ETHICAL AND LEGAL ISSUES OF SKIN STEM CELLS RESEARCH: INFORMATION CONFIDENTIALITY, ACCESSIBILITY AND INFORMED CONSENT

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Abstract: Stem cell research (SCR) is an important modern field of biomedical advances with many therapeutic applications for many diseases that also debates about the source of the cells. Skin contains specialized adult stem cells to maintain a proper protective function and can be included fibroblasts, keratinocytes, melanocytes and even hair follicles and epidermis contained keratinocytes that are clonogenic. There is already amount of research on ethical, legal, and social issues in stem cell research that specialists debate in relevant areas facilitation of biomedical research critically depends on the use of personal information. When personal information is used in research, it is necessary to consider the confidentiality of the information and privacy of the person throughout the research process and in any publication resulting from it. Bioethics analysis, theories and standards is needed to guide and conduct policymaking in this field and to provide an appropriate evidence-based policy in developing countries. Authorities must be required to establish statutory framework and appropriate ethical and scientific supervision for information confidentiality and accessibility limitation. Consents should be observed standardized regulation and obtained for both researches and access to human subjects or patients information.

Key words: Ethical, Legal, Stem cell, Informed consent

INTRODUCTION

Stem cell research (SCR) is an important modern field of biomedical advances with many therapeutic applications for many diseases that also debates about the source of the cells [1]. Stem cells are derived through different ways [2]. In fact, these research applications are including both embryonic stem cells (ESCs) and various types of non-embryonic stem cells that most scientists agree both of them should be studied to increase the chances of developing successful therapies [3]. Non-embryonic type such as skin stem cell is considered as adult stem cells. Skin stem cells, are thought to reside at precise locations, termed niches, where they benefit from self-renewal through symmetrical or asymmetrical divisions [4-6].

There is already amount of research on ethical, legal, and social issues in stem cell research that specialists debate in relevant areas [7-11]. Parallel to advanced knowledge, more developing countries have the opportunity to benefit from new developments of health biotechnology [12]. Facilitation of biomedical
research critically depends on the use of personal information [13]. Further, increasing regulation of biomedical research has numerous subsequently regulations for information management [14].

When personal information is used in research, it is necessary to consider the confidentiality of the information and privacy of the person throughout the research process and in any publication resulting from it. Hence, it is important to identify the most salient ethical issues relevant to stem cell research. Main aims of this article are to review of the ethical issues with overview of information confidentiality and informed consent in stem cells research as it moves towards clinical trials and applications, and finally to present some recommendations regard to ethical challenges.

**Stem cell research in current bioethical issues category** (Table 1): Bioethics is the study of ethical issues that result from biologic and medical technology or advances [15] principlist theory is commonly accepted a number of theories formulated to bioethics, particularly in ethics applied to research involving human subjects. This theory requires the existence of 4 principles which would act as the co-ordinates of any moral problem that might be posed by research involving human subjects [16,17], that are applied through moral norms, such as assessment of the benefit-risk ratio, informed consent, equitable sample selection and protection of confidentiality [18]. The Council for International Organizations of Medical Sciences (CIOMS) is a non-governmental organization founded in 1949 with collaboration with WHO and UNESCO in particular, has established a series of guidelines on the ethics governing research involving human subjects [18].

In 2001 the Council of Ministers of the European Union adopted a Directive on clinical trials, which will be binding in law and is developing a Protocol on Biomedical Research, which will be an additional protocol to the Council’s 1997 Convention on Human Rights and Biomedicine staining and Improving quality of life and included genome project, gene therapy and stem cell research [15].

**SCR promises for understanding basic mechanisms of human development and differentiation**, as well as the hope for new treatments for diseases [20]. There are two populations of stem cells: embryonic and adult stem cells [21]. Skin contains specialized adult stem cells to maintain a proper protective function [4,22,23] and can be included fibroblasts, keratinocytes, melanocytes and even hair follicles and epidermis contained keratinocytes that are clonogenic [24,25]. With consideration of SCR in bioethical issues category, it can be demonstrated that principles existed in bioethics theories, applied in SCR that are especially informed consent and protection of confidentiality are this study target. It is also true about regulations and laws. For instance in UK, according to Human Tissue Act 2004, donations for stem cell research and transplant will be largely governed by the common law [26].

**Privacy, confidentiality and accessibility of patient information**: There should be regulation for personal information accessibility, and its utilizes, and therefore many scientifically advanced countries have established ethical and legal frameworks to maintain confidence and safeguard for the research enterprise [27]. The information may be derived from tissue samples, medical records, researchers’ data files, or institutional databases and the privacy of the persons needs to be protected, when the information is personal and sensitive. Consequently, there are rules regarding the confidentiality and use of research data in general, and medical records in particular [13]. There is the growing importance that modern laws attach to the protection of privacy and confidentiality of personal data, reflecting social concern for such protection [28]. In order to the need for protect the human subjects or patients rights including medical confidentiality and privacy, cell banks must take the necessary steps to protect confidentiality of the data [29]. Generally, when information of a personal nature is gathered, subjects should be informed that their data may possibly be used for research purposes, and be given the chance to object to same [18].

