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Zonta International Position on Umbilical Cord Blood, Stem Cells and the Role of Women December 2005

At the 2004 Zonta International Convention, the following motion proposed by the Zonta Clubs of District 27 was adopted:

“Whereas Zonta Clubs of District 27 have supported the banks for umbilical cord blood and desire that women (1) become aware of how they can play an active role in making precious baby blood available to help seriously ill patients, especially children with leukaemia and (2) be informed on the potential danger of using women as suppliers of umbilical cord blood and egg cells.

Whereas, Zonta Clubs of District 27 desire to draw the attention of mothers who want to donate blood of the umbilical cord and of women who want to donate egg cells, to have a say in the matter of where this precious material will go or how it will be used.

Whereas, Zonta Clubs of District 27 are concerned that the blood of the umbilical cord and egg cells would be used correctly worldwide and hereby bring this issue to the attention of the Zonta International organisation.

BE IT RESOLVED:

- That awareness should be raised and information should be provided to women on the issue of the use of the umbilical cord blood and stem cells so that women have a say in this matter in order to safeguard women’s interest, health and position

BE IT FURTHER RESOLVED:

- That clubs and members be encouraged
 - To inform themselves on this issue
 - To provide information to women (particularly pregnant women), nurses, doctors, teachers, politicians, ethnic communities and all those who can be interested in this subject
 - To take steps to improve the information and education of young girls and training of young women on this issue; and
 - To contact interested and appropriate organisations and/or NGO’s to share concerns and exchange information, know how and experience.

All this effort will allow clubs and members to focus on the Zonta International mission to improve the status of women and women’s health.”

This paper provides Zonta clubs with information on the issues of umbilical cord blood and stem cells produced from egg cells so that Zontians will have a basic understanding of the subject to enable them to progress the motion and its resolutions.

Advancing the Status of Women Worldwide

Stem Cells from Cord Blood and Egg Cells

In the past twenty years there has been enormous progress in the clinical use of stem cells. Blood stem cells were traditionally collected from bone marrow and transfused to recipients. Cord blood has now proved to be an alternative source, because this blood is also very rich in blood stem cells (haematopoietic, i.e. producing bone marrow and blood cells). Because stem cells multiply through self renewal, blood stem cells are perfect for treating children and some adults who have malignant blood diseases, such as leukaemia, and also some non malignant blood diseases.

Since, then it has been discovered that almost every organ has its own reserve of stem cells and that it may be possible to obtain these organ specific stem cells from the very early stage of development, which is the fertilised ovule or egg cell. Meanwhile, the techniques of medically assisted reproduction in particular In Vitro Fertilisation have steadily developed. These two combined discoveries have caused a genuine explosion of research on the human Embryonic Stem Cells (hESC).

A stem cell (SC) is a cell able to mutate to a specialised cell while renewing itself at the same time. Depending on its potential and strength a stem cell will be able to develop into:

- only one kind of cell, e.g. a blood cell or a liver cell - it is then called a **multipotent SC**
- one of a variety of different cells e.g. a liver cell and a brain cell and a cell of a joint – it is then called a **pluripotent SC**
- all the kinds of cells of which an organism is composed and – this is a **totipotent SC**

the totipotent stem cell *par excellence* is the ovule or egg cell.

A fertilised human egg cell (in vitro or naturally in a woman's body) multiplies to give two cells, then four, then eight cells by about two days after fertilisation. The stage of eight cells is called "morula." Each one of these eight cells is still a totipotent hSC. Any one of them, if isolated, will develop into a complete human being. If a cell at this stage is taken away, the others will continue their development: the morula is not therefore killed but it is "simply" cut down by one cell.

Cells continue multiplying and after four or five days form a small ball, that is called a blastocyst which has a small cavity in its centre and, surrounding it, a denser cellular mass. The cells of this small mass are the famous **human embryonic stem cells, hESC**; they are pluripotent.

Therefore from the 4th or 5th day after fertilisation there is something that can be called an embryo.

When development occurs in a test-tube (in vitro) one can remove the cells of interest, in particular hESC, but, of course, the human embryo is then killed.

If development continues, body outlines appear in this small cellular mass. These first cells will be specific stem cells of one or another organ, they are multipotent.

When this development happens in a laboratory (in vitro) and, assuming that the cells are regarded as being owned by the research workers, it is possible to isolate these multipotent stem

cells, put them in separate cultures, and have what are called **Stem Cell Lines** (on which numerous patents have already been taken out).

