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SCIENCE AND ETHICS A JOINT PERSPECTIVE

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The Ethics of Conjoined Twins

Judy Alkoby

Sometimes life presents interesting challenges, which question our ethical beliefs. Often, the answers are not easy and are dependent on various factors. In the case of conjoined twins, is it ethical to terminate the life of one twin in order to save the life of the other? Should nature be allowed to run its course? Should the advance of science and technological studies be used to save conjoined twins? Religious leaders and doctors have struggled with these questions and continue to search for answers.

One of the fundamental rules of Jewish law is that it is prohibited to sacrifice one life for another. Among the exceptions to this rule is the termination of a fetus in order to save the life of its mother. Another exception is the killing of a pursuer who is threatening to take the life of a victim. At first glance, this law would seem to imply that one is not allowed to terminate the life of a conjoined twin in order to spare the life of the other. However, the aforementioned exceptions to this rule will play a critical role in the case of conjoined twins. After a thorough examination of these two exceptions, it becomes evident that there are instances in which the life of one twin can be terminated in order to save the life of the other.

The permissibility to kill a fetus *in utero* to preserve the life of the mother has relevance to the case of conjoined twins. The Babylonian Talmud in Tractate *Ohalot*, Chapter 7, states:

If a woman is in difficulty during childbirth, it is permissible to perform an embryotomy because the mother's life takes precedence over the life of the fetus. If the majority of the fetus has emerged, we do not touch the fetus because one may not take one life in order to save another.

According to Jewish law, the fetus is entirely dependent on the mother and is not considered a legal person until its birth. Therefore, the Talmud commands that the life of the mother takes priority over the fetus whose real source of fetal life is from the mother. Consequently, it is necessary to terminate the life of the fetus. However, once birth has taken place, the child is able to breathe independently and is treated as a separate entity from the mother. The child is given the same rights as an adult, including the right to life. The Babylonian Talmud, Tractate *Sanhedrin* (72b) states that the child is not considered a pursuer, even though the child is threatening the mother's life, since "Heaven is the pursuer." In other words, the child has no intent of attacking the mother and is therefore not considered a pursuer. In the *Mishne Torah* (Laws of Murder 1:9), Maimonidies adds that the child does not qualify as a pursuer because "this is the

natural event of our world." Maimonides's comment reinforces the Talmud's assertion that the child has no control over his actions and is therefore not a pursuer.

In many instances of conjoined twins, analysis shows that one twin, much like the fetus in the Mishnah, has no independent ability to survive. Rabbi Moshe Feinstein was once presented a case of conjoined twins who shared a six-chambered heart and a conjoined liver. Only one twin would be able to survive. After doctors tested the twins, a circulatory defect was found in Baby A. This defect would make it impossible for Baby A to survive without the assistance of Baby B. In other words, Baby A had no independent ability to survive. Furthermore, Baby A was threatening the life of Baby B, making it vital to terminate Baby A to save the life of Baby B. Rabbi Feinstein determined that it was permissible to kill Baby A in order to save Baby B. However, Baby A was not technically considered a pursuer since the baby had no intent to harm and was simply behaving in the "natural way of the world". It was permissible to kill Baby A based on another concept in Jewish law which is discussed in the Babylonian Talmud in Tractate Sanhedrin (72b) and in Rashi's (Rabbi Shlomo Itzchaki) commentary regarding the case of Sheva ben Bichri recorded in Samuel II (20:22):

> There was an evil man named Sheva ben Bichri....and he said, "I have no allegiance to David HaMelech (i.e.,

he led a rebellion against King David). Yoav's men chased after him, and they came to a town and laid siege to it. Yoav announced to the townspeople, "Sheva ben Bichri has raised his hands against David HaMelech. Send him out of your town, for he is the one that is guilty, and I will then withdraw my forces from the siege." A woman responded to Yoav, "Behold, here is his head which I am throwing to you next to the walls of the city."

This entire story is cited in detail in Jerusalem Talmud, Tractate *Terumot* (47:1). A legal ruling derived from Sheva ben Bichri's case is applied there to a case concerning a caravan of Jews surrounded by hostile enemies. The enemies were threatening to kill all the Jews, but offered a deal: "If you will give us one of you so that we may do as we will with him and kill him, then you can all go free. If not we will kill you all."

The Talmud there rules that it is forbidden to hand over one Jewish life to the enemies, even at the risk of forfeiting all their lives. If, however, the enemies had singled out one individual against whom they had some complaint, as specified: "Give us *this* man," just as in the case of Sheva ben Bichri, the legal ruling states that he must be turned over to the enemies so that the entire caravan will be saved.

In the case of the conjoined twins, this implies that it would be ethical to sacrifice Baby A since the baby is a singled out individual that is threatening the lives of both babies. Reish Lakish (a Talmudic sage) qualifies this ruling by saying that this only applies if one is guilty of the death penalty, as was Sheva ben Bichri who rebelled against the king. Although there was no ruling of the Jewish courts that Baby A deserved the death penalty, there was an edict from G-d that this baby could not live. Despite all the surgical efforts, Baby A would die and was classified as if she were Sheva ben Bichri for whom there was no hope. After a complete and thorough investigation in Jewish law, it is evident that it can be permissible to sacrifice one conjoined twin to save the life of the other in certain cases.

The Roman Catholic Church believes that it is unethical to terminate the life of one twin in order to save the other.² There was once a case of conjoined twins who were brought to England. The parents of the twins were devout Roman Catholics and were opposed to killing one of the twins. "We believe that nature should take its course. If it's G-d's will that both our children should not survive, then so be it." However, the hospital took the case to court pleading that saving one of the twins would be morally preferred to losing both. Archbishop Cormac Murphy-O'Connor, head of the Catholic Church of England and

Wales, submitted a statement to the court of appeals in which he said:

Though the duty to preserve life is a serious duty, no such duty exists when the only available means of preserving life involves a grave injustice. In this case, if what is envisaged is the killing of, or a deliberate lethal assault on, one of the twins, Mary, in order to save the other, Jodie, then there is a grave injustice involved.²

Alice D. Dredger, a Michigan State University medical historian agrees with this decision of the Roman Catholic Church. She reasons that, "When it comes to cases in which one of the twins must be 'sacrificed,' it is ethically wrong to take one life so another may live." She argues that it is unethical to kill a conscious person, given that one would not do that in any other case. She also states, "It is unethical to treat children with unusual anatomies according to a different set of ethical guidelines than other children." Dredger agrees to the separation of very young twins provided that the surgery is simple enough and that it does not result in the death or long-term disability of one of the twins. She points out that separation surgeries in which one of the twins is sacrificed have never proven to be successful. At least nine have been attempted and not one has resulted in along-term, healthy survivor. "In all of the cases, the intentionally sacrificed twin died," she says. "But, notably, in not a single case has the twin chosen to survive ever actually survived to go home or even live free of a ventilator."³

Dr. Dennis P. Hollinger takes yet another stance regarding the case of conjoined twins. Dr. Hollinger is Vice Provost, College Pastor, and Professor of Christian Ethics at Messiah College in Grantham, Pennsylvania and Fellow of The Center for Bioethics and Human Dignity. He claims that based on five different propositions, it is ethical to terminate the life of one twin in order to save the other.⁴

His first proposition is that the intention behind separating the twins is not to kill, but to save the life of a human being. Given the doctor's best judgment that neither twin will live without the separation, this is an attempt to save one human life in the midst of a very unfortunate situation. Dr. Hollinger states:

The surgical separation to save one life is analogous to an ectopic pregnancy in which a child is growing in the fallopian tube of a mother, rather than in her uterus. In such cases, a failure to operate and remove the child will almost certainly result in the death of both mother and child. Removing the child will indeed result in the loss of precious life, but it allows one [the mother] to live rather than allowing both to die.⁴

The Roman Catholic moral tradition allows for such actions through the doctrine of double effect, which dictates: "When an action has two effects, one intended and the other unintended, the intended effect carries the moral weight." Other traditions have argued on similar grounds, noting that intentions must be considered in the difficult choices one must sometimes make. In the case of conjoined twins, the intention behind the surgical separation is to preserve one human life, since it appears clear that neither twin would live without the procedure.⁴

The second proposition is that one twin would already be dead if it was not connected to its twin. Legal specialists have debated whether a twin dependent on the other twin meets the criteria of legal life. In most instances, the factual data regarding the situation clearly confirms that one twin would not be alive if it was not conjoined. Barring a miracle, the dependent twin has no possibility of continuing to live whether it remains joined or separated to its twin. Dr. Hollinger explains:

Ethical decisions must always incorporate factual or empirical judgments about the situation at hand. Our moral norms do not arise from the facts of a case, but such facts ought to be considered when determining how to apply our norms. Factual realities often shed light on what courses of action are feasible and infeasible for a particular case. In this case the facts seem clear: Mary [a conjoined twin] would not be alive if she were not joined to her sister, and she will not live if she remains joined to her.⁴

