

PUTTING PATIENTS FIRST:

Dame Suzi Leather - Speech to National Infertility Day, 10 June 2006

I am extremely pleased to be here today and it is so nice to see so many of you here.

In the last couple of months we have seen a significant indicator of the potential and success of infertility treatment with the birth of the UK's hundred thousandth IVF baby since official records started in 1991. It is deeply heartening to think of the amazing difference that this technology has made to people's lives and the terrific joy and happiness that those hundred thousand children have brought to their families.

And yet there is still so much to do. We hear every day personal stories of how individuals are dealing with their own problems and of the support and strength they gain from sharing their experience of other people on the same journey.

National Infertility Day is a vital opportunity for people to get to know more about infertility and also hear not just from the many experts present but also gain support from fellow patients. Can I, on your behalf, thank IN UK and Ace Babes for organising this day.

All of us at the HFEA attach great importance to working with patients and are very much looking forward to meeting you today to provide whatever assistance we can. Please do come and visit the HFEA stand in the exhibition area.

Having a strong patients' voice led by good patient organisations is, I believe, crucial throughout the health sector and particularly so for infertility.

Today I want to focus on how we are working for you by putting patients interests much more at the forefront of our concerns and what the HFEA is doing in the world of fertility treatment.

The challenge I've set myself this morning is to answer one of the views expressed to us from our on line patients consultative group – Fertility Views. This patient said "*What does the HFEA actually do*

with the £103 charged for each treatment? Obviously to come up with a stupid idea of minimising transferred embryos”.

I want to demonstrate what the HFEA is doing for **you** by reviewing some of the issues and concerns that patients have told us about: issues and concerns that they you and your fellow patients want us to help fix.

We do have to work within the law – which we know is not always perfect. But I certainly don't want the HFEA as the regulator to be a negative influence or to place unnecessary burdens on either clinics or patients.

Uppermost in our minds must be to improve the sector and to do our bit to ensure that patients get the treatment they need and the level of care that they have a right to expect.

I have a clear personal view of what I want to see for patients:

- I want to see treatment for patients delivered in a safe way, carried out to high standards
- I want to see proper access to treatment for patients. I would like to see the Government follow through on its stated desire to fully implement the NICE guidelines
- I want to see patients being fully informed about infertility, not kept in the dark or fed misleading claims. Each and every patient should be in a position to make the best possible personal choice for them including information about cost.
- I want to see good customer care with clinics treating patients fairly and **not** like just 'another number' on an impersonal production line
- And I want to see safety of treatments being paramount at all times

So, where does the HFEA fit into all of this? In a nutshell, we exist to ensure that the treatment patients receive is safe, appropriate and conducted to a high standard - and that any research carried out is

also safe, necessary and ethical. Clearly, in an area of fast moving science our job is to inform patients as much as possible. The law makes clear the areas that we are not responsible for – and have no say over – like finance, access and availability of treatment – but I shall come back to those later.

I have been keen to ensure that the HFEA is much more patient-focussed in its work. The only reason the fertility sector exists is to provide patients with the treatment they need and so it is absolutely paramount that we have patients and patient views at the heart of what we do. We must always put patients' interests first.

I think we have taken great strides in the last 12 months to put this into practice.

Firstly, we work closely with patient organisations meeting them regularly and consulting them on policy. Our "Fertility Views" patient panel also provides an invaluable insight into the experiences of people going through treatment.

We feel it is also very important to have patients' experiences of a particular clinic before we inspect it, so we can take this into account both in the inspection and in our final findings. This means that patients' views are not simply stated, but acted on.

Alongside this patient feedback, we also receive a wide range of enquiries from patients which give us a picture of what they are thinking about current issues or the latest stories that have surfaced in the media.

And, finally, in my official capacity, I speak with patients and their supporters who tell me their concerns and problems.

All this feedback provides us with a rich source of information. So what are the key concerns and how can we address them?