Scientists see the possibility of using these different human stem cells to treat many degenerative diseases; they think that it will be possible to replace sick or destroyed organs by new cells of the same type produced, in vitro, in a laboratory.

It is currently hoped that the following will be treatable:

- Parkinsons disease
- Alzheimers disease
- Myocardiac infarction
- Brain damage
- Diabetes
- Osteo-arthritis

This kind of treatment should replace organ transplants.

So egg cells are the source of the most potent and most interesting human stem cells, these are the human Embryonic Stem Cells (hESC), and also of course the totipotent human stem cells and the multipotent human stem lines. To achieve the treatment that is hoped for research needs a lot of human egg cells.

How are Umbilical Cord Blood and Egg Cells harvested?

The harvest of umbilical cord blood is performed either before or after the delivery of the placenta (the third stage of labour). A metal tube is used to draw off the fluid and an amount of cord blood is mixed with citrate AC. This may then be frozen with no further manipulation or centrifuged or filtered.

Egg cells are produced by the ovaries, usually one every month. The egg cell travels through the fallopian tube to the uterus; if not fertilized the egg cell is eliminated through the vagina.

To harvest human egg cells for In Vitro Fertilization or for research, a women has to take hormones to stimulate her ovaries to produce as many egg cells as possible at once (10 to 30 or more). These egg cells are picked up in the uterus by a small pipette (with or without anaesthesia).

The hormonal stimulation can be the cause of a Hyperstimulation Syndrome which can be very severe, even deadly. The pick up procedure can cause bleeding or infection. The long-term effects of this kind of hormonal stimulation on the ovaries and the general health of women are not clearly known at this moment – is there higher risk of ovarian cancer, early menopause, or other effects?

Ethical Issues

Human umbilical cord blood banking and the proliferation of commercial banks raise a number of ethical issues. Parties with very different interests – private, academic and public sector – have become involved in different aspects of cord blood banking and use.

Parents may elect to store cord blood for the use of the child or for a sibling (leukaemia treatment is one of the most common uses). However, if a parent elected to use the stored blood for the treatment of anyone other than their own baby, it would raise questions of conflict of interest.

Commercial companies are advertising the advantages of cord blood banking to prospective parents and requesting on the order of US\$1,500 for collection and US\$95 per annum for storage. This means that only parents who can afford the fees have this option.

A public bank approach would ensure that there was equal opportunity for all parents, regardless of economic status. It would also ensure adequate racial and ethnic diversity in the banks.

There is also the issue of the donor having a genetic or infectious disease, which would mean that these conditions could be transmitted to others if the blood or stem cells were used for other than the donor. It is recommended that screening for genetic disorders be undertaken for potential donors. This screening, and especially direct testing, poses a significant risk to both mother and baby.

The issue of the privacy of the donor, if details are kept, then becomes the challenge. If details are kept, this also raises the issue of the cost of maintaining the records and who would have access to these.

Informing expectant mothers about the cord blood donor program and obtaining their consent if public banking be set up raises further issues about the social and emotional risks, as yet unidentified, to the mother.

Given the issues raised above, it is mandatory that specific guidelines and regulations be put in place to control the collection and use of cord blood.

There are numerous issues about the use of human egg cells and their "products:" hESC, human totipotent SC and hSCLines. Human egg cells are used as raw material for the production of human stem cells.

There are many questions and concerns about this whole area, the majority of which are still largely open and can therefore be influenced. They include:

1. What is the value of an embryo or of an egg cell? Some people will say that neither one nor the other have a legal status, according to the law and therefore "they are at one's disposal" within certain provisions like any other human material, for example human blood or a human organ. Although every woman knows for her self that egg cells play a role in her life as a woman, does she really understand how important this role is? Recent studies showed that, even well educated, most women feel still embarrassed to speak about their egg cells. So they will be very embarrassed to defend the value of their egg cells in public discussions.
2. At the time of in vitro fertilisation procedures, there are very often unused egg cells and supernumerary embryos i.e. not used or not usable for the woman wanting fertilization, but these cells can be used for research or other procedures. Even if these egg cells or embryos are no longer usable by those wanting to be parents, they are nevertheless carrying the complete genetic material of the donor and they still have the unique capacity of potential development. As such they can be used for the manufacture of clones, for example. But would a woman donor of egg cells, and therefore "the owner and person responsible" for her egg cells, concur with this type of manipulation?
3. The manufacture of a clone (therapeutic as well as reproductive) necessarily involves the use of an egg cell. The nucleus of an egg cell is replaced by the nucleus of a cell of the person's organ of which one wants to make a clone. The cloning is also called Transfer of

Somatic Cell Core (TSCC) or Somatic Cell Nuclear Transfer (SCNT). It is very important that women recognize the terms often used in the press and which in fact signify/mean/cover the use of egg cells.

