

## Somatic Gene Therapy: Ethical Consideration and Islamic Fiqhi Perspective

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**Abstract:** The significant development of science and technology particularly in medical treatment breakthrough has offered great potential and new hopes to treat some genetic disease and disorders. Somatic gene therapy for example is important discovery which offers promising successful treatment in several genetic disorders. Nonetheless, such technique has given rise to ethical and legal issues. In view of this point, this study seeks to explore in the light of Islamic rulings on the ethical issues surrounding somatic gene therapy. It would take an inspiration from the Qur'an and Sunnah (tradition of the Prophet Muhammad PBUH) principles in examining the Islamic medical ethics principles. These underlying principles are important to maintain flexibility to respond to this trial. Its position is then analyzed within the application of Maqasid Al-Syariyyah (Objectives of the Shari'ah) and the branches of Qawaid Fiqhiyyah (Islamic Legal Maxims) to draw the parameters of somatic gene therapy. With regard to Malaysia position, current fatwas (Islamic verdict) shall then high lighted. This study adopts qualitative method using content and doctrinal analysis approach. This study concludes that somatic gene therapy is ethically permissible in Islamic doctrine as it confers benefits to the public at large. However, the permissibility is subject to certain restrictions and stringent requirements. Thus, thorough assessment need to be observed before somatic gene therapy decision making is made. Therefore, given Islam is the official religion and Muslim is the majority in Malaysia, it is vividly important for Malaysia to also having comprehensive Islamic framework governing somatic gene therapy.

**Key words:** Human gene therapy, somatic gene therapy, Islamic medical ethics, Maqasid-al-Syariyyah (objective of Shari'ah), Qawaid Fiqhiyyah (Islamic Legal Maxims), religion

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### INTRODUCTION

Over the years, conventional method of approaches were used to treat genetic disease with the primary aim are to improve the quality of life and to save life of human. These include, dietary manipulation, surgery to correct deformities and avoidance of inciting factors in the environment. These novel treatment of this genetic disease, however has seemed to many a daunting challenge (Balicki and Beutler, 2002). Nevertheless within the last few years, enormous studies and research have revealed that the possibility of this new landmark discovery to change the faulty genetic blueprints via. human gene therapy technique. Rather, genetics researchers persuasively argued that defective genes could be replaced by those with the correct genes. On the same note (Giacca and Zaccagna, 2012) further indicate that gene therapy is now an important discipline which has progressively overcome several of the challenges that hindered the clinical success in the early stages of its

application. Gene therapy is likely to be part of medical practices in the future, since, thousands of people have already participated in the trials.

Current trend signifies that human gene therapy has been widely used in developing countries especially in USA and European countries. Moreover, it is likely to be part of medical practice on the future, since, thousands of people have already participated in the trials. Human gene therapy can be best described as the transfer of DNA or RNA into human cells for therapeutic purposes ranging from inherited disorders to certain malignancies to infectious diseases. UK Gene Therapy Advisory Committee (GTAC) defines it as the introduction of genetic material into human somatic cells for therapeutic, prophylactic or diagnostic purposes (Turnpenny and Ellard, 2007). Rubanyi (2001) describes human gene therapy as a transfer of nucleic acids to the somatic cells of an individual which resulting therapeutic effect either by correcting genetic defects or by overexpressing proteins (David and Peebles, 2008). El-Aneed (2004) is of

the same view emphasizing that gene therapy includes the treatment genetically based and infectious diseases by introducing genetic materials which have therapeutic effects or preventive purposes (Karpati and Lochmuller, 1997). Research shows that the success of these techniques is proven where it could effectively research by various means. In essence, human gene therapy may involve changes in either somatic cells or germ cells. It comprises (Mele, 2012; Anderson, 1985) of two different therapies namely somatic gene therapy and germ line gene therapy. However, discussion will only narrow down to somatic cell gene therapy.