The third proposition is that preserving one human life in better than preserving none. In many cases, the act of separating the conjoined twins will increase the likelihood that one lives, while allowing them to remain joined will almost certainly ensure that neither lives. Some oppose the surgical procedure on the grounds that it seems to be "playing G-d"—deciding who will live and who will die. While the death of one twin would be tragic, choosing the course of action with this unfortunate result may be the best alternative. One must seek to uphold the value and dignity of human life; acting to preserve one life is better than failing to preserve either.⁴

The fourth proposition is that when one can preserve human life, one has a moral obligation to do so, "even if miraculous intervention could possibly be a means of preservation." Dr. Hollinger believes that while some support a non-intervention approach on the grounds that G-d could intervene with a miracle to preserve the lives of both, one cannot base one's actions on the expectation of a miracle. One can pray for a miracle, but should not depend on it since "miracles of this nature are not the everyday experience." He further notes:

G-d has created human beings, made in his image, to be stewards over the created world. This sometimes entails making difficult choices, even of a life and death nature. While we should never act to cause death, thousands of decisions are made daily in hospitals and nursing homes to legitimately withdraw treatment from terminal patients and allow divine providence and nature to take their course. Of course, families could-and sometimes do-refuse to make that decision, hoping that G-d will yet intervene to perform a miracle. However, rarely do such miracles occur. Thus, families commonly make their moral decisions within a framework of stewardship, reverence for life, and an understanding of the cycle of life which ends in physical death.⁴

Dr. Hollinger concludes that the choice to separate conjoined twins is the right moral choice. He adds that holding out hope that G-d could perform a miracle does not negate the responsibility to preserve human life when it appears likely that neither twin will survive unless one takes action. Separating conjoined twins is not a rejection of divine power, but a humble recognition that G-d has created us to be moral agents who must sometimes make difficult choices in a "finite, fallen world." Though a miracle is always possible, one should not let such a

possibility override taking action which could preserve the life of

The fifth proposition is that the consequences of our actions in complex ethical dilemmas are not submissions to "utilitarianism in which the ends justifies the means." Dr. Hollinger defines utilitarianism as "a social calculus which fails to recognize the intrinsic goodness and value of each human life." He understands that many argue that one should never do wrong in order to achieve good, and agrees that they are certainly right to reject a moral decision based on the grounds of utilitarianism. Dr. Hollinger states:

In each of these frameworks we come to the decision with norms and predispositions from beyond the moral situation itself. When our normative frameworks do not in themselves yield immediate clarity on what to do, it is sometimes wise to examine the potential results of our action. This does not push principles, virtues or theological paradigms to a back seat, but rather applies them in conjunction with the expected results of each course of action that we might take.⁴

Choosing to surgically separate the conjoined twins will likely result in one twin living and the other dying, though one will not live with either course of action. Dr. Hollinger affirms that such a decision is not rooted in the greatest good for the greatest

number of people. It is rooted in clear affirmations that life is precious and ought to be preserved, that G-d is providentially involved in all human affairs, and that G-d sometimes calls us to make difficult choices in the midst of complexity and even tragedy. Considering the anticipated results of surgical separation, which one twin will live and the other will die, is still acting within the "confines of the biblical story and within a commitment to the dignity and value of all human life." It is not subject to the utilitarian ends justifies the means ethic.⁴

The case of conjoined twins presents a classic example of moral complexity where the ethical course of action is not immediately clear. Complex ethical situations involve opposing principles, virtues, and theological or world view paradigms. They generally involve competing interest groups, each making legal and moral claims, and often embody rivaling sets of facts or empirical judgments about the case at hand. When confronted with a morally complex situation, one should never assume that one choice is as valid as another. Rather, one must recognize that even if armed with moral absolutes or universals the ethical choice is difficult, sometimes tragic, and always cause for great humility. In complex dilemmas such as this in which one may not be able to choose the absolute moral good, one should seek the wisest resolution to the most grievous and trying dilemma.

Works Cited

- [1] Tendler, Moshe. Responsa of Rav Moshe Feinstein: Care of Critically Ill. Vol. 1. New Jersey: Ktav, 1996.
- [2] Landenson, Robert F. "Siamese Twins." 15 Nov. 2004. http://ethics.acusd.edu/resources/cases/Detail.asp?ID=54>.
- [3] Dredger, Alice D. "To Separate or Not to Separate." 15 Nov. 2004. http://www.conjoined-twins.i-p.com/>.
- [4] Hollinger, Dennis P. "So That One Twin May Live... (The British Siamese Dilemma)." 15 Nov. 2004. http://www.cbhd.org/resources/healthcare/hollinger_2 000-09-14.htm>.

Gender Selection

Chava Fischer

While it may seem to be a recent technological development, the concept of choosing the sex of one's child, rather than leaving it purely up to chance, dates back to ancient times. The Talmud discusses various permissible methods that can increase the chances of having a child of one particular sex. These include timing of intercourse, practices during intercourse and special diets (Babylonian Talmud, Tactate *Niddah* 25b, 28a, 31a, 31b, Tractate *Gittin* 57a).

Modern science and technology have since come up with more scientific methods of gender selection. However, along with the introduction of new methods come new ethical dilemmas. This article will attempt to address the different forms of gender selection that are available, the reasons people seek to implement these procedures and the many ethical consequences, both from the secular and Jewish viewpoints, that arise in the process.

There are now a few scientific ways to perform sex selection. Firstly, an ultrasound or other forms of prenatal diagnosis may be performed on a fetus *in utero* to determine the baby's sex and subsequently, the fetus may be aborted if it is not of the desired gender. A second method of gender selection that is available is pre-implantation genetic diagnosis, more

embryos in a laboratory setting through in-vitro fertilization (IVI) and selecting the embryos of a chosen sex to be implanted into the uterus. The third and newest means by which gender melection may be performed is by sperm selection.¹

While there are a number of ways to carry out sperm selection, one popular method is called "MicroSort." This technique was originally used for reproduction in livestock but a number of years ago the Genetics and IVF Institute, whose main offices and laboratories are located in Fairfax, Virginia, modified this process for humans. MicroSort relies on the fact that symnosperm, or sperm bearing X chromosomes, contains 2.8 percent more DNA angiosperm, or sperm bearing Y chromosomes. The entire sample of sperm is treated with a fluorescent dye and a laser light is then shined onto the specimen. Since the DNA is what activates the dye and symnosperm contains more DNA, scientists are then able to separate the two forms of sperm based on the amount of dye that they have activated. The sperm that produces the child of the desired sex can then be used to fertilize eggs and embryos can be implanted in the uterus.

It is universally agreed that performing sex selection through the employment of infanticide, or killing of babies who are not of a desired sex, is ethically wrong.² However much controversy exists regarding whether there are other stages of reproduction at which gender selection would be morally sound. Abortion has been a widely debated bioethical issue ever since Roe vs. Wade in 1973. In addition, while most can see a clear difference between aborting a fetus and discarding unwanted sperm, the distinction between preconception sperm sorting and post-conception PGD is more subtle and is surrounded by much debate.

Nevertheless, before the ethical grounds for gender selection technique can be evaluated, one must understand the various reasons a couple would decide to undergo this process and consider such reasons when deducing its ethical ramifications. One incentive for parents to resort to the methods of sex selection would be in order to prevent the chances of having offspring with severe genetic disorders. There are hundreds of X-linked genetic diseases, such as hemophilia and a variety of forms of muscular dystrophy. The probability of a male fetus inheriting the disease is higher than that of a female fetus due to the fact that males only have one X chromosome. Sex selection enables modern society to assure that couples who are carriers of X linked genetic diseases have female children and eliminate the chances of giving birth to males with the genetic disorder.³

Aside from medical reasons such as the prevention of mentic diseases, other advantages of sex selection include religious, social and cultural considerations. In many countries, much as India and China, male children are preferred either for menomic reasons or for the purpose of carrying on the family mane. In addition, population growth in China is so explosive that in 1979 the country instituted a one-child policy. Daughters are viewed as economic burdens because they cannot perform the same amount of physical labor as men and because they require dowries. Consequently, couples in these countries may look to sex selection to assure them the birth of a son. Studies show that due to widespread sex selection in these countries, major gender imbalances have occurred and between sixty and one hundred million women are "missing" from the world today.

Family balancing is one more motivation for parents to rely on the techniques of sex selection. For instance, if a couple already has four sons and they would like a daughter, sex selection would seem like a good option to guarantee that their next child will in fact be a girl.⁵

Thus in debating the issue of sex selection, the various reasoning and techniques are important in deciding when and what sort of sex selection is ethical. While some ethicists may not see a difference in any of the cases, many do deem certain

situations of sex selection permissible based on the motivations and method under which the procedure is performed.

