you like uniform legislation? Obviously, in New South Wales you are happy because it works.

Dr Porter—The answer to that question is I would like everyone to be like New South Wales, of course.

Dr Pope—Can I comment on that. I have been involved in a lot of the RTAC code of practice in recent times. They all contradict each other.

Ms HALL—That is what I have heard.

Dr Pope—I work between three states and, in all honesty, every time I move states I have to think, 'What's appropriate in this state?' It is very difficult. This whole concept of contradictions is a very tricky thing for patients and all our staff.

Ms HALL—That is what we heard in Victoria.

Dr Pope—It would be very nice if we could try to come up with some consensus on how we would like to do this. That is partly what RTAC did. We spent 18 months on this exercise. We took all this legislation and all the quality systems around the world and came up with something that covered all these activities.

Mr TURNBULL—This is an advertisement for another inquiry: the House of Representatives Standing Committee on Legal and Constitutional Affairs is conducting an inquiry into the harmonisation of laws in Australia. What you are describing is a great example of disharmony. I will make sure this transcript is shown to the committee but it might be worth while if you or your colleagues fire in a—

Dr Pope—That would be ideal.

Mr TURNBULL—It does not have to be a tome, just a two- or three-page letter. It would be great to get that on the agenda because this is exactly the sort of thing we are looking at.

Dr Pope—I have written something very similar on that because the Victorian Law Commission are doing a review at the moment and I have just made a submission to them as well on exactly this issue.

Mr TURNBULL—As you know, you can get it all off the parliament web site—the address and so on.

Dr Pope—Yes.

Mr TURNBULL—That would be great.

Ms HALL—Would you be arguing that the New South Wales legislation should be used as a model for Australia?

Dr Pope—There are lots of good things among all these different activities. In all honesty, having reviewed the entire thing and come up with the RTAC code of practice, I think this covers it very nicely. What the RTAC code of practice does is look very specifically at the activities within IVF units and how to make them work. We have some copies of this if you

would like to take them away. They highlight all the areas that we consider to be of concern. We have based this on risk management. We have looked at all of the things that could possibly go wrong within the industry, how we can protect the people involved, the best things we can do for patients and how we can go about that.

What I have had to do, with the group of people we work with under consultation, is to try and take the best out of each of these activities. But it is very tricky when I travel between states for my own business—and also within the RTAC approach. Each of the legislative groups in those states uses RTAC as the accrediting body—when we go out on an inspection, the ITA in Victoria and the ITC in South Australia come along—so they are actually utilising all of that information to start with. It seems to me that we are all trying to duplicate the activities, whereas we are probably amongst the first group that has been proactive in trying to take all of that information from every state and pick out the best things from them and make it work relatively well.

Where we differ from a lot of the other areas is that we are looking for continuous improvement. Not only do we want set minimum standards; we also want to continue to improve the whole industry. That is what the state legislation does not allow for. Yes, we can push our own wagon or barrow, but there is something about a conscientious look at the whole thing which is not happening at the moment—but it may happen with this other review.

CHAIR—I am quite happy to write to the chairman of the legal and constitutional committee and refer to this briefing, and they should have a look at it.

Dr Pope—Thank you.

Prof. Chapman—As a New South Wales individual, I would certainly not be wildly enthusiastic about picking up the Victorian legislation—moving away from something that works well to something that ends up with an increased bureaucratic process. My understanding is that, when the Victorian authority was set up, instead of having three consent forms to be able to have an IVF cycle there ended up being something like 20 consent forms to satisfy the bureaucracy.

Dr Porter—It is rare to find something hitting the front page of the papers for something going wrong in New South Wales. It rarely happens, because of self-regulation. This industry-profession has a very good reputation for self-regulation, and it seems to work in this state. Why the heck can it not work everywhere else?

This slide shows why we have got so much better. Do you remember the curve Michael showed where the success rate of conception was fairly flat in IVF and then it suddenly took a rise at the end? Why did it take a rise? Because we now have better culture medium. We understand a bit more about what a human embryo needs in its early developmental phases and we have got very good at reproducing the fluid that we grow embryos in. So there has been improved culture medium and this has been from research around the world, as well as in Australia. Some of the research would not be permissible in some states now that have got us as far as we have.

Again, it is the same argument: we are improving our culture conditions. These are now tiny little incubators that we grow individual couples' embryos in, as opposed to huge warming

incubators of old. This is giving us a much better standard of quality of care of our embryos, which translates into higher pregnancy rates. This also enables us, for our techniques, to understand—just by looking at the embryo—what is an embryo that is more likely to have the best potential to go and make a baby. We are starting understand how we can select the better embryos that are more likely to make babies. These have been some of the huge improvements, just in the last few years, in IVF which, as I stress, may not have occurred with some of the tight legislation that would have prevented this.

I will go very quickly through this because I know I am way over time. This next slide deals with sperm preparation. This is a normal shaped sperm, a round to teardrop shaped sperm with a neck for energy and a tail for propulsion. But lots of men—even very fertile studs—produce large amounts of abnormal sperm. Big heads, small heads, round heads, double heads, no tails, heads without tails, tails without heads—you name it. We are very wasteful in our sperm production, but it is up to our scientists to pick out that particular sperm as opposed to the rest.

That is a human egg. Do you remember my saying how small it was? That is it blown up. You can see this is a mature egg. It has what they call a polar body out here which, to a scientist, would dictate that that is a good mature egg. You can see a little cluster of these little cells around the outside. There are those tumular cells I talked about. That is what we like to see at an egg collection.

Eggs also come in all shapes and sizes and, take my word for it, these are abnormal eggs. You may not, as a layperson, be able to detect them, but they are out of shape. They might be discoloured, they might have nuclear problems, they might have extra bodies outside, but the trained embryologist can distinguish these as abnormal eggs.

Ms HALL—Does an abnormal egg being fertilised, or a normal egg being fertilised by an abnormal sperm, lead to an abnormality in the child?

Dr Porter—In my general teaching of medical students I would say that an abnormal pregnancy results from a normal egg meeting a normal sperm and something going wrong in the process after that. Nature is very good; she usually will not allow an abnormal sperm anywhere near the egg. That is her first barrier, and she is good like that.

I want to show you this ICSI video. This is the ICSI; this is an egg being sucked up against a hollow pipette. It is like a balloon on the end of a vacuum cleaner. A very, very fine needle is actually injecting the sperm—there it goes—down into the egg. It is a very short video, but I will go through it. Here is the egg that we showed you in the previous slide. It is sucked up against a tiny pipette—remember how small it is and, therefore, how small the pipette must be. It is a fairly sophisticated piece of machinery. Then the needle, which is smaller again, and the sperm, which is about one-twentieth the size of the egg, has to be physically injected.

The needle makes a puncture and in just a second you will see the sperm going down that tube—there it goes. Here it comes—no, it is not; I missed it myself. That is why I am a gynaecologist! That is called an intracytoplasmic sperm injection. The sperm has been selected out. It has been loaded into a fine tube, tail first. It is like chasing a mouse around the room with a vacuum cleaner and sucking it up, tail first. Then you have to inject it into the cytoplasm of the egg. You are keeping clear of the nucleus, which tends to be just up under that polar body there.

You are injecting the egg; you are overcoming some of the barriers that the sperm and the egg may have faced because of poor sperm quality or motility or even the surface of the egg not allowing normal fertilisation.

Mr TURNBULL—You used the term 'motility'. Is that the same as mobility?

Dr Porter—Yes. You are either mobile or motile; I never quite understood the difference. As far as I am concerned they are the same.

Mr TURNBULL—In natural fertilisation, the sperm burrows its way into that cytoplasm itself, does it?

Dr Porter—Yes. You know your masonry drill bit, it has not only a circular motion but also a hammer effect as well. The sperm is not only digesting through enzymes on the surface. If you picture the moon and you picture a sperm coming up to the edge, it is digesting its way and it is being forced by its tail. It is an active process to get that DNA material in through the outer layer of the egg, called the zona pellucida. What is magical about it is that, as soon as one sperm gets in there, there is an instantaneous change in the biochemistry on the surface of the egg which prevents any more sperm getting in. Of course you have got all of us chasing: we were the best ones; we got there first; all our mates missed out.

Ms HALL—Except occasionally.

Dr Porter—Very occasionally; you are absolutely right. There is always an exception to every rule. Yes, you do get two sperms in very rarely and nature does not allow that to go very far because there are too many chiefs and too much nuclear material inside the egg. You are absolutely right.

This is what we want to see after fertilisation. Here you can see, once the sperm gets inside the egg, that the head of the sperm with the DNA swells up and looks very similar to the DNA component of the egg. So now you have got the DNA from the egg, the DNA from the sperm, and these chromosomes start to fuse. This is what we want to see the day after fertilisation. After that, we then go on to division. We go through the single cell to the double cell, and now this is a four-cell embryo. Remember it is in three dimensions, so what you are seeing here is one, two, three, and, if you look very carefully, there is a cell sitting on the top here like a pyramid. This is a three-dimensional view of a four-cell embryo.