4. Research has asked the question: "can the use of hESC be replaced by the use of human adult stem cells?" The answer from specialists is unanimously "no, they are complementary." The intrinsic qualities are so different the hESC have a far greater plasticity and potential and are much more easily stimulated to multiply and develop in vitro than adult stem cells. It is obvious that the need for egg cells for research will not decrease in the near future.
5. Research on hESC and cloning has accelerated so much in the last few years that the need for human egg cells has greatly increased. The therapeutic prospects are so great that very few people hesitate to support this research; the majority, both men and women, want research to continue and succeed. There is a tendency, and even a certain societal pressure, for one to accept everything that is required to make this research possible without a great deal of reflection or analysis. It seems today almost inevitable to assume that it is obvious that women should put their egg cells at the disposal of the 'general asset' of the cell bank. Let us note by the way that this so called 'general asset' is in fact for the treatment of the degenerative illnesses specific to our Western society, so the 'general asset' is rather a particular asset of Western society.
6. Women are still relatively uninvolved with research and investment decisions. It seems 'the world' dreams of a reproductive method that is neat, clean and under control, on request, without sexuality, without need for uteruses; but today nothing like that is possible, nor even thinkable, without obtaining human egg cells. Consequently there is a major need for egg cells. From whom should they come? Perhaps from women in countries where information is much less available and disseminated?
7. How do women live with this new form of requirement for one of the most specific part of their body? Is it right that young women be asked to give their eggs? Should hormonal stimulation and manipulation be performed repeatedly, with or without remuneration? We know the extent of the phenomenon of trafficking in human beings (especially young women and children), we know the reality of the trade in organs. It is therefore foreseeable that human egg cell trade will start up. Women's status is threatened yet again.
8. A recent international study by transfer patent attorneys, Marks and Clerk, shows that more than three thousand patents related to stem cell usage have been filed worldwide in the past five years – in the US, Japan, Australia and the U.K. – 25% to 40% are related to embryonic stem cell technology. As well as universities, several multinational drug companies appear on Marks and Clerk's list: Bayer, NovoNordisk, Johnson and Johnson, and Pfizer Roche are in the top 10. The specialised embryonic stem cell biotech companies are Geron and ESCell International. See www.ft.com/stemcells. So there is not only a scientific and medical interest in stem cells but also a pure economic interest for some companies. Of course the patents are said to have been taken on "the technical particularities of work with embryonic stem cells" but it is clear that the frenetic development of and interest in stem cell research also has a financial impetus. How do women feel about and live with the fact that their egg cells (potential children) are a source of great profit for commercial companies?

9. If the removal of egg cells from a woman appears to have negative effects, even if remote, on her health, who will bear the consequences, including the costs?
10. The use of egg cells and/or of supernumerary (left over) embryos is the subject of legislation in a number of countries already. Do these laws take account of the very specific effect of the removal of egg cells on the physical and mental health of a woman? Or is it thought to be comparable with collection of spermatozoon? The natural egg supply is set at birth and is exhausted by the menopause, while the spermatozoon reserve is almost unlimited for a man after puberty. The rate of natural production is of one egg cell per month while man produces on average 200 million spermatozoon per day. Egg collection for in vitro use is artificial and risky, while spermatozoon giving is natural and without risk. Finally the "value" for research is definitely higher for egg cells than for spermatozoon.
11. It has been suggested that laws should specify that the written agreement must be obtained from a donor of egg cells for their use in scientific research, and that this must be "an informed consent." What precisely does this mean? How can one authorize something that one does not understand, about which one has virtually no knowledge? For example, who understands the possibilities of using supernumerary or immature egg cells to make clones? Even in our well informed environment, "informed consent" will be more of an ethical shield for professionals, to protect them from possible later objections. For the patient, the woman, and the partner, it is, rather, a formality which they do not understand or take major interest in at a time when their attention is entirely about their hope of at last having a child. They are dependent on the doctor, under the pressure of time constraints, and the doctor is seen as their powerful potential saviour. Under these conditions one has to wonder seriously about the meaning and value of such "informed consent."
12. We cannot expect research workers, investors or legislators to come up with answers to these questions. These are questions specifically for women and their status in society and only women will and must bring specific answers.

At the end of this briefing is a set of recommendations for Zontians' actions.