There are a number of ethical arguments in favor of sex selection. Firstly, a child of the "correct" sex may benefit from a higher quality of life in a situation where parents prefer one gender over the other. In addition, mothers may also achieve superior quality of life due to sex selection since they will not have to undergo many pregnancies and births to bear the child or children of the sex they desire. Sex selection may even prevent husbands from abusing their wives for not conceiving children of a certain gender.3 Tangentially, it is ludicrous for a man to criticize a woman for bearing the wrong gender child considering the fact that it is ultimately the father's genetic contribution that decides the baby's sex. Finally, many argue that a benefit of gender selection may be a lower population, an advantage for countries where high birth rates are causing economic and social distress. Thus assuming that people have preconceived wishes about the genders of their children, if people could program the genders of their children before they are born, they will not just reproduce by trial and error until they give birth to the children of the genders they desire.³

While there are many benefits that sex selection can potentially provide, these techniques also carry many dangers and disadvantages. Ethicists claim that sex selection only reinforces the idea of gender inequality by blatantly preferring one sex to the other. American society is constantly working to oradicate sex discrimination in all aspects of life and by allowing gender selection techniques to run rampant, we would be strengthening sexist mentalities. Secondly, many bioethicists criticize sex selection by claiming that it is wrong to use medical procedures that are meant to prevent the continuation of genetic diseases for purposes as mundane as the satisfaction of parents' gender preferences.³ In addition, there is the fear that if parents feel that they can program the sex of their children, they may start manipulating other kinds of traits to their liking and reproduction will be a made-to-order concept.⁵

When faced with the question of whether or not one would support the idea of sex selection, many people indignantly answer that they feel it is their right to make decisions regarding their own procreation and family structure. At least, they claim, the option should be available. However, this self-seeking mentality is not entirely an accurate representation of the issue at hand. Sex selection may in fact lead to gender imbalances, having negative effects on all of society. A higher percentage of males brings higher crime rates, increased prostitution, and numerous other negative externalities. Thus while parents may feel they have a right to make choices for their own family, the

decision to undergo gender selection does affect others and societal benefit must be considered as well.⁶

In 1996, the American College of Obstetricians and Gynecology (ACOG) criticized the use of sex selection for non-medical purposes because it involves amoral actions including the killing of embryos, abortion, and prejudice. However, ACOG did agree that there may be room for exception in certain isolated cases.⁶

The American Society for Reproductive Medicine (ASMR) reached the conclusion that sex selection for medical purposes is ethical. However, the society raised many moral issues regarding PGD and sperm sorting as a means of gender selection for non-medical purposes such as gender biases and imbalances, as well as the misuse of medical procedures. Nevertheless, in 2001, the ASMR loosened its suspicions of sperm sorting and PGD even for purposes as mundane as family balancing. Since 2001, however, the ASMR has once again changed its mind stating that while sperm sorting may be an ethical way of performing sex selection, PGD involves discarding of embryos and thus presents more concern from an ethical perspective.⁶

The United Kingdom has banned sex selection for non-medically related purposes.⁵ While no legislation has been passed in the United States, the President's Council on Bioethics

the discussed the issue on a number of occasions. The committee is agreed that sex selection for the purpose of preventing is agreed that sex selection for the purpose of preventing is agreed that sex is morally sound. However, in 1983 this group is a such that the prevention by amniocentesis is "morally suspect" as such that the prevention of the purpose of prevention by amniocentesis is "morally suspect" as such that the prevention of the purpose of preventional love of preventional love of the purpose of preventional love of preventional love of the purpose of preventional love of preventional love of the purpose of preventing the purpose of preventional love of the purpose of preventing the purpose of pre

Thus it is apparent that as yet no clear or uniform policy exists among bioethicists as to what conditions and forms of sex selection are considered ethical. Similarly, there is much controversy about this concept in the field of Jewish bioethics as well. A range of rabbinic authorities present varying views regarding what practices may be acceptable in different cases when it comes to gender selection. However, these discussions merely revolve around the methods of PGD and sperm selection, since according to all *halachic* (Jewish legal) authorities, aborting a fetus merely because of gender preference is prohibited without a doubt.⁷

A number of issues arise within Judaism when the question is posed about the ethical ramifications of choosing gender. Firstly, the first commandment in the Bible is that of p'ru ur'vu (be fruitful and multiply). The Mishnah in Yevamot (6:6) cites a dispute between Hillel and Shammai regarding what this commandment constitutes. Hillel explains that the requirement is to bear one male child and one female child, while Shammai argues that the obligation is to bear two males. Practically the opinion of Hillel is followed, as is the general rule. Consequently, would it be permissible for couples to seek the aid of sex selection in order to fulfill the commandment of p'ru ur'vu? Furthermore, would it be required for Jewish couples to actively pursue and exhaust all possible methods in order to discharge this obligation?

Rabbi Moshe Feinstein clarifies that the commandment of *p'ru ur'vu* is not goal oriented but rather process oriented. A man is required to do his part and attempt to have children by getting married and having intercourse. The obligation of having one boy and one girl is merely the point at which a man has dispelled his biblical requirement. In this case, it is the effort that counts. The final results, whether a couple actually gives birth to a child of each sex, is up to G-d and is not within the realm of man's control. Consequently there would be no reason to employ PGD or MicroSort to fulfill the requirement of *p'ru ur'vu*.⁸

However, other rabbinic authorities hold that *p'ru ur'vu* is only fulfilled by obtaining results, by having a boy and a girl.

Nevertheless, Rabbi Shlomo Zalman Auerbach explains that one does not have to go out of his way financially or cause himself physical pain in order to fulfill this commandment, as would be the case with methods such as gender selection.⁸

Rabbi Moshe Tendler, a well-known rabbinic authority, author and bioethicist, explains that sex selection done for the take of p'ru ur'vu may in fact be counterproductive. People may utilize gender selection to produce one boy and one girl and aubsequently cease to procreate because they feel that they have fulfilled their religious obligation. Yet, we must keep in mind that two children of different sexes is the minimum amount to fulfill the commandment. A drop in birthrate seems to be the opposite of what G-d had in mind when He commanded us to "be fruitful and multiply."

Another *halachic* question in reference to sex selection is the issue of *hashchatat zerah*, the destruction or waste of sperm. Rabbi J. David Bleich states that many forms of fertility treatment potentially utilize all sperm, either in actuality or as backups, and therefore this does not constitute *hashchatat zerah*. However, when performing sex selection, half the sperm is useless from the start. Thus it would seem that the

prohibition of destroying reproductive material applies in this case.⁸

In his commentary Nishmat Avraham on the Shulchan Aruch (Code of Jewish Law), Dr. Abraham S. Abraham quotes the opinion of Rabbi Shlomo Zalman Aurbach, a foremost rabbinic authority. Rabbi Aurbach discussed a case where a couple that has already fulfilled its obligation of procreation but wants to continue to have children either to fulfill the commandment of shevet (to populate the earth) or because the wife is psychologically troubled by the fact that they do not have more children. In this case, the couple would be allowed to submit sperm counts to aid in their continued procreation. Although sperm counts result in the physical wasting of reproductive material, Rabbi Aurbach explains that since it is for an honorable cause it is not under the category of hashchatat zerah. Dr. Abraham then asked Rabbi Aurbach whether sex selection would be in the same category as sperm counts and artificial insemination since all of them involve discarding of sperm? Rabbi Aurbach answered that the problem with sex selection is not hashchatat zerah. Rather, he quotes a passage from the Babylonian Talmud, Tractate Berachot (10) that cites a conversation between King Hezekiah and the prophet Isaiah. Hezekiah proclaims that he does not want to have any children because he saw in the future that the evil Manasseh will come

from him. Isaiah answers that man cannot get involved in G-d's plans and he must still fulfill the commandment of procreation. Thus, Rabbi Shlomo Zalman Auerbach concludes that the problem with sperm selection is that man is not supposed to "play G-d" and get involved in aspects such as the gender of a child. However, Rabbi Auerbach states, there is room for exception when a couple is a carrier for a sex-linked genetic disease and through gender selection they may prevent the birth an affected child.¹¹

There is also a *halachic* concept of not causing oneself undue pain or risk. Rabbi Moshe Feinstein holds that unlikle fertility treatment where the pain is for a medical purpose and therefore allowed, undergoing sex selection to serve one's personal preferences may not be permitted halachically. In addition, Rabbi Feinstein writes in *Iggerot Moshe* (*Orach Chaim* 3:90) that while intervening with the reproductive process for medical reasons is acceptable, it may be *halachically* problematic to use medical procedures for non-medical purposes.⁸

Thus, Rabbi Joshua Flug concludes in his comprehensive article on the topic of gender selection that since each case is different, there cannot be an overriding *halachic* ruling. Judaism maintains the advantage of reliance on *halachic*

authorities and thus allows for each case to be evaluated individually and for appropriate action to follow.⁸

In 1902, John Beard of the University of Jena proclaimed, "Any interference with or alteration of the determination of sex is absolutely beyond human power." Modern science and technology has proven Beard wrong and these advances have greatly improved medicine and fertility treatment. However, misuse and perversion of science can sometimes have devastating effects on society's values and cause difficulties for future generations. Perhaps if society would once again view children as gifts rather than made-to-order objects, many of the negative externalities that accompany these miraculous treatments would cease to exist.