Access to treatment is probably the number one problem faced by patients. Unfortunately this matter is out of the remit of the HFEA – although you've heard my personal wish that better funding should be available.

However, there are a number of areas of patient concern where we do have power to act. These fall into three important groups:
Ensuring high standards, Better informed patients and what happens
When things go wrong.

In **ensuring high standards**, we know that patients want a high quality of service across clinics. There have been numerous concerns about what are seen as different standards operating. There is patient demand and support for us inspecting clinics to make sure patients can be confident that every clinic operates to at least a good basic standard and that they are accountable for the service provided – particularly in the private sector

90 per cent of our Fertility Views patient panel mentioned this as one of most important things done by the HFEA to help generate and ensure trust in the sector.

In the words of one panel member, “The HFEA should be inspecting the clinics so they are consistently good - they should all offer the same opportunities and standards”

We have revised the way we carry out inspections on the day – trying as much as possible to look at a clinic’s operation from a ‘patient’s eye’ perspective. Our inspections are designed around the patient’s journey from the first time they contact a clinic, through the various stages of their treatment until they leave the clinic for the last time.

But we don’t want to inspect for inspection’s sake – this would just distract from the valuable job of treating patients. So we are targeting our efforts on those clinics that are most in need of improvement. Clinics that are working well will be “rewarded” with a less intrusive and less frequent regime of inspection.

We also want inspections to benefit clinic staff – helping them focus on the development of their professional practice; providing clear feedback (both positive and negative); sharing good practice between clinics and highlighting opportunities for clinics to improve by learning from others. We want them to be the best they can be.

The second area of concern I want to focus on is getting the right information to patients – we see this as one of our main roles.

Infertility treatment is among the most fraught areas of medicine - with a high emotional cost to couples. One leading clinician has said it is “as challenging as having cancer treatment”.

Knowing whether you’ve made the right choice or been given the right information is always difficult. Access to information is clearly a good thing – but a sea of meaningless ‘facts’ and figures can also prove bewildering.

As one patient told us “There are so many differing “experts” it is difficult to know which one to place one’s trust in”.

People want honest, expert, reliable and impartial information that they can trust to help them make their decisions. They feel that some clinics aren’t always honest with their information. And if you’re going to spend many thousands of pounds on a single cycle of IVF you want to be sure you’re spending your money in the best possible way.

The new Guide to Infertility is a one stop shop to basic information about infertility, treatments, issues to consider when choosing a clinic and where to find out more detailed information. We’ve built on the successes of previous editions and acted on patient feedback. Free copies are on the HFEA stand - please take one and tell your friends.

The Guide is designed to sit along our new website (www.hfea.gov.uk) which again has been put together with constant involvement from patients throughout the design process. The website will have downloadable fact sheets for patients on particular issues which can be quickly updated.

Last week, we also launched our new interactive search facility on the website on how to choose a clinic. This allows you to type in your postcode, age, treatments required and it will produce a list of clinics for you to see what treatments are offered and what the success

rates are. Essentially it creates for you your own “personal league table” tailored to your circumstances.

Yet it would be wrong to see patients as simply following league tables. Patients have told us that they are circumspect about outcome figures and consider a range of other factors in finally choosing a clinic. As one said – “Fertility treatment sadly does not have a one size fits all solution as you have to be an informed consumer and shop around to find the clinic that best suits your needs”.

One issue that we do feel is significant is patients having the right information about the costs of treatments. I am worried that more than one in three patients tell us their treatment ending up costing more than they expected. They tell us that the cost of treatment can add up like a taxi meter with additional items coming out of the blue so they never know quite what they’re paying until the end of the journey.

Though finance isn’t within our remit, we’ve proposed to the Government that clinics should be required to give patients a fully-costed treatment plan at the very start of their treatment. This would give a total cost for a cycle of treatment together with a detailed breakdown of how that total is made up.

A final part of the information jigsaw comes with the publishing of individual Inspection Reports for clinics on the HFEA website.

