

THE HUMAN EMBRYO AS RESEARCH MATERIAL

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Sydney, 2033,
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Paper presented in the Congress Symposium "New Birth Technologies"
56th ANZAAS Congress
Palmerston North,
New Zealand
27th January. 1987

Introduction

In Australia we have had several 'firsts' in the IVF area. On the scientific front we were the first in the world to produce babies from frozen embryos as well as from frozen eggs. On the legal front we have the law in Victoria entitled "The Infertility (Medical Procedures) Act", which is the first law in the world to deal specifically with IVF. And on the public participation front we have had a major inquiry conducted solely by Parliamentarians. But far from mutually supporting each other, these Australian world firsts are embarked on a collision course. The scientific research front is being met head-on by regulation and legislation designed to slow it down. The conflict hinges on research with the human embryo, or as I have put it in the title of this paper, the use of the human embryo as research material.

The Victorian Law.

Let us first look briefly at the Victorian law. This is based on and continuous with the so-called Waller Committee which was set up in March 1982. A bill was prepared along the lines recommended by the Waller Committee and after considerable political negotiation between the parties this bill was introduced into the Victorian Parliament by the Attorney General in March 1984. The Act was passed by the Parliament 6 months later, and for the most part the legislation came into effect in August 1986.

One of the key features of the legislation is the new Victorian Standing Review and Advisory Committee on Infertility, chaired by Professor Louis Waller. All proposals for research with human embryos must go before this Committee and there are criminal penalties for infringement, including gaol terms of up to four years. Infringements arise from conducting embryo experiments without going to the Committee in the first place, or from stepping beyond what is recommended by the Committee. Recently a research proposal involving the use of 40 embryos was knocked back by the

Committee.

The Parliamentary Inquiry.

This goes back to a bill introduced by Senator Brian Harradine from Tasmania into the Australian Senate in April 1985. As a response to it, six months later the Senate Select Committee on the Human Embryo Experimentation Bill was set up. A year after that, in September 1986, the Senate Committee released its report. In reaching their decisions the seven Senators on the Committee considered 270 submissions put forward by scientists and by members of the general public. The Senators also interviewed 64 witnesses who were mostly professionals involved in IVF. Like the Victorian law, the Senate Committee has also opted for a severe restriction on experimentation with human embryos.

Distinctions

However the basis for distinguishing between permitted and prohibited embryo research differs somewhat. The Victorian law draws a major distinction between 'spare' or 'surplus' embryos which are left over as a result of patients' participation in an IVF program on the one hand, and embryos which are created specifically for research purposes on the other hand. While some research is permitted on spare embryos, according to the Victorian law no embryos should be brought into existence for the purpose of conducting experiments with them. In this context I should mention that the French Government has just accepted the recommendation of its National Ethics Committee to ban fertilisations carried out solely for the purpose of producing embryos for research. The European Parliament imposed a similar ban a few months ago. (Dame Warnock, however, feels that morally there is no difference between surplus embryos and those created for research, and so this distinction has not been taken into account by the Warnock Committee in

Britain.)

There are two major concerns regarding the use of IVF to produce human embryos for laboratory research. The more obvious concern is that this practice will reduce human embryos to the level of experimental material and there is a general, world-wide abhorrence about doing this. A second major concern has been emphasised by the feminist critique of IVF. Here it is pointed out that embryos created specifically for research are often derived from the ova of women who are not at all involved in infertility treatment. Quite to the contrary, these are women who seek sterilisations as a form of contraception. Such women are often asked to contribute some ripe eggs as part of their sterilisation operation which of course complicates the surgery considerably. The women first have to undergo drug-induced superovulation. Following extensive testing to determine the moment of ovulation their sterilisation operation is then performed at the time when the superovulation has taken effect and about half a dozen ripe eggs can be collected from them. It is obvious that these women are submitted to far more medical intervention than is required for their own sterilisation, and some of this intervention could endanger their health. In spite of these risks, many women will go along with egg donation, not wanting to be seen by their doctors as impeding the search for cures and for knowledge. Of course the women will be asked to give so-called "informed consent" first. But in regard to such consent even Robert Edwards, the pioneer of IVF in Britain, has noted that "We soon discovered that patients needed to be restrained from volunteering too much". There is no doubt that in practice patients do not act in such a way as to impede the research interests of their medical practitioners, sometimes to the detriment of their own health.

