Ethical and practice Issues in stem cell Research and Therapy. “Egyptian Situation”.

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No Disclosure
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Agenda

- The beginning
- Egyptian Stem Cell Situation
- Guidelines
- Stem cell. Egyptian controversy
- Future
Egyptian Stem Cell Situation
Stem Cell Therapy

- Illegal but exist
- private sector
- All adult stem cell from bone marrow
- Hepatic failure – Renal failure – Diabetes
  Spinal cord injury – peripheral ischemia – Wound healing – Cosmetic surgery
Egypt has two banks licensed to keep cord blood cells, and three other BANKS wait for license.
Experimental Stem Cell Studies

(Medline Sep 2012)

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All The clinical stem cell research in Egypt are in adult category
No Embryonic Stem Cell (ESC) Research

• Absent due to lack of funds.
• (ESC) Research basic in nature, no expedited clinical application.
• Conflict of regulations regarding (ESC).
• Majority of IVF Sitting in private sector (Clinical Research forbidden in private sector).
• Disagreement of couples to use their leftover fertilized ovum.
In March 2011, the Egyptian Ministry of Health decided to form the National Committee of stem cells, with a membership group of professors in different disciplines.
Guidelines
No law or clear national regulation to control the use of stem cell until now.

A draft law is being prepared to regulate stem cell work, to be submitted to the parliament.

Detach recommendations from different regulatory authority.
Article 46: It shall be unallowable to establish ovum, spermatozoon or embryo banks.

Article 51: It shall be prohibited to trade in the human organs, tissues and cells, and human embryos. Under no circumstance shall the physician be allowed to take part in these operations, otherwise he shall be subject to disciplinary accountability.

Article 60: The researcher shall be prohibited from conducting researches and practices that involve the suspicion of mixing lineages, or participating in them in any way. He shall also be prohibited from carrying out or participating in medical research which aim at cloning the human being.
Egyptian Medical Syndicate

• In 2005, when stem cell research first began in Egypt, then-President of the Egyptian Medical Syndicate approved of adult stem cell research, but opposed the use of embryonic cells.

• "Destroying embryos for research is not ethically right, it's not morally right, and it does not conform to our Islamic religion as it stands now"

    Hamdy el-Sayed
According to the Egyptian Fatwa Council: Research Issues on Human Organ Transplantation, May 2007 (Chapter 4, “Stem Cell Transfer in Egypt”), it is allowed to obtain and use stem cells for research or therapeutic purposes provided that no damage is inflicted on the person from whom the stem cells originated. It is, for example, permitted to use stem cells from surplus embryos and legally aborted foetuses, provided that the parents’ consent is obtained.
Recommendations of Stem Cells Seminar
"Dilemma of Stem Cells: Research, Future and Ethical Challenges“
in Cairo, Egypt, November 2007

"in cooperation with the WHO regional office in Cairo; UNESCO; ISESCO; and the Islamic Fiqh Academy in Jeddah. under the auspices of the Egyptian Minister of Health.
**Stem Cells Seminar**

- **First:** It is accepted to conduct research on stem cells or using them in the treatment of diseases if these cells are obtained from permitted sources.

- **Second:** It is accepted to use IVF leftover fertilized eggs before their implantation.

- **Third:** It is forbidden to implant a fertilized egg in the uterus of a woman other than its owner.
**Stem Cells Seminar**

- **Fourth:** It is prohibited to do intentional abortion to deploy the fetus in transplantations.

- **Fifth:** If the fetus shows no potential of life, it is accepted to benefited from after its death.

- **Seventh:** Neither coercion nor temptation is to be used to obtain fertilized eggs.

- **Eighth:** It is accepted to benefit from the blood of the placenta or the umbilical cord.
Stem Cells Seminar

• **Eighth:** The couple's consent is must, after clarifying the aspects of use for them. Donors are protected against a DNA identification.

• **Ninth:** It is forbidden to use the aborted fetuses' primordial tissues for sperm or ovum production, except of using these eggs and sperms in infertility research.

• **Tenth:** It is accepted to use chimeras in conducting research in place of human.
Stem Cells Seminar

- **Eleventh:** It is accepted to obtain stem cells from adult donors after consent.

- **Twelfth:** It is accepted to use adult stem cells to produce sperm or ovum. In same person.

- **Thirteenth:** Do not use Organ implantation for commercial purposes.

