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EXPERIMENTS ON WOMEN IN IVF PROGRAMMES CONTINUE: MISLEADING CLAIMS ABOUT NEW IVF DRUG

Calvin Miller in The Herald (2.5.89) reports that the Epworth Infertility Medical Centre has been conducting 'a world-first clinical trial' with 90 volunteers since September 1988 using Buserelin: 'a new IVF drug [which] has boosted pregnancy rates for some infertile patients from virtually zero to 30 per cent'. According to Miller, IVF pioneer Carl Wood and his team hope the drug 'taken in a nose spray' will boost "take home baby rates" possibly up to 75 per cent - 'a world high' - because 'Buserilin (sic) improved the blood levels of hormones and prevented hormone surges'. The unit claims that a 50 per cent "take home baby rate" could be reached when one woman undergoes five IVF attempts.

This Information about Buserelin is both incomplete and inaccurate:

* Buserelin is not a new drug. A report on its use in the IVF protocol was published in the Lancet in 1984 by an English IVF team. In 1986 it was used in 60 percent of IVF attempts in France, in 1987 the figure was 80 per cent. Since then Buserelin and other LH-RH 'agonists' have been used in many European countries as more and more adverse effects from clomiphene citrate treatment are recognised .

*The simplistic way of describing the administration of Buserelin as a 'nose spray' is misleading. Buserelin is a powerful drug which desensitizes the pituitary gland and induces an artificial menopause. Women experience hot flushes and other menopausal symptoms. Once the natural cycles are suppressed, the women are then put on the same superovulatory drugs as in other IVF regimens (ie hMG, Pergonal, often also hCG to release the eggs). Significantly, these drugs are often administered in increased dosages. Also, before the hormone production stops, Buserelin stimulates the production of the LH-RH hormones through an unavoidable and very dangerous effect called 'flare up'. This may lead to serious hyperstimulation and the production of cysts on the ovaries. In other words, it may jeopardise the women's health. In some cases the women may even experience a second hyperstimulation after the administration of the egg releasing hormone (hCG) in the same cycle.

*Despite the claims reported by the. Epworth team for significantly improved success rates, in no country where the use of Buserelin is already established have significantly improved 'take-home baby rates' been reported; the number of live babies born per IVF

attempt is still between 8 and 10 per cent internationally. What is reported are clinical pregnancies, and very often multiple pregnancies. At the recent 6th World Congress on In Vitro Fertilization and Embryo Transfer in Israel (April 1989) there was substantial disagreement between European IVF experts about the number and quality of eggs and embryos produced by the Buserelin regime: the new 'wonder-drug' has already lost some of its initial allure.

* To stipulate that women have to undergo five IVF attempts to achieve a 50 per cent "take home baby rate" is to totally ignore the physical dangers for the woman implicit in each attempt as well as the emotional and financial cost of repeated IVF attempts. Also, concern is being expressed by IVF experts themselves, eg. Jacques restart, Paris, who said at the IVF and ET World Congress in Israel that the application of Buserelin might cause premature menopause and heightened rates of cancer in the future.

We are alarmed and concerned about the misleading statements and urge you to consider the following questions:

* The scientific literature reveals that the use of Buserelin leads to an increase in mature eggs available for IVF. The question is what will happen to all the 'surplus embryos' particularly when Buserelin appears to contribute to more successful implantation by using one or. two embryos only?

* It is no coincidence that the team from Hammersmith Hospital London which has recently been granted approval to use embryo biopsy techniques on human embryos for genetic screening and selection also promotes the use of Buserelin for IVF. Will the use of Buserelin by the Epworth team favour its own embryo biopsy research if that research is permitted by the Victorian government?

We strongly condemn get another experiment conducted on women in IVF programmes and the deliberate attempt by an IVF unit to raise the hopes of Infertile people for a child of their own with inconclusive and misleading Information. We call this false advertising and believe It violates medical ethics.

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IVF drug boosts pregnancy rate

BY CALVIN MILLER
MEDICAL REPORTER

A new IVF drug has bolsted pregnancy rates for some infertile patients. from virtually zero to 30 per cent in a .world-first clinical trial in Melbourne.

The drug was a key factor in boosting "take-home baby rates", possibly up to 75 per cent - a world high.

IVF pioneer Professor Carl Wood and his team at the Epworth Infertility Medical Centre have used the drug Buserilin in 90 volunteers since September.

