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REPRODUCTIVE TECHNOLOGIES AND THE BIRTH OF THE HUMAN FERTILISATION AND EMBRYOLOGY AUTHORITY

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Why are so many of you interested in this topic? There are practical and ideological reasons that have brought you here tonight. The practical ones are that infertility affects one in seven couples (not counting the application of IVF techniques to single and same-sex would-be parents). The facts are set out on the Human Fertilisation and Embryology Authority website (www.hfea.gov.uk), where you can see that the causes are multiple. One third of infertility cases are due to male factors; 25% are unexplained; and the rest are female and a mixture of the two. Of course, one only knows about the couples who seek medical assistance. There may well be many more who have difficulty in conceiving but do not seek help. The causes? To understand them, and to reduce the incidence of infertility means looking beyond mere medical factors in men and women, to social issues. Rising infertility is attributed to more sexually transmitted diseases that have had damaging effect, for example, chlamydia, and possibly environmental factors. But the rise in infertility is more readily explicable as a feature of modern family living. Women marry much later, for example in their 30s, and may not start trying for a baby even then, because they believe implicitly that IVF can achieve fertility for them if the worst comes to the worst. They may have difficulty finding a permanent partner at that age, having pursued careers and contraception before reaching their 30s.

The rise in infertility has come as a surprise to the 1960s generation of women, who were the first to be led to believe that they could control their fertility absolutely (because of legalised abortion and efficient contraception), and choose fertility/infertility at almost any stage of life at will. As more of them, and of later generations of women, entered higher education and careers, they postponed childbirth to older ages, finding a shortage of childcare facilities, a lack of family-friendly policies in the workplace, and that men are still unwilling to shoulder their fair share of the burdens of parenthood. Divorce and remarriage have also led to older childbearing. Fertility drops quite dramatically at the age of 38 or so, which may coincide with the age at which a woman who has been divorced remarries. There is little alternative to IVF because the number of babies available for adoption has dropped. Insufficient information is given to young people about the reasons for infertility, certainly when compared with the amount of information given about control of conception; this is a topic to be explored later in connection with feminism and fertility. Our understanding of infertility, medical and social, is relatively recent and still growing.

This year sees the 30th birthday of the first IVF baby, Louise Brown. Her parents were a young couple from Bristol who had spent 9 years trying to conceive, because Mrs. Brown had a blockage in her fallopian tubes. This meant that she had eggs but that they were unable to travel to the uterus in order to be fertilised in the normal way. Dr. Robert Edwards and Mr. Patrick Steptoe were the doctors who were researching at that time on fertilising eggs outside the body. The Browns were the first couple to succeed, and Louise was born on 25 July 1978. She subsequently had a sister, also by IVF, and both girls have given birth naturally to their own children. That fact is reassuring because the fear was always that even although the IVF technique seemed to succeed there would be some future abnormality to deal with.

The birth of Louise was met with enormous press interest all over the world. Thousands of couples immediately signed up for the same treatment, but the Catholic Church promptly objected, drawing battle lines that are evident today. Reporters besieged the hospital in which the birth took place. A bomb scare, perhaps started by reporters hoping to get a glimpse of the mother, cleared the maternity building. Today we tend to treat IVF as almost routine but it is salutary to remember the headlines then: it was thought that IVF children might be damaged or deformed because of lack of some early essential ingredient of the mother's womb, or be different in some terrible shocking way. Then there were the ethical concerns about conception outside the body and treatment of the embryo, concerns which are even stronger today than they were 30 years ago: millions around the world believe that the soul enters the body at the moment of conception and that it is wrong to interfere with nature and wrong to tamper in any way with the embryo, let alone do research on it or store it in a freezer.

These beliefs are the other reason why you are here. IVF goes to the heart of many of our most important beliefs and traditions

about the commencement and sanctity of life; the nature of the family and marriage; the soul, dignity, autonomy, the difference between humans and animals, our control over the nature of the next generation and indeed the purpose of life and childbearing. There are no more profound debates to be had in any other topic, and they all started with the British success in achieving fertilisation of the egg by sperm in the laboratory. Britain has enjoyed a further success in this field. By creating a climate in which embryo research is regulated and supported, Britain encouraged the use of that research not only to create babies but to cure lifethreatening diseases. My theme is that from the day of Louise Brown's birth to this, the story of IVF is one of a struggle for dominance, a struggle arising from the fascination and power of the techniques involved. Any government or church will want to have their say, indeed to control, the ways in which the next generation may be born and shaped, and this is what is presented by the scientific development of infertility medicine.