Review of the literatures demonstrates that the research works relating to the position of human gene therapy from the Islamic perspective are extremely lacking. Not many substantial works have been done by Muslim scholars in discussing the position of human gene therapy from the Islamic point of view. Moreover, very little is found in assessing and evaluating its specific ruling within Maqasid Syariyyah and Qawaid Fiqhiyyah perspective. It is against this background, this study attempts to carefully examine the position of the human gene therapy technique and its application from the Islamic perspective. To embrace Shari'ah holistic approach in this new medical treatment, a thorough study of the position of human gene therapy in the light of other Islamic medical principles concept namely Masalih Mursalah (public interest) Maqasid Syariyyah (Objective of the Shari'ah) and Qawaid Fiqhiyyah (Islamic Legal Maxims) shall properly be addressed.

## **MATERIALS AND METHODS**

**Somatic gene therapy; An overview:** Somatic gene therapy involves an insertion of the gene directly into the host's (somatic cell or tissue). This gene therapy enables to further correct a genetic defect in the somatic (i.e., body) cells of a patient such as the lung if the patient is suffering with CF. As by Achonu (2011), somatic gene therapy has been simply described as a medical procedure that uses DNA in the therapeutic treatment of a patient's disease which involves adding genes to cells other than egg or sperm cells (reproductive cells). Through this, a normal functioning gene is introduced into a cell that contains a defective counterpart as an attempt to restore cell's function. In somatic gene therapy, therapeutic genes are transferred into the somatic cells of a patient. Any modifications and effects will be confined to the individual patient only and will not be inherited by the patient's descendants or any future offspring (Misra, 2013).

**Ethical issues related to somatic gene therapy:** Wide range of academic research on somatic gene therapy have highlighted its potential and successful treatment in many

clinical trial. This therapy is not only capable to treat genetic disease caused by single gene recessive disorders (cystic fibrosis, hemophilia, muscular dystrophy, sickle cell anemia, etc.) but also some of the most important acquired genetic diseases ranging from cancer and certain viral infections like AIDS. On top of that, this treatment could be targeted at certain conditions such as heart disease, diabetes mellitus, arthritis and Alzheimer's disease (Cotrim and Baum, 2008; Knoell and Yiu, 1998; Rubanyi, 2001; Misra, 2013). Nevertheless, this new scientific breakthrough in medical treatment has been confined due to some technical and ethical limitations.

Numerous research have been conducted to discuss the ethical issues surrounding somatic gene therapy. Issue of safety and efficacy is amongst the major concern highlighted by Evans *et al.* (2005), Friedmann (2000) and Nielsen (1997). Cohen (2011) raises significant areas within safety and regulatory aspects of somatic gene therapy that need to be overcome. Another equal concern on this novel therapy is that there are still a lot of risks associated with it (Misra, 2013). Few studies share the same concern that many fear that the risks inherent in using these procedures in humans far outweigh the potential (Wertz *et al.*, 2003; Willgoos, 2001). Hence, it may raise tension between harm and benefit. Other scholars who highlight on the limitation of somatic gene therapy include (Edelstein *et al.*, 2007; Sade and Khushf, 1998; Williamson and Kampmann, 1998). Applicability of non-clinical data to human subjects can also complicate the risk-benefit assessment and few unexpected complications and side effects have also been identified (Sade and Khushf, 1998).

The effects of corrective gene therapy are not limited to the target tissues but can also reach to other cells as well (Kaspar *et al.*, 2009). The adverse effects include, leukemia, immune reactivity very serious health risks such as toxicity and inflammation. Indeed, there are viral vectors derived from retroviruses can inadvertently cause mutagenesis and cancer (Achon, 2011; Freeman *et al.*, 1993) due to random insertion. The most challenging ethical issues of human gene therapy trial is a profound interference in the course of human nature, since, the most fundamental blueprint of life is affected (Karpati and Lochmuller, 1997).