Turning now to the Senate Committee Report, we also find a distinction between permitted and prohibited experimentation. Here the distinction hinges on whether or not the research is in the interest of the

particular embryos experimented on. Thus it is permitted to conduct so-called therapeutic experiments which are designed to enhance the prospects for development of the particular embryos being tested. But on the other hand, there are destructive, non-therapeutic experiments which, "whilst advancing medical science, inevitably, and in the nature of the experiment, destroy the embryo". According to the majority report of the Senate Committee such experiments are to be outlawed. Like in the Victorian law it is also recommended that a licensing body be set up to determine which experiments may be done and which not. And again, it is envisaged that criminal penalties would apply to those who do not comply.

Embryo experiments

With this background, I will now discuss briefly the types of experiments which are likely to be turned down both by the Victorian Standing and Advisory Committee as well as according to the recommendations of the Senate Committee.

First there is the freezing of unfertilised eggs. Dr. Christopher Chen at Adelaide's Flinders Medical Centre has been successful in achieving live births from frozen eggs, but in general it is recognised that more research is needed to perfect this technique. Interestingly, freezing of eggs has been promoted by Dr. Chen as well as by the Catholic Church in South Australia as an ethical breakthrough'. The reason is that with this technique frozen eggs can be stored, and there would then not be a need for banks of frozen embryo which many people find unacceptable.

But the ethical considerations of both the Victorian Standing Committee and of the Senate Committee run counter to this view. In order to perfect the technique of freezing unfertilised eggs, embryos will need to be created from such eggs and examined closely to see whether the freezing of the eggs has damaged the embryos in some way. In order to be reliable, this

examination will involve the destruction of the embryos tested. According to the Senate Committee this would amount to non-therapeutic, destructive experimentation and is not allowed. The Victorian Standing Committee is also not in favour of such a research program. The embryos produced from frozen eggs would not be "spares" but rather created especially for experimental purposes, and as we have seen, this is opposed by the Victorian Law.

A second type of experimentation involves the genetic screening of embryos. In animal systems it has been shown that a small number of cells can be cut off and removed from the early embryo without this being harmful to the embryo. The cells which have been removed can then be screened for chromosomal and genetic defects, and for the sex of the embryo. The point is that the embryo is implanted only if the screening and sexing results are considered satisfactory. In Australia and in the United States such research has also been pursued with human embryos (Trounson, Wilton et al reported in Time Magazine. October 27, 1986; Verlinsky and Pergament, Journal of In Vitro Fertilisation and Embryo Transfer. 3(2), 1986, p.83).

As with egg freezing, in order for the techniques of genetic screening and sex determination to be improved requires the production of IVF embryos specifically for research purposes. Moreover, so-called destructive, non-therapeutic experimentation also needs to be involved. For these reasons, genetic screening and sex determination would at this stage be prohibited by the Victorian law as well as according to the recommendations of the Senate Committee.

There are further lines of research which would be assessed in the same negative way and prohibited. These include mechanical fertilisation, where sperm which is incapable of entering the egg even in the artificial IVF environment, is actually injected into the egg. Secondly there is the commonly used test to determine the effectiveness of sperm, in which hamster or rat eggs are fertilised by human sperm. Thirdly there is the

implantation of human embryos into the uteri of other mammals. And lastly I should mention cloning. In the cattle industry it has been shown that dividing the embryo into halves or quarters gives a much better chance at pregnancy. The Monash University IVF team and others (Verlinsky & Pergament, op.cit) have been interested in pursuing this type of research with human embryos. These embryos would of course be created for research purposes and destroyed in the process of the experimental evaluation. According to the regulations we have looked at such research would obviously be prohibited.

To sum up, the following types of experiments with human embryos would be prevented by both the Victorian law and the Senate Committee:

Types of experiments with human IVF embryos:

- freezing of eggs and the characterisation of the embryos derived from them;
- genetic screening of the human embryo;
- determination of the sex of the human embryo;
- injection of dysfunctional sperm into human eggs;
- fertilisation of hamster or rat eggs by human sperm;
- implantation of human embryos into animal uteri;
- splitting the human embryo into halves or quarters.

The costs of prohibiting embryo research

Having looked at some of the experiments which would be prohibited by the Victorian Law and by the Senate Committee, I would now like to consider the societal costs involved in such prohibitions. In other words, as a society can we afford to be so rigid?

We have to realise that regulatory decisions which prevent experimentation on the human embryo have a number of social consequences. For a start, it is quite likely that as a result of implementing the prohibitions

we have looked at, Australian research in this area will lose its lead. As we know, this is a field in which we are doing remarkably well on the world scene. So we need to ask ourselves if we are prepared to give up on this.

