

# Speech delivered by Margaret Gilmore Deputy Chair of the HFEA at the Society for Reproduction and Fertility, Manchester

**25 July 2018**

Thank you

Good afternoon - it's a privilege to be sharing a platform with so many distinguished speakers.

There are certain types of story which a journalist knows will always be of interest and therefore widely read, stories about water, food and reproduction because without these things the human race would not exist. Louise Brown's birth was always going to be massive - the first time scientific development enabled a birth which before could not have happened.

I was a cub reporter working for local radio stations including one in Bristol in the years after Louise Brown was born and I remember so clearly her parents house just outside the city. I remember knocking on the door time after time hoping for that special interview. One day the door was actually opened and there was her Dad John Brown. I think he'd hoped all the press had disappeared but local journalists like me weren't going away. He was charming but apologetic. He had a contract with the Daily Mail and he couldn't speak to anyone else. The Browns had taken advice and decided to sell their story to the Mail to help cover the cost of the decade they had spent trying to conceive a child, and to help them deal with finding themselves at the centre of what many believed was the biggest story in the world right then. It was something they had never prepared for or wanted. They just wanted a baby.

I also remember the Daily Mail front page after her birth. It was the first time I had ever seen a newspaper run a front page that simply had a headline and a photograph - with the bulk of the words inside. That headline? "The Lovely Louise" above a beautiful picture of a new born babe. It was a hugely powerful, moving way of introducing this normal baby born thanks to cutting edge science, to the world. In journalistic terms that front page was also a ground breaker.

The birth itself was filmed. We saw part of it at the lecture last night and it's been on the TV News today but for those of you who haven't seen it you can access it on the Science Museum website where it's

being used to promote an exhibition currently running in London to celebrate 40 years of IVF. The short film clip records that momentous event, the first live IVF birth - a surprising mix of matter-of-fact professionalism and a real tear-jerker.

I didn't catch up with Louise for another 40 years until this year when she attended the HFEA's annual conference - along with John Webster who was in the room when Louise was born and who was here at the lecture last night.

40 years on it is significant that today, on Louise Brown's birthday, we celebrate this medical innovation that has changed so many people's lives. Louise's birth was a defining moment in medicine and one that went on to have a huge impact on both the lives of individuals and society as a whole. The UK has reached the milestones of 1 million IVF treatment cycles and 300,000 babies born. Estimates of the number of children born through IVF across the world vary as we've heard today from 5 million, 6 million maybe even 10 million. We'll probably never know the exact number. A recent article in Reproductive BioMedicine Online estimated that by 2100, (in just over 80 years time) 400 million babies or 3% of the global population could exist by virtue of IVF, if you include all original IVF babies and their descendants. That's quite a statistic to come out of Oldham and Bourn Hall clinic, where the first lab work and clinical treatments were carried out.

If we rewind 40 years though, it certainly wasn't plain sailing. The public's initial reaction to the development of IVF was divided. Some were proud that the UK spearheaded this new technique, while others were uneasy about the apparently uncontrolled advance of science, bringing with it new possibilities for manipulating the early stages of human development.

IVF was so controversial that the Medical Research Council refused to fund it and Dr Kay Elder, who worked in the early days at Bourn Hall has revealed that much of the money for it came from an American millionaire, Lillian Lincoln Howell, who herself suffered from fertility problems. She chose to remain anonymous as a benefactor, until her death in 2014.

The Observer newspaper recently claimed the birth of Louise Brown transformed public opinion. The paper pointed out how people who'd warned of all sorts of potentially dire moral and physical repercussions with her birth, found that once she was born, a "test-tube baby" was like any other. It pointed out how newspapers which had previously warned that IVF threatened human welfare and dignity suddenly became rather sentimental, announcing the "baby of the century" and "She's beautiful". After their dystopian forecasts, the paper said, the media was confused by the normality of it all - as in the cognitive dissonance in Newsweek's headline at the time: "She was born at around 11.47pm with a lusty yell, and it was a cry round the brave new world."

The public wasn't so easily appeased. It was society's unease that led the then Government to commission an inquiry, chaired by Mary Warnock, to consider the social, ethical and legal implications of IVF and what safeguards should be put in place. The Warnock report, published in 1984, identified the need for principles and limits to govern fertility treatment and human embryo research.

MPs from all parties came together to support the Human Fertilisation and Embryology Act because they supported the idea of the regulation of fertility treatment and embryo research, and ultimately of our organisation. The Human Fertilisation and Embryology Authority (HFEA) started work in 1991.

If you listen to MPs who supported the Parliamentary bill at the time, it wasn't a given that the legislation would succeed, and at the HFEA we pay tribute to those across the political spectrum who had the

courage and foresight to support pioneering legislation, just as Edwards, Steptoe and Purdy had pioneered IVF as a medical treatment.