## **RESULTS AND DISCUSSION**

**Islamic medical ethics; The guiding principles:** Generally, ethics associate with all professional disciplines and their codes of conduct be in the medical profession, legal profession, accounting profession, etc. Resnik (2015) also shared the same view stressing that "ethics" mainly focus on the disciplines and standards of conduct such as philosophy, theology, law, psychology or sociology. Often, the most acceptable definition of

ethics is the moral principles for a conduct to differentiate between what is right and what is wrong (Afifi, 2007; Ojeka *et al.*, 2017; Resnik, 2011). Rachels (2003) describes ethics as a set of moral principles, rules of conduct or values (Al-Aidaros *et al.*, 2013) on the other hand contend that ethics is concerned with the good worth sought in life and rules governing human behaviour and interaction.

Islamic ethics on the other hand is interrelated with science encompassed with aqeedah (belief) and legal rulings. According to Siddiqui (1997) the source of Islamic ethics are scattered ranging from the Islamic sciences of Fiqh (jurisprudential understanding), Tafsir (Qur'anic exegesis) and Kalam (scholastic theology). Often, it is used interchangeably as akhlaq and adab. While akhlaq entails morality or character, Adab represents the learning and acquiring knowledge of the foundation of human conduct and personality with the aim to refine character or akhlaq. Both are under purview of Islamic medical ethics discourse and were given greater emphasize in the field of medicine and health care. Evidently, it has been emphasized in outstanding classical literature relating to medical field such as the treatise Adab al-Tabib (Practical Ethics of the Physician) (Padela, 2006). Olawale (2013) adds some other important words closely associated with Islamic ethics namely, Iman, Islam, Taqwa and Ihsan. These elements shall be considered in defining as what is morally correct or morally acceptable in Islam.

The differences between Western medical principles and Islamic medical ethics lies on the fact that the foundation of Western ethical principles are not rooted on a comprehensive ethical theory of Maqasid al-Syariyyah found and Qawa'id Fiqhiyyah. The Islamic medical ethics framework is designed based on the divine revelation, Hadith of the Prophet Muhammad SAW and Shari'ah (Islamic ruling) with the primary aims to achieve the goals of the Maqasid al-Syariyyah objectives (i.e., protection of religion, soul, mind, wealth and progeny) (Daar and Khitam, 2001; Mustafa, 2014). It is not separated from the religion, thus being a comprehensive religion which govern all aspects of life, laws of medical ethics are rooted from the commandment and teachings of the Holy Quran and the saying of the Prophet Muhammad (PBUH) too. In essence, it encompasses a set of societal values and beliefs that are used to diagnose illnesses, refrain and control diseases and provision of care for patients (El-Hazmi, 2011). More precisely, some passage in the holy Qur'an and the traditions of the Prophet Muhammad (PBUH) have provide specific ethical guidelines associating with a range of medical issues. The underlying general principles contain therein emphasized on the noble characteristics inherent within Islamic medical ethics which commonly recognized by medical profession namely, fear of God, the principle of honesty, preserve sound performance, truthfulness, compassion,

sympathy, patience and tolerance. Therefore, this serve as a guidelines to medical professionals and should be adopted while bioethical decision-making is carried out as its substance, spirit and firm parameters derived from Islamic teachings (Hathout, 2006; Khan, 2016).

It is strongly believed that the ethical values and social concerns could assist and perceive as an aid to comprehend how to appropriately apply medical genetics knowledge that could maximise the benefits and minimize the harm (Afifi, 2007; Mustafa, 2014). Above all, there exists a strong relationship between medicine, ethics and fiqh where every single medical issue is subject to the rulings of fiqh. Therefore, genomics research need to be regulated in accordance with culture and religion in Islamic countries to maintain the continuity between ethics and jurisprudence.

#### **Somatic gene therapy; An Analysis from the principle of Maqasid al-Syariyyah (Objective of Shari'ah):**

Islam persistently promotes the significant progress of science and technology particularly in medical field, since, the advancement of treatment breakthrough has offered great potentials and new hopes to treat some genetic disease and disorders. Though there is no absolute and specific quranic verse speaks on human gene therapy, some relevant text and general injunction derived from Quranic verse are often used to various contemporary medical issues and practices currently exist including human genetics and genomics and in producing judgement in the field of medical treatment. Allah SWT said, "We have indeed created humankind in the best of molds" (Surah al-Tin 95:4). "Behold thy Lord said to the Angels, I will create a vicegerent (Khalifa on Earth). He endowed Adam with knowledge of all things as the Qur'an relates And He taught Adam the names-all of them" (Surah al-baqarah 2: 30-31).