Day 3: this is the division of the embryo. This is the stage where a lot of units are putting embryos back—either at that four-cell stage the day before on day 2, or at this six- to eight-cell stage on day 3. Individual units around the country get used to transferring embryos on different days—some at day 2, some at day 3 or, if we allow the embryo to continue to grow, we get to day 4, where you now cannot make out the cells of the embryo because they are so small and there are so many of them that they are starting to adhere to each other, they are starting to talk to each other. What you have got is: the embryo has not changed in size, but all the cells inside have got smaller and smaller and they are now starting to talk to each other.

This is day 5. We are now five days after egg collection; we are now up to what we called the blastocyst stage. Again, you have got these cells where they start to get compacted against the

edge. It is like a balloon where the cells are now plastered around the edge because there is now fluid. This is fluid through here; this is what is called the blastocyst cavity. This is fluid that the embryo is starting to produce inside. You might be able to see that there is actually a cluster of cells where all the other cells are layered around the outside. This is what is called the 'inner cell mass'. These are those particular differentiated cells—the specialised cells—that will actually go on and make the baby. If you were going to do stem cell research, these are the cells that you would use because these other cells are responsible for making the 'back-up team', if you like, of the placenta, the membranes and the cord. But this is the bit that makes the baby.

In our particular clinic at the moment we favour—and it varies around the country, as I said—putting our embryos back at this stage, because it allows us that selection, from day 1 through to day 5, to say, 'Well, if you are going to make a baby, you have got to get to day 5 first. If you do not make it to day 5, you are not going to make it to day 6; you are not going to make it to the birth day.' So we like to set our embryos at that stage. They are robust enough to have got through the blastocyst, and that is how we tend to transfer our embryos.

What happens after that is the embryo hatches. We have a membrane around the outside, just like a chicken breaking out of an egg—I am wary of making analogies like that, but it is a similar process, because the membrane breaks down and the cells then literally exude. Up to this stage, the embryo sits inside the uterus and does not communicate with the maternal environment; it just grows and it is independent. But once it hatches the cells physically make contact with the maternal environment and start sending signals to mum to say: 'I'm here. Don't have a period, and turn that pregnancy test positive.' So the embryo has to hatch, and that is what implants into the wall of the womb. That happens the day after we put these embryos back in.

CHAIR—On what day do you freeze them?

Dr Porter—Again, it varies. Sometimes we are freezing at blastocyst and sometimes we are freezing at day 2 or 3. It is an individual, technical, scientific decision. There is not a lot to choose between them. Some units favour one versus the other, but we freeze at both. This is what happens then: this is an electron micrograph of a human embryo. It does not look like anything that you might recognise, but this is all those cells, now physically implanting into the wall of the womb. That is the magic time. As far as we are concerned, as reproductive endocrinologists, that is a pregnancy because now we have got an embryo that is implanting into the wall of the womb.

We have mentioned cryopreservation. We are talking about freestanding tanks full of liquid nitrogen. These are not connected to the power supply so, if the building's power goes down, these are independent. They are filled with liquid nitrogen. They are tanks like these, with little straws very much like popper drink straws that you get on the side of drink containers. Each straw is individually marked and the sperm—or, indeed, occasionally eggs and embryos—are stored in tanks of liquid nitrogen for an indefinite period.

Turning to the last slide: I just want to show you that we are fanatical about (1) patient confidentiality and (2) safety issues. You put the wrong embryo into the wrong person, and you can lock your door. So we work very hard at making sure that every single piece of biological material—whether it be sperm, eggs or embryos—is clearly marked with an identifying, unique number, whether it be your unique clinic number or your date of birth and full name. This is the

way things are stored; we do not deal with two couples' gametes, embryos, eggs or sperm on the same lab space at the same time. There is a huge amount of quality control that goes into a laboratory to make sure that things do not get mixed up. I am going to stop there; I think I have reached the end of the line.

Prof. Chapman—I hope we have not overloaded you with information.

Proceedings suspended from 11.29 am to 11.40 am

Prof. Chapman—We thought we would move on and talk about where we are now in terms of what ART is in Australia in 2005. Since ART began—our first baby was born in 1980—there have been over 60,000 ART babies born in Australia. I looked at the ABS statistics last night on the net. If all those babies were in one town it would be something like the 16th biggest town in Australia—or city; in fact it would classify as a city of IVF babies, bigger than most rural towns. I had a list of the ones it would be bigger than. I think it would be twice as big as Tamworth. The message is there: we have made a significant contribution to the population of Australia.

Over half of those births have been in the last six or seven years because the success rates are higher and because more women are moving to ART as a way of creating their baby. Last year around 7,000 ART babies were born, which constitutes nearly three per cent of all babies born in Australia. Yesterday Ms Gillard was making comments in newspapers that if we restricted ART we would have an impact on the birth rate in Australia and she is probably right.

On the basis of the figure of three per cent, within the next couple of years in every classroom in every school in Australia there will be one IVF child. It is now commonplace in our society. Some work has shown that one in three individuals has a friend or a family member who has used IVF. I am sure the figure would be even higher for you, probably because being politicians you associate with lots of people—even Mr Costello acknowledged that he has friends who have used IVF. Some politicians have used IVF. One in seven Australians is related to somebody who has used IVF. One societal change that has occurred is that coming out of the closet in relation to how you had your children is now much more acceptable. So people learn about it, although as a doctor I still have many patients who want to keep it a secret—certainly a secret from their work, which is why we started doing the scanning and blood tests at 7 am. Women can do this before they start work in the mornings and we keep the number of treatment days in the month, where they will not be able to work, to a minimum. Usually they need to miss work only on the day of egg collection and perhaps on a half day for the embryo transfer. And, as we have already shown you, the success rates per cycle have doubled in the last decade and we have seen the reasons why that is the case. The number of cycles that have been performed has nearly doubled in the last 15 years and that is for a variety of reasons, which I will take you to now.

Why has there been more IVF? Obviously it is costing taxpayers more money, but they are getting more babies. Concerning community acceptance, as I said before, today most people see IVF as a helping hand, rather than something done behind closed doors because there is a terrible stigma associated with it. There is still some stigma but not much. Each group of my medical students does a community medicine project and the last group of students did one on IVF—in fact it was about sex selection. The first question that they asked was 'Are you in favour of IVF?' and they went out into the streets of Kogarah and asked over 200 men and

women what they thought about IVF. And 98 per cent accepted that IVF was an appropriate treatment for infertile couples.

The other influence is delayed child-bearing. As you get older—this is boring now—your chances of conceiving are fewer. Therefore once you have tried for six or seven months, you are less likely to be pregnant if you are 38 than when you were 30 and so you start to panic. Usually, if you are 38-year-old woman you have planned your career or alternatively you have not met the right man because we are much more discerning in this day and age of increased divorce and you want to have the right man before you settle down. You want to be financially stable and so you put off child-bearing. But that then leads to the panic of 'I'm not getting pregnant when we want to.' So you turn to IVF to give you that extra kick to enable you to have the child at the earliest opportunity.

There is also, particularly in the last 12 months, increased accessibility—that is, geographically, the increasing number of satellite units means that in a rural centre like Dubbo once every three months an IVF unit will take a semitrailer with a laboratory onboard out there and treat patients locally. Local gynaecologists are involved in that process. Probably, the organisation with the most satellites in Australia is Monash IVF. Adrianne is one of the chief scientists in that unit. How many satellites do you have?

Dr Pope—We now have satellites in six rural areas of Victoria. We were in Ballarat until it set up a permanent facility recently and we literally go from Casterton, over in the west of Victoria, across to Sale and we do a round. For 32 weeks of the year, there is this group on the road doing IVF in these facilities. We send our staff backwards and forwards to do the counselling and all of the preliminary work beforehand and then the group come to town and take over in each of these areas.

Prof. Chapman—Each of the satellites has to be licensed through the RTAC procedures so the full range of services has to be available.

CHAIR—What about the other states?

Dr Pope—Queensland has IVF units in many places right up along the coast but we are just about to move one into Townsville as well. We have one in Rockhampton these days, so they do cover that and the Queensland Fertility Group in Brisbane—I worked with them for many years—have satellites up and down coast as well. New South Wales has just started.

Prof. Chapman—Sydney IVF run a number of country units in that sort of way.

Dr Pope—There is one in Tamworth, Grafton and Coffs Harbour.

Prof. Chapman—They are also in Wollongong and the Hunter. To sustain full-time IVF services with all of the infrastructure and the nurses, you require a population of 300,000 or 400,000 to draw on to provide sufficient number of cycles to be cost effective. So the notion of going on a cyclical basis to the smaller places has taken off. There are actually questions as to its economic viability in many cases because it is very intensive but it does provide services around the countryside.

CHAIR—We are talking about private health now.

Prof. Chapman—Yes we are.

CHAIR—What is happening publicly?

Prof. Chapman—Because of the costs involved, state governments have not seen that provision of IVF is their responsibility. They provide basic fertility investigations, the semen analysis and laparoscopies. In some states, intrauterine insemination, a simple treatment, is done in the public sector. There are public hospitals that do IVF but they still charge the Medicare moiety as well to enable it to work as a private unit within a public service. Their costs are lower because a lot of it is cross-subsidised—the rent for the rooms, the nursing staff—so there is dual funding in some public systems.

Dr Pope—One of the things that we have done over the years is actually recognise health care cardholders. We have reduced rates for different groups as well.

