REVIEW ARTICLE

The Concept of the Legal Protection of Stem Cell Use Based on Prophetic Norms

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ABSTRACT

This paper has the objective to explore the legal formula for the use of stem cells in Indonesian legal regulations. It also aims to analyze the effectiveness of the prophetic law's accommodation in the Indonesian legal concept as well as offer a policy formula on stem cell utilization. It is known that stem cells are a highly versatile therapeutic option. This research is urgent because it is an effort to invent a prophetic-based legal concept of stem cells usage in the Republic of Indonesia. This research aims to find a concept on the therapeutical practice of stem cells that is according to the law, norms, ethics, and religion. This research employed the legal research method with a normative approach that was combined with the prophetic law. When using stem cells, things must be considered on a prophetic basis. The prophetic ethics contain three main principles, namely: (1) humanization which means humanizing humans, (2) liberation which means the efforts to neutralize all forms of dehumanistic or anti-humanity actions, and (3) transcendence which means returning all worldly affairs to God. These principles are efforts to optimize human spirituality as a servant of God. Research results showed that there must be strict legal regulations on stem cell utilization other than for treating degenerative diseases. It is hoped that the law may regulate the therapeutical practices of stem cells so that such a therapy is according to the principles of the law, norms, ethics, and religion.
Malaysian Journal of Medicine and Health Sciences (2024) 20(SUPP9): 261-267. doi:10.47836/mjmhs20.s9.41

Keywords: Indonesia, Law, Legal protection, Prophetic, Stem cell

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INTRODUCTION

Medical technologies which use human stem cells are expected to increase the expectancy of recovery. Therefore, in its development, with its various applications, human stem cell therapy becomes a realistic target to achieve (1). Kalthoff described that stem cell treatment does not merely bring the benefit of treating various degenerative diseases that are so far untreatable and unhealable, but it is also highly beneficial for reversing aging, making people more pretty, gorgeous, intense, fresh, and dynamic. This therapy's capabilities in replacing dead cells with cells that are fresh, youthful, and healthy are crucial for people who wish to stay attractive and have good physical condition. It is also useful to protect people from diseases that are caused by the body's depleting functions or damage to bodily organs (2,3).

Even though it is still categorized as expensive, it cannot be denied that the stem cell brings new hope in the medical field. Embryonic stem cells have an important role in therapy and healing. It can decrease the rate of cases of degenerative diseases like neural, heart, and liver disease (4). The stem cell usage is currently not merely restricted to the sector of health. On the contrary, it has reached the beauty sector as well. Comforming with its characteristics to fix damaged cells, it has been claimed that the stem cell can heal various skin diseases caused by aging (5). Somatic stem cells contain multipotent stem cells that may be differentiated into specific body tissues. These types of stem cells have caused a stir in the scientific realm, as they are a possible source of autologous cells which may be used for transplantation therapy without immunological complications. Examples of somatic stem cells that are commonly studied are erythropoiesis and central nerve

system stem cells (6) . Global data on stem cell therapy shows there needs to be a careful consideration of several potential side effects, such as reactions at the area of use, the possibility of cells moving from their proper place to other types of cells or several cells, the failure of stem cells to work as they should, and the risk of tumor formation.

It has been suspected that several beauty clinics in Indonesia committed illegal medical practices by illegally injecting stem cells into the bodies of patients (6). Criminals have committed commercial stem cell transactions with a price of USD 16,000 which is equal to Rp230 million to victims. The stem cell serums were imported from Japan and were brought to the clinic to immediately be injected into patients (7) . without a permit are sometimes carried out by several parties by injecting stem cells without a distribution permit from BPOM (Badan Pengawas Obat dan Makanan/the Food and Drug Supervisory Agency).

The controversial issue is that while isolating the stem cells, there is the process of destroying a human embryo. This leads to controversies as it contains a human ethical code issue. Apart from that, such practices are deemed to violate religious rulings . Stem cells are taken from blood, bone marrow, and babies' umbilical cords. They may also be obtained from the inner cell mass of five-day-old embryos and no ethics needed or from umbilical cord after baby born. To gain the features of the stem cells which have the potential to grow into all bodily cells (pluripotential), the cells must be removed from an embryo during the blastocyte phase (around five to seven days after conception), prior to the uterine attachment process. The process of stem cell extraction is deemed as destroying the initial phase of a human life. Many parties suggest that just like a born human being, an embryo also has the right to live and develop (8).