Therefore without clear and definite ruling on somatic gene therapy, Muslim jurists have resorted to the Maqasid al-Syariyyah (the purposes of the law) perspective to make with viable solution via. ijtihad. The use of ijtihad (independent judgment) should be conducted in accordance with the guiding principles requirements and within the Islamic philosophy framework. The established principles underlying within the Maqasid al-Shariyyah (Objectives of the Shari'ah) would aid to resolve some moral and ethical dilemmas associates with this novel application. The objectives are to protect, facilitate and fulfill human life.

#### **The application of the principles of Maqasid al-Shariyyah (Objectives of the Shari'ah) in somatic gene therapy:**

Maqasid al-Syariyyah according to Auda (2008) contains the objectives, purposes, intents, ends and principles behind the Islamic rulings. Maqasid al-Syariyyah is significant to address and resolve

contemporary issues challenging Islamic thought. Five goals of Maqasid al-Shari'yyah under dharuriyyat (necessity) include, preservation of religion (ad-din), life (al-nafs), intellect (al-a'ql), progeny and blood lineage (al-nasl) and wealth or property (al-mal). Accordingly, the legality of any act is judged against these five goals (Alkaabba, 2016) and neglect towards it would lead to total disruption and chaos. As such, the theory of medical ethics in medical research should be conducted in accordance with the underlying framework keeping of five pillars of the Shar'iah laws (Khan, 2016). This implies that although, Islam gives full support in finding a cure for a disease, the principle of Maqasid al-shari'yyah which are protecting the five main pillars of public benefit should be given greater attention in ethical and medical procedures. Hence, to be considered ethical any action must satisfy and achieve one or more of the pillars. Failure to fulfil during the medical procedure shall be deemed unethical. Albar (2007), however, specifies that the preservation of life, mind and progeny are those closely related with medicine.

#### **Protection and preservation of faith (al-Din):**

Generally, Quran has in a number of verses mentioned to establish faith in the form of worshipping Allah SWT. Therefore, somatic gene therapy is one of the greatest discovery that most welcome in Islam. It has been proven in a series of clinical trial, this therapy in the absence of other treatment could possibly cure and treat genetic diseases. Having medical treatment with the aim to cure disease to maintain healthy life and prolong life inevitably contribute to have direct worshipping towards Allah SWT entrusted upon each Muslim. Adherence to the obligatory pillars of worship would protect the religion of Islam, since, it has both individual and communal aspect. Any efforts made to preserve al-din are strongly encouraged, promoted and obligated. This commonly include, performing the 5 daily prayers (Salah), Fasting in the month of Ramadhan (Sawm), Paying the Zakat, performing the Hajj Pilgrimage. Performing prayer is obliged and given highest priority in the Holy Quran. Thus, if the body of a person is physically fit and healthy, one could perform prayer towards Allah SWT in the best manner. In this context, Yusuf al-Qaradawi states:

“One of the blessings granted by Islam is that it does not ever stop or restrict the scope of the scientific program of the mind in science and technology, there is no conflict between science and religion in Islam. The Quran shows that God is powerful, bestowed various awards to people by enabling them to discover the mystery of the nature around them and recognize the laws that govern the universe” (Al-Qaradawi, 2006, 2002).

Analysing to the above facts, the application of modern medicine like somatic gene therapy is obviously

permissible in Islam. Nevertheless, it requires to obey certain rules and ethics as a precaution. The application of medicine for the benefit of humanity and to reduce sufferings are amongst the concerted element that need to be observed. Islam puts an emphasis on the sanctity of human life and not to destroy faith. Therefore, it is vividly important to review the position somatic gene therapy to avoid any conflicting with the goals of Islamic Shari'ah.