Works Cited

- [1] McMillian, John C. "Sex Selection." Encyclopedia of Bioethics. 3rd Edition. Ed. Stephen G. Post. Vol. 4. New York: Macmillan Reference USA, 2004.
- [2] "MicroSort General Information." 17 Jan. 2005. http://microsort.com/>.
- [3] Wertz, Dorothy. "Sex Selection." Encyclopedia of Bioethics. Ed. Warren Thomas Reich. Vol. 4. New York: Simon and Schuster Macmillan, 1995.
- [4] "China's One Child Policy." 17 Jan. 2005. http://www.overpopulation.com/faq/population_control/one_child.html>.
- [5] Kalb, Claudia with Springen, Karen. "Brave New Babies." Newsweek. 26 Jan. 2004.

- Aspects of Sex Control" 18 Jan. 2005.
- Perspectives. United States: Ktav Publishing House,
- Preconception Gender Selection." Journal of Halacha and Contemporary Society. Vol. XLVIII (2004): 5-27.
- Cohen, Debra N. "To Choose or not to Choose." 17 Jan. 2005. http://www.jewishaz.com/jewishness/981030/ch
- Meich, Rabbi J. David. "Survey of Recent Halakhic Periodic Literature: Stem Cell Research." <u>Tradition</u> 36 (2002):72.
- Jerusalem, Israel: Machon Schlesinger, 1993.

Tampering with the Human Genome: Ethical Perspectives on Genetic Therapy

Michelle Goldberg

Science fiction writers have long imagined a future world in which people are genetically engineered to have superhuman strength, intelligence, or other abilities. Such genetic manipulation is far beyond current technical possibilities, yet the ethical questions raised by genetic therapy, such as the morality of creating a smarter human, have sparked considerable debate over the past several decades. Although there is some disagreement among Jewish rabbinical authorities, most agree that at least certain forms of genetic therapy are sanctioned by halacha (Jewish law). While a universal consensus on moral guidelines for genetic therapy is extremely unlikely, these issues must still be addressed, because man's response to these ethical questions will be increasingly relevant as genetic therapy becomes a reality.

Human genetic therapy is defined as the use of genetic engineering to insert a new gene into a person's cells to replace a defective gene and thereby cure or alleviate a disease. The new gene can be delivered either by infecting the patient with an attenuated virus that will insert the gene in the target cells or by removing some of the patient's cells, inserting the gene, and replacing the cells. Using genetic therapy to replace a defective

produce the protein or hormone that was lacking. While genetic therapy may one day be a common treatment for numerous pathologies, at this point the clinical trials of genetic therapy have only achieved limited success.¹

As the ethical issues involved in genetic therapy depend on the procedure employed, it is useful to divide genetic therapy into several categories. Somatic cell gene therapy (SCT) is performed on non-reproductive cells, so the resultant genetic changes caused by the procedure are limited to the patient and cannot be transferred to progeny. In contrast, germ line gene therapy (GLT) is performed on either sperm or eggs before fertilization or on early embryos. Because GLT affects all cells of the person who develops from the modified embryo, including his or her reproductive cells (sperm or eggs), the new gene will be inherited by future generations. A second distinction is made between corrective genetic therapy used to treat disease, and genetic therapy used for trait enhancement, such as improving intelligence or physical appearance.

Of the categories of genetic therapy, somatic cell gene therapy, when used exclusively to treat disease, raises the fewest number of ethical concerns, with most of these issues nonspecific to genetic therapy. Clinical trials of SCT, like trials of any other medical treatment, involve ethical issues such as safety, informed consent, and the balance between risks and benefits to the participants. The moral validity of pursuing SCT when millions lack basic healthcare is also an issue shared by many other expensive medical therapies.² Similarly, the claim that SCT is "unnatural" because it interferes with normal human development could easily be applied to traditional medical or psychiatric treatments that also change nature.³

One argument that is specific to SCT, however, contends that manipulating peoples' genomes undermines their humanity or human dignity. This position assumes that the individual is a direct product of his or her genome, and any alteration of that genome detracts from the patient's very identity and position within the human species. Supporters of SCT, however, argue that one's genome is not the sole determination of personal identity. Each person is shaped by environment, experiences, and past decisions, in addition to his or her genetic makeup. As the genome is only a part of the individual, changing a defective gene does not automatically detract from the humanity or identity of that person. Furthermore, some defend SCT by comparing it to generally accepted procedures such as organ transplants and claim that genetic therapy is no more of a threat to the patient's humanity or human dignity than a lung transplant.3

Based on historical precedent and the rulings of modern rabbinic authorities, it is clear that therapeutic applications of SCT are *halachically* permissible. Dr. Fred Rosner suggests that genetic therapy is included in the "mandate on physicians to heal the sick." Furthermore, Rabbi Akiva Wolff justifies genetic therapy under the obligation of *pikuach nefesh*, saving a life, for which a Jew is allowed to transgress any commandment except idolatry, adultery, or murder.⁵

There is a discussion as to whether *halachic* prohibitions are relevant to genetic therapy at all, because in general, *halacha* only considers that which is visible to the naked eye to be significant. For example, the Jewish dietary laws do not prohibit the ingestion of microscopic organisms, because the organisms cannot be seen without magnification. As the genes transferred in genetic therapy are sub-microscopic, perhaps they are considered insignificant in *halacha* as well. However, Rabbi Yehoshua Neuwirth maintains that genetic therapy is, in fact, under the jurisdiction of *halacha*, due to the significant consequences of the genetic transfer. Rabbi Shlomo Zalman Auerbach similarly regards the genetic material as a *halachically* significant entity. He explains that since the genetic transfer is performed by a human, it is considered as if the genetic material can be seen by the human eye.⁶

Most rabbinic authorities agree that genetic therapy is not considered *kilayim*, one of the prohibited mixtures or forms of crossbreeding mentioned in Leviticus 19:19. Rosner cites the views of Rabbi Auerbach and Rabbi Neuwirth who permit genetic therapy on the grounds that it is not *kilayim*, because the goal of genetic therapy is to "cure disease, restore health, and prolong life, all [of which are] within the physician's Divine license to heal." Rosner also suggests that "gene grafts" are similar to organ grafts, which are *halachically* permissible. Additionally, Rabbi Wolff notes that according to the majority of rabbinic authorities, the definition of *kilayim* is limited to the specific cases listed in Leviticus, so the non-sexual transfer of genetic material involved in genetic therapy would not be included in the prohibition. 5

Unlike SCT, germ line gene therapy raises a significant number of unique ethical concerns, because any genetic modification performed in germ cells will be inherited by future offspring. However, despite ethical concerns over the long-term effects of GLT, this type of genetic therapy will probably be permitted by *halacha* because it is still part of healing the sick.⁴ Although GLT research is currently banned in the United States, there is an active debate over its ethical validity. Objections to GLT fall into five categories: safety, the use of embryos, the rights of future generations, biodiversity, and eugenics.

The first objection to GLT involves the issue of safety. While safety is a concern with any new medical treatment, the danger is usually limited to the individual patient. However, a mistake in GLT could also harm future generations, who will inherit the modified gene. Additionally, perhaps there are unknown dangers involved in GLT that will not become apparent until the second or third generation. On the other hand, the risk posed by GLT is offset by the unprecedented potential to cure disease in all of the patient's future descendents.

The second ethical concern connected with GLT is the creation, use, and destruction of human embryos that will likely be involved in GLT research. In *halacha*, although the early embryo is not generally considered an actual person, there are a range of opinions regarding the exact status of the embryo. Research on surplus pre-embryos, that may otherwise be destroyed, is *halachically* permissible on the condition that the pre-embryos were created in-vitro for the purpose of starting a pregnancy but were not implanted in the uterus. Using in-vitro fertilization to create embryos for the purpose of destroying them, however, is not permitted.