Human stem cells have various benefits to human beings. Unfortunately, the lack of clear regulation, especially that which regulates this issue in the research and utilization stages, opens a chance for the misusage of the stem cells of human beings . It is considered illegal as there are no permits for the use of stem cells in Indonesia. This issue is not yet clear because it has not been fully regulated. The stem cells of humans which originate from the body of human beings certainly cannot be deemed as a commodity which is is developed for commercial uses which will certainly only bring profits to several stakeholders. The stem cells of human beings are a human civilization richness the which must be maintained for people's lives (9). Research on stem cells started from a curiosity on how tissues are maintained in adults, rather than how these cells emerge in embryos. Historically, the interest in stem cells was based on the spirit to cure diseases, especially cancer (10). In the last few years, stem cells have also been used in combination therapy with other medicines to achieve the benefits of health services to all types of tissues in the body (11) . In Indonesia, the use of stem cells is only permitted for research and there needs to be a fatwa from the Indonesian Islamic Scholar Council (Majelis Ulama Indonesia/MUI) because the majority of the Indonesian population consists of Muslims.

Stem cell therapy usagebrings about support and contradiction from various parties. In the case of degenerative diseases, the stem cell therapy is allowed under the principle of prioritizing the interest of aiding human life. But its use for beauty, rejuvenation, and anti-aging purposes must be regulated as there are still debates between religious leaders on the stem cell extraction process. Such an extraction process is deemed inhumane. It is hoped that the arrival of the prophetic law may regulate the practice of stem cell therapy according to legal, normal, ethical, and religious principles. Thus, in this paper, the issue which is going to be discussed is the prophetic-based legal protection concept on stem cell usage. The urgency of this research lies in efforts to discover models or a new postulate on the prophetic law-based legal model of stem cells in Indonesia. Previous research was conducted by Bouzenita (12), whose research invited interested parties to discuss the use of several legal methods in the ongoing Islamic bioethical discourse on the use of stem cells for cosmetics. This is so that in the end, stem cells are mostly used for beauty purposes (13). The research, which aimed to find the concept of stem cell practice in accordance with Islamic law, was based on legal research methods with a normative approach combined with the perspective of prophetic law.

MATERIALS AND METHODS

This research employed the method of normative legal research which was employed to study several applicable legal regulations on stem cells. According to Fajar and Ahmad, the method of empirical legal research is used to analyze a regulation's application, whether or not it is well-regulated. Apart from that, it is also used to describe the issues which occur as an effect of the enactment of such regulations (14). In the first stage, using the literature study method, data will be inventoried regarding the application of stem cells in Indonesia and implementation in several countries. The data that has been inventoried is then processed and analyzed using descriptive methods. The second stage, the literature study method will inventory data sourced from the opinions of scholars and clerics regarding prophetic law, so that in the final stage a practical formula for using steem cells is found that is in accordance with Islamic law. The third stage is the heurestic analysis method, the results of the analysis in the first stage will be combined with the results of the analysis in the second stage, so that the practice of using stem cells in accordance with Islamic law in Indonesia will be discovered. (15).Based on all the activity stages

above, in the final stage it is hoped that a practice of using stem cells that is in accordance with legal norms in Indonesia will be found.

RESULTS

The Use of Stem Cells

1. Its use in treating degenerative diseases
At this time, stem cells in the baby's umbilical cord blood have the capability to be utilized to treat various diseases. Stem cells have the potential to be used to treat hematopoietic and genetic diseases. When transplanting the umbilical cord blood, the stem cells are injected into a patient's blood flow. Here, these cells work to heal as well as recover the cells and tissues that have been damaged. Following the engraftment of stem cells has been carried out, the patient's blood and immune system will experience regeneration. Then, stem cell therapy is a therapy that is highly effective in treating degenerative diseases. The treatable degenerative diseases are diabetes mellites, Parkinson's, stroke, myocardial infarction, Insulin Dependent Diabetes Mellitus (IDDM), Alzheimer's, atherosclerosis, etc. It can heal other degenerative diseases such as autoimmune diseases like lupus, etc. (2).

2. Its use in clinical aesthetics
As was previously described, stem cells are a highly versatile therapeutic option. Therefore, it can also be used in the beauty industry. In the medical field, the beauty sector is a specialization of dermatovenerology (which is treated by doctors for skin and genital diseases). Stem cell therapy is an option that has started to generally be given in cases of skin issues.