Our remit at the HFEA remains the same today as it was in 1991 – to ensure treatment is safe and ethical. We want to ensure that everyone who steps into a fertility clinic, and everyone born as a result of treatment, receives the best quality care. We do this by licensing, monitoring and inspecting UK fertility clinics, as Mary Warnock's Committee envisaged and as was set out in the HFE Act.

We set standards by which clinics operate and we use the data we collect by law, to improve the quality and consistency of clinic performance and the service patients receive. The UK has the largest database of fertility treatment in the world (all one million cycles) and we seek to analyse that data, for the sector and for patients so that they can make the best informed decisions on their treatment.

There have been huge advancements in scientific research and medicine over the past 40 years and the UK remains at the forefront of scientific and clinical development in IVF. We are also leading the way with a regulatory model, which has managed to support innovation and at the same time maintain the trust of the public and patients, who see that we are ethically robust in our decision-making. Our Chair Sally Cheshire and our Chief Executive Peter Thompson describe it as a bargain between science and society where our regulatory oversight protects patients and provides the essential conditions for public trust, which in turn allows clinicians and scientists to innovate responsibly.

The HFE Act has now been in place for 27 years and society is very different in 2018 to 1978. The public controversy though, hasn't gone away. In partnership with the fertility sector and Parliament, we face continued public debate and legislative change head-on. We have managed to successfully navigate changes to legal parenthood and donation for example.

Doubtless there will be calls for further legislative change in areas Mary Warnock's committee were simply not forced to consider, like storage of frozen eggs and sperm beyond the current 10-year limit, but that is a matter for Parliament.

What we can say in 2018 is that the ethical lines laid down by Baroness Warnock, such as the 14-day rule for keeping embryos for research, still stand (and we're well aware of the question marks, controversy and some will argue even contradictions over that specific length of time, which was reached because there were considerations that she felt it was astute to take into account other than just the scientific).

And looking back, despite the fears of those against, there has been no unethical slippery slope. The UK still bans sex selection and human cloning and I believe we have successfully upheld the morality the HFEA was set up to preserve.

On a positive front, we have seen embryo testing developed to allow people to avoid passing on serious inherited diseases to any children they may have. The UK was the first country in the world recently to license new ground-breaking mitochondrial donation techniques which allow women who carry the risk of serious mitochondrial disease to avoid passing it onto their children. With all the newspaper coverage sensationally dubbing the likely outcome to be "three parent babies" I really thought Parliament may have vetoed the idea. It didn't. Perhaps the most stimulating, challenging and difficult part of my job is chairing the Statutory Approvals Committee.

This year on this Committee we have licensed - approved - the first individual cases where patients may now undergo this technique which involves using sperm plus parts of the eggs of two women. The techniques were brilliantly explained by Dagan Wells of Oxford University in his talk this morning. He referenced Newcastle and the team there are currently putting through applications to carry out PNT.

Our Committee is made up of lay and expert members. We have a professor of clinical and biomedical ethics, and a senior fertility counsellor who are lay members, as I am. My experience is in Governance, risk management and communications. I've sat on several Government bodies and regulators since I left the BBC 11 years ago - so I have good experience of the workings of Whitehall and of the media, and a

feeling for how far the public and politicians are likely to go in supporting something or not. I understand risk and security which I specialised in as my day job after leaving the BBC, working for the leading independent security think tank RUSI on more academic areas of security.

The expert members on our Committee include a consultant in reproductive medicine and gynaecological surgery, and a consultant in clinical genetics. When we receive an application from a clinic to carry out the process it's peer reviewed in advance. And we have a lawyer, and a clinical specialist expert in this particular field in the room during our meetings to help us consider each and every case.

Our Committee also licenses PGD - Pre-Implantation Diagnosis - not on a case by case basis but by the condition, with the benchmark being the condition in its worst form. Where they meet the criteria and choose this option, this is also helping prevent patients with genetic conditions passing them on to their children. Many of the most serious conditions have already been licensed and we are now increasingly receiving applications for conditions that are less clear cut. We have to decide what constitutes a serious disease, so our debates become more difficult as we work our way through the strict criteria that must be met before we may license a condition for PGD. Sometimes it's really tough.

So, what of the future? As we pursue our 2020 strategy, the aims we have set out remain absolutely central to our ambitions. These are safe, ethical and effective treatment combined with high quality research; consistent outcomes and support for all patients; and improved standards through intelligence. We are making good progress.

We've done a lot of work to ensure patients are fully informed about their treatment, including much work helping them understand offers of so called 'treatment add ons'. We've developed a traffic light rating system to give patients a visual indication of the evidence base supporting the various treatment add ons they may be offered. We hope this will provide a first step to empowering patients to ask questions of clinicians offering treatment add ons. We are also working with professionals in the sector to develop consensus views on the responsible use of treatment add ons in fertility services.