Second, as Dr. Trounson has threatened repeatedly, we may lose some of our researchers. Indeed, Dr. John Kerrin and his team from the University of Adelaide's Queen Elisabeth Hospital, have left Australia to pursue their IVF work in the US. This, however, did not occur because of any regulatory restrictions since none were as yet in place or even contemplated when Kerrin and his colleagues departed.

Third, if the research is restricted and this results in an exodus of our pioneering researchers, the training of new IVF scientists will be impeded. This would occur at a time when our governments are urging us to improve the national skills base.

Fourth, in this as in other technological areas, research inevitably leads to improved practice. The technological products and services which can be provided in a country ultimately depend on how much research is carried out. It is therefore obvious that research prohibitions will lead to a more restricted range of IVF services than would be the case if embryo research were allowed across the board. We might then miss out on genetic screening of the IVF embryo, on its sexing and so on.

Fifth, by restricting embryo research we might miss out on some commercial benefits. You will probably have heard of the company IVF (Australia) which is the commercial counterpart of the Monash IVF team. This company engages in technology transfer - the techniques developed and perfected by the Monash team are transferred to clinics located in the US which are owned by the Australian company. Many of the practitioners operating in the US clinics are trained at Monash. What the university has gained through this arrangement was an initial downpayment of \$300,000 and significant ongoing royalties from the company's operations.

Now one of the crucial negotiating terms in setting up IVF (Australia) was that as the Monash team develops new technology, this will be passed on to the company in order to be implemented as effectively as possible in the US clinics. It is obvious that prohibition of embryo research will cut into the negotiated technology transfer. The Monash team might no longer be in the technological lead, and it would then no longer be in a position to develop new technologies as rapidly as overseas competitors. IVF (Australia) will then not have the latest technology to offer. The Victorian law and the Senate Committee recommendations would therefore undermine some of the possibilities for commercialising Australian IVF research.

Balancing the costs

These, then, are some of the costs of restricting embryo research. To summarise, they could include: loss of Australia's lead in IVF research, loss of fine research talent, downgrading of scientific training, stagnation of clinical services, and a lessened scope for commercialisation. The question then needs to be asked: is this too high a price to pay? Undoubtedly the scientists involved, and many of their IVF clients, will think so. But many others in our society believe that these costs are minor, especially when they are compared with the costs involved in unrestricted embryo manipulation.

Now these are less tangible costs, and they fit in less well with the currently popular ideology of pushing to the limit scientific and technological developments and their commercialisation. They are moral costs. They involve a belief, a gut feeling, that it is not right to produce human embryos just so that they can then be used as research material. In this context we should remember that it is not difficult for scientists to come up with justifications for the experiments they wish to conduct, particularly in the biomedical areas. We have heard that research with human embryos is essential for developments leading to the prevention and cure of infertility, to

improved contraception, and to the prevention of genetic disease. But when the journal Nature held a competition in 1985 to discover the best proposal for a research program involving human embryos, no reasonable contenders were forthcoming.

Indeed, a number of embryologists and IVF practitioners have come out openly and criticised experimentation with human embryos. For example. Mike Rayner from Oxford University has said recently:

Many scientists are sceptical about the feasibility of much of the so-called 'essential' research with human embryos, but are publicly mute, for fear of seeming to support restrictions on their colleagues' work. The general public and the media seem to have forgotten that scientists have a vested interest in promoting their own research and that they may occasionally be guilty of exaggeration in order to further their own ends in the race for results and an ever diminishing number of jobs. (New Scientist. 27 February. 1986.54-55)

In France, the leading IVF researcher, Professor Jacques Testart, has decided to withdraw his team from the race of research on the human embryo. He has announced publicly that he is most worried about what he calls "future perversions" of IVF. In particular, he is highly critical of experiments designed to develop the techniques of genetic screening and of sex determination. According to him, "With genetic progress the way is open for eugenies"(Nature,323,1986,385).

Conclusion

Many of us who have been trained in the biological sciences can well understand the sensitivities involved in treating human embryos as research material. We know the attitude of researchers and of technicians to common laboratory material, say for example rat liver. With this we have no problem. But human embryos are not rat liver, and in the view of many, the only reliable mechanism for ensuring that human embryos are not treated as research material is through government legislation and licensing.

To be sure, there are costs involved in such restrictions, as I have indicated before. But there is also a price to pay in going ahead with unrestricted embryo experimentation. On balance, it appears that at this stage of our social, political and economic development we have more to gain than to lose by opting for regulation and restriction. I hope, therefore, that mechanisms will be developed to ensure that legislation such as that already in force in Victoria, and currently being designed in France, West Germany and by the Council of Europe, becomes applicable to IVF research in all of Australia.