CHAIR—Is that a form of—

Prof. Chapman—Cost-shifting—absolutely. Another hat I wear is director of the public hospital up here in the area of women's and children's health. If it were not for cost-shifting we would not be able to run a service. Certainly, what we have seen in the last 12 months is the impact of the Medicare safety net and this substantial reduction in the cost to patients in relation to the gap, which has grown over the years. When we look at the number of cycles done in the second six months of last year—and we will see some numbers in a minute—we will see that the rise in the number of cycles in 2004 was 14 per cent of all treatment activity. That is against the background of somewhere between five per cent and eight per cent in previous years. So different access from a financial perspective has occurred. We have certainly seen different sets of patients. In our service previously something like 70 per cent of patients coming for IVF had private medical insurance. It was those people who could afford private insurance who were coming to do IVF. Those who do not probably have been staying away. What we are seeing is a drop in the number of privately covered patients. This still means that patients, particularly those who are uninsured, are paying somewhere between $2,000 and $2,500 dollars a cycle because—

Mr CADMAN—Are these figures wrong? You have $2,100 in 2003 and—

Prof. Chapman—That is an average. We will come to that in a minute.

Mr CADMAN—and in 2005 it is $1,200. So there is a substantial drop.

Prof. Chapman—That is if you are privately insured. If you are not privately insured, Maroubra Day Surgery, where you will go this afternoon, will charge you $900 for the privilege of being admitted and for theatre costs. Those patients will not get any rebate on the anaesthetist fees and the gap on the anaesthetist fees. They are two extra things.

Ms HALL—I think there is a fifth point on the increasing uptake—that is, the increase in the success rate and better performance.

Prof. Chapman—Yes, success breeds success.

Ms HALL—Yes. I think that is a fifth point that you could have on that slide.

Prof. Chapman—Part of that is the community acceptance. People see that it is a successful treatment and therefore—

CHAIR—Is there any demand from overseas for the treatment here?

Prof. Chapman—Very little.

Dr Pope—Yes, we get a lot.

Prof. Chapman—Monash gets a lot. Monash has a profile internationally, perhaps more than any other clinic in the country, and therefore patients do come. We see the occasional patient coming down. In most Asian countries, for instance, there are pockets of good IVF. In some instances that was set up by Australian companies at some point in the past and doctors have come down and trained or we have gone there. Monash has a clinic in China. So transfer technology is occurring. Most places do have their own services—some are better than others. Internationally, there is a fair bit of movement for training. People are coming out of their countries and then going back. The background costs around the world are pretty much the same. Our difference is that we have a subsidised system, which is relatively unique in the world.

The fourth factor was changes in fertility. The particular worry is this chlamydia story, which is just starting to show. The next slide shows you that the average age of first pregnancy in 1990—this is through natural conception—was 27. It has already moved up to around 30. There has been a substantial shift in this age at which you decide to have your baby. For IVF there has also been a substantial shift. Whereas it was primarily a treatment for young women with blocked tubes, we are now moving to dealing with women who have delayed childbirth.

Also, the male factor has become more prominent as age increases. There is a relationship between age and male factor infertility. We are about to publish some data from the national perinatal statistics unit which shows that, if you are a female and you are 40, you are actually far better off in terms of pregnancy rates with IVF if you pick a man of 30 rather than a man of 50. So there is a difference. If you control for the female age there is a difference in the chance of success depending on the age of the male. We think that might be partly because women of 40 who get 30-year-old men are probably fit and healthy females! We are struggling for reasons, because in terms of sperm count there is not that much difference.

We have already mentioned the increased success rate. For those who are privately insured the safety net was something in the order of $2,100 and has dropped to around $1,200. It depends where you are in terms of the safety net and in terms of whether you have reached your $1,000. But if you are out of pocket for IVF Australia your out of pocket expenses for a simple IVF cycle are $2,700. If it is your first cycle then there is $1,700 that you get your 80 per cent back on, but if it is your second cycle you have already gone through that barrier and so you are getting 80 per cent of $2,700 back. So it depends where you are in the cycle in your calendar year. I have to say that one of the artificial things that occurs with that concept is a December rush. We had a December rush last year because people who had reached the threshold wanted to

get an extra cycle in before Christmas and be pregnant so that they would not have to restart the threshold on 1 January. It is an artificial thing, and I think that has also contributed to that 14 per cent rise in that here was a pre-new year rush. If you are not insured your expenses are up around $3,500 because of the theatre costs and the anaesthetic costs.

I have here the Medicare item numbers, and because in every cycle of IVF there are a number of item numbers—there is not just one item number—you are talking about large numbers of item numbers, gradually rising over the past five years. Then there is a kick up: in terms of total item numbers there was a nine per cent rise but in terms of fresh cycles there was a 14 per cent rise. Not surprisingly, with increasing numbers of item numbers you get an increase in the amount of taxpayers' money being spent. But then, when you add in Medicare Plus there is a big jump. The inference that was made in the stories in March this year was that this was all due to doctors in IVF clinics rorting the system—that was the first stage of this debate, as I understand it. I then rang around to every IVF clinic in Australia in my role as chairman of the IVF Directors Group to ask them what fee changes had occurred in the last 12 months. None had gone up by more than 10 per cent, and half had not put their fees up at all because they were scared of this event occurring—of being accused of taking advantage of the system.

Two of us had spoken to the department of health immediately after the implementation of the safety net to say that patients have turned up with this big cheque asking, 'Who does this belong to?' and having not realised what the safety net meant. In those early days of the safety net, patients were surprised they were getting more money back and so were we. We rang up and said, 'Do you realise what you are doing? Do you realise what has happened?' The numbers of IVF patients we were seeing were rising. We did not look for a sudden increase in numbers because of the financial background, but this caught everybody slightly by surprise, including the department of health. In fact, I was told by them that they had taken this into account in working out the costs of Medicare Plus. Obviously, I do not think they had.

My understanding is that when the figures were looked at this year, to see why more was spent on MedicarePlus than was predicted by the department, we stood out because of the figure of 57 per cent. It was not because of the amount. The amount is relatively small in the total MedicarePlus budget. We stood out because it was such a big jump. The jump was because of the gap, which has grown over the years because the background item number payments have not risen in quantum, although the cost to the clinics has jumped substantially. The gaps had risen, MedicarePlus picked up the gaps and suddenly it looked like we were rorting the system. But I can vouch for the fact that around Australia there has not been a substantial rise in costs to patients. I think that is also substantiated by the patient support group. I understand that the department of health rang the patient support group to find out whether there were any clinics that were being naughty. There is one slightly more complicating feature in this in that, while I say the gaps had got bigger and they were picked up by MedicarePlus, some clinics were charging a gap separate to an item number. The HIC, in their data, could not have predicted that that was going to come on board once MedicarePlus came in.

Mr CADMAN—How can they do that and present accounts that are understandable to the patient?

Prof. Chapman—Our billing system says that item whatever it is—for example, 3,200—is $2,700 all inclusive. Other clinics would present a bill listing the management and laboratory

charge, 2,600, and say it is $100 for that particular item number and keep the two separate. That was historically the way they would bill, because it did not matter to the patient that there was a separate moiety to an item number. But it did make a difference when the safety net came in.

Mr CADMAN—And HIC has never tracked that?

Prof. Chapman—No, because it does not come up on the item number data. But obviously to keep a level playing field between us, say, and a clinic down the road who did it that way, they loaded that onto their item number the next week, not surprisingly, so that patients were out of pocket the same way. It has all been done to make sure the patients maximise their benefit, which is what you would expect.

CHAIR—They get $3,000 when the baby is born.

Prof. Chapman—Yes. On top of it they get the $3,000 with the baby bonus.

Dr Porter—They get $4,000. It has gone up.

Prof. Chapman—While I think there has been increased accessibility because of the financial changes, how much of a difference it has made is difficult to quantify. It is certainly not the nine per cent, because there is a background rate. If you keep going, probably only two or three per cent has been drawn in because of the safety net. Ultimately—and it shows in other countries—patients generally are prepared to pay. We have the second or third highest IVF rate per head of population in the world. Denmark has the highest, because it is a fully subsidised system.

Ms HALL—How do the success rates of the services here and in Denmark compare?

Prof. Chapman—They are very similar. We go through phases of one country getting ahead because they have discovered something first. We were ahead in the eighties. Australia led the world from 1982 to 1992. When ICSI came in we fell behind. When the new culture medium came in we caught up. We went ahead for a while. In fact, our results now are probably as good as those anywhere in the world.

Dr Pope—We use two embryo transfer procedures in Australia, whereas in the United States they will put as many as 10 embryos back. So we always have to make our comparisons based on the fact that we are looking at embryo numbers as well.

Prof. Chapman—Because of the success rates, the cost per live delivery—if you want to know what a baby costs the taxpayer—in 1992 was around $24,000 and today it is around $13,000. So the taxpayer is getting more babies for their buck; there is no question about that. We are getting better value because of our improved success rates. Thirteen thousand dollars is not much for somebody who is going to live 70 years, contribute to the tax system and to the work force and be a valuable member of society. But—and this is where the argument is—if we look at the young patients, it is less than that. As we go down through the years, the cost per baby, which reflects the success rate, rises. Even in the over 40 group we are getting up to around $80,000 per baby.