**Protection and preservation of life (al-Nafs):** The main key goal of Maqasid al-Syariyyah is the need for the protection and preservation of life (al-nafs) (Ibn' Ashur, 2006). In the medical aspect, it entails the preservation of health and ward off disease and restoration of health when it is lost and to remove ailment (Al-Bar and Chamsi-Pasha, 2015). In the medicinal aspect, it entails the preservation of health and ward off disease and restoration health when it is lost and to remove ailment. In this regard, many places in the Quran have repeatedly saying that saving and the sanctity of life remain as a predominant value in Islam. For example, this following Quranic verse depicts from Al-Qur'an states to the effect that.

“Because of that, We decreed upon the Children of Israel that whoever kills a soul unless for a soul or for corruption (done) in the land-it is as if he had slain mankind entirely. And whoever saves one-it is as if he had saved mankind entirely. And our messengers had certainly come to them with clear proofs. Then indeed many of them (even) after that throughout the land were transgressors” (Surah al-Maidah 5: 32).

Therefore, seeking remedy may be obligatory in life-saving situations or when there is an infectious disease that will affect the society. For that reason, Islam urges to seek for treatment and cure disease to gain better health and prolong life. It is coincides when in his argument claiming that Islam considers access to health care as a fundamental right of the individual. Hadith Prophet Muhammad (PBUH) depicting this issue is Hadith narrated by Abu Hurairah RA “There is no disease that Allah has created, except that He also has created its treatment” (Sahih Bukhari). The urge to seek for cure for any disease and to maintain healthy life could also be found in another Hadith in Sunan ibn Majah narrated by Usamah bin Sharik when Prophet Muhammad PBUH has been reported to have said: “I saw the Bedouins asking the Prophet SAW, ‘Is there any harm in such and such is there any harm in such and such?’ He said to them: ‘O slaves of Allah! Allah has only made harm in that which transgresses the honor of one’s brother. That is what is sinful.’ They said: ‘O Messenger of Allah! Is there any sin if we do not seek treatment?’ He said: ‘Seek treatment, O slaves of Allah! For Allah does not create any disease but

He also creates with it the cure, except for old age.’ They said: ‘O Messenger of Allah, what is the best thing that a person may be given?’ He said: ‘Good manners’ (Sunan Ibn Majah).

Encouragement to seek for a remedy in medical treatment has been highlighted by Ibn Taimiyah. According to Ibn Taimiyyah in his renowned *Majmu’Fatawa*, seeking remedy is encouraged (Mandub) if the therapy is most likely to bring success and no harm would be inflicted. In the debate of human gene therapy, it is evident that the genetic disorders related to the autosomal recessive disease has increased significantly in Islamic communities (Albar, 2002). The inborn errors of metabolism which are mostly recessive has also shown an unprecedented surge recently hinders the activities and duties of a Muslim to himself, family and community at large. Thus, allowing somatic gene therapy with the aim to cure genetic disease and to lessen the hereditary disease is thus fall under Mandub (Encouraged and preferred) in which though harm may in certain cases be inflicted in many cases has proven to be successful in preventing genetic disorders at the early stage, for example, thalassemia, cystic fibrosis, leukemia, cancers and to name a few. Moreover, in the absence of traditional method of treatment, somatic gene therapy may offer an effective means to cure such ailment and to lessen the hereditary disease.

**Protection and preservation of progeny (Al-Nasl):** The next pillar of the dire necessity stipulates within the *Maqasid al-Syariyyah* framework is the protection of progeny (al-nasl). The progeny or lineage is a must to be protected and any harm endangers should be avoided and hence, considered prohibited. Allah SWT instructs human to form families through legal marriage as this is the only lawful way of having children and maintaining our future descendants. In a number of the following Qur’anic verses, for example:

“And marry the unmarried among you and the righteous among your male slaves and female slaves. If they should be poor, Allah will enrich them from His bounty and Allah is all-Encompassing and Knowing” (Surah al-Nur 24: 32).