Data of a persons subjected to research may only be disclosed to a third party for purposes with lawful functions and the party to whom such information is released, subject to the interested party’s prior consent [18]. Data of individual subjects can be disclosed only under the orders of the presiding judge in courts or in some cases may be required to communicate to drug registration authority or to health authority [30].

Patients have the right to expect that their physicians and other health-care professionals will hold all information about them in strict confidence and
disclose it only to those who need, or have a legal right, such as others involved with the diagnosis and treatment of patients. Any identifying information could be disclosed to an investigator if each patient has given consent to such disclosure and if an ethical review committee has approved such disclosure [19].

Use of medical records in biomedical research: In a healthcare institution, all personnel who handle medical records are under a legal and ethical obligation to observe the confidentiality of the information in the records and to safeguard the privacy interests of patients concerned. A similar obligation should extend to any other person coming into contact with medical records [13].

Medical records and biological specimens may be used for research without the consent of the patients/subjects only if an ethical review committee has determined that the research poses minimal risk, that the rights or interests of the patients will not be violated, that their privacy and confidentiality or anonymity are protected, and that the research is designed to answer an important question and the requirement for informed consent were to be applied. Knowing that records or specimens may be used for research is one of the patients rights [19]. Any use of data relating to the health of persons for purposes except those whom consent given, is prohibited [18].

Informed consent: For all biomedical research with human subjects, the investigator must obtain the voluntary informed consent of the subject or, if subject is not capable of giving informed consent, the permission of a legally authorized representative in accordance with applicable law is required [18]. A researcher should obtain appropriate consent before using or storing a tissue sample for the purposes of research or transplant and if fails to obtain it, could be prosecuted for a criminal offence [3]. Human Tissue Authority has published draft codes of practice that include guidance on consent [31]. It is clear that the patient must be fully informed. There should be a standardized protocol that ensures the term “fully informed” is meaningful and can be include written information [32].

Essential information for obtaining informed consent: The informed consent doctrine has 3 goals: 1- to consider patients as members of the decision-making process; 2- to involve the patient to consequences and effects resulted from values and choices in patient life; and 3- to ensure the patient is aware of the potential benefits and risks of the treatment or other procedures [33], specially a dermatologist should notify the patient as to the benefits of photography and videotaping, because the use of such photography for teaching purposes is valuable, and so requires an appropriate patient consent [34].

For obtaining informed consent in research, the investigator must provide the following information, in proper form of communication that the individual can understand [19]:

1. that the individual is invited to participate in research, and that participation is voluntary;
2. that the individual is free to refuse to participate and will be free to withdraw from the research at any time;
3. the purpose of the research, the procedures to be carried out by the investigator and the subject,

Table 1: Current bioethical issues

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<tr>
<th>Relating to the beginning of life</th>
<th>Family planning</th>
<th>Abortion</th>
<th>Perinatal ethics</th>
<th>Eugenics</th>
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<tr>
<td>Relating to sustaining and Improving quality of life</td>
<td>HIV/AIDS</td>
<td>Organ transplantation</td>
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<td>Relating to death and dying</td>
<td>Human Genome Project</td>
<td>Gene therapy</td>
<td>Stem cell research</td>
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<td>Planning for the end of life</td>
<td>Euthanasia</td>
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Heidari et al.
and an explanation of how the research differs from routine medical care;
4. for controlled trials, an explanation of features of the research design (e.g., randomization, double-blinding);
5. the expected duration of the individual’s participation (including number and duration of visits to the research centre and the total time involved);
6. that, after the completion of the study, subjects will be informed of the findings of the research in general;
7. that subjects have the right of access to their data on demand, even if these data lack immediate clinical utility (unless the ethical review committee has approved temporary or permanent non-disclosure of data);
8. any foreseeable risks, pain or discomfort, or inconvenience to the individual (or others) associated with participation in the research;
9. the direct benefits;
10. to immediate family relatives or to others (e.g., insurance companies or employers) without the consent of the subject;
11. in what way, and by what organization, the subject or the subject’s dependants will be compensated for disability or unpleasant resulting from such injury.

CONCLUSIONS

Stem cell therapy can be applied to eradicate most of health problems all over the world. By consideration of different types of stem cells resources, we inserted our review upon on adult stem cell in skin. Skin stem cells have variety of specialized cells and so have various applications in many skin diseases and problems such as its application in leishmaniasis scars, burns, ulcers, hair problems and ect.

Advances in SCR continue to generate considerable ethical and legal issues. Most of these issues pose unique questions for researchers, policymakers, stakeholders, and the public [35]. Doing the best ethical practices in SCR, requires a process of identification of international ethical standards that consequently requires people, investigators and any one involve in SCR, throughout the world in honest conversations about the science and ethics of stem cell research [36]. In addition maintaining public confidence is necessary for strengthening future research plans [1], that this confidence should be considered for human subject information.

Finally, it can be stated that bioethics analysis, theories and standards is needed to guide and conduct policymaking in this field and to provide an appropriate evidence-based policy in developing countries [1].

RECOMMENDATIONS

Authorities must be required to establish statutory framework and appropriate ethical and scientific supervision for information confidentiality and accessibility limitation. Consents should be observed standardized regulation and obtained for both researches and access to human subjects or patients information.

REFERENCES