Because of the worldwide interest in the first IVF baby, a feeling arose that government should take some action to demonstrate that scientists were not simply to be allowed to run amok. There followed a move typical of how the British government handles complex issues: the establishment of a committee of the "great and the good" charged with considering the future. It was chaired by the philosopher Mary Warnock, subsequently Baroness Warnock. Its remit was to consider what policies and safeguards should be put in place, and the social, legal and ethical implications of the developments. The Warnock Report (Cmnd 9314) was issued in 1985 and in my view remains to this day the wisest, most pragmatic, farsighted and influential report of its kind, for this and other countries. It is remembered best for the comment that: "people generally want *some principles or other* to govern the development and use of the new techniques. There must be *some* barriers that are not to be crossed, *some* limits fixed, beyond which people must not be allowed to go . . . A society which had no inhibiting limits, especially in the areas . . . of birth and death, of the setting up of families, and the valuing of human life, would be a society without moral scruples. *And this nobody wants.*" (Report page 2.)

The Warnock Report laid the foundation of the Human Fertilisation and Embryology Act 1990, which brought into being the now famous HFEA. This body, half lay people and half scientists, has the flexibility and authority to make decisions on a case by case basis as reproductive medicine advances. It set up the most extensive database of its kind in the world, recording the treatments and the gamete donors; it monitors all the laboratories and clinics carrying out research and treatment; it gives advice to patients and donors and to the government if required; and it approves new treatments and research using embryos. One should note the combination of practical and philosophical tasks. I discovered during my chairmanship that it highly salutary for an ethical body to be faced with the need to make immediate decisions involving real individuals and their health. For on a Friday afternoon the telephone would ring, and there would be an inquiry from a surgeon about to operate, say, on a small child with cancer - was it permissible to store a slice of his testicular tissue in order to safeguard it from the fertility-destroying effects of chemotherapy and radiotherapy, so that one day there might be a chance that the little patient would be restored to fertility by having the testicular tissue reimplanted? No time to call together the body for discussions over months on this new technique; the answer has to be given by interpreting the law as it stands (the answer was yes.) This differentiates the HFEA from the many ethical bodies in the field of embryology all over the world, most notably in the USA: bodies that discuss, study and report but do not have the executive power to make decisions nor to ensure that their recommendations are carried out.

In retrospect it was a clear advantage for Britain to have enacted legislation at the outset, before anyone knew what complexities lay ahead. In many other countries, a lack of early controls over IVF meant that disagreements over controversial issues had a chance to become entrenched, making it harder to formulate research-permissive - or even any - regulatory legislation. Italy, for example, went from being totally unregulated to a situation of very restrictive prohibitions based on the firm religious beliefs of the majority of the population: in 2004 embryo freezing and research were banned and IVF limited to heterosexual couples.

There are those who say that we are overregulated, or that there should be no interference at all with people's rights to reproduce. Interference can be justified on the utilitarian ground of preventing harm to others, including the future baby. The dangers of uncontrolled medicine have occasionally been evident and no amount of compensation can make up for ruined lives and reputations. Examples abound - the Italian doctor prosecuted for selling sperm to countless clinics from a donor affected by HIV and hepatitis; the American doctor who fled to South America after the discovery that his clinic had deliberately "donated" embryos without the donors' knowledge or consent. At the opposite extreme, government can simply introduce blanket bans, thereby saving themselves from the discomfort of dealing with highly complex matters that have no obvious solutions. Such approaches may claim intellectual or religious clarity, but in reality they often represent a kind of intellectual cowardice and hypocrisy. They do not allow for developments both in science and society, and they can ride roughshod over the interests of patients who have strong needs to be fulfilled. For various reasons, embryo research, treatment of unmarried couples, and egg

donation are each banned in some European countries, depending on religious and cultural beliefs.

