

## **Speech to BFS Winter Conference – opening session Tuesday 4 December**

### **“Improving baby safety by reducing multiple births”**

**Walter Merricks, interim Chair, HFEA**

Good morning.

I'm very happy to have this opportunity to speak to the profession at this year's Winter Conference and to be able to bring you the first news of one of the HFEA's most significant recent policy reviews.

Alongside the unimaginable happiness that the IVF sector brings to patients every day with the birth of healthy children - sometimes one at a time, sometimes twins or more - there are also some darker stories we must not ignore.

The issue the challenge of IVF multiple births – or as I would prefer to people to understand it – the issue of tragic baby death and of life-long damage to babies resulting from prematurity, low birth weight, and cerebral palsy caused by IVF techniques. Researchers have told us that in 2003 alone, the deaths of 126 IVF twins could have been avoided, had they born as singletons.

I am talking about baby safety, and of our duty to reduce the number of babies who are at risk of dying at birth, of being born seriously damaged and requiring intensive care, with conditions that affect them through the rest of their lives.

I speak as one whose brother is affected by cerebral palsy. I have enormous admiration for him and how he has managed to lead an extremely successful life despite his speech impediment and motor disorder. But I am also aware of the impact that bringing him up had on my parents' lives and on our family.

In maximising baby health and safety we should remember that maximum safety means one child at a time. The advances in neonatal care in recent years have been impressive, but it cannot be right for significant numbers of children to end up in neonatal units just because of decisions made in the treatment designed to help the mother conceive. I know that I do not have to convince the people in this room about the importance of this topic. When we launched our public consultation on this issue, every professional body and patient organisation in the sector publicly agreed to a commitment to reducing IVF's biggest risk – its incidence of multiple births and the risks they bring to mother and babies.

The number of IVF treatment cycles and patients increases every year. IVF, together with other assisted reproduction techniques probably accounts for half of all the twins born in the UK. IVF alone accounts for 1 in 5 of all multiples. The latest HFEA clinic data for treatments carried out in 2005 has shown a slight increase in the proportion resulting in both twin and triplet births following IVF, compared to 2004. It is clear that the increasing success of IVF is driving the number of multiple births up instead of down.

The HFEA is committed to reducing the rate of multiple births after IVF, but we cannot pretend it is not a difficult and complicated issue for us. Sitting in last week's Authority meeting trying to decide on a way ahead, we had to weigh patient choice and professional autonomy with the impact of multiple births on public health and the welfare of the children.

After all, IVF is one of the areas of medicine in which the treatment of one person can profoundly affect the health of another, and therefore it is enshrined in our law that doctors must consider the well-being of any child to be born following assisted reproduction.

So we had to decide what the appropriate level of regulatory intervention would be.

But the issue of multiple births and the problems that they can present is bigger than just IVF and, therefore, bigger than just the area which the HFEA alone can influence. IUI and drugs for ovarian stimulation also contribute to a higher incidence of multiple births. This is an issue that will take time to tackle, and that is why we are going to need a long-term strategy. There is no single lever to pull that that will deliver an overnight result.

The initiative to tackle this problem came from the profession – with the report into multiple births from the expert group chaired by Professor Peter Braude – and it is right that we should turn to the profession to lead action on a solution.

The HFEA has pledged to engage with this issue where we can within our remit, but we are today calling for an overarching national strategy to look more broadly at the risks that multiple births can cause to mothers and babies.

However, we always have in mind that still the greatest risk in the eyes of patients is the risk of not having a baby. This means we need to find a solution that is fair and workable for patients and does not reduce their chances. Clinicians tell us that the main key to this is skilfully and sensitively practised elective single embryo transfer, and I applaud your timely decision to devote today's agenda to this very subject. But we know that increased NHS funding for IVF is also key. Women with access to only one funded cycle of treatment are

only acting rationally if they beg for double embryo transfer in their single chance of becoming pregnant. The risk of a twin pregnancy seems nothing to the risk of no pregnancy. Guaranteed up to three cycles, including frozen embryo follow-up treatment, patients would be more relaxed about single embryo transfer. So yesterday, on behalf of the HFEA, I wrote to Dawn Primarolo the Health Minister who I know understands and shares our concern about the baby safety issues, to enlist her help to see that PCTs making funding decisions understand the connections between access to IVF, the costs of treating of pre-eclampsia in women carrying multiples, neonatal intensive care funding and the costs of continuing care for long-term conditions that may be caused by prematurity, low weight birth and cerebral palsy. There is growing evidence that PCTs have simply not made that calculation. A national strategy demands all the weight and influence that national government together with the devolved administrations can bring to bear. So, I have written in similar terms to the Minister's counterparts in Scotland, Wales and Northern Ireland.