The third objection to GLT is the claim that genetic alterations of germ line cells would violate the rights of future generations, as the genetic therapy is performed without their consent. However, Adam Hedgecoe offers several criticisms of

the view that all humans have the "right to an unaltered genome." He notes that, while the language of human rights is powerful, it is difficult to establish the rights of a non-existent person.8 Similarly, Rosner asserts that any medical procedure halachically permitted for an adult would definitely be allowed if performed on sperm, eggs, or pre-embryos, because an embryo is not even considered to be a potential human being until it is implanted in the uterus.⁴ Furthermore, Hedgecoe argues in support of the ethical rights of parents to choose GLT for their children. He reasons that although the choice of one's spouse will significantly affect the genome of any children to come from such a union, it is not unethical for an individual to choose a certain spouse. By extending this principle, it is also ethically acceptable to make other choices that will affect the genome of one's children, such as opting to have GLT. Hedgecoe also responds to the argument that future generations might not want to have been subject to genetic therapy. Although he acknowledges that it is difficult to predict which enhancements

The fourth issue raised as a challenge to GLT is the positive value of genetic diversity. Proponents of the biodiversity argument claim that variation within the human gene pool is beneficial because it allows the species to adapt to new

will be valued by future societies, he considers it unlikely that

they will want to suffer from debilitating diseases.8

conditions, and GLT would reduce this variation. Alternatively, it can be argued that although some seemingly harmful mutations may also have advantageous effects, mutations that cause death or severe disability are not beneficial to the human gene pool. In that case, GLT directed at eliminating severely damaging mutations would not reduce the positive diversity among humans.⁹

The final objection to GLT stems from the negative comparisons made between GLT and the type of eugenics program implemented by the Nazis. Historically, the eugenics movement sought to improve the human genetic pool by eliminating undesirable genes. In the United States, sterilization laws were enacted in twenty eight states by 1931, and in Nazi Germany, eugenics was used to justify the extermination of Jews and other groups that were considered inferior. 10 However, supporters of genetic therapy argue that GLT is significantly different than eugenics. While eugenics was used as a justification for murder or forced sterilization, GLT would presumably be an optional treatment offered to parents. Additionally, eugenics was used to prevent "undesirable" people from reproducing, but GLT would enable couples to bear healthy children. Despite the numerous factors distinguishing it from eugenics, the social consequences of widespread GLT may still be cause for concern; if genetic therapy can produce healthy

babies, but only the wealthy have access to this technology, then the children of poorer classes will be at a distinct health disadvantage.⁸

The future implications of GLT, such as safety concerns and social consequences, do not seem to be a major concern from a halachic perspective. Indeed, this issue has not been raised by any major rabbinic authority. One possible explanation for the lack of attention paid to the long-term effects of GLT may be the principle that existent needs take precedence over conjectured future complications. For instance, Rabbi Barry Freundel argues that regarding GLT, the best course of action should be determined based on the present reality, because G-d is responsible for future consequences that are not under our control. 11 This approach is based on an incident recounted in the Babylonian Talmud in Tractate Berachos (10a). When the prophet Isaiah rebukes King Hezkiah for failing to fulfill the commandment of having children, Hezkiah justifies himself by explaining that he saw with divine inspiration that his descendants would not be virtuous, so he thought it was preferable to remain childless. Isaiah admonishes him, "Why do you [concern] yourself with the hidden matters of G-d? What you are commanded to do, you must do, and what is good before G-d, He will do." In the case of genetic therapy, physicians must fulfill the commandment to heal the sick, and trust G-d to take

care of aspects of the future that are not under their direct control.

While the effort to alleviate suffering is a powerful justification for many types of genetic therapy, the ethical basis of genetic enhancement is much more controversial. Some argue that humans do not have the wisdom to design themselves, and the attempt to do so via genetic enhancement is like "playing Gd." However, if a society values certain traits and promotes the use of conventional means to enhance those traits, why is it wrong to achieve the same results through genetic therapy?⁶ For example, exercise is a socially acceptable way to increase one's physical strength. Why, then, would it be unethical to give fetuses certain genes to make them stronger than the average human, as long as their strength is still with the normal range of human variability? Responses to such arguments include the claim that genetic enhancement is a form of cheating or an abuse of medicine. Furthermore, there is a fear of the social consequences of enhancement if it becomes a common treatment.8 If some parents use genetic enhancement to create children who are smarter, stronger, or more beautiful, parents who chose not to use genetic enhancement or who were unable to afford such procedures may produce children unable to compete with their genetically-enhanced peers.

Due to the controversy over genetic enhancement, it may seem reasonable to restrict genetic therapy to the treatment of disease. However, there are several indications that a ban on genetic enhancement may not be a sufficient response to ethical concerns. First, some fear that if genetic therapy becomes available in any form, it will inevitably be used for nontherapeutic purposes, as other medical treatments have been. 12 Furthermore, the distinction between therapy and enhancement can be unclear. There are no absolute boundaries between traits that are within a normal range of human variability and those labeled as diseases. Should correcting short stature be considered treating a disease or enhancing an aesthetic trait? What about reversing baldness? The way disease is categorized is often dependent on society's expectations. Additionally, some claim that enhancements aimed at preventing disease may be justified even if other enhancements are not. For example, a genetic immunization to make a patient resistant to the HIV virus seems ethically similar to the accepted immunizations currently performed.⁶ Genetic modifications that span the grey area between therapy and enhancement would make it difficult to apply an absolute ban against genetic enhancement.

The validity of genetic enhancement in *halacha* has not yet been established. The *halachic* justification for genetic therapy discussed so far is derived from principles involving

healing, which clearly do not cover genetic enhancements that are unrelated to health. Rosner conjectures that most enhancements are probably not permitted. However, he does note that Rabbi Moshe Feinstein allowed plastic surgery to improve appearance or physical features to help an individual find a spouse, and Rosner acknowledges that genetic enhancement may be allowed in similar cases. Similarly, Dr. Miryam Wahrman quotes Rabbi Rosenfeld, who states that many authorities allow cosmetic surgery in cases of psychological distress, thus potentially allowing cosmetic genetic enhancements in certain situations if the procedures are shown to be safe. 13

Of course, the ethical debate over genetic therapy and enhancement has not been restricted to the scientific and Jewish communities; most of the world's major religions have also weighed in on the controversy. Various Christian denominations have expressed a range of ethical positions on genetic therapy. For example, the Episcopal Church has no theological or ethical objections to genetic therapy as long as the technology prevents or alleviates suffering, is available to all, and does not involve excessive risk. Conversely, the Methodist church rejects both GLT and any genetic enhancement. The Roman Catholic Church follows the moral guidelines for genetic therapy established by the former Pope, John Paul II, which were based on the values of respect for life from conception to death, human dignity, and

liberty. John Paul II was critical of genetic enhancement, although he supported genetic therapy used to treat disease.¹¹

The development of genetic therapy is permitted by Islamic law, as Islam does not generally impose limits on the development of scientific knowledge. There is a prohibition against changing G-d's creation, but Islamic scholars agree that genetic therapy, like any other medical intervention, is not considered an illegitimate alteration of the creation. Nevertheless, Islamic authorities prohibit GLT and advocate restricting genetic therapy to corrective medical treatments rather than allowing enhancement or eugenics. ^{11, 14}

Buddhists are not opposed to genetic therapy in principle. Raphaël Logier, an expert in Buddhism, explains:

The body is only a vehicle for karma [the ethical consequences of a person's actions that determine his or her destiny in the next incarnation]. If the body has been genetically altered or cloned, it's really not very important.¹⁴

According to the Dalai Lama, leader of Tibet's Buddhists, genetic therapy is not inherently good or bad; rather, the morality of genetic therapy must be determined based on the positive or negative consequences of such treatment.¹⁴

Considering the positions of various religions regarding genetic therapy is beneficial for several reasons. The debate over

the ethical validity of genetic therapy cannot be fully understood without a basic idea of the religious perspectives that influence the way many people relate to the issue. Furthermore, recognizing the way different religions approach genetic therapy is essential for the health professionals who will be asked to treat patients from diverse backgrounds. Similarly, government bodies representing many groups, charged with the responsibility of establishing ethical guidelines to limit research or genetic therapy, need to be aware of the different positions on the subject.

Once genetic therapy becomes available as a safe and effective option, governments, communities, and individuals will need to confront the ethical issues surrounding genetic intervention as they decide what types of treatments are acceptable. Like many modern bioethical concerns, genetic therapy is a forum for often-conflicting values, such as the respect for human life and the desire to alleviate suffering. Conflicts can force people to choose one ideal over the other, despite the fact that both are undeniably worthy. While people struggle with the challenges of new medical advances such as genetic therapy, *halacha* guides a Jew's efforts to find a balance between the ever-increasing potential for progress and for harm. As Rabbi Dr. Avraham Steinberg writes:

As long as the act of perfecting the world does not violate *halachic* prohibitions, or lead to results which would be *halachically* prohibited, then we are given a mandate to use science and technology to improve the world.⁵

Works Cited

- [1] National Human Genome Research Institute of Health. National Institutes of Health. 10 July 2005. http://www.genome.gov/10 001191.
- [2]Nelson, R. "Gene Therapy, Ethics, Germ Cell Gene Transfer." Encyclopedia of Ethical, Legal, and Policy Issues in Biotechnology. Eds. T.H. Murray and M.J. Melman. New York: John Wiley & Sons, Inc., 2000.
- [3] Haÿray, M. and Haÿray, H. "Genetic engineering." The Concise Encyclopedia of the Ethics of New Technologies. Ed. R. Chadwick. San Diego, CA: Academic Press, 2001.
- [4] Rosner, F. "Judaism, genetic screening and genetic therapy." The Mount Sinai Journal of Medicine. 65 (1998):406-413.
- [5] Wolff, A. "A Jewish Perspective on Genetic Engineering." 2 June, 2005. http://www.besr.org/library/engineering.html>.
- [6] Abraham, A. Nishmat Avraham. New York: Mesorah Publications, Ltd., 2004.
- [7] Resnik, D.B. "Genetic Engineering, Human." <u>Encyclopedia of Bioethics</u>. 3rd edition. Ed. Stephen G. Post. New York, NY: Macmillian Reference, 2004.
- [8] Hedgecoe, A.M. "Gene therapy." <u>The Concise Encyclopedia of the Ethics of New Technologies</u>. Ed. R. Chadwick. San Diego, CA: Academic Press, 2001.
- [9] Reiss, Michael. "Biotechnology." <u>The Concise Encyclopedia of the Ethics of New Technologies</u>. Ed. R. Chadwick. San Diego, CA: Academic Press, 2001.
- [10]Reilly, P.R. "Eugenics, Ethics, Sterilization Laws." Encyclopedia of Ethical, Legal, and Policy Issues in

Biotechnology. Eds. T.H. Murray and M.J. Melman. New York, NY: John Wiley & Sons, Inc., 2000.