Just as OFSTED reports have changed the way we look at the quality of schools, our inspection reports will help people making that important choice of fertility clinic.

Clinics still need to improve the quality of the information they give to patients. I am dismayed when patients tell us their clinic has given them misleading or incomplete information. It would be helpful if there was some equivalent of a ‘kite mark’ on good patient information which clinics could use if they met a minimum standard. Perhaps this is something which IN UK could play a role in establishing.

Finally I want to look at **what happens when things go wrong**. Most patients' experience of clinics and treatment is positive and this is due to the skill, expertise, hard work and commitment of the teams working in clinics across the UK, but we must take criticisms very seriously.

We asked patients to rate the service they received on a scale of 1 - very poor – to 10 - excellent. 60 percent rated it as 7 or above but 18 per cent rated their service as 4 or below.

One common complaint is the lack of customer care or emotional support for patients. One patient told us “At most clinics the service is very impersonal – it feels very much like a sausage factory – go round the IVF conveyor belt and if you're lucky it will work and you'll fall off, otherwise go the back of the queue and we'll see you on your way round again (oh and give us £5000 each time you go round)”. This may not be typical but it is disheartening. We're trying to address this by carefully examining the support given to patients as part of customer care.

Patients do complain. As the regulator we usually receive complaints after they've been through the clinic's own complaints process. Making a complaint is not something that anyone does lightly – particularly given the emotional challenges of infertility - so it's absolutely vital that complaints are thoroughly and sensitively handled.

Since 2000 we've formally investigated 273 complaints. The main issue over the past year has been concern about information: too much, too little or simply unclear. Other issues include poor clinical practice, lack of understanding of - or empathy with - patients.

We are also on the lookout for any problems occurring in clinics. We undertake unannounced inspections on clinics with inspection teams turning up without warning to check how the clinic is performing on the day. We do some unannounced inspections on a random basis each year but also use these when we suspect there may be pressing issues which need investigating.

Finally we require clinics to report any “incidents”, however minor, when they occur. This might include for instance problems with storage dewars, risk to embryos or mix-ups on patient notes. Thankfully, these are relatively few but it’s important that they are properly investigated and lessons learnt. In each and every case we work with the clinic concerned to assess how the problem occurred and we also feedback to **all** clinics any lessons they need to know.

Now what are the issues affecting patients that concern me at the moment?

The first is whether the current law is still serving patients well. The **1990 HFE Act** was based on thinking from the early 1980s and, Twenty five years on, there are signs that it is getting close to its sell by date. Times have changed, science has moved forward enormously, the way clinics work is profoundly different and patient expectations have changed.

The Government has been consulting on how the Act should change and we are hoping that a clear way forward will be announced very shortly.

The second issue I want to raise is **travelling abroad for treatment**. Although there is a lot of media coverage about this, there is a lack of hard information about exactly how many people travel and what they think.

Of course some people will get good care and, hopefully, healthy children as a result. But we do hear about bad patient experiences of travelling abroad for treatment and also hear of treatments being offered which might be dangerous or banned in the UK. We receive some complaints - even though there is nothing we can do about foreign treatment – and our fear is that this may be just the tip of the iceberg.

All we can say is that patients need to consider the risks and implications of going abroad for fertility treatment. They need to check the standards and regulation of the clinic and be happy about the

legal situation and what might happen if things go wrong. We're not saying don't go – but if you do go, go with your eyes open.

As I've said before, I really want to see infertile families have healthy children. So my third concern is about the effects of **multiple births**. Newspaper headlines of quadruplets from multiple births have - thankfully - long disappeared. But the UK still has a high rate of twins and triplets compared with other European countries. This is a serious matter. Twins and triplets are more at risk of conditions such as cerebral palsy, low birth weight and developmental problems that can last a child's lifetime. Mothers are also more likely to have dangerous complications during their pregnancy.