Regulation is responsible for safety and good practice; it gives clinicians a shield against accusations of malpractice, and gives researchers a haven of safety, provided they act within the guidelines drawn up by the HFEA under its statutory powers. Regulation has reassured the public and reduced, if not eliminated, commercialism. It has enabled this small country to speak with a large voice and impact in the world debates on these issues, and it has caused each and every player on the IVF scene to think about, justify and monitor his or her research and actions, knowing that they will be visible.

The downsides of regulation are that it can be slow and expensive, and a barrier to progress (although not so, judging by the record of scientists in this country). It has meant that there are constant legal challenges to HFEA decisions, for they all have to be within the law, and every disappointed doctor or patient can invoke judicial review and human rights standards. It has meant constant media spotlight and battles fought in the press over public approval or otherwise. There is a struggle between politicians, churchmen, scientists, clinicians and the public for dominance. But British regulation has enabled progress to be made in tandem with public acceptance and in a safe zone for the practitioners for 30 years, now to be continued with a refreshed piece of legislation.

In those 30 years IVF reproductive medicine has gone from simple infertility to matters of convenience and preference, for example the insemination of older women past the age of menopause, posthumous insemination, choice of sex of the baby, egg freezing to prolong and protect female fertility, import and export of gametes, preimplantation genetic diagnosis (PGD) for the purposes of eliminating inherited diseases and then also to achieve the birth of a sibling with blood that might save an older sick child; then cloning and stem cell work that may give us renewed tissues and the ability to live forever.

What are the various techniques? They are illustrated in the handouts accompanying this lecture. Briefly, and starting with the most straightforward, **donor insemination**, a way of supplying sperm when the man cannot, for whatever reason. In IVF practice it may be the husband or a known or unknown donor's sperm that is used. The procedure is very well known in animal breeding, and has been practised on humans for centuries. It is of course open to unethical practices, and there are stories of early infertility doctors using their own sperm on anaesthetised patients; it is also the method of choice for lesbians with helpful male friends. Much legal thinking has been addressed to the question whether it amounts to adultery, and the general answer is that it does not, because there is no physical penetration, but there might be religious objections to the use of sperm of a man who is not the husband of the woman.

IVF is used where there is a difficulty in eggs reaching the uterus where they may be inseminated in the normal way - it might be blocked fallopian tubes, or unexplained infertility. Under anaesthetic eggs are removed from a woman who has followed a hormonal drug regime in order to maximise the number produced (difficulties with this are examined in a later lecture.) The eggs are mixed with the husband's or a donor's sperm, which might have been produced at the clinic by him or have been in storage. The resulting embryos (assuming that the process succeeds) are allowed to grow for a couple of days and the best and healthiest ones selected for insertion into the womb. The law restricts the number used to one or two. Any surplus embryos may be frozen for future use, donated to other couples or to research, at the written request of the patients.

Frozen embryos may be kept for 10 years under the law, but it is asserted that they may be frozen for much longer without deterioration, and there are stories of babies born from embryos or sperm frozen 20 years earlier. The possibilities are immense. Soldiers going to war, or astronauts, may freeze their sperm in case they do not return. In a small window of opportunity, sperm can be removed from dead men. Eggs may be frozen and thus preserve for decades a young woman's fertility for a post menopausal woman, especially relevant in cases of cancer treatment by radiotherapy and chemotherapy. Frozen embryos may only be used with the consent of the man and the woman, and plenty of problems present themselves when divorce intervenes between creation of the embryo and the desire to use it, of which more later

ICSI (intracytoplasmic sperm injection) has proved particularly successful for men with no or little sperm, and was approved under my chairmanship after doubts about the safety of immature sperm were resolved. It involves the removal of sperm from the scrotum in conditions where ejaculation is not possible, the genital tract is blocked or the man has undergone a vasectomy. If he is unconscious then sperm can be removed by inserting an electric baton into the rectum and using current to force ejaculation. Then, however obtained, a chosen single healthy sperm is injected into the egg by a needle, bypassing the normal penetration process that is undertaken when a sperm reaches an egg naturally. This process enables a naturally infertile man to have children (if sons, they may suffer from the same problem). It has raised fears of abnormalities because there are processes undergone when a sperm slowly penetrates the outer shell of an egg naturally which are not present when it is injected into the egg.