Albar (2007) asserts that the progeny or lineage is a must to be protected and any endangering harm should be avoided and hence, considered prohibited. Deriving this cardinal principle from the Islamic doctrine, somatic gene therapy could offer and promotes great deal in the prevention and control of genetic diseases. By conducting this therapy, it could ensure that the future generation will grow healthily and free from any genetic

disease. This principle signifies that concentration given by Islamic doctrine is on the prevention of such disease rather than cure.

**The applications of Qawa’id Fiqhiyyah (Islamic Legal Maxims) in somatic gene therapy:** Islamic legal Fiqhi principles have been enumerated by Muslim scholars to aid to draw Islamic legislation and regulation. However, it is notable that the regulation cannot be solely on a particular maxim but shall be derived from the Quran, Sunnah and supported by evidence. *Qawaid Fiqhiyyah* refers to a body of abstract rules which are derived from the detailed study of fiqh (Mustafa, 2014). These basic methods enable us to easily understand fiqh when it could encapsulate under one simple principle. These legal maxims play an important role in the formulation of Islamic law for they are used as principles to deduce many rules of fiqh (Laldin, 2014). This implies that the application of *Qawa’id Fiqhiyyah* (methods of fiqh) to put aside *Al-Quran* and as *Sunnah*. Rather it plays a great role in the formation of Islamic law as they and manage to apply in various cases, religious and social affairs. Hence, it shall be accustomed in tandem with the problem for the benefits of the people and to attain *Shari’ah* purpose (*Maqasid al-Shari’yyah*). As emphasized by Aqeel (2010), a number of basic jurisprudential principles (Fiqh principles) could be taken into consideration in deliberating the contemporary medical treatment and therapy in the absence of absolute and rulling from the Quran and the Sunnah.

Those principles are relatively encourage achieving ends, warding off corruption and avoiding harm and evil, e.g., when removal of harm is followed by an after-effect harm, a balance has to be sought to reach the lesser degree of the two harms. Further to that the doctrine of *maslahah* (benefit or interest) as suggested by Ibn Asyur is to uphold good and confers benefits (*jalb al maslahah*) and refuted of the evil and harmful (*dar al-mafsadah*). This implies that the doctrine of *maslahah* (benefit or interest) is predominantly the most established jurisprudential principles that could be invoked in relation to medical treatment, so as to somatic gene therapy. Few methods have been used relating to fiqh particularly in the field of medicine. Hence, this study further submits the relevant Islamic legal maxims that could be applied in somatic gene therapy. These include.

**Matters are determined according to their intentions (Al-Umur bi-Maqasidiha):** This maxim means the ruling of the *Shari’ah* and all human daily life shall be judged according to the doer’s intention behind the acts at the

time of the implementation. Abd Al-Karim *et al.* (2015). This maxim originates from the famous Hadith in which the Prophet Muhammad SAW said, "Actions are judged by their intentions (Sunan Abi Dawud). Which means that actions in Shari'ah are to be judged by the person's intentions. However, the same action may bring a different ruling when it is executed with a different intention in Islam, effort to seek for a remedy to cure disease is strongly encouraged and permissible as has been emphasized in Hadith Abu Hurairah and Sunan Ibn Majah. However, the intention and implementation must not contradict with Maqasid al-Shari'yyah. Thus, some Islamic scholars allow human gene therapy in pursuance if this principle particularly to somatic gene therapy to be done with a few requirements as follows somatic gene therapy technique and application by way of manipulating the genes which already in the human cell to find which one causing certain disease and the malfunctioned gene is engineered to eradicate the affected gene can relieve genetic disease in human, cure the existing disease (for example cancers, leukemia and multifactorial disease) thereby can save millions of lives and preservation of life is upheld by Islam it can help many people suffering from various genetic diseases who are in urgent need of gene therapy treatment.

**Certainty should not be removed by doubt (Al-Yaqin la Yazulu bi-al-Shakk):** This maxim implies that a matter which is certain cannot be removed except by decisive evidence and it must not be cancelled or abrogated by mere suspicions. Applying this maxim to medical field, all medical procedures are considered permissible unless there is evidence to prove their prohibition *al asl fi al ashiya al ibaahah*. Another example would be if there are two medical interventions where one has higher certainty of achieving cure then it should be used (Alkaabba, 2016).