- Perspectives." Encyclopedia of Ethical, Legal, and Policy
 <u>Issues in Biotechnology</u>. Eds. T.H. Murray and M.J.
 Melman. New York, NY: John Wiley & Sons, Inc., 2000.
- [12] Tauer, C.A. "Gene Therapy, Ethics, Gene Therapy for Fetuses and Embryos." Encyclopedia of Ethical, Legal, and Policy Issues in Biotechnology. Eds. T.H. Murray and M.J. Melman. New York, NY: John Wiley & Sons, Inc., 2000.
- [13] Wahrman, M. <u>Brave New Judaism.</u> Lebanon, NH: Brandeis University Press, 2002.
- [14] Boukhari, S. "Religion, Genetics, and the Embryo." 31, July 2005.http://www.unesco.org/courier/1999_09/uk/dossier/tx t04.htm>.

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Euthanasia

Alisa Kahn-Rose

The sanctity of life should be so fundamentally embedded in the fabric of our society that the question of euthanasia would be in itself distressing. Yet, somehow man's priorities have been distorted in such a way that it has become a fundamental debate. While there are many possible approaches to this debate, the argument for not allowing euthanasia can be disputed on both a religious and a secular level. From a secular perspective, one turns to philosophy and to the political realities of a society. From a religious standpoint, the answers are derived from an essential belief in a higher power.

One might wonder how the concept of euthanasia ever came about. It can be argued that it resulted from a simple question: what is the purpose of one's very life? This basic question is like a stalking ghost, haunting one's subconscious and casting doubt as to whether or not one's time on this earth even matters. When does a life not become worth living? Should it be ended based on emotional or physical pain? Does pain diminish the value that life contains? When faced with doubt of this magnitude, it is natural for one to become hopeless and depressed. Being in the state of psychological despair, one begins to contemplate the pursuit of freedom. Death becomes a

presentable option to obtain this freedom, creating a dangerous and threatening solution – euthanasia.

There are many reasons as to why euthanasia should be illegal. The first is that it has many elements of a crime such as act, intent, and consequence. If allowed there is also the additional question of where to draw the line between which lives can be ended and which cannot. If euthanasia is made available to some people, how can it be denied to others? The ultimate question that arises is when is a life no longer valuable. Should it be when a person is diagnosed with a terminal illness or even when a baby is born deformed and an elderly person grows senile? There is only one state in the United States that allows the use "mercy killings." In 1994, the ballot for euthanasia in the state of Oregon was approved and it went into effect in 1997. The law was called "The Oregon Death with Dignity Act." This law, however, allows only the patient and not the doctor to administer the lethal drugs.¹

Euthanasia goes against the Hippocratic Oath, the basic foundation of medical guidelines in the United States. According to Dr. Daniel P. Sulmasy, a bioethicist, there is a difference between actively killing someone and allowing him to die by withholding treatment. The Hippocratic Oath clearly states "I will not give poison to anyone though asked to do so, nor will I suggest such a plan." Based on this, the question of euthanasia's

The Christian belief is that G-d gives life and that man is created in the image of G-d. Additionally, one should not impede with the natural process of death. Specifically, the Catholic Church is of the opinion that under no circumstances should euthanasia be permitted. They equate euthanasia with murder. As Pope Benedict XVI stated:

others.2

Freedom to kill is not a true freedom but a tyranny that reduces the human being into slavery...While the Church exhorts civil authorities to seek peace, not war, and to exercise discretion and mercy in imposing

punishment on criminals, it may still be permissible to take up arms to repel an aggressor or to have recourse to capital punishment. There may be a legitimate diversity of opinion even among Catholics about waging war and applying the death penalty, but not however with regard to abortion and euthanasia.³

Likewise, Islam also believes that euthanasia is immoral and prohibited. Muslims hold that all life is sacred because it is given by *Allah*. Therefore only *Allah* can choose when a human should live and when a human should die. The Koran (4:29) explicitly states, "Destroy not yourselves. Surely *Allah* is ever merciful to you." This verse appears to support the idea that any form of suicide is forbidden, including euthanasia.³

According to the Jewish position, G-d created each individual for a specific purpose. Every moment of one's life is important and imperative. Some Jewish authorities hold that one's body does not belong to oneself and therefore, one cannot make the decision to take one's life.

Many Jewish authorities believe that every second of pain is merely a chance to cleanse one's soul before it is returned to the Creator. Therefore, it is far better to be punished in this world than to be punished in the World to Come. In the Babylonian Talmud, Tractate *Avodah Zara* (18a), this lesson is personified by Rabbi Chanaya ben Tradyon. He was captured by

the Romans who wanted to kill him; in order to torture him before death, they placed sponges of wool soaked in water by his heart so that when he was burned alive, his death and suffering would be prolonged. Rabbi Chananya's students begged him to open his mouth and allow the flames to enter, thereby hastening his death, but he refused. He explained that each and every moment that G-d wanted him alive was significant, and he would do nothing to change the will of G-d. According to Maimonides in his Laws of Mourning, each second of a person's life is vital and one cannot even close the eyes of a dying person because they are compared to a flickering flame. Just as if you touch a flame its light will go out, so too if you touch the eyes of a dying person, his flame may expire and his soul may leave even seconds too early; it is therefore prohibited.⁴

There is also proof in the case of a woman who is suspected of committing an act of adultery. She is given a cup of special water which is meant to kill her if she is guilty but will do no harm if she is innocent. In the *Mishnah Sota* (3:4), one learns that the more merit she has, more time elapses before her death. As Maimonides teaches in the Laws of *Sota* (3:20), "Her merit prolongs [her life] and she does not die immediately. Instead, she continues to be weakened and suffers sever illness until she dies after a year, two years, or three years, according to her merit." This appears to support that idea that it is better for one

to be in pain in this world in order to spare any pain in the World to Come. Otherwise, what could account for the fact that in this case, delaying death and prolonging suffering is more of a reward than a punishment?

One of the major reasons why euthanasia is prohibited according to Jewish law is because it is not up to humans to play G-d and decide when it is time for a person to die. In the Babylonian Talmud, Tractate *Pesachim* (54b) it says "the moment of death is something that is left up to G-d." When one takes their own life or the life of others, they are defying G-d and discarding His most precious gift. To reiterate this point, the Babylonian Talmud in Tractate *Avodah Zara* (18a) states "Better is it that He who gave the soul should take it, and that a man should do himself no injury."

Someone who is ill should never think that it is G-d's will that they be sick so they should not seek medical attention. One must try as hard as they can to survive. According to Nachmanidies in his book *Toras Ha'Odom*, when a person is feeling any sort of physical ailment, he should not even question getting the opinion of a physician. In addition, Rabbi Moses of Premesla, the author of the *Mateh Moshe*, says that a physician has the responsibility to heal all physical illnesses that he can and one will receive merit in the eyes of G-d if one goes to a doctor. The sooner one seeks medical attention, the more merit he will

reap. Dr. Fred Rosner quotes the *Shulchan Aruch* (Code of Jewish Law) as saying that "it is incumbent upon us to heal and save life and that withholding treatment is equivalent to shedding blood." Additionally, one is certainly obligated to ease a person's suffering if it is possible to do so without hastening death. However, once treatment for suffering could potentially cause a more imminent arrival of death, the prospect of suffering and postponing death outweighs that of not suffering and hastening death.

There are many sources in the Bible which forbid the use of euthanasia. The first is the basic commandment of "Thou shalt not kill." Many equate euthanasia with murder. There are several places in the Bible where G-d says that He alone is responsible for the lives of people. In Deuteronomy (32:39) G-d declares "I put to death and I bring to life, I struck down and I will heal." In Ezekiel (18:4) G-d exclaims "Behold, all souls are mine." The Babylonian Talmud also states that "One who is in a dying condition is regarded as a living person in all respects." Finally, Rabbi Jakobovits clarifies that "any form of euthanasia is strictly prohibited and condemned as plain murder...anyone who kills a dying person is liable to the death penalty as a common murder."