Preimplantation genetic diagnosis is a tool, developed from the techniques above, which is being used for the prevention of disease, especially inherited. It is PGD that first gave rise to the fear summed up in the phrase "designer babies." The embryo, however created, is biopsied: that is, after a couple of days' growth, one cell is removed and examined. Various genes, especially inherited ones such as those for cancer or cystic fibrosis may be detected at that stage and, if the parents are willing, affected embryos will be allowed to perish and only healthy ones used. This technique may be used in conjunction with tissue typing, (HLA typing) where parents desire a sibling for a sick child, one whose tissues will match in order that cells may be removed from the umbilical cord of the new baby and used in an attempt to cure the older child of a fatal disease.

Cloning first came to public attention when Dolly the sheep was cloned in 1996 - although there were claims beforehand and later of more extreme achievements, this is the first properly documented cloning of a mammal. A clone is an entity that is genetically identical to another mammal. Children are not clones because each parent contributes half of the child's genetic makeup; twins are clones, born from a split egg, but they still are composed of equal contributions from the genes of mother and father, and are not identical to one parent, but to each other. It is forbidden by law to split a naturally created embryo in order to have twins.

Dolly was created as follows. An egg cell was obtained from a donor and the nucleus (yolk) removed. The nucleus of a cell of the person or animal who is to be cloned is inserted into the enucleated egg in its place. It is fused by an electric shock which causes the egg to think it has been fertilised and to grow. It is illegal to allow such an embryo to grow in the womb. But for research purposes, specifically stem cell work, individual cells may be removed from the growing embryo and become objects of research. It may be that because they are totipotent, they may one day be coaxed into growing new brain, heart, etc., cells for the person who has been cloned, and because they match they will not be rejected in the way that transplanted organs are today in medicine. Of this, more later.

The fascination and power contained in embryology and infertility medicine is such that it is and for a long time has been a battleground for domination between the various forces involved. This was brought home to me when I entered a room in the Palace of Westminster to give evidence to a select committee on the topic, and the opening question was: "Who do you think you are, playing God?" The playing of God has been resumed by parliamentarians, for in this year, the 30th anniversary of the birth of Louise Brown, Parliament has passed (or very nearly passed) a new Bill to replace the one of 1990. The Bill gives legal sanction to mixed animal-human embryos, PGD and saviour siblings where there is a risk of serious disability, while banning cloning and sex selection. It preserves the framework already in place for regulation and for stem cell work. It enters the field of social engineering with the abolition of the consideration of the need for a father in the welfare assessment of women to be treated, and it provides for the registration of two women as parents on a donor-conceived child's birth certificate. The final assent to the Bill has been delayed some weeks because of the continuing controversy about the abortion time limits which, most unfortunately, are also contained within the ambit of the Bill, although they have nothing to do with IVF and embryology. The Bill maintains the internationally agreed prohibition - that only a properly fertilised egg may be placed in a woman, not a cloned one; it permits the mixing for research of human and animal gametes, recognising the shortage of human eggs for research purposes. There is a case for saying that with the new social engineering provisions, as I call them, the wise maxim of Lady Warnock, that the public need to know that there are *some* limits to what may be done, *some* barriers that should not be crossed, has been abandoned, and overall the regime of the 2008 Bill is a less ethical one than the 1990 Act. It enshrines scientific advance, which is good, but in a way that leaves more scope for judicial challenge than was the case under the 1990 Act drafting; it pursues current anti-discrimination aims by placing the interests of would-be parents over those of the child, and it sacrifices the truth principle that should underlie birth registration.

In practice nevertheless, it does little more than confirm every single decision taken by the HFEA between 1991 and 2008 under the discretion afforded to it by the 1990 Act. It also makes a statement that British lawmakers recognise, embrace and control the tremendous advances made in alleviating infertility and disease by our clinicians and embryologists, and that progress in this field will remain as controlled and thoughtful as it has been in the past. Britain should be proud of its achievement in recognising that the science that can give a baby to an infertile couple can also be extended to saving lives.