Look at the $13,000 baby, the overall one. There is a methodology used in health economics called quality adjusted life years, or QALYs. For treatments like heart transplants, the cost of adding an extra year of good life is $20,000 per year for the rest of that person's life. For renal dialysis, it costs taxpayers $13,000 to keep that person alive. If we look at a child that we produce, it works out at about $150 per every quality life year—so it is cheap to get an added year of quality life. We are creating a life which is then productive for at least 45 years, or maybe longer as we work into our seventies. When you compare it with other health economics, this is not too bad. Even if you take the worst case scenario of an $80,000 baby being born to a woman over 40 and do the same sort of calculation, your extra years are going to be about $1,000 per year, which is still better than some of the treatments that we spend a large amount of money on.

Mr TURNBULL—What percentage of those born to over 40s are $80,000 babies?

Prof. Chapman—To get a baby when a woman is over 40 costs $80,000. We might invest $10 million in that and we will get 10 babies.

Mr TURNBULL—So you are saying that for women over 40 it will cost the taxpayer $80,000 on average?

Prof. Chapman—Yes. When you get to the over 45s—certainly Melbourne has taken a view in relation to that that not all of the doctors in the IVF profession would necessarily agree with—you are getting one baby in every 400 cycles. That child is then costing of the order of $250,000 to get out of the system. Therefore, is that worthwhile?

Dr Pope—We recently introduced a policy that no female over 45 is allowed to have IVF with their own eggs.

Prof. Chapman—Some of us would say that that is still ageist.

Dr Pope—Yes; we may be in court.

Prof. Chapman—There is a balance between ethics and practicality.

Mr CADMAN—That is what I was driving at earlier.

Dr Porter—I am sorry, I was uncertain of that. Do you mean that they can have a privately funded cycle?

Dr Pope—Yes. They can have it privately funded but not—

Dr Porter—There is a big difference.

Mr CADMAN—That needs to be taken into account. Where does the public step in?

Dr Pope—Yes.

Prof. Chapman—We thought that it would be good for you to meet some patients. They were hand selected from my own clinic here. Two women have been successful and one woman is still

trying. The first woman had a set of identical twins from IVF. It was not from two embryos; one embryo divided. The second woman has had one successful pregnancy and saw me yesterday to organise another cycle. She is over 40. The third woman has been through a number of cycles of treatment.

During the RTAC visits, when the group of assessors come to each clinic, there is a session devoted to the patients at the clinic. On the RTAC is a patient representative, and they seek out these patients for discussion. Patients have probably tripped up more clinics in getting their full accreditation than any other factor. Patients have raised issues in relation to the care provided. Patients are a substantial part of the accreditation process. It is about taking into account what the consumers are saying about the clinic. We are most concerned about patient confidentiality, so we will now meet the patients privately.

Proceedings suspended from 12.11 pm to 1.07 pm

Prof. Chapman—We will now move on and take a look at the fertility profession. Adrianne is an embryologist, as you have heard. The Fertility Society of Australia have been very fortunate in having her as our leader over the last couple of years. From a background of running embryology laboratories, she has developed an understanding of quality systems that perhaps clinicians do intuitively but not bureaucratically; therefore, not all doctors make the right decisions at any moment in time. But the majority do.

On a scientific level, there cannot be any mistakes. The Fertility Society have produced a code of practice, which Adrianne has put hours of work into. The previous document had been acknowledged internationally as a world standard best practice. The new document I think goes even further in controlling the profession. The reason you are here is that it is on the borders of social and medical boundaries the whole time. We are very sensitive about it, as clinicians. Because of that, we have been able to gain acceptance amongst our colleagues—and getting a bunch of doctors together agreeing on everything is virtually impossible. In relation to our quality and controls, there is unanimity that this is the way to run our profession. Adrianne has really played a major role in updating that to the 21st century. She will give a background of the organisation.

Dr Pope—To give you a little bit of an idea of who I am as well, I started IVF back in 1987—not quite as long as these two have been at it but still quite a number of years. I started in Brisbane, where I went to university. I have travelled around the world with IVF; it is one of the beauties of being in a science that allows you that international travel and the opportunities to work in different places. I have come back to Australia, to Melbourne and to Monash IVF, where I have been overseeing IVF now for quite a number of years, along with many other components.

The other part of my job these days is to oversee the pathology components of our business. That includes all of the genetics work that we do, which is a lot of the new investigative work that will be the future of our industry as we get better and better at it. As you have seen from the presentations this morning, we are moving towards addressing particular issues. We get better because we identify the problems, we understand how they work and then we are able to address them with different treatments.

Today I am here in my role as President of the Fertility Society of Australia to talk a little bit about it and to give you a background into the profession and what goes on. As you may have guessed, there are a lot of people involved in this. It is quite interesting to have a professional body that covers so many disciplines. In this group we have obstetricians and gynaecologists with specialties in fertility. We have many scientists with specialties in embryology, genetics, andrology—the study of males—and also counselling. We have a lot of counsellors involved in this, both social workers and psychologists. We have a lot of fertility nurses. There is now a specialty in fertility nursing. This is not to mention all of the business people we need to continue to run our facilities as well.

There are over 70 clinics in Australia at this stage. These are broken down into different types of clinics. We refer to primary clinics in the notes for you, which are those that are like the facility here at IVF Australia: they are fully established with everything on site and all the capabilities. There are associated units, because we recognise that there are not enough specialists in all of these areas in Australia. Sometimes we need to oversee these facilities in other areas so that other doctors can give a hand in offering services. You have heard about the satellite clinics that roam around the countryside. We occasionally do what we call transport IVF, where we may take our embryologists, doctors and anyone else we require to the hospital where the patient has an egg pick-up, and the eggs are then taken back to a laboratory somewhere else so that we can undertake IVF in a specialised facility.

In Australia at the moment there are over 1,500 people employed in this industry. As you can see from the break-up of these different groups, there are varied groups with many nurses at this stage, because we rely hugely on the educational component. To do an IVF cycle takes about six weeks of the patient's true attention and dedication, with all of these people to help make it happen. When we talk about the global costing of this, it involves all of that cost. It is not merely about seeing your doctor; it is all of the other components as well.

CHAIR—What is the difference between a gynaecologist and an obstetrician?

Prof. Chapman—Gynaecologists look after women's problems and obstetricians deliver the babies. But, as a specialty, we learn both. Some people decide that, because they do not like getting up at night to deliver twins, they are going to give up obstetrics and concentrate on gynaecology. So most fertility specialists are gynaecologists. Ric and I are actually exceptional to still be delivering babies.

Dr Pope—It is very hard work to do IVF and deliver babies too.

Prof. Chapman—There is one point I would like to make in relation to what Adrianne said about there being a whole lot of people involved, and that is that the global fee, when it comes with the item number, covers a lot of people. I am sure it will be used against us in this review that we appear to be the richest doctors in the world because all the item numbers come to a doctor's name. Even though I am paying all of these people in my clinic from that—

Ms HALL—So it is a skewed perception.

Prof. Chapman—Absolutely skewed.

Dr Pope—It is not a doctor's fee; it is a fee for all the staff.

Prof. Chapman—But the item numbers come through a provider number, and in my clinic the provider number is mine, so I look as though I am one of the wealthiest doctors in the world. But unlike an obstetrician, for instance, who only has himself and the midwife, I have a team of 17 people working for me.

Dr Pope—Monash IVF currently employs 130 people. None of those people are doctors. That is merely the number of auxiliary staff needed to make everything function. Just to give you a little bit of history of the Fertility Society, it was initiated back in 1983. There was a first scientific meeting of people interested in this industry back in 1982, then in 1983 it was decided that they should form a society, which was then established.

The aim of the Fertility Society of Australia is to promote and improve human reproductive health within Australia and New Zealand. Our New Zealand colleagues are part of this as well, but we do not ever mention them in the name, I am afraid to say, so they are sometimes a little offended. But we are covering New Zealand as well. The Fertility Society of Australia has a board of directors, which is an elected group from the society. It represents all of these different areas. We are about to go into a new series of elections very shortly.

As well, we have associates who advise this board. These can be the likes of Michael as chair of the IVF Directors Group. 'Scientists and reproductive technology' is another subcommittee, along with the Fertility Nurses of Australasia, ANZICA—being the counselling group—RTAC and ACCESS. ACCESS is our consumer group and they are part of these meetings. They offer advice on how the Fertility Society of Australia is progressing.

The board of directors oversees the subcommittees, which at this moment are the nursing, medical directors and scientist groups. We also have affiliated organisations, such as ACCESS, who are there to provide us with patient information and advice. We also have ANZICA. The counsellors separated from the group many years ago and I am about to try and draw them back into the group again after all these years so that they become part of the society.

We also support, through financial contributions to ANZARD, the collection of all of the data in Australia that relates to all of the cycles that are undertaken. As Michael mentioned earlier, we were the first country in the world to start collecting this data and to attempt to try and gather all of the information that could be relevant in future decision making. We also fund RTAC, the Reproductive Technology Accreditation Committee. We appoint a chair to that committee from the Fertility Society of Australia and a secretariat to run it. This group operates at arms-length from the society. We merely provide the funding necessary for them to continue.