In somatic gene therapy, scientist have found certain disease interact with genetic factors could be treated using the genomic medicine. In a series of trial it is scientifically proven that somatic gene therapy is more likely and have high probability of effectiveness on human, since, there are proofs of success on animals. This technique is capable to reduce suffering and the death caused by genetic diseases compared to other treatment.

**Harm must be eliminated (Al-Darar Yuzalu):** The evidence for this principle could be found in the Qur'an and Sunnah. These include the following verse which says, "Deal not unjustly and ye shall not be dealt with unjustly" (Surah Al-Baqarah 2: 279). A renowned Hadith Prophet Muhammad (PBUH) further said, "let there be no infliction of harm or its reciprocation" ( ). In a nutshell, this maxim is primarily intended to repel and protect from evils. The maxim indicates the importance to

remove all kinds of harm whether towards individual, society or the environment. Conversely, this maxim closely related to the previous principle, non-maleficence upholding the concept of avoiding the risk of harm to others aims to balance the benefit with the harm.

Reflecting the above maxim, disease is considered a harm that should be removed. Thus, based on leading principle, most of medical treatment and interventions are permissible. Human gene therapy by means of somatic gene therapy is one of the best and effective mode of treatment compared to other traditional method. Moreover, it has been considered the last solution that may ameliorate some human genetic diseases in the future. It may lessen harm and cure the disease of the patient suffering from genetic disease ranging from monogenic hereditary disorders such as Duchenne muscular dystrophy, lysosomal storage diseases or cystic fibrosis to acquired disorders like AIDS, cancer, thrombo-embolic cardiovascular diseases at the early stage. It is capable to revive and restore the good health which in line with this respective maxim that major harm should be eliminated.

**Islamic declaration and fatwas (Islamic verdict) on somatic gene therapy:** Imperatively to protect human and future generation, Muslim prominent scholars has thoroughly discussed on the position of this human genetic engineering and has come out with dedicated declaration and fatwa (Islamic verdict). Islamic Organisation for medical sciences, for example, has regularly organised few seminars with the primary purpose is to discuss this issue in depth and to reveal all the facts and ramifications and possibilities. Through this way, consensus opinion could be achieved thereby enable to find the best solution to resolve the ethical issues in human genetic engineering. The eleventh seminar was held in the state of Kuwait with the Islamic Fiqh Academy, Jeddah, the World Health Organisation Regional Office, Alexandria and the Islamic Education, Science and Culture Organisation (ISESCO) from 23-25 Jumada al-Akhirah 1419 AH, 13-15th October 1998 to deal with the subject of "Genetics, Genetic Engineering, the Human Genomes and Gene therapy-An Islamic Perspective".

Amongst the recommendation from this seminar include. Genetic science are strongly encouraged by Islam. As such Muslim scientists should be at the forefront of research and inquiry in this field. Even so, the results and finding from such research should not contravene with the Islamic legal principles seek for treatment to cure for an ailments and acquired diseases is urged by Islam and thus in conformity with Islamic ruling encouraging to safeguard man health and avoidance of harm as specified. Human dignity and rights should be respected. Any subject of research involving human

should firstly go through a rigorous evaluation on its possible risks and benefits entails from such activity.

This signifies that despite their acknowledgement on the benefits of scientific research that might being offered to the application and used should be not contravene with Islamic guidelines. Hence, the resolution unanimously agreed that genetic engineering is permissible to be used in the prevention, treatment or alleviation of diseases, whether in the form of genetic surgery in which genes are replaced by other genes or genes are implanted in the patient's cells or when genes are planted in another body to obtain larger amounts of the same gene to be used in the treatment of certain diseases. In contrast, the used of the genetic engineering on germ cells is forbidden due to certain reservations imposed by Islamic legal ruling.