However, the director of bioethics at St Vincent's Hospital, Mr Nick Tonti-Filippini, warned the trial could supply more human embryos for experiments.

He also claimed the drug had "nasty" side effects.

Epworth chief embryologist Ms Catriona King said Buserilin improved the blood levels of hormones and prevented hormone surges.

Doctors were then able to more accurately schedule the retrieval of mature eggs.

"Taken in a hose spray, the drug allows more of the difficult IVF patients to get to the egg pick-up stage," Ms King said.

"For especially difficult patients who have had almost no chance of pregnancy, the pregnancy rates have increased to 20 per cent for , test-tube fertilisations.

"For GIFT (gamete intra-fallopian transfer) patients, the rate can be up to 30 per cent."

'The drug is central to the program's aim of reaching, a take-home baby rate of 50 per cent in five treatment cycles.

"I expect Buserilin could improve the take-home baby rate to 75 per cent - that's speculative but not unreasonable," Ms King said.

IVF general manager Mr David Hodge said the Buserilin trial was approved according to government standards and patients were given plain-language pamphlets about side effects.

According to Mr Tonti-Filippini, Buserilin is another i "player in the ovulation game", has dangerous side effects on the heart and blood and causes rashes, fever and blurred vision.

"The scientists have mixed motives in being able to pro-duce more eggs and embryos," he said. "More embryos could become available for experimentation."

But Prof. Wood said embryos from the Epworth would not be available to IVF scientists until the present moratorium on legal embryo experiments was lifted.

IVF not a big earner

THE Auditor-General's report found that after expecting to receive $20.6 million from overseas royalities on an IVF program, Monash University had terminated. It receiving only $2.6 million

IVF Australia Pty Ltd, set up in 1985, was expected to earn $20 million by exporting skills services and technology.

After an Initial advance of $300,000, no other royalties were received.

Settlement arrangements, last year provide further payment of $2.3 million by 1994.

The Auditor-General found that last year the University was "in a most difficult situation... with the likelihood of any significant royalty payments in the foreseeable future very remote.

The termination agreement also includes IVF Australia indemnifying Monash against legal action arising from its motivities, and the university regaining its worldwide rights to developing IVF clinics.

The report said this was "the most yiable option".

Alert on IVF drug threat to women

BY CALVIN MILLER
MEDICAL REPORTER

An experimental drug given to infertile women in the Epworth Hospital IVF program could cause, birth defects, cancer, and premature menopause, an international women's group opposed to reproductive engineering claimed today.

A spokeswoman for Finrrage Australia, Dr Renate Klein, called on Epworth IVF doctors to stop using the drug buserilin.

The drug has .unacceptable side effects in patients and caused birth defects in laboratory animals in overseas experiments according to Dr Klein, a Deakin University biologist and humanities lecturer.

However, the Epworth team defended its clinical trial of buserilin and will support Government approval from the Australian Drug Evaluation Committee.

The international drug firm Hoechst has been supplying buserilin for the trial.

Women talking buserilin are being treated like guinea pigs," Dr Klein said.

"Their, health is being jeopardised. Doctors desperately are searching for. something to improve IVF and don't know. the long-term effects of the drug."

She said hopes .of infertile couples were being, raised falsely. "Buserilin Is being promoted as a new hope for infertile patients, but some overseas groups have stopped using it," she said.

"It is not the 'wonder drug1 once promised. The Government should resist any pressure to approve it."

Buserilin is a hormone treatment which allows more IVF patients to progress to the egg-collection stage.

For some patients, the drug has improved pregnancy rates from virtually zero to 30 per cent.

..Dr Klein. said buserilin also could lead to more surplus human embryos being available for proposed experimental by Monash University scientists.

"The drug can lead to multiple pregnancies, so only two embryos, may be transferred, leaving a surplus to be frozen - what win happen to those embryos?" she said.

Epworth IVF general manager Mr David Hodge said the clinical trial on 160 women had just ended successfully and no major side effects had been noticed.

"This trial was important because others had been very imprecise, with only 10 or 20 patients," Mr Hodge said.

"We will continue using buserilin once it gets approval.

"The volunteers are completing a questionnaire on side effects and how they responded to the drug".

Melbourne Hoechst director. Mr Michael Pont said the company was seeking Government approval to market buserilin, which was approved overseas and also used treat prostate cancer.

"We have no information on the side effects of buserilin that would cause "us concern." he said.