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Beyond Embryo Politics: Women's Health and Dignity in Stem Cell Research

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"Which comes first—the egg or the cure?" asks an advertisement enticing young women to provide their eggs for stem cell research. The ad lists several diseases and asserts that "It could happen to you or your loved one", and encourages the reader to: "Let your eggs be part of the cure." These slogans mark the re-entry of U.S. scientists into what many see as a global stem cell race. The downfall of disgraced South Korean scientist Hwang Woo-suk, who fabricated data to support his claim that he harvested stem cells from a cloned human embryo, has prompted scientists to scramble to truly be "the first."

The hype around stem cell research and the resulting media attention have raised public hopes that research will soon lead to cures for chronic diseases such as diabetes and Parkinson's. These hopes overshadow serious risks associated with one approach to stem cell research that has been receiving increased attention from scientists. This technique, somatic cell nuclear transfer (SCNT) or "research cloning", raises serious concerns because it requires a huge number of women's eggs and poses a host of problems for women's health and dignity. These problems include the short-term health risks associated with the egg extraction process, a lack of information about long-term effects, the potential for exploitation of economically vulnerable women, and the possibility of increased commodification of women's bodies.

In the U.S., vocal opposition to SCNT has largely come from religious conservatives

who oppose all embryonic stem cell research. They view research on embryos as the destruction of human life and collapse the issue of embryonic stem cell research into their anti-choice agenda. Many reproductive rights advocates and other progressives have countered by supporting unregulated stem cell research. Issues beyond the ethics of using embryos for research are then overlooked. Reproductive rights and women's health advocates can voice support for advancing stem cell research while simultaneously calling for adequate safeguards for women who participate in the research.

The science behind SCNT

Until recently, all embryonic stem cell research was conducted on cell lines derived from "leftover" embryos that had been created for *in vitro* fertilization (IVF) procedures. SCNT, on the other hand, differs in that it requires the use of fresh eggs. To harvest these eggs, women undergo the same procedure as in IVF, which includes several weeks of daily hormone injections to first "shut down" and then "hyperstimulate" their ovaries. Surgical extraction of multiple eggs follows while the woman is under light anesthesia. Once the fresh eggs are extracted, technicians remove the nucleus of each egg and replace it with the nucleus of a body cell. The resulting "clonal embryo," with DNA identical to that of the body cell, can then be used to derive stem cell lines.

Scientists initially became enthusiastic about SCNT because it offers the possibility of creating "personalized" stem cell lines that would not be rejected by a patient's immune system. Some led the public to

believe that the development of treatments and cures based on SCNT was imminent. Only recently has it become clear that this prospect is highly unlikely, due to both the huge number of eggs needed and the enormous cost required. Most scientists now acknowledge that SCNT is more likely to be used to study diseases at the cellular level.

Finally, it is important to note that SCNT involves cloning an embryo. Some advocates have raised concerns about the possibility that this technology could be a “gateway” to other technologies that allow for inheritable genetic engineering (the creation of “designer babies”) and reproductive cloning (cloning humans). These developments, in turn, cause trepidation about the exacerbation of health and social inequities, the use of such technologies for eugenic purposes, and the creation of new forms of inequality.

The health risks of egg extraction

Stimulating the ovaries to extract multiple eggs is time-consuming, invasive, and involves both short-term and long-term risks. Some of the drugs used for egg extraction have never been subjected to rigorous safety studies investigating their use for the procedure. According to Dr. Suzanne Parisian, former Chief Medical Officer of the Food and Drug Administration (FDA), “Pharmaceutical firms have not been required by either the government or physicians to collect safety data for IVF drugs regarding risk of cancer or other serious health conditions despite the drugs having been available in the United States for several decades. Lack of FDA approval and/or review of these drugs as part of egg extractions procedures should be a major concern of anyone considering SCNT research.”(1)

We do know that many women undergoing IVF experience side effects from the egg extraction process, primarily caused by the hormones used to allow retrieval of multiple eggs in one cycle. The

reported side effects of Lupron (the drug most often used to shut down the ovaries for IVF) include hypertension, chest pain, depression, amnesia, bone pain, insomnia, and migraine. Lupron has never been approved specifically for use in IVF and, while such “off-label” use is permissible by the FDA, women lack adequate information about adverse consequences they may face when the drug is used in this context.(1,2)

In addition, the drugs used to hyperstimulate the ovaries and produce multiple eggs can lead to Ovarian Hyperstimulation Syndrome (OHSS). Mild forms — which can cause ovarian cysts and abdominal discomfort, have been reported by 20-33 percent of women undergoing IVF.(3) Severe cases — which can lead to hospitalization, infertility, and death — are estimated to occur in between 0.1 and eight percent of women.(1,3,4) Five women have died from OHSS in the United Kingdom (UK).(5)

Both the wide range of estimates on the incidence of OHSS and the lack of statistics about the number of women who experience side effects from Lupron highlight the inadequacy of available research and the urgent need for more data. Even though women have been undergoing egg extraction procedures for several decades for IVF, it is almost entirely unregulated: no federal and few state standards exist for women who undergo egg extraction, and there is no government mandate to report data on the process’ short- and long-term effects. Studies have not ruled out a link between the hormonal drugs and an increased risk of ovarian and uterine cancer, but there is no conclusive evidence because research on the long-term health of women who provide eggs has been extremely limited (1, 6).