The skin has a coordinated and organized healing system to treat damaged skin. Skin tissues' integrity as well as function may result in recovery. Such a process may be blocked by several special conditions which may then result in unhealable, chronic (continuous) injuries. A condition that may result in such a case is the insufficiency of the artery and vena capillaries, diabetes, trauma, kidney diseases, old age, and continuous pressure on a certain part of the body. Local factors like tissue hypoxia (lack of oxygen), ischemia (inhibited blood flow), strange objects' existence, tissue maceration, exudate, infections, disturbances in regulating the inflammation process, and systemic factors such as a bad status of nutrition and immunity may inhibit the skin's recovery process. Today, there is an increase in the rate of non-communicable disease sufferers, which may then also increase the rate of such cases of chronic wounds (16).

Ahmadi-Ashtiani et al. (17) wrote an updated journal article, found that stem cells contain various uses in treating skin-related diseases. It has benefits in treating non-life threatening non-communicable diseases that disturb a person's aesthetic aspect, such as vitiligo as well as psoriasis.

An example of a skin disease is vitiligo. It is due to the melanocytes' destruction (the cell that colors the skin) by abnormal body immune cells, which is named the cytotoxic T-cell. Such a condition makes the skin area with damaged melanocyte cells to have a brighter color compared to the rest of the skin. Vitiligo disease may be closely linked to the low life quality and self-confidence of patients (18).

Meanwhile, psoriasis is a skin inflammation illness which is caused by genetics and immune cells. Likewise, psoriasis is strongly linked to the patients' low quality of life, as its symptoms disturb their lives. Apart from bringing impacts to a person's aesthetics, psoriasis also causes pain, itchiness, and bleeding (19). Through treatment with stem cell therapy, there is an expectation that the patient's life quality may increase from the aspects of symptoms to aesthetics. Thus, it can be concluded that the dogma on the development of stem cells is a totipotent cell that becomes a pluripotent cell; a pluripotent cell, that becomes a multipotent cell; and a multipotent cell that becomes a unipotent cell. The more specific the type of cell, the lower its capacity to regenerate itself (20).

In other cases of clinical aesthetics, stem cells are used in treating anti-aging or dysfunctions linked to age. In the process of aging, the DNA experiences damage. Such damages accumulate, harming the homeostasis of protein; cell function and communication; as well as the physiology of normal organs. Other aging symptoms include the endogen stem cell population dysregulation or fatigue in an aging person's body. This impacts a decrease in the homeostasis function and the damaged tissue reparation. Aging is strongly linked to the stem cell integrity. One of the targets of the stem cell biology and regenerative medical science is how stem cells are used to reverse aging as well as to treat the dysfunctions related to it (21).

Skin aging may happen due to damage caused by ultraviolet (UV) light, inflammation, environmental factors, as well as the increase of stress oxidative species in comparison to antioxidants. Stem cells that are commonly used are multipotent cells that have the ability to proliferate and reprogram the epidermis layer, which will then create stem cells in the basal cell. Finally, it will result in the creation of new keratinocytes (21).

Stem cells are highly promising in the beauty industry, but many parties often misuse them. In the beauty industry, an issue which often occurs concerning stem cells is that often, they are wrongly advertised. Even worse, people still lack proper knowledge of the stem cells. Medical companies often have baseless strategies and they often exaggerate claims, which endanger

patients (22). There is also misusage in the use of stem cells in fighting aging, as they are often promoted as facelift operations. "Stem cell facelift" is at term that is rampantly utilized. It is a non-surgical procedure which actually aims at tightening the skin. It is incomparable to facelift procedures. What is usually advertised and promoted as a new and original technique called "stem cell facelifting" is actually merely lipofilling that is enriched with stem cells (23).

The Stem Cell Legal Protection

In terms of regulations, the Republic of Indonesia's Ministry of Health cooperated with the Committee of Stem Cells and Cells to enact the following regulations: the Regulation of the Ministry of Health No. 48 of 2012 on Bank Umbilical Cord Blood Stem Cells, the Regulation of the Ministry of Health No. 50 of 2012 on the Establishment of Stem Cell Processing for Clinical Application, the Regulation of the Ministry of Health No. 62 of 2013 on the Establishment of Tissue and/or Cell Banks, as well as the Regulation of the Ministry of Health No. 32 of 2018 on the Establishment of Stem Cell and/or Cell Services (24) .