Actions by Zonta Clubs since the 2004 Convention

Belgium

District 27 proposed the Motion at the 2004 Convention. On return from the Convention, with the Motion having been successfully resolved, a press release was released on the topic which was a real exercise in Zonta Legislative Awareness and Advocacy. The press release was distributed on 23 November 2004

That same evening Radio 1 (De Wandelgangen) played an interview with Dr. Agnes Vermeulen and Professor Marc Boogaerts (initiator of a cord blood bank). *La Libre Belgique* published an article which included an interview with Dr. Vermeulen. There were also articles in *De Standaard* and the *Gazet van Antwerpen*.

In January 2005, *Le Vif l'Express* published an article titled *Questions to Dr. Agnes Vermeulen – stem cells: the great silence*. The Dutch Vrouwenraad also published an article concerning women and stem cells.

As a result of the press release Zonta met the press and the press met Zonta. This was a concrete action coming out of the Motion put to the Convention.

Dr. Vermeulen has been invited to speak at a number of Belgian Clubs, and also at the French-speaking Swiss Clubs. All Area Club Presidents have been informed of the resolution and their reaction has been positive to 'getting the message out.'

The Area organized a Symposium with six Academic speakers from different disciplines or fields: a gynaecologist, a blood bank director, a philosopher, a member of committee of ethics, a scientific administrator of the European directorate-general for research and a jurist. It was a great success: Zontians were numerous and very interested – some speakers changed their mind convinced by our vision on the specific place of women in this subject.

Zontians (ZC Brussel Zavel) did participate in several public discussions organised by members of the Belgian Parliament and by members of the European Parliament.

The D27 Area 01 LAA Committee in collaboration with several members of ZC Brussel Zavel made also several flyers about the topic, one for nurses and the last one for the general public; they were largely distributed during **Confettia**, the Belgian National Day of Women celebrating the centenary of the Dutch-speaking Vrouwenraad and Conseil des Femmes Francophones de Belgique.

Dr. Agnès Vermeulen was invited by the Belgian Feminine Interservice Club (Kiwanis, Soroptimist, Innerwheel, Fifty One a.o.) to speak about the Stem cells and the Involvement of Women. As stated in the Resolution, we must share our concerns with other interested organizations.

The model developed by the Belgian Clubs can be transferred to any District in the Zonta world and should assist in being a vehicle for bringing the issue and Zonta International to the attention of the community.

United States of America

Rochester NY, hosted the District 4 conference in September 2005 and organized a speaker from the University of Rochester. She was both an attorney and professor in the bioethics department and focuses on Stem Cell Research. This topic was chosen because of Zonta International's goal to educate members about Stem Cell Research. This is a very hot topic in the USA right now!

This club has just held an LAA dinner presentation by a medical researcher at the University of Rochester. What was supposed to be a 15 minute overview turned into a riveting one hour discussion. Members were absolutely fascinated with the topic. While we often hear about the political and religious debates, members had not heard much about Stem Cell Research from the research side.

This speaker also gave an overview of what other countries are doing and how they compare to each other which was perfect for an international organization!

Cord Blood Legislation in the USA

In January 2004, Illinois became the first state in the nation to offer all pregnant women the opportunity to donate, at no expense, their umbilical cord blood for medical treatment or research.

New Mexico State Senator Nancy Rodriguez (Democrat) introduced legislation in February 2005 (SB 605) that would require doctors to inform pregnant women about umbilical cord blood donations and compel hospitals to allow such donations in an effort to promote stem cell treatment in the state. The Umbilical Cord Blood Banking Act would provide the New Mexico Department of Health with \$25,000 to publish and distribute pamphlets with information concerning umbilical cord blood donation. According to Rodriguez, approximately 400 cord-blood transplants take place annually in New Mexico. Florida, Illinois, Texas and Maryland currently have laws promoting cord-blood donations, and another four states are considering similar laws, according to a memo to Rodriguez from the New Mexico Legislative Council Service.

What can be done by Zonta?

Inform and re-inform Zontians and women (and everybody else) so that women become more conscious of their value and of the problems related to the need for egg cells to produce hESC, and can think about their wishes and hopes for this matter. Women who have done this will be valuable contributors to decision making.

Zontians can develop clear views about the position of women on this subject; this is advancing the status of women.

Women will play their natural and important roles

- as mothers in the production of umbilical cord blood
- as responsible people in the supply of their egg cells.

Therefore women must be completely and correctly informed in order to be

- prepared to take the best decisions for themselves, their baby and the community about their umbilical cord blood
- warned against commercial abuse, especially in less developed regions and countries

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