Multiple births also cause massive problems for neonatology units. This is what one consultant told us:

Last week our hospital needed to do an emergency caesarean on a woman with IVF triplets. One of the triplets was very poorly and at risk of dying.

There was no spare ICU cot in the hospital or anywhere in the East Midlands. None in Birmingham. One pregnant woman was being transferred to Wales. Two babies needed urgent surgery and we had already squeezed in 4 cots more than we had space.

How do we deal with this the woman with triplets? – We could find one cot in Manchester, one in Brighton and thought we might have one in Newcastle, while the mum would stay with us. We could care for the babies by treating in the equipment storeroom in our transport incubators temporarily until we could arrange the ambulances and our transport teams. This would have been traumatic and far from ideal.

In the end we decided to delay the caesarean for 48 hours and gamble on the triplets survival. We got our outreach team to send two babies home who weren't ready for it, with their parents agreement and our support. We sent another baby back to Birmingham – to a different hospital than it came from. Then another baby required urgent admission from our labour ward which we again temporarily had to treat in the transport incubator rather than on the main intensive care unit.

We felt we could manage if we spread our medical teams very thinly. The caesarean section went ahead and all fortunately survived. We made it by the skin of our teeth. Another typical week,

This year as you will have read we have been much more explicit in our Guide to Infertility about the risks of multiple births and have published figures for multiple births in each UK clinic. I understand that this is a complex and emotive issue for clinicians and, importantly, patients.

Thinking back to that the patient quote I started with, it is worth remembering that action that the HFEA has taken in previous years on the numbers of embryos transferred has significantly reduced the problems of multiple births but without impacting on live birth rates.

We are currently looking at how we can make a workable and acceptable policy to further tackle the problem of multiple births and have brought together a working group of patients, experts and NHS staff to help come up with a solution. Finally, if the safest course of action for some patients is two embryo transfer – but one at a time – then NHS funding for a cycle of treatment should cover a fresh as well as a frozen embryo transfer.

Finally I come to another issue which is not strictly within our remit, but is causing a lot of concern. This is the **shortage of donors** of sperm and eggs which is causing difficulties across the country.

The HFEA isn't responsible for securing the supply of donors but we do monitor the system and have a picture of the state of donation across the UK. A lot is spoken about 'a crisis' being caused by the Government's decision to remove donor anonymity. The evidence we have just does **not** back this up. We have seen a steady decline in the number of sperm donors for a number of years now. But there has not been a sudden drop in the numbers of new donors registering immediately after the change in the law.

I think the big question is what are the clinics doing to tackle the problems of supply? They are the ones responsible for recruiting

donors. If you look at the issues around sperm donors, for example, you only get a lot of blame and not a lot of responsibility.

How can one clinic have doubled its number of sperm donors in a year when it works under the same law as everyone else? When there is such a demand for donor treatment, how come only one in three of the UK's treatment centres is registered with us to recruit sperm donors?

We also have evidence that some clinics are hoarding their supplies of sperm and refusing to release it to other clinics where patients need donor sperm for their treatment.

Outside the clinics, efforts have been made. The Government-funded campaign by the NGDT last year to raise awareness of the importance of donation was successful – the campaign needs to be continued. We at the HFEA have told clinics that the kind of people who become sperm donors has been changing and is now typically a family man in their 30s.

I can't help feeling that patients needing donor treatment are being sold short by the fertility sector. We need to have a radical rethink and everyone involved needs to pull together. We need to see a national system of co-operation between clinics to tackle the problems of patchy supply and to better co-ordinate recruitment.

Those places with a donor shortage must learn from the successful clinics where a steady stream of donors can be found. We want to see sperm released from storage to treat those patients who need it now. We want to see positive action, not negative words.

So though we are proud of the successes we see daily in the UK's fertility clinics, there is still much to do. By the next Infertility Day I want to see a continued improvement in success rates, even safer treatments, a greater satisfaction from patients with more publicly-funded treatment and the HFEA continuing to work hard for patients.

ENDS

3675 words (30.5 minutes)