Chapter 3 entitled Services, Part One entitled General of Article 4 regulates the following: (1) Stem cell and/or cell services may only be implemented with the aim of treating diseases and recovering health and it is prohibited for reproductive goals; (2) the diseases aforementioned in clause (1) encompasses degenerative and non-degenerative diseases; (3) recovering health aforementioned in clause (1) includes cell, tissue, and organ rejuvenation; and (4) the prohibition for reproductive goals aforementioned in clause (1) is a prohibition in using stem cells and/or cells for the creation of a new individual.

In Indonesia, the regulation of stem cells is contained in Articles 64 and 70 of Law No. 36 of 2009 on Health. Article 64 regulates that: (1) the treating of diseases and the recovery of health may be applied through organ and/or bodily tissue transplantation, the implant of medicines and/or health instruments, plastic surgery and reconstruction, as well as the use of stem cell; (2) the transplantation of organs and/or bodily tissues as aforementioned in clause (1) is carried out solely for humanity reasons and it is prohibited to be carried out through commercial reasons; and (3) organs and/or bodily tissues are prohibited from being sold under any reason.

Article 70 regulates: (1) the use of stem cells may only be carried out for the aim of healing diseases and recovering health and it is prohibited for reproductive objectives; (2) the stem cells as aforementioned in clause (1) cannot originate from embryonic stem cells; (3) further regulations on the use of stem cells as aforementioned in clause (1) and clause (2) are regulated in Ministerial Regulations. The Indonesian Ministry of Health conducted cross-sector cooperation in conducting a public examination of regulations derived from the Health Law, namely regarding stem cell services. Through this derivative regulation, the government prepared Minimum Service Standards for stem cell services in the public examination of the 2023 Health Law derivative regulations. This is regulated so that stem cell therapy can improve efforts to cure diseases, restore health, and improve the life quality of patients (25) .

DISCUSSION

Prophetic-Based Concept of Stem Cell Usage

The prophetic paradigm or what is also commonly called the term *prophetic social studies* is the process of discovering Qur'anic verses and making concepts and theories that are relevant to the needs of the religion's embracers. The prophetic paradigm illustrates a process of scientific integration (between religious science dan non-religious science) that in essence has already existed in the development of Islamic science. Therefore, the prophetic paradigm can become a new alternative paradigm in the post-modern era which has dedifferentiated characteristics (26). The prophetic paradigm comprises the following principles:

a. Humanization

Based on the religious terminology, the concept of humanization is a creative translation of *amar ma'ruf*. It contains the true meaning of encouraging the upholding of virtues. Based on the scientific language, etymologically, humanization originated from the Latin word *humanitas* which means human beings as well as the condition of becoming human beings. Terminologically, *humanization* means humanizing humans and eradicating materialism, dependence, violence, and hate from humans (27). According to this understanding, Kuntowijoyo suggests that this humanization concept is rooted in humanism-theocentrism. Thus ,such a concept cannot be holistically understood if one fails to understand the transcendence process which becomes its basis.

Ali Syari'ati suggests that humanism is an expression of a group of divine values that are contained in the human self. It is a direction of religious and moral guidance for human beings, which cannot successfully be proven by modern ideologies due to their negligence of religion (28).

This concept certainly permits the use of stem cells to save human life according to norm, legal, and religious principles, but under the condition that no other treatment exists. Meanwhile, stem cell usage for the interest of treating aging and for rejuvenation actually violates the humanization value, as such actions do not humanize humans. This is because embryonic cells are used only for nonurgent interests. Therefore, there

must be the best efforts to prohibit rejuvenation using embryonic cells for any interest other than the condition that this therapy becomes the only solution for the good of humans. Apart from that, even if embryonic stem cell therapy is used on humans, it must be applied very cautiously by considering to its impacts on people. Then again, its use for beautification objectives without more urgent goals must be hindered.

b. Liberation

According to Kuntowijoyo, liberation is the scientific term for the religious term nahi munkar. In the religious term, *nahi munkar* means preventing any harmful criminal actions, such as eradicating gambling, loans with high interest, corruption, etc. Then, in the scientific term, *nahi munkar* means freedom from ignorance, poverty, and oppression (29). Etymologically, *liberation* originates from the Latin word *liberare* which means *freeing*. Terminologically, liberation may mean freedom, all this with a connotation which has social significance (27). Kuntowijoyo perceives that the aim of liberation is to free human beings from the evilness of structural impoverishment, extortion of abundance, technological arrogance, a fake awareness hegemony, as well as an oppressive structure's domination. This liberating spirit is sought in the transcendental prophetic values which originate from religion which have transformed into a science that is factual and objective (30).