On research, we have taken steps to publish more widely the research projects we've licensed and clinical trials which may be taking place, in which patients can participate. We're discussing with clinics their rates for consent to research, with the ambition of improving these and making them more consistent. We are also trying to connect research projects and clinics with available donated embryos to allow more research to take place more quickly.

We are also pursuing emotional support as a key priority. We know this is often a huge concern of patients and the critical factor in whether patients have a good experience through treatment, even if it's unsuccessful. We are running a project at the HFEA to improve the emotional support that clinics offer to patients. It's prompting a useful debate about how patients would like to be (and should expect to be) treated - which is with compassion, dignity, respect and the very best care. Whoever you are, seeking treatment for infertility or to prevent a serious genetic disease is a life changing rollercoaster process and, if we can all show compassionate leadership to patients during their most difficult moments, then that will surely lead to better quality care overall. Infertility treatment may be more common but it is never commonplace, and more often than not, it is still unsuccessful.

We are also receiving increased enquiries from clinics about surrogacy. This is in a context of a wider interest in the practical and legal arrangements around surrogacy. In the UK, surrogacy is regulated by HFEA only to the extent that the surrogacy arrangement involves treatment at an HFEA licensed clinic.

We've updated our new Edition of the HFEA Code of Practice so that it more clearly sets out what clinics should consider when treating people entering into surrogacy arrangements. We are specifically asking clinics to ensure that the surrogate (and her husband or partner, if she has one) and the intended parents, all understand the arrangement and its implications for them, and that the clinic determines that they are all suitable candidates to enter into a surrogacy arrangement based on evidence. We would like to see clinics ensure that they are all offered counselling (separately and together) and given appropriate emotional support by clinic staff throughout (regardless of whether or not they take up the offer of counselling).

We believe that this will ensure that both surrogates and intended parents are supported and well informed enough to give careful consideration to the medical, emotional, legal and

practical issues involved in surrogacy, and to the implications of surrendering the child after the birth. Given that emotional issues may surface during these discussions, in all cases involving third party donation and surrogacy arrangements, our expectation is that the discussion of implications should be delivered by a qualified counsellor. Because some UK clinics will only occasionally see patients who are seeking to begin surrogacy arrangements, we're requiring all clinics to have standard procedures for their surrogacy arrangements, which must be understood by all of their staff caring for these patients.

Looking further forward we are keeping abreast with new technologies. One key future challenge (which is also mirrored in other healthcare areas) is ensuring that novel and innovative technologies are introduced responsibly and that patients are properly informed of the experimental or innovative nature of treatments they are using, whether add ons or anything else - and whether they will actually improve their chances of success. The HFEA has embarked on a programme of work aimed at facing this challenge.

Some of the talks throughout the day have highlighted that research is heading in exciting new directions and we as the regulator need to be prepared for things becoming possible which hadn't even been dreamt of when the HFEA was first created. Mitochondrial donation is a clear example of science and regulation developing side by side. The processes used in the years running up to first use of mitochondrial donation in clinical practice may well become the blueprint for future scientific developments not currently permitted by the HFE Act. But other scientific developments may be running ahead which is why it is so important to encourage open public dialogue when considering the introduction of new treatments which may raise ethical questions. It took many years but it worked in the end when it came to mitochondrial donation. Some examples of possible treatments to consider in future may include genome editing of human embryos or the use of in vitro derived eggs and sperm in treatment. The prospect of either being used in treatment in the UK is still a very long way off, requiring leaps in scientific research and a change in the legislation. We've also heard highlighted today the need for debate and support for far more work on male fertility.

In conclusion, as we celebrate Louise Brown's birthday today, we see that IVF now happens globally; but the way it's regulated varies from country to country. There is no doubt the world looks to the UK model as the blueprint, we are world leaders - with the right mix of allowing innovation and maintaining public trust. The bargain between science and society that we discussed earlier.

We, as the regulator, will continue to encourage world class research and clinical trials. We will continue to help patients make informed choices by being the go-to source for clear, unbiased and reliable information on fertility treatments and clinics. And as we encourage the fertility sector and researchers to develop that evidence base and further increase success rates, the HFEA will continue to act as a bridge between scientists, clinicians and patients.

40 years after Louise Brown was born, we do live in a different world, but as I touched on earlier it's important to remember the heartache her parents went through is still very real for millions of people. For a fortunate minority, IVF has been the 'miracle' science that's brought them the baby they've longed for

but the reality is that around two in three people who have fertility treatment are unsuccessful. Which is why 40 years on from Louise's birth, clear information from clinic staff about a patient's real chance of success without some of these unproven add ons, and emotional support before, during and after treatment is so important.

In the country, indeed in the part of the UK which gave the world IVF, we also celebrate the UK's achievements and look to a bright scientific future. Happy 40th birthday Louise Brown and Happy Birthday IVF.

Thank you.