Dangerous potential for exploitation and commodification

Extracting eggs from women also raises

concern about the potential for exploitation of women and deepened commodification of their bodies. Dr. Hwang’s initial breach (prior to the discovery that he fabricated his data) involved unethical practices used to obtain eggs. Two of the women who provided eggs were junior researchers on his team, a violation of international standards that scientists not involve those in dependent relationships as research subjects. Hwang used 2,221 eggs (vastly more than his initial claim of 427 eggs) collected from 119 women, many of whom reported that they had not been properly informed of the risks associated with the procedure. Twenty percent of the donors experienced OHSS and 16 were hospitalized. More than half of the women were paid for their eggs, and several said they sold their eggs because of dire financial situations.

In the U.S., there is an on-going debate about whether or not to compensate women who provide eggs for research. Voluntary guidelines issued by the National Research Council and Institute of Medicine of the National Academies in 2005 recommend that women be reimbursed for direct expenses, but not otherwise compensated for their eggs. In California, the second state after New Jersey to approve public funding for embryonic stem cell research, the institute governing its \$3 billion stem cell initiative adopted these guidelines. Those who oppose payment raise important ethical concerns, noting that compensation creates a financial incentive for economically vulnerable women to expose themselves to both known and unknown health risks for money. A market in eggs for research would emerge, valuing women’s reproductive tissue over their well-being.

In fact, a market in eggs for use in fertility treatments already exists in the U.S. and Europe. Many prestigious U.S. college newspapers include advertisements offering large sums — sometimes as much as \$50,000 — for young women

with characteristics such as “athletic, 5’10” and SAT scores 1400+.” In Europe, Romanian women sell their eggs for the equivalent of more than a month’s wages to women in the U.K., where there is a shortage of eggs available for IVF. (7) The shortage stems from limits on compensation (UK law only allows payment of 15 pounds) and a law requiring the identity of egg providers to be available when a child turns 18.(8)

Alternative methods of egg extraction

Some women’s health advocates and bioethicists assert that more information on the effects of the drugs and identification of safe alternatives to hormonally stimulated egg extraction are needed before SCNT research proceeds. Other safer methods of egg retrieval could include natural cycling, in which a single egg is extracted without hormonal stimulation; egg extraction during ovariectomy or tubal ligation; and biopsy of ovarian tissue during gynecological surgery, in which many immature eggs could be collected and matured *in vitro*.

While the promotion of alternative methods is currently being proposed by women’s health advocates concerned about medical risks, researchers are predicting the need for new methods as well, but for different reasons. Robert Lanza, the head of Advanced Cell Technology (one of only a few U.S. research institutions working on SCNT) stated in the prestigious journal *Nature*, “I can’t conceive there will be enough eggs to use on a wide scale. In the end, we have no choice but to develop other methods.”(9) Another article in the same issue states: “many researchers now think therapeutic cloning [SCNT] is unrealistic, largely owing to the scarcity of human eggs. So the spotlight is turning on to different strategies [for egg retrieval].”(10)

Recommendations

Several countries are far ahead of the U.S. in adopting policies to protect the health and dignity of women who provide eggs. Both the United Kingdom and Canada, for example, have comprehensive laws regulating the use of all eggs, sperm, and embryos in both research and assisted reproduction. The U.S., however, has no federal regulation of egg extraction and few state policies on the issue. States that have moved to put policy in place, such as California and Massachusetts, could set important precedents in this area.

The anti-choice movement’s single-minded focus on the moral status of the embryo has put women’s health advocates in a defensive position and obscured concerns about the safety of the procedure for women whose eggs are being extracted. It is time to ensure that women’s health and dignity are central in the development of stem cell research. Policymakers and scientists can take steps toward that goal by acting on the following recommendations, being promoted by organizations such as the Center for Genetics and Society, Our Bodies Ourselves, and the Pro-Choice Alliance for Responsible Research:

Require oversight and get more information

- Establish federal regulatory review and oversight of drugs used for egg extraction
- Require that fertility clinics and stem cell researchers report adverse reactions experienced by women undergoing egg extraction
- Conduct studies to determine the long-term health risks of the hormonal drugs used and of surgical extraction

Investigate alternatives to current egg retrieval methods

- Advocate for the development of safe, alternative methods of egg retrieval

Establish ethical and medical protections for women participating in SCNT research

- Guarantee that women understand both the health risks of egg extraction and the lack of data on long-term consequences
- Ensure that women understand stem cell research is in the early stages of development and they will receive no direct benefits from the research
- Require medical follow-up and long-term medical coverage to address any adverse reactions women may experience from egg extraction
- Prohibit payment to women providing eggs to prevent the commodification and exploitation of women
- Prohibit doctors with financial conflicts of interest from conducting egg extraction
- Maintain confidential records of the demographics and adverse health reactions of research participants; analyze this data to determine the health effects of the egg extraction procedure and to ensure socially and economically vulnerable women are not disproportionately recruited for research

For everyone’s benefit

Women and other disenfranchised groups have often been used as guinea pigs in research for “the benefit of science.” Marginalized populations have repeatedly been exploited in the name of “progress,” with violations acknowledged only decades after the fact. The contraceptive pill, for example, was tested on poor women in Puerto Rico in the 1950s. They were given high doses of the pill to prevent pregnancy without being informed they were participating

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in a clinical trial or that it might have potentially dangerous side effects. Norplant, another hormonal contraceptive, was tested on women in India, Indonesia, Brazil and other countries before distribution in the U.S., in studies that involved serious breaches in obtaining informed consent.

Those of us committed to promoting women's health must not become so caught up in overheated scientific expectations that we fail to act responsibly to address the serious health questions we face today. We know that sacrificing women's health is a detriment to all, and promoting it in the context of any research will benefit everyone. We still have time to shift the course of stem cell research so that scientific advances can be accompanied by a genuine commitment to women's health and dignity.

RESOURCES

For more information about egg extraction for research, see <http://www.genetics-and-society.org/resources/background/eggextraction.html>

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