### **Our approach**

The principles of good medical practice in this country are that it is evidence-based and professionally led. This issue is no exception – the profession needs to lead the way and we will do everything we can to support that. We can supply a range of independent information about IVF and its contribution to the incidence of multiple births which can be used as an aid to clinicians to make sure that patients are well-informed when making choices about their treatment.

But how can we as a regulatory body in partnership with professionals deliver a real contribution to a national baby safety strategy? We have decided that we need a national objective. Overall, our aim should be to bring down the rate of IVF related twin births from around 25% now to a more acceptable level of no more than 10%, - over a 3 year period – while maintaining overall IVF pregnancy success rates. This should see a virtual end to IVF triplets. We know from the experience of other countries that this outcome is entirely attainable. We do not have to risk a fall in success rates to achieve a reduction in risk to baby health and safety. Nor do we have to have a system that places artificial constraints on the treatment of any individual woman.

We think it is right to use the fundamental principles of good practice and good regulation – where key changes are evidence based and professionally-led; and regulation is proportionate and risk-based. This means that our regulatory approach will be to set the

overall outcomes we expect rather than relying on detailed – and arbitrary - rules governing the mechanics of an individual woman's treatment. We will not be micro-managing your practices or second-guessing your clinical judgements, but we will be expecting you to achieve satisfactory overall outcomes that will have minimised multiple pregnancies.

### **Timing and implementation**

Of course, it would seem unreasonable to expect clinics to start making changes towards this tomorrow before a national strategy or professional guidelines are in place. We need to make sure that clinics and their patients have sufficient time to prepare for any changes in practice.

So it makes sense that we should look for co-ordinated change from the start of 2009 which can be measured through our annual reporting. Between now and then we will be working with professionals and patient organisations to put in place the range of measures needed.

Exactly what the targets should be, how elective single embryo transfer will play a part and how this will work with different clinics will be decisions that are led by you, the professionals in this sector. It is your profession who are best placed to create any guidelines needed to steer clinical practice. Next year will be a period of transition for professionals and for patients, preparing for the changes to come in the years that follow.

So in an outcome based regime we will be looking for clinics to set outcome targets leaving it to clinicians following professional guidance to judge best how to achieve the target in practice. The targets set each year will need to deliver an overall national year on year reduction in multiple births. So we may need to set a maximum acceptable target rate, and the clinics with the highest current rates will need to contribute more than those where multiple rates are already low. Our regulatory role will be to help see that targets are set, and if they are not met, to allow our licence committees to assess whether or not this has resulted from a failure to put in place suitable practices designed to meet the target.

At the HFEA we have our own part to play in creating the climate in which reducing multiple pregnancies becomes a shared objective. It is said that the way live birth rates are published by HFEA at the moment may be discouraging clinics to reduce their multiple birth rates. As part of the HFEA's work, we will be re-considering how our data on IVF success rates is presented. In terms of outcomes, if a singleton birth is a sign of success, should twins or higher order births resulting from multiple embryo transfer not be recorded as a complication? How we change this will also be worked out in close collaboration with professional and

patient bodies to ensure that we drive change in the right direction while maintaining the transparency of information that the public expects and that patients need.

This entire process of building the national strategy that will improve baby safety, urgent though it is, cannot be rushed or it will not deliver. The hearts and minds of every clinician, nurse, embryologist, and counsellor in the sector need to be engaged, together with the communication of information and reassurance to patients. We are not in the business of sacrificing women's chances of conception to eliminate a non-existent problem, nor are we underestimating the ability of patients to make judgements for themselves. We are not asking clinicians to force women to have treatments that offer sub-optimal chances of success. That would be unethical and irresponsible. But there is a balanced route to tackling a real problem; that is the path we are taking and we are serious about it.

We will move progressively and carefully, step by step, with a proper process and structure in place for clinics to follow and a clear focus on the outcomes for, and the autonomy of, individual patients. I look forward to working with many of you directly on this, and on behalf of the Authority I want to applaud the commitment that the British Fertility Society has shown in demanding that a solution be found to what we all know is IVF's biggest risk for mothers and babies.

**1974 words (17 minutes)**