The subcommittees at this point are: the medical directors group, the scientists in reproductive technology, group, the Fertility Nurses of Australasia, the counselling group and the consumer groups. Just to give you a little bit of a breakdown as far as the membership goes, at this stage the scientists are an overwhelming group, purely because, while science is a multidisciplinary area, this is a highly specialised group so they do tend to be attracted to professional groups that represent them. The nurses are the next largest group. As you can see, it breaks down into fertility specialists, counsellors and others. I am not quite sure who the 'others' are.

CHAIR—Where are those scientists trained?

Dr Pope—Most of them are trained in Australia. I lose more scientists from this area overseas than from any other area I have ever worked in, purely because the level of training and expertise offered by our scientific staff here means they are absolutely fair game for anywhere else in the world. Needless to say, they are snapped up very easily.

CHAIR—Is there a university which specialises—

Dr Pope—Monash University has a course.

Mr GEORGANAS—Flinders, too, I think.

Dr Pope—They are not doing the scientist course. They did have a nurses' course at one stage.

Prof. Chapman—New South Wales has a masters of reproductive medicine.

Dr Pope—Yes, that is reproductive medicine. There is a masters of clinical embryology offered through Monash University. Part of my role is doing some of the training of those people through the university. A lot of staff, though, are trained within our facilities as well. As I said, we often lose them overseas. We hope that they will all come back. If they are going to go, we hope that they come back to us and bring with them any expertise they may have gathered, as well as offering the same to people around the world.

The vision of the society has been to promote the study of the science of human reproduction, to encourage research—we are into this in a very big way; we give grants to research projects around the country and in New Zealand—and to offer clinical guidance and direction. It is important to make sure we overview the whole profession very carefully so that the best levels of care can be offered.

Mr TURNBULL—How is your society funded?

Dr Pope—Through membership fees and through fees we generate from the IVF units. To be accredited through RTAC you have to pay a fee, which is over $8,000 a year. There are also scientific conferences. We have run a number of international conferences that have proven to be quite financially viable for us. At the moment, we are doing reasonably well from a financial view, but it has taken us 25 years to get to that stage. We are never going to be one of those groups that can afford to fund huge numbers of things. That is something that I like to put to this committee: things that we think are really important for the community that we would love to think that the government may be interested in—educational activities, particularly.

Mr TURNBULL—Do you have a foundation which is a tax deductible gift recipient?

Dr Pope—No.

CHAIR—Was medical indemnity an issue in your—

Dr Pope—It has been. It has been phenomenal.

Prof. Chapman—There are two aspects to that. Firstly, there is the individual doctor. That is the same as anywhere else in the medical profession, and gynaecologists have been one of the higher groups. If you are an obstetrician it is even higher. Secondly, there is the indemnity of a clinic by the insurance world.

Mr CADMAN—IVF, with the 25-year factor, could be extremely difficult to cover.

Prof. Chapman—Insurance companies do not seem to have had a problem, as long as you pay them enough money.

Mr CADMAN—The bookies are the same!

Prof. Chapman—There have been occasions in the past where an insurer—certainly our insurer has—the following year says 'no' and you have to move on to another insurer.

CHAIR—You would have to build that into your fees.

Prof. Chapman—Absolutely.

Dr Pope—Yes. The costs of all this accreditation and insurance are phenomenal in this industry. Our indemnity is half a million dollars a year without the doctors insurance.

Ms Channon—That is right.

CHAIR—For the clinic?

Dr Pope—Yes, for the clinic. We have to have all of our doctors insured privately on top of that to supplement the fund.

Mr CADMAN—Yes—double insurance.

Dr Pope—And I have had our insurers out from London to go through every one of our processes, about which they have said they are wonderful but if they go wrong they will cost us a lot of money. So it is a difficult situation, unfortunately.

Prof. Chapman—The problem with the insurers is that, because they are international companies, they see the mistakes made in some other countries which are not quite as rigorous as we have been.

Mr GEORGANAS—And you might not be able to pick them up while you are here, but they obviously have expertise in that area.

Prof. Chapman—Yes.

Dr Pope—So what the Fertility Society gets up to is funding RTAC, as I have mentioned, and setting professional standards. We award research grants every year; we awarded $80,000 worth of research grants last year.

Ms HALL—But that is not much, is it?

Dr Pope—No, that is nothing in the real field. To us it is a huge amount of money but to those involved it is not. We have been aiming to give opportunities to scientists, clinicians and to whoever may be interested—interest in this is quite broad—to apply for grants where they would not have been considered. It is very hard to get into the NHMRC run of huge grants et cetera, so it is to give new people an opportunity to get started and to give them credibility so that they can do some research and get into the system where they can indeed tap into these more lucrative funding situations.

Ms HALL—What about attracting grants from those more lucrative areas? What sort of success rate have you had?

Prof. Chapman—It has been relatively small.

Dr Pope—Yes.

Prof. Chapman—The PGD stuff has got some funding because it is molecular biology, but clinical research is very difficult to get funding for.

Ms HALL—Are you basically saying it is deemed to be not a very sexy area to invest in?

Dr Pope—Yes. It once was but not anymore.

Prof. Chapman—I suppose we have been our own worst enemies in the sense that we fund that research internally. There is a range. There is the University of Adelaide and their commercial arm, Repromed, which is a joint venture. All their funds go back into research. Regarding Sydney IVF, I think Professor Jansen would say that something like 60 per cent of their profitability goes in to funding research. Others do nothing and live off the research of others. Of the bigger organisations, IVF Australia is embarking on half a million dollars a year worth of internal research, but again that comes out of the patient moieties.

Dr Pope—Monash IVF has been the same. Until recently it was a not-for-profit organisation and the funding went back to the university for research. That is where a lot of money is going at this stage. We hold an annual scientific meeting to bring the group together and to discuss all of the advances at that stage. We have subcommittees with educational meetings. The scientists group, the nurses and the councillors hold meetings of their own, usually one weekend a year, to bring their communities together to discuss what is going on and what is new in their areas.

We provide educational activities to the public. We are trying to work on that very hard these days because it is crucial that we get through to people what it is we do. There is a lot of mystique behind this, I am afraid. Many of you will now be discovering that what your perceptions are and what the reality is are often quite different. So that is something we have been focusing on.

We provide professional expertise to governments, to the public and to other professionals, and that is something we have all been involved in over the years. The RANZCOG recognise the Fertility Society and this area of expertise of ART, and also with regard to data that has been available that the government has tapped into. Things like the ANZARD data that has all of the statistics on IVF in Australia have been funded out of the industry but yet has been available to government bodies to be able to tap in and to determine what is available, and also for state government bodies as well. We offer the expertise of the groups like RTAC, ITA in Victoria, the RTC in South Australia and in Western Australia. They all utilise the expertise of this industry to determine whether everyone is actually within the legislative requirements in those states.

I am just going to touch very quickly on all that I have listed. I am sorry that it is quite busy but it is in the notes that you have there. When we talked about regulations and legislation at this stage, from a regulatory point of view, the Reproductive Technology Accreditation Committee—that we have made reference to a few times this morning—is the body that oversees everything that happens within this community. I have mentioned to a couple of you in passing that when the Research Involving Human Embryos Act 2002 came through it named RTAC as the accrediting body for ART. So consequently you cannot be a licensed ART unit in Australia unless you have been accredited by RTAC. This has also now been recognised by the New Zealand government which introduced legislation last year covering the ART industry and they have also recognised RTAC at this level.

The ANZARD perinatal statistics are the figures that must be presented by IVF units. That is a compulsory action. You have no choice about whether that data is collected; it must be provided to this group for use. State wise, Victoria, South Australia and Western Australia have legislation. New South Wales is still thinking about it and at this stage, as Michael said, at the moment they have not, but they have had a great deal of discussion. Queensland has the Surrogate Parenthood Act 1988 and the Status of Children Regulation 2002.

Federally, we have the Research Involving Human Embryos Act that determines some of the areas of IVF that can take place, in particular in relation to research and training. There is the Prohibition of Human Cloning Act 2002 which also has some impact, though certainly not in that area, but again the legislation does. The NHMRC licensing committee, now that it has been set up in relation to these acts, has a licensing section that come to visit IVF units and they have the right to visit any ART unit in the country whether they have been licensed to do research or not; that is part of their parameter as well.

Australian Customs implemented some changes a while ago so you have to have a Customs licence to import or export embryos into and out of Australia, which had quite a lot of significance for patients who live overseas who do come to Australia for treatment. Those who are Australian citizens and choose to come to Australia and those who are not and who have paid fully to have treatment then have to get a licence from Customs to be able to export their embryos back overseas, because they may actually seek further treatment in another facility, so it goes to another ART unit somewhere else in the world for use at a later date.

Back in 1996 the NHMRC introduced some ethical guidelines on the practice of ART. It was a 15-page book—it was a nice easy read. They re-released it last year and it is a 50-page book, so there is a lot more in that and that is where we are starting to get some confusion because we have contradictions between that, which is a regulation, and some of the legislation at a state

level. Under the RTAC code of practice ART units are to comply with that unless they have some specific reason for going against the RTAC code of practice or the guidelines, and do so with the involvement of data and the research to back their decision making and also their ethics committee. All IVF units in Australia must have an ethics committee associated with them, not necessarily for research alone but for social ethics as well, so there is a great deal of follow-up of that.