In knowledge, Kuntowijoyo suggests that liberation is efforts to free people from a materialistic scientific system, from the domination of structure, such as class and sex (31), considering that Islamic teachings do not acknowledge the existence of a structure or differences in the social classes in society. Islamic teachings also contain moderation, namely an equal partnership between men and women from the gender perspective (32).

In the liberation concept, the use of stem cells only for saving human life is in line with norm, legal, and religious values under the condition that no other treatments exist. Meanwhile, stem cell utilization for the interest of treating aging or for rejuvenation contrarily violates the liberation value. (33) This is to prevent human beings from becoming trapped in technological arrogance, where they use any means to achieve their interests. In this case, people undergo rejuvenation/anti-aging treatments using baby stem cells which can actually be strived for using better means such as sports, consuming healthy foods, and permissible beauty treatments.

c. Transcendence

The word *transcendence* originates from the Latin word *transcendere* which is defined as *to transcend*. In English, *to transcend* means *to pass, to surpass*, and *to exceed*. Terminologically, transcendence means a journey above or beyond. Kuntowijoyo regards that in theological terminology, transcendence has a meaning of divinity and supernatural creatures (34). Kuntowijoyo defines *transcendental* by basing it on the belief in God (Allah). He introduces the prophetic studies with the principles of humanization (*ta'muruna bil ma'ruf*), liberation (*tanhauna anil munkar*), and also transcendence (*tu'minuna billah*) (35).

Certainly, based on the aforementioned concept, stem cells can only be used for saving human life according to the norm, legal, and religious principles. But this may only be carried out under the condition that no other treatments exist. Meanwhile, the use of stem cells for treating aging or for rejuvenation actually violates the value of transcendence, namely the belief in God. Stem cell therapy usage for rejuvenation violates the nature of faith. The stem cell concept for anti-aging is categorized as the action of changing Allah's creation because aging is a natural part of the fate of humans .

The Sociological Concept of the Embryonic Stem Cells

The sociological concept of embryonic stem cells is according to the principles: (36) Autonomy originated from the Latin term *autos* which means independent and *nomos* which means regulation. Meanwhile, the term autonomy means the capability to determine or regulate oneself. A nurse or doctor must ask the patients whether or not they want to use stem cell treatments to heal their disease; Beneficence is a principle to do good deeds that do not bring harm to others. A nurse or doctor must follow the desires of the patients and refrain from violating the patients' beliefs by using stem cell treatments; (37) Justice is a moral principle of acting justly to all individuals. It means an action that is equal, although not always identical. In this case, equality means giving relatively the same contribution for the good of one's life. A nurse or doctor must act justly to all patients. In this case, acting justly means treating and healing according to the diseases that the patients are suffering from; Non-Maleficence means not harming or not causing danger or injuries to other people. A nurse or doctor must treat and heal patients according to standardized procedures. If stem cells bring harm to patients, thus there is no need to apply such a treatment; (38) and Moral Right is crucial because the use of stem cells violate society's beliefs as they originate from embryos and baby umbilical cords that are obtained from abortion victims .

Society's Values and Norms

Stem cells are useful for treatment, but they come from illicit sources and violate societal norms. This is because the stem cells come from abortion victims, whereas abortion is prohibited by religion because it is the killing of an innocent baby. Therefore, the usage of stem cells should be punishable by the law. Without clear laws and strict punishments, it will be easy for various parties to commit the act of using stem cells. The government should create a deterrent effect by imposing severe sanctions on the perpetrators.

CONCLUSION

The legal protection for stem cell usage based on the prophetic values encompasses the principles of humanization, liberation, and transcendence. There are several offers of concepts for the more beneficial use of stem cells that do not violate the law, norms, ethics, and religion. These concepts are crucial as they do not harm other beings and they respect the creations of God. The first concept is that stem cells are used only for degenerative diseases with emergency characteristics that cannot be healed using other treatments other than stem cells. The second concept is that the usage of stem cells for reproduction, aesthetics, as well as to counter aging is not allowed under any excuse. This is because is a nonurgent need that is not according to ethics, norms, the law, and religion. Those who carry out such deeds must be imposed with legal sanctions. Then, the third concept is that the stem cell extraction from baby embryos must be imposed with criminal sanctions rather than mere administrative sanctions that do not create a deterrent effect. Finally, the fourth concept is that the commercial transaction of stem cells must be criminalized according to the applicable regulations.

ACKNOWLEDGEMENT

This Research is Funded by Universitas Muhammadiyah Surakarta Through Tridharma Integration Research Grant (HIT Grant Scheme).

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