Euthanasia becomes an option when one finds oneself trapped in such a hopeless state that death is the only way out.

the necessity of life. However, it is clear that it is not only against what G-d desires but can also be detrimental to society, degrading the value of life and sensitivity people feel towards the manetity of life. Many believe that their goal in life should be to make every moment count. Life should be viewed as a precious wift and as an opportunity to accomplish and succeed. Changing the entire world is too great a goal for a person, but instead, one should concentrate on changing themselves, to appreciate life to its fullest, and never to take the great gift of life for granted.

Works Cited

- [1] Meisel, Alan. "Right to Die, Policy and Law." Ed. Stephen G. Post. Encyclopedia of Bioethics. 3rd ed. Vol. 4. New York: Macmillian Reference, 2004.
- [2] Torr, James D. Ed. <u>Euthanasia Opposing Viewpoints.</u> San Diego: Greenhaven Press, 2000.
- [3] "Religion and Euthanasia" 8 Feb. 2006. http://www.euthanasia.com/page13.html.
- [4] Rosner, Fred and J. David Bleich. <u>Jewish Bioethics</u>. New York: Sanhedrin Press, 1979.
- [5] Rosner, Fred. Medicine and Jewish Law. Vol 1. New Jersey: Jason Aronson Inc, 1993.
- [6] "Goses." Ed. S.J. Zevin. <u>Talmudic Encyclopedia</u>. Vol 5. Jerusalem: 1963.

Human Research and Clinical Trials

Eliana Muskin and Meredith Waisbord

Human experimentation has been a valuable tool to advance medical knowledge of human illness. Without human experimentation, the medical community would not have made the huge strides it has in combating disease. Just as medical ethics deal with the legal and moral aspects of human experimentation and clinical trials, so too, Jewish law provides guidelines based on traditions derived from the Bible, both the written and oral laws. Although specifics of each new medical protocol are not addressed directly in traditional Biblical law, Jewish ethical laws are based on correlated issues found throughout Torah discourse.

When approaching the ethical and moral issues involved in clinical trials from a Torah perspective, one must first question whether a doctor is allowed to perform any form of treatment on patients. In Exodus (15:26) it is written that G-d is the ultimate healer, as the verse reads, "I [G-d] am your healer." If G-d is the ultimate doctor, then any act of healing by man may be seen as an attempt at diminishing G-d's omnipotence. In addition it can be considered a lack of belief in His capabilities.

Rabbi Abraham Ibn Ezra, a commentator of the Middle Ages, expounds on the verse quoted above, saying, "because I am your G-d, I will be your healer from every illness that I have

decreed into existence on the earth." Nevertheless, most rabbinic authorities agree that even though our health is in G-d's hands, there is still an obligation to obtain medical help when ome becomes ill. The Babylonian Talmud in Tractate Baba Kama (85a) cites Exodus (21:19-20), "V'rapoh v'rapheh," as a source which permits doctors to treat patients. The sages translate the latter to mean, "And you shall surely heal"; this not only allows physicians to provide medical treatment, but also obligates doctors to fulfill a positive commandment. The Book of Education (272)Maimonides in his Book of and Commandments (45, 295) count the act of healing as an obligatory commandment. Another source in the Bible that approves of physicians practicing medicine is found in Deuteronomy (22:2) where the Bible commands "and you shall return it to him." Maimonidies in his Laws of Personality Development comments that the commandment not only alludes to man's permission, but also his obligation, to return another man's health. However, this responsibility only applies when man is physically capable of doing so.

There are many different issues one needs to consider when studying clinical trials. Judaism addresses many of these issues by codifying laws to guide the Jewish people. Many countries have established laws to protect participants of research studies.

In the aftermath of the Nuremberg Trials in 1947, the world became aware that the unregulated and unethical medical experimentation on concentration camp inmates by Nazi doctors was commonplace. The Nuremberg Code established the first set of secular codes to protect human subjects in research experiments. However, Jewish Law established a code of ethical treatment and a set of standards that pre-dates these secular laws. Over the past half-century, ethical standards and codes have been established globally, to protect participants of research experimentation. In 1947, The Nuremberg Code was created as a result of the Nuremberg Trials, which charged Nazi doctors with performing unethical human experimentation on concentration camp prisoners during World War II. The Nuremberg Code established the first set of codes to protect human subjects in research experiments. The Code set forth that human subjects must give voluntary consent in all research experiments. In addition, participants must understand the risks and benefits involved, and cannot be coerced into giving their consent.

In 1964, in Helsinki, Finland, the World Medical Association created the Declaration of Helsinki. Since it was first established, the Declaration has been revised numerous times, most recently in 2002. The Declaration, which includes eighteen basic principles and guidelines for all medical research, was created as an international statement regarding ethics in human

about only be used if the risks to the subjects are not greater than the results gained.¹ The Declaration "influenced the formulation of international, regional, and national legislation and codes of conduct.²

On July 12, 1974, the U.S. Congress signed the National Research Act into law, creating the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research.³ The Commission outlines the basic othical principles surrounding human research, as well as recommendations for enhancing the protection of humans in medical research. The National Research Act established that human subjects must be protected in research experiments.⁴

In 1979, the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research released The Belmont Report.⁴ The Belmont Report established three basic ethical principles: respect for persons, beneficence, and justice. Respect for persons encompasses two ethical principles. The first principle is that "individuals should be treated as autonomous agents." The second principle is that "persons with diminished autonomy are entitled to protection." These two principles are the foundation for "informed consent." Beneficence dictates that people must be treated in an ethical manner by ensuring their well being during a trial. Human

participants cannot be subjected to unnecessary harm. Thus, researchers must attempt to minimize harm to subjects participating in experiments. Today, beneficence is included in the protocol. The benefits and risks of an experiment must be detailed before an experiment can commence. Finally, justice ensures that when subjects are selected for a trial, there must be an equal distribution of people. There cannot be any advantage to one population over another.³

Due to the Belmont Report, in 1981 the Food and Drug Administration (FDA) released regulations on human research.5 In 1991, the Federal Policy for the Protection of Human Subjects, also known as Common Rule, was adopted. The Common Rule ensures "a uniform system in all federal agencies and departments that conduct research."

Just as the international world has established boundaries to protect human subjects in research experiments, Jewish law has also created boundaries. When first looking at the verse, "And you shall surely heal," one might assume that physicians and medical researchers have free reign to practice medicine. However, this is not so. Rabbi Abraham Ibn Ezra was of the opinion that a doctor could only heal superficial wounds and external injuries; however diseases of the internal body, illness, or anything pertaining to the organs or body systems, muscles, or bone had to be left to G-d alone. In contrast, some

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commentators on the Babylonian Talmud, Tractate *Baba Kama* (85a) say that man may cure all forms of illness. This principle does not always apply. For example, may doctors conduct human experimentation if the doctor is unsure if he can heal these patients?

To understand the limits set up by both secular and Jewish law, one must first learn the various approaches to human experimentation and clinical trials. Clinical trials or clinical research is a study where human volunteers are used as subjects in order to address a specific medical question. A trial can be designed to answer a simple question, such as whether a drug has therapeutic value or not. Additionally, a trial can be designed in a more complex manner, involving several controlling and contributing factors.

There are many different trial designs: treatment, prevention, diagnostic, and screening. Treatment trials typically test novel therapies, whether they are drug, surgical or radiation, or new combinations of treatments, or approaches. Prevention trials test new approaches to prevention of disease, or to lowering the risk of getting the disease. Diagnostic trials are used to improve tests in order to better diagnose patients. Screening trials typically test the most efficient and rapid method to diagnose a disease. Quality of Life (QoL), or Supportive Care

trials typically examine the optimal methods necessary to improve the quality of life for patients.⁶

Before a clinical trial can begin, extensive research must be conducted in a laboratory, on in-vitro models, then on animal models and finally on human volunteers. All clinical trials must be carried out according to strict scientific and ethical principles. Each clinical trial has a protocol, which the researchers must follow. A protocol outlines all aspects of the study, i.e. objectives, eligibility criteria, start points and end points of the trial. The study can have multiple objectives.

The major purpose of a clinical trial protocol is to protect individuals involved in the study. Researchers performing a clinical trial can only use a protocol that is approved by both the sponsors of the study, and the Institutional Review Board (IRB) at each hospital or study site. Federal regulations require all research institutions to have an IRB. The IRB must include a diverse group of people including doctors, scientists, other occupations, and at least one member who does not have any financial or scientific interest in the trial. After the IRB has approved the study, it continues to oversee every aspect of the study throughout the duration of the trial. The IRB decides whether the protocols used are safe, and determines if they can potentially expose trial participants to unnecessary or unethical risks. The IRB monitors that the risks to human subjects do not

exceed the benefits, ensures that all participants sign an informed consent document, and guarantees the privacy of all subjects involved in the trial. 4,6,7

Utilizing carefully designed eligibility criteria serves to produce reliable results and helps protect patients' safety. The eligibility criteria ensure that those patients who are too vulnerable will not be allowed to participate in the trial. Eligibility criteria also facilitate the derivation of sufficient information from the trial, so that the results can be analyzed in the future.