We also comply with the National Statement on Ethical Conduct in Research Involving Humans. The majority of laboratories in Australia are now also complying with NATA. If you are accessing Medicare rebates on pathology items you must have NATA accreditation in Australia. Many of our embryology labs have actually undertaken that as a voluntary process as well, so they are audited routinely by NATA as well. A lot of units have taken on ISO9001:2000 accreditation, again just to make sure that they are meeting the quality management standards that are being imposed by all of these requirements now, and then the TGA decided to get in on the act last year as well.

Mr CADMAN—They are a different bunch altogether.

Dr Pope—Yes, but we have had some success. I am very pleased to say I had a letter last night to say that they finally recognised RTAC in all of this process.

Prof. Chapman—I am over the moon.

Dr Pope—We cannot believe how difficult this has been.

CHAIR—Recognised or discovered?

Dr Pope—No, we took it to them.

Prof. Chapman—RTAC has introduced a well-considered document which should form the basis of an industry standard, which the TGA can recognise as the mandatory principle in the manufacture of these products. We have a big stamp on there, which is very good.

Dr Pope—So we are very pleased about that.

Mr CADMAN—Is that automatic approval or does that mean they still have to—

Dr Pope—No. Now we have to go to Canberra.

Prof. Chapman—Now they have invited us to Canberra to talk about it.

Dr Pope—Their interest at this stage is twofold—one in culture medium. Last year, after six years of thinking about it, they decided to impose the authorised prescriber mechanism upon culture medium, which is a mechanism with the use of experimental drugs for patients undergoing things like chemotherapy et cetera. They decided that the easiest way around it would be to make all culture medium literally an experimental drug. As such, every person who comes to IVF has to sign another consent form for the TGA to say that they will accept the risks associated with using culture medium, which has been in use all around the world for many

years, because they have not decided how to assess it. So we are playing that little game at the moment as well.

Mr CADMAN—I am not surprised.

Prof. Chapman—Be careful what you say; this is in *Hansard*!

Dr Pope—I know; I am sorry. The reason for the interest at this stage is also with regard to tissue banking, because at the moment a huge review is going on in Australia and right around the world in relation to the safety and efficacy of tissue banking. Because we freeze embryos and sperm, they have decided we now fall under that category. There has been some discussion that having embryos in our incubators is a process of tissue banking as well.

Prof. Chapman—There needs to be an education program there.

Dr Pope—Yes. So that creates a few—

Ms HALL—It is going to become more and more difficult for you, isn't it?

Dr Pope—We have an audit nearly every month in our facility. Somewhere in the country an external audit is going on by somebody.

CHAIR—Some government body?

Dr Pope—Some government body. When you realise what goes on, it is quite amusing when you hear people talk about this industry as being unregulated. That is not to mention the expenses. Every one of these comes with a cost. They are not free; they charge fees to come and do all these activities.

CHAIR—Which are paid for by the patient.

Dr Pope—No, the public.

Mr TURNBULL—If you could give us some sort of estimate, even if it is ballpark, about the cost of complying with all these audits and the extent to which they overlap, that would be a very useful thing.

Dr Pope—I did that a few years ago, but I will do it again.

Mr CADMAN—I think the productivity commissioners are currently doing an inquiry into the TGA as well.

Dr Pope—Yes.

Mr CADMAN—I think you should make sure they understand your point of view.

Dr Pope—Yes, it would be very worthwhile. I will give you a bit of an idea of our self-regulatory body, the RTAC. This was based very much on our commitment to make sure that the standards in Australia are as high as they possibly can be. We are all in this industry because we have a commitment to it. As Michael said before, both he and Ric love the jobs they job. I am afraid we are all here because we really like what we do. It is a wonderful, rewarding profession, and that is why it attracts so many people to it.

RTAC was set up in 1987, so it has been around for a long time. It started out as guidelines just to help people get through the process and make sure that they were running it as they should. But, in view of the changes that have taken place—and we have reviewed RTAC a number of times over the years—in the last two years we decided that we needed a complete revamp of the whole process, and it went from being guidelines to a code of practice. Now there are compulsory actions within this. If you do not comply you will lose your accreditation. Consequently you will not be able to access any of the Medicare rebates that exist for IVF. So it is a fairly big stick to be able to wield to get that cooperation. The chair is appointed by the FSA board of directors, and it has representatives from each of the groups that we have talked about, including a consumer representative. It is quite interesting to have this, because it creates a whole new approach to how this group works. It looks not only at how everything is done technically and at the professional level we would like but also at how people as a group are treated and how we offer IVF units some advice on how to do things even better. It is often through those consumer groups and, as you have seen today, through the value of talking to people one on one that gives you a very good idea of just how well an IVF unit is working within the environment. The college has a representative on this group as well, so they feel they are overseeing the standards within obstetrics and gynaecology.

RTAC is now internationally recognised. The New Zealand government have named it in legislation as part of their component as a recognised body for setting standards. The Canadian government have been very interested in what RTAC has been doing and are looking at a similar model to use in Canada. With much interest, I keep getting emails because our RTAC code of practice is just about to go on to our web site, where it will be able to be accessed by anyone in the world. I am starting to get a number of inquiries from people from varied backgrounds and from different parts of the world who would like to be able to access copies of this document. In New Zealand at the moment, they are about to set up some new standards for something a little bit outside this area. They have actually approached us to use this document as a basis for their future requirements there.

RTAC gives accreditation up to three years. If a unit reaches a standard and a level that we consider to be appropriate, they will be accredited for that length of time. If they do not, that time frame can be reduced to whatever is considered acceptable by that unit. It can be up to three months, if that were the situation, maybe a year with a return visit at that stage or, if the facility has been running for some time and things continue to be appropriate, up to three years. In that, too, we utilise the ANZARD data so that we have national standards, or international as we use in New Zealand as well. We can compare every IVF unit in the country to those standards and determine if they are there. It is not their figures; it is the ANZARD figures, so we are not reliant on them providing the figures anymore. It also means we can do snap audits on data. We are given a list of IVF numbers or unique identifying numbers for our patients. We go in and actually pull those charts to determine if the data that is in the chart is the same as the data that has been entered on the statistics. So, as I say, it is recognised by the Health Insurance

Commission, who say that if you do not have RTAC accreditation you cannot tap into any of the refunds, and all of these groups around Australia and New Zealand.

To finish up, I will talk a little bit about the National Perinatal Statistics Unit, which is this ANZARD component. It is a university based facility. We are financing our component of it to actually look at all of this data and to collect the information that is relevant to IVF. It is now required that all ART units submit this electronic submission—we have put a lot of time and energy into getting it to an electronic submission—every six months. It means that we can access and provide information on global figures. It has been interesting as we continue to review what we are doing and the benefits we can get from it and also for the community.

We want some more patient linked data, which is something we need to look at now, so that we can actually tie individual information back. For reasons of confidentiality, it is based on numbers. We would like to start looking at ways we can link that. We also need to start talking about educating the community as a basis for some of the figures that we have. We have a huge amount of data sitting in this database. This is where we could actually determine what are some of the useful tools and what should be funded, what is appropriate and where treatment would best be utilised. So that is the type of thing we are looking to do with this information. It is a tool that many researchers would love to have but as a group we have agreed to contain all of this data so that at times we can actually go and analyse it. There has been some very interesting data come out of Australia based on this database.

Prof. Chapman—NPSU is funded by the Australian Institute of Health and Welfare. Therefore, in that sense, it is a government body. That is the National Perinatal Statistics Unit, part funded by the University of New South Wales and part funded by the IHW. They then take on contracts to do specific projects. ANZARD is one of their specific projects. It is not funded by the university and not funded by IHW, but funded by the IVF units themselves. So that is where the funding comes from to do this. We basically, in their staff, employ 1½ full-time people to process the data and produce reports.

Dr Pope—I am going to finish there. Some of our discussions over the last week or so have been, too, about things that we feel are valuable for this committee to be aware of and things that we would like you to take into consideration. There are a few things that are very valuable, we feel, to this industry as well and we would really like to see this promoted as maybe the wish list of the Fertility Society of Australia. They are things we would like to be involved with, which we will fund ourselves to start with but we would really like to look at ways this can be done across the country and New Zealand so that we are getting to all the people that we would like to inform in relation to this area.

Prof. Chapman—This is the last little bit before we head off to our laboratory so you can have a look at things. The last three months of IVF have introduced me to politics in Australia. I will not say they have been without stress and some surprises at the way in which business is done. Perhaps I am too naive. I now refer to what has come out of the discussions in relation to the proposals that were put up—or the kites that were flown—prior to the budget and the notion put by some people that in some way this profession or industry, whatever you would like to call it, needs more regulation and more restriction in relation to government funding. I have found that somewhat disturbing, but out of it have come a number of issues that we in the Fertility Society and the IVF Directors Group feel we are addressing.

We feel that the inquiry, the independent review, is going to cover a lot of ground in what we consider—maybe we are wrong—to be one of the better fertility treatment regimes in the whole world. We are so regarded by others. My colleagues look at us and say: 'You're really lucky. You do things well. You get good results.' My concern is that—this is personal, although I think I speak for the IVF Directors Group—this review, particularly given the terms of reference that were announced in the last 48 hours, is very broad ranging. First of all, an incredible length of time will be required for it to be done properly, and I am afraid a lot of it will be navel gazing while saying, 'What a wonderful navel we've got.' But there are things that we can improve, and these are the things that I would like to see as some of the outcomes of the review committee and perhaps of this group as well.