- **Fourteenth:** Donors should be protected against DNA identification
Stem Cells Seminar

- **Fifteenth:** Stem cells used only in medical fields. And not in illegitimate plastic surgeries, trifling with and changing Allah's creation.
- **Sixteenth:** Informed voluntary consent the couple for destiny of their fertilized ovum.
- **Seventeenth:** Stem cells themselves as well as all their types cannot be patented, but methods of separating or producing specific therapeutic stem cell lines can be patented.
General Considerations

- Some Muslims in Egypt, a deeply conservative and religious country, are open to allowing embryonic stem-cell research, saying the embryo does not have a soul until later stages in its development.

- But others agree with Coptic Orthodox and Catholic clergy, who say it is immoral, even infanticide, to destroy embryos at any stage to harvest stem cells.
General Considerations

• Cloning, even for therapeutic purposes, is currently forbidden in bylaws instituted by the Egyptian Medical Syndicate, an independent body overseeing all private and public medical practice in Egypt.
• The Egyptian Ministry of Health (MoH) issued in 2009 a ministerial decree (ban all the stem cell therapy, All the stem cell use must be in research sitting in public hospital after the approval of research ethics committee)
Stem cell - Egyptian controversy

• Research or therapy we only use autologous adult stem cell.
• Why we need ethics here?
The Main ethical problem that face the IRB members during stem cell research are:

- Deficient of scientific background or normal cascade of research steps
- Lack of detailed methodology in the protocol or infrastructure for safe use and identification of stem cell.
- Lack of enough experience of research team
- Indeterminate Risk and Benefit
- Deceiving Informed Consent
• The health policies should take into account the giant expenses and complex technicalities of stem cell research.

• Inadequate health funding impose assess of expenses and degree of benefit before providing new technique.

• These techniques should be also regarded on condition that this should not run counter to the equity of distribution and priorities.
Stem cell therapy in Egypt

- Illegal
- Lack of Approved clinical and ethical procedure.
- Exploiting desperate patients
The adult stem cells have in effect become enablers of “stem cell tourism - i.e. desperate patients traveling across borders for fraudulent therapies.”
XcellIn

أكس سل

دوسلدورف - ألمانيا

نفخر بأن نقدم لكم منا ابتكارنا لعلاج الخلايا الجذعية للكبراء

فإن مركز أكس سل XCell يعد أول مركز بأوروبا معتمد وخاص بعلاج الخلايا الجذعية ،

ويعتبر المركز الرائد بعلاج الخلايا الجذعية البالغة وتوفير العلاج السريرية والمختبرية.

و لدينا معايير يحكمها قانون الطبية الألمانية ، وبرنامج الرصد العالمي حسب لوائح الاتحاد الأوروبي. و هذه المعايير على قدم المساواة مع الولايات المتحدة الخاصة بلوائح الهيئة الطبية.

في مركز XCell يتم اتباع أفضل الطرق لضمان سلامة ونجاح كل مريض وتشمل الرعاية الطبية.

ويتم تقييم كل حالة من قبل فريق طبي معتمد من المختصين في

مرض السكري ، وجراحى الأعصاب ، والقلب ، وأطباء الورم بالإضافة إلى أنها عالجت أكثر

من 1500 مريض ،

وينظرا إلى النتائج الممتازة التي تحققت ان استخدام علاج الخلايا الجذعية البالغة الذاتي هي خالية

من الشواغل الأخلاقية ، وليس هناك من خطر التلوث أو الرفض وعدم احتوائها على

الفيروسات.

Beirut- Lebanon - 14- 15 September 2012
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- Click here to close this webpage.
- Continue to this website (not recommended).
- More information
Current Hope
In April 2012, a specialized center for stem cells in the Sheikh Zayed Hospital was established working in the field of conducting clinical studies and in preparation for start of stem cell therapy within 2 years.
Strict clinical criteria for stem cell center

• Lab systems Construction
• SOP
• skills Staff and required
• Site doctors
• Initial & Continuing Training
• Quality Control
The project of Stem cell therapy will include in the beginning:

- Treatment of Diabetic Foot
- Peripheral revascularization
- Hepatic Cirrhosis
• We need for rapid response of the regulatory authority, to the rapid advance of science
  – Ethical dilemma of new stem cell techniques (Induced pluripotent stem cell) with reproduction probability
  – The embryonic stem cell research is accepted now but what will happen when the need for more differentiated embryonic stem cell older then 5 days?
Thank You