Following this, guidelines on the use of genetic information and technologies in the management of genetic disease has further issued in the Islamic Jurisprudence (Fiqh) Council of the Islamic World League of the Organization of Islamic Countries (OIC) in its 15th session 11th/07/Hijrah/31th October 1998. The fatwa "allows the use of genetic engineering for disease prevention, treatment or amelioration on the condition that do not cause further damage". The fatwa committee hold a view that human genetic engineering could confers benefits to human, thus, allowing its application and usage in an "extreme needs". The usage, however should ensure that no further damage would not be inflicted and thorough assessment has been made. This indicates that the somatic gene therapy is permissible to be conducted as it usage is for the prevention and the treatment of the diseases.

As far as Malaysia situation is concerned, the relevant fatwa that could be relied on is the fatwa issued by the Malaysia National Fatwa (NFC) on the position and ruling on therapeutic cloning and stem cell research, 22th February 2005. The fatwa decision includes amongst others.

Therapeutic cloning for therapeutic purposes namely to generate new cells and to replace defective organ is permissible (*diharuskan*) provided that all the necessary precautions have been made in accordance with Shariah legal ruling.

Pre-embryos genetic engineering involving the modification of perceived beneficial characteristics and to enhance known characteristic such as the of hairs colour, increased intelligence, a tendency to tallness or specific eye colours including gender selection are strictly forbidden (*haram*).

Review from the National Fatwa Council of Malaysia further demonstrates that National Fatwa Council of Malaysia has taken a clear stance on allowing therapeutic cloning which only permissible for therapeutic purposes

and forbidding the modification of perceived beneficial characteristic. No direct fatwas have been issued towards the position of human gene therapy in particular somatic germline gene therapy. There is still no clear guideline, concise and precise ruling and regulations for human gene therapy from the Islamic perspective ever established in Malaysia.

## CONCLUSION

From the constitutional point perspective, although, human gene therapy is still in an early phase, it is believed that this new medical treatment will emerge in the future due to its potential benefits offers towards patients to alleviate suffering of genetic disease. It appears that no single piece of literature has been conducted in examining the issue of regulating human gene therapy in Malaysia in place. In addition, a study of the adequacy of the Malaysian regulatory framework in regulating human gene therapy practices in Malaysia has never been conducted so far. Similarly, writing that seek to propose the suitable policy of human gene therapy that should be adopted in this country or the comprehensive model that should be followed by Malaysia has also not been found.

In Malaysia, the only guideline that we may refer to is the "Medical Genetic and Genetics Services 2006" by Malaysia Medical Council. The guideline however should be read in conjunction with the Medical Act Regulations, code of Professional Conduct of the Malaysian Medical Council and other Guidelines issued by the Council or any related organization as well as any statute or statutory provisions in force and all related statutory instruments or orders made pursuant thereto. The guideline dedicated to medical genetics and services is merely general in nature where it appears to merely reaffirm that gene therapy is likely to present with ethical dilemmas. It demonstrates that concerns over the lack of comprehensive guideline on technique and application involving human gene therapy in Malaysia have been raised by the abovementioned guideline.

Based on the above analysis on the position of somatic gene therapy from *Maqasid al-syariyyah* and *Qawaid Fiqhiyyah* perspectives, this study concludes that somatic gene therapy is ethically permissible in as it confers benefits to the public at large. However, the permissibility is subject to certain restrictions and stringent requirements that need to be observed before somatic gene therapy decision making is made. Therefore, given that Islam is the official religion of Malaysia in pursuant of the Federation Article 3 of Malaysian Federal Constitution where Muslim is the majority, it is vividly important for Malaysia to also having comprehensive Islamic framework governing somatic gene therapy. The legal framework on human gene therapy should be developed by proposing the policy which is in

accordance with Islamic perspective by taking into account all the established Islamic ruling and principles as discussed above. Thus, full effort and endeavour shall be taken by a policy maker to take a clear stance for legislating human gene therapy thereby enable to be a model to other Islamic countries across the globe.

#### ACKNOWLEDGEMENTS

The researcher would like to extend our deepest appreciation to the Research Management Centre (RMC) Universiti Teknologi MARA (UiTM) for making available its publication fund.

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