The first one relates to ANZARD, which we have referred to on a number of occasions, the Australian and New Zealand Assisted Reproduction Database. We have spent what we call a fair bit of dough—in the order of $200,000—on converting it from a very old-fashioned platform into a PC based system with a whole set of new questions. That came online two years ago and we are updating it all the time. One of the defects of it, because of the privacy issue, is that each individual cycle is put on it. We can guarantee that every cycle that is done in Australia is there. Take the lady with the red-haired twins. That database will not show that she has had another cycle with success. It will show two cycles with success but it will not link them, because we in the organisation had concerns that patient information, including the patient's name, should not be in a database that was not necessarily 100 per cent secure. Perhaps by some government involvement we can 'ensure', at least legislatively, that the data will be secure and that therefore we can move to a database that is linked.

I refer to the arguments about numbers that went on in the pre-election debate. The only way we could get to most of the linked data, such as how many cycles an individual woman needs to get to be pregnant and how many women got pregnant after three cycles if they were over 42, was to go back to our own databases. Adrianne went to hers and I went to ours. They are big databases. Ours has 18,000 patients. We can get data out but it is an individual clinic's data. We need to be able to do that across the nation. I think that, to gain security of that information, we are going to need some sort of government legislation or regulation so that people can feel comfortable that their privacy is not going to be breached.

There is still a need for more information. People ask questions like 'in a 42-year-old woman in her third cycle how many fertilised eggs did they get?' It is difficult to get that data out. We need to spend more money on the database. It is a two-edged sword. It is good for us to know for our quality systems but it is also good for the government to know in trying to assess where things are in terms of cycles and their outcomes. We think there should be some government involvement there.

The other thing that came out of that was that the department of health data being used by Mr Abbott was found to be deficient. The HIC data works on item numbers. If you have a donor cycle IVF, for instance, or a normal IVF it is the same item number. It does not tell you the difference. So there are deficiencies in using item number data. Does item number data linked to Medicare number pick up the outcomes? Does it pick up the pregnancies? It is debatable whether it does. The department of health were giving information to Mr Abbott but with some guesstimates in it. Even he admitted at the end of the day that they were probably wrong. We got into a stupid argument about 2.7 or 2.3 per cent which did not need to be there if we had robust

data. We do not have it totally, and certainly the HIC does not have it. I think this review committee will run into the same problems. They will get varying guesstimates of these numbers.

At the Fertility Society meeting in Adelaide in October last year, Ian Fraser, who is chairing this review committee—and therefore I hope this will be an outcome that will come from the committee; it always helps being the chairman—brought together a group of us to look at a national education program which the FSA would fund to promote the preservation of fertility. That ranges from avoiding sexually transmitted diseases and HIV through to having your babies early and convincing men that their wives should have their babies early. A range of issues were discussed. It is simmering in the background. It needs funding to pull together a secretariat which would then start the process. We are talking about public relations and marketing people. It will be a substantial cost to get it off the ground. A national campaign, we believe, will help reduce the number of IVF cycles because it will hopefully produce pregnancies in the future at an earlier age and avoid some of the things that are stopping women getting pregnant at the moment. We see that as a potential great outcome for the review committee.

Clinical appropriateness has come up again and again. Mr Costello said that the restrictions would be based on clinical appropriateness. Mr Abbott at one point said it was to save money. The savings estimate from the health department based on their figures—which, again, I potentially question—was in the order of $7 million. Based on our data and the Monash data the best we could get up to was about $2 million. We are talking about 1.5 per cent of women over 42 having more than three cycles in a budget of $78 million.

Mr TURNBULL—That is 1.5 per cent of women over 42 having more than three cycles?

Prof. Chapman—Yes. Work out 1.5 per cent of $78 million.

Mr TURNBULL—Yes, exactly.

Prof. Chapman—In relation to having three cycles this year and three cycles next year, you just wait for the next year to come around. Just as with MedicarePlus women got an extra cycle in this year, they will put one off till next year, saying, 'We could have had one in December but we're not allowed to, so we'll do it in January.' There is no saving with that, is there? They might have become pregnant in the meantime, in 0.3 per cent of cases. So $7 million was a gross overestimate, I think, but Mr Costello told us it was not a financial argument anyway; it was about clinical appropriateness. Clinical appropriateness is about deciding in a particular situation with a particular women and her husband: is this the right treatment for you? As you have heard today from our patients, in saying to a particular patient in a particular situation, 'Six and you're out,' or, 'Three and you're out,' or, 'You're over this age or that age,' it is extremely difficult to make a decision—rather than just draw a line in the sand—without all the facts involved.

What we can get, however, and this happens in virtually all areas of medicine today, are clinical guidelines which do not say, 'You're wrong because you treated someone who was 45¼,' because someone laid a line down at 45, but rather say, 'You treated the patient at 45¼; why did you do it?' I did it because, at 44, when we last did her IVF cycle, she produced 10 eggs—which is exceptional for someone of that age—with five of them fertilising, and we put two good embryos back. Therefore, she is not a normal 45¼-year-old. It is likely she will

produce seven or eight eggs and we will get one or two embryos, and therefore she does have a chance of getting pregnant. Potentially she is the exception, but it is there. This is opposed to the patient of 30, whom Ric mentioned. If we stimulate her with a maximum dose of drugs, she gets one egg and it produces an embryo which only goes to two cells and does not grow on. We put it back, but we know the chances of success are almost nothing. In her next cycle, what should we say? 'You should stop. Your chances of getting pregnant are virtually zero.'

An individual choice for individual patients is what is required. We can set clinical guidelines. There is some science—not total science, I have to say—in a collection of parameters in relation to a woman's chances of conceiving and of producing eggs. There is a hormone, FSH, that you have seen us giving women to stimulate eggs. If their background rate of FSH is high, it suggests there are not many eggs. If it is greater than 12, your chances of getting pregnant through IVF are substantially reduced.

Mr CADMAN—But you could still go private and do it that way.

Prof. Chapman—But why should money make the difference? I am talking about doctors treating patients; not worrying about what it is going to cost. If her level is greater than 12, there are still pregnancies that occur in that group, so I am not going to write her off on the basis of that; I will give her a trial. The chances are she will not do very well and will require big doses of drugs.

The next parameter is the number of antral follicles. We saw follicles of two centimetres being described as we went along, but at the beginning of the cycle they all start out as follicles of one or two millimetres. There is some evidence from Germany that I saw in Copenhagen that shows that, if a woman has fewer than five antral follicles at the beginning of a cycle, the chances are she is only going to get one or two eggs. So, if she has a high FSH level and an antral follicle count that is low, she is becoming more and more negative. Then there is a hormone called mullerian inhibiting factor, which the group in Adelaide have been working on for the last three years. There has been some publicity about the time clock. You can do a test to see how fertile you are likely to be. You take the antral follicle count, the level of mullerian inhibiting factor, which is released by the ovary, and the FSH levels and you come up with a formula that says, 'You have very little chance of getting pregnant.' But that could happen at 30, while at 45 you could still be in the category that should be treated. This is evolving all the time—two weeks ago I found a little more information—so to put lines in the sand is just crazy, in my view.

The IVF Directors Group has set up a clinical guidelines committee. Its role is to work through the evidence that is around and produce some guidelines—not things that say, 'If you don't follow this, you'll be kicked out.' What has been shown overseas and here in other areas of medicine is that, once you produce a set of guidelines, people move towards them. We have a problem in relation to IVF doctors in Australia in that we have all been doing it for so long that in our hearts we believe two embryos give you a better chance of success than one. We used to use four embryos back in the eighties, three embryos in the early nineties and two embryos in the late nineties, and now we are moving to one. Sometimes a patient says: 'But, doctor, if I get two, I want twins; I do not mind twins. Please put two back, because I've got more chance of getting pregnant.' But the facts do not show it.

Again, in Copenhagen there was a lot of data about single-embryo transfer for women under 36. Interestingly, in Finland and Belgium there were two different systems, which I will come back to. By reducing the number of embryos transferred, they dropped their twinning rates in these countries over a two-year period from something in the order of 23 per cent to eight or nine per cent. That in itself—that saving on those babies—would outweigh anything we will save in relation to IVF. The cost of prematurity and neonatal care is paid for by the state, so therefore you are perhaps not interested—

Ms HALL—Cost shifting is in the terms of reference.

Prof. Chapman—But it is about the total package to the health care of this country. If we could halve the twinning rate, the $78 million would go into a minor issue or an equivalent issue. The interesting thing was the two different systems. In Finland, they had done it by the doctors getting together and agreeing a guideline. Over a three-year period, they dropped the average number of embryos replaced by about half. In Belgium, they did it a different way—an interesting way. I do not understand their health care payment system, but in a sense the patients only got their Medicare rebate if the doctors only put one embryo back when the patient was under the age of 36. If they put two embryos back, they did not get a Medicare rebate. That is an interesting financial way of controlling it. Needless to say, within 12 months they saw the same change. But it puts restrictions on some situations. There are situations where you get two very mediocre embryos and ask yourself, 'Which one am I going to choose, or do I put two back?' We would choose to put two back. So there are clinical situations where an imposed government restriction is not actually a good idea. By those of us within the profession creating a group of guidelines, we can actually move practice to be more cost-effective for the community as a whole.

CHAIR—Asking from the point of view of the bean counters in Finance, who believe, I am sure, that you want to churn out as many IVF procedures as possible because of the amount of money that comes in to you or the clinic, is there a waiting list for IVF? Do you have to go out looking for customers or do they come to you? Is there a shortage of them or is there a waiting list?

Prof. Chapman—I think it is in homeostasis, basically. Why do you need more patients? There are levels of financial return, in a sense. It is a business—there is no question about that. Doctors are reasonably well-paid people. We are no more well paid than plastic surgeons or orthopaedic surgeons. There is, I believe, a fair price to pay our professionals. But, when you are building a service, it is basically uneconomic until you get to around 200 cycles for a full-time service. Then when you go to 300 cycles you get to another level where you have to put on three embryologists rather than one, because people get burnt out, and so it goes on. So, if there is more demand, we have to build our services. At the moment, embryologists are hard to find, because they take about 18 months to train properly, and they go overseas or a new clinic starts up and you lose some of your embryologists. They are the critical points.

CHAIR—But how do we counter the argument that I put to you?

Prof. Chapman—That all we are doing is trying to build cycles?

CHAIR—Yes.

Prof. Chapman—There is not a waiting list in the private sector. In the public sector there is a waiting list, but in the private sector if you want a cycle you can start next week. However, we are responding to patients knocking on our door, and we increase our staff in response to that demand. The demand has been rising steadily.

Mr TURNBULL—Your position is that the clinical advice as to whether a patient should continue having cycles should be based on the prospects of success and the decision should be made by the patient after receiving the advice from the doctor. Is that right?

Prof. Chapman—Yes.

Mr TURNBULL—Are there any circumstances where the prospect of success is so low that you would not treat the patient—you would not provide further cycles—even if the patient wanted it?

Prof. Chapman—I know there are colleagues who would say that that is definitely what they would do. I have certainly given strong advice. I am accused by my staff of not being able to say no. I think Bettina Arndt made that point in the paper yesterday, and I thought, 'She's talking about me.' I do find it difficult to say no.

Mr TURNBULL—If a patient wanted to continue having cycles—like a rain dancer wanting to keep dancing until it rains—notwithstanding that the probability was terribly low, is your position that you would continue to make those cycles available, even though you would continue to advise that it was a waste of time and money?

Prof. Chapman—Yes, because I ultimately believe in a patient's choice.

Ms HALL—Would you provide counselling—

Prof. Chapman—Absolutely.

Ms HALL—and would that be counselling to direct someone away from it?

Prof. Chapman—It is as specific as, 'You are banging your head against a brick wall.'

Mr TURNBULL—Earlier today, Ric Porter talked about decisions that would be taken with respect to giving intensive care unit treatment to a very old patient, and he suggested or implied that, in circumstances where a patient was very old and their life expectancy was short or their position was very frail, it would not be as appropriate to put them into ICU as it would be if they were younger, and that is a decision to withhold treatment. Are you familiar with that happening in medicine?

Prof. Chapman—Yes.

Mr TURNBULL—Why are you saying that you would not take a similar decision to withhold treatment in this area?

Prof. Chapman—I have certainly said no on a couple of occasions, but not very often. Part of the skill of being a good doctor is manoeuvring the patient around so that she does not say to a doctor when they have seen another doctor, 'He said no.' I will manoeuvre the patient around to make a decision. In one of my more difficult patients endometriosis has destroyed her ovaries, so she does not stimulate, she loses one or two eggs. I have now got her to a point where she virtually accepts her situation. I see my role as one of manoeuvring patients into accepting their position, not me saying, 'I'm a policeman; you can't do it.'

Mr TURNBULL—But you are dealing with public money, and I was putting this to you because this is the issue that Alex was raising earlier. There will be circumstances where you believe there is very little chance of pregnancy and where you have appropriately advised the patient that they should not continue but the patient says, 'No, I want to continue.' What do you say to the proposition that in those circumstances the patient's persistence should be at their own expense and not that of the Commonwealth?

Prof. Chapman—I think that is a reasonable choice. If there is less than a one per cent chance of success, the taxpayer should not pay.

Mr TURNBULL—You are saying that having lines drawn at ages is too mechanistic; it is too simplistic. We understand that. Let me put this to you for your comment: what if there were a rule, a principle or an ethical guideline which said that Medicare funding would not be available where the doctor certifies in effect that there is a greater than a nominated percentage chance of success?

Prof. Chapman—We are getting back to nominations again.

Mr TURNBULL—I am just asking a question.

Prof. Chapman—I think that is fair. That is to some extent what the Melbourne people have done. They have said it is 45. I still treat patients over 45, and I get responses from them. I had a pregnancy delivered in February last year from a 47-year-old after natural IVF, who is coming back for more.

Ms HALL—But that is age nomination. Malcolm is asking about the clinical indications.

Prof. Chapman—Then there is a debate as to what that level might be.

Mr TURNBULL—What do you think the level should be?

Mr CADMAN—You suggested guidelines, which I thought was very sensible, and perhaps a formula, but how do you prevent patients going clinic shopping?

Prof. Chapman—They will.

Mr CADMAN—Of course they will.

Dr Pope—That is partly what we did in introducing that 45-year-old age limit. We looked at the statistics of those 45 and over and said that it is too low to warrant offering it. What has been

happening, and we were greeted with this even just recently, is they move to the next doctor—and there are a dozen or so within our group—and say, 'Dr So-and-so won't treat me because I'm 46, so I'm coming to you.' They liked it because it actually gave them somewhat of a stance to be able to say, 'No, our policy is that we do not treat people over 45. I'm terribly sorry, but my colleagues and I have all agreed that it is not warranted.'

Prof. Chapman—What will happen next year, I can bet you, is that the New South Wales average age of treatment of patients will rise because all the 45-year-olds will come over the border.

Dr Pope—All the Victorians will be sent to New South Wales.

Prof. Chapman—Just as they come up for donor insemination.

Mr VASTA—We heard in the UK that they do not fund as much as we do. Is that true?

Prof. Chapman—The whole of their health system does not fund what we do. If you want to wait 2½ years for a hysterectomy, that is fine. The health care systems are different around the world. I worked in the National Health Service for 15 years, so I have been there and, in my view, Australia has one of the best systems in the world; the combination of public and private. I think patients should pay something for the IVF, but it is not black and white. If you make a rule that blocks people from getting any rebate, as soon as you block a Medicare item they do not get anything back from their private fund either.

Mr VASTA—What is it in New Zealand?

Prof. Chapman—In New Zealand it is primarily private, though there is some public funding through hospitals which makes it free for, I think, two cycles.

Dr Pope—They are up to two now.

Prof. Chapman—Two cycles are totally free.

Mr VASTA—We are one of the best in the world?

Prof. Chapman—Yes, and that partially explains, I think, why we have a high take-up rate, because it is accessible. We see a number of areas in which we can produce clinical guidelines that will ultimately end up getting even more value for money for the taxpayer. We talked about intrauterine insemination. Certainly my own experience is that 30 per cent of patients can be treated with intrauterine insemination successfully without going to IVF. Some of my colleagues do not believe in IUI, because they are scared of the model pregnancy rate; therefore, they go straight to IVF. That is their justification. One might say that they have missed a step in the cycle. But I think if we could create standards—and there are some UK standards in relation to IUI—and we put those in place then again we will probably reduce the number of ART cycles. I think that, over 20 years, we have demonstrated a capacity to self-regulate in a way that is almost unique in the world. The clinical guideline structure will determine internally clinical appropriateness that should be acceptable to any government that is funding IVF through taxpayers' money.

CHAIR—How are you going to have an input into this committee?

Prof. Chapman—That is a very good question. I am extremely upset that the profession, which has been accused of rorting and inappropriate practice, has not been approached in any form to discuss the issue at any level. I have not spoken to Mr Abbott; I have not been invited to. As Chairman of the IVF Directors Group, I would have expected to have been. The President of the Fertility Society has not been approached to enter into discussion.

CHAIR—Will you get a chance to appear before the committee?

Prof. Chapman—There is some question whether it will be an open committee with submissions. Certainly I have been told they will not be advertising for submissions. There may be some private requests for submissions, and one would hope that we are on the list. Since the formation of the committee—which has taken some six to eight weeks, because I understand the original members of the committee were hand-picked by Mr Abbott—there have been negotiations, through the Prime Minister's office, on getting more appropriate people, and we now have some representation from the profession. If you want answers on clinical appropriateness, you involve the people who are making the clinically appropriate, or inappropriate, decisions and ask them to face the music.

CHAIR—I thank the witnesses for giving this presentation today. It has been very valuable. We decided to look into IVF some months ago, before the budget, when quite a few of us were not satisfied with what was being proposed. Today's evidence has certainly given us knowledge that we did not have before.

Mr TURNBULL—I just add to the chair's remarks, thanks to your chairman for helpfully arranging the meeting today.

CHAIR—I would like to thank Malcolm Turnbull, who has facilitated it!

Resolved (on motion by **Ms Hall**):

That this committee authorises publication of the transcript of the evidence given before it at public hearing this day.

Committee adjourned at 2.14 pm