In order for the trial to be 'powered', it must have a specific minimum number of participants. In the past, clinical studies were small, involving one investigator, with few patients. The results were not computerized and it took a long time to analyze the data. Today, with enhanced technology and electronic databases, analysis of clinical trials has evolved immensely.

Judaism dictates its own rules and regulations for a physician or clinical researcher to implement a clinical trial. Rabbi Eliyahu Bakshi-Doron, former chief rabbi of Israel, says that according to the *Code of Jewish Law*, if a doctor does not know what he is doing, running a trial is murderous, but if he is knowledgeable, the doctor will not be considered a murderer if a patient in the experiment dies. Rabbi Eliezer Ben-Shlomo, a

contemporary of Bakshi, claims that when success rates are higher than those of failure, a doctor may create a clinical trial. Ben-Shlomo says, "As a rule, the physician is permitted to cause pain and suffering to the patient as long as the pain and suffering might be beneficial to the patient." Accordingly, a fifty-one percent chance of success would obligate a doctor to run a trial so as not to transgress Maimonides' statement (Laws of Murder 2:14), "Anyone who is able to save and does not, has transgressed that commandment of 'do not stand by idly while your friend is being killed'."

The source for taking a risk with the possibility of being healed comes from Kings II, when lepers who were dying of starvation risked entering enemy territory in order to be saved. Dr. Daniel Eisenberg, renowned Jewish medical ethics lecturer, quotes opinions that "range from requiring a greater than fifty percent chance of cure, to allowing even a 'remote' chance of cure." However, when success rates for a trial are only fifty percent, or the outcome is unknown, Dr. Eisenberg says that Jewish law does not mandate a patient to enter the trial.¹⁴

In an article on decoding the human genome, Rabbi Aveener quotes Rabbi Kook who says, "It is not clear if these trials are permissible...but there is no other path for man." Sometimes there is no other choice for a patient other than an experimental drug or procedure, so doctors must make clinical

trials available to patients.⁸ Rabbi Kook would have discouraged such trials if another choice of known consequence was available. Rabbi Kook requires a doctor to ask a competent rabbinic authority before he begins a clinical trial. It is quite routine in Jewish law and even more commonplace in medical matters to require a rabbi's approval. Rabbi N.D. Freedman quotes rabbinic opinions who all advise that a personal sanction be granted based on an individual's own specific circumstances.⁹

Clinical trials that promise to heal may cause injury, danger, or even early death. One must ask himself, "Do the benefits outweigh the possible risks?" Rabbi Immanuel Jakobovits cites five issues that must be discussed before it can be determined if clinical trials are permissible. First, there is the prohibition against wounding oneself, as stated first in Leviticus (19:25) and then later in Deuteronomy (14:1). Even successful trials often have harsh side effects, such as a weakened immune system, severe nausea, limited mobility, and slurred speech.

Second, there is a prohibition against committing suicide. Is a trial that could shorten life an act of suicide? Maimonides in his Laws of Mourning (1:1) defines suicide as "not only someone who goes up to a roof, jumps, and dies, but also someone who goes to the roof in an angry or disturbed mood" Suicide is when someone terminates his own life because

he wants to die. In contrast, early death from participation in a clinical trial is because someone wants to live; it is therefore not suicide.

The third issue Rabbi Jakobovits discusses is referred to in the Baylonian Talmud as "chai'ye sha'ah", short term life. This can be combined with the fourth, the possibility that a doctor has murdered his patient by ending the patient's life early. Tractate Avodah Zara (27b) says in the name of Rabbi Yochanan, "If it is an uncertainty whether someone will live or die, you cannot use experimental treatment on him; if it is certain that he will die, such treatment may be used on him." On the same page of the Talmud, it is written that if the man will die, "chai'ye sha'ah is negligible." This definition needs clarification. Chai'ye sha'ah is a fixed amount a time that is considered life. Rabbi Jacob Reischer is quoted by Dr. Eisenberg as stating that if a patient will only live a few days less if a treatment fails, it is negligible and we allow it. It appears according to most, though, that longer time periods are also permissible. A few months may be negligible and Rabbi Moshe Feinstein and Rabbi Shlomo Kluger say that if a failed trial causes a patient to die up to a year early, it still may be conducted.11

Clinical trials are classified as *safek pikuach nefesh*, a case where there is the potential for saving a life. It is therefore

permissible to conduct the trials but only when they have been well tested. Maimonides says that the potential to cure a disease and save a life overrides compromising short term life. Rabbi Yosef Kairo writes that it is better for someone to die without intervention than to actively end someone's life early. According to Maimonides in the Laws of Murder, "If you kill a 'treifa' [someone who is about to die]...you are exempt from transgressing the sin of murder." But in the preceding paragraph Maimonidies writes, "One who kills... a sick person who is going to die, or even someone on his deathbed, is liable for murder." These two statements seem contradictory, but they are not. Commentators explain that when someone is going to die from "general illness of old age," and a trial ends his life early, it is murderous, but a man dying from an "ailment in his organs," may take part in a clinical trial, even at the risk of cutting off chai've sha'ah.

The fifth and final concern about clinical trials is the obligation of "and you shall live." In Deuteronomy (30:19) G-d says, "I place life and death before you," but recommends "and you shall choose life". Life is a precious gift and should be treated as such; one cannot act carelessly or dangerously when a life is at stake. Trials are known to pose threats to life or to a person's quality of life.

Once both rabbinic and medical professionals have approved a clinical trial, it can proceed forward. Clinical trials can include data from three different phases of research. Each phase of research addresses different questions about a novel modality or therapy. Phase I trials are the earliest phase in testing a new treatment in humans. In Phase I studies, researchers examine various methods of drug delivery, and compare their safety profile.

The objective of these trials is to identify the minimal dose necessary to be both safe and efficacious, i.e. to cause a therapeutic effect on the patient. Unwanted side effects of the new therapy are monitored. Phase I studies usually include only a limited number of patients who are willing to expose themselves to potential risks. ^{6,7}

The focus of a Phase II trial is different than a Phase I trial. Phase II trials focus on the efficacy of an experimental therapy, rather than its safety, as the drug's safety has usually been previously established in Phase I of the trial process. However, similar to Phase I trials, a limited number of people participate in these trials, due to the unknown potential risks involved. ^{6,7}

Phase III trials are typically larger and have several arms, or options. In these trials, patients on a novel therapy (the experimental or interventional arm) are compared to patients on

a "standard of care" treatment (the control arm), in order to determine if the new approach is superior to the old one. There are often multiple sites to these trials. The trials may be randomized, where patients are assigned to one arm of the trial or another. To avoid any bias in the trial, they can be singly or doubly blinded, where the participants do not know which arm they are assigned to. In general, a treatment or therapy will progress to this stage only if it was promising in Phase I and II trials. The results of a Phase III trial can elucidate whether one therapeutic approach is superior to another, both in terms of efficacy and in terms of side or adverse effects. ^{6,7}

In addition to the IRB, the Data Safety Monitoring Board (DSMB) is added for Phase III clinical trials. The members include statisticians, patient advocates, and doctors. Not all members of the DSMB have an interest in the clinical aspects of the trial. The main concern of the DSMB is the safety of the volunteers involved. The DSMB must guarantee that the drugs involved are not causing any unforeseen negative effects. In addition, the DSMB observes the results of the trial to insure that one arm of the trial is not at an unfair advantage over the other.^{4,7}

There are ethical issues specific to Phase III trials. If a Phase III trial compares a new therapy against a standard of care therapy, in order to discover a better treatment, all participants in this trial should receive some potential treatment. It would be unethical to have a placebo arm in this trial. If a Phase III trial was to incorporate a placebo arm, patients must be aware that they may be administered a placebo versus an experimental or therapeutic therapy. Another issue that must be addressed is what should the legitimate endpoints of the trial be? In the past, there have been cases where Phase III trials were terminated due to ethical concerns. ^{6,12}

Clinical trials can also be divided into three separate groups, based on *halachic* issues and rulings. The first is called "*choleh she'yesh bo sakanah*," which is defined as someone who will die from an illness that lacks sufficient treatment. A "*choleh she'ain bo skanah*" is someone who suffers from chronic pain, where the pain is not fatal but interferes with normal functioning. The first two categories of patients volunteer themselves because they are willing to undergo harm with the possibility of being healed. The third, an "*adam barie*," a "healthy man," is slightly different. This person volunteers for the sake of research, for the general good of mankind, as well as economic benefit. A study will not benefit a type three person directly, yet he is willing to be part of the experiment. 13

Many rabbis discuss issues related to *choleh she'yesh* bo sakanah. Dr. Abraham Steinberg refers to a case quoted by the *Darchei T'shuva* where a baby had an illness that was

untreatable except for a very dangerous surgery that could potentially kill the infant. The prevalent rabbinic opinion was that this procedure was permissible to perform. After reviewing the issues posed earlier by Rabbi Jakobovits, the general consensus among rabbis is that experimental procedures and surgeries are permitted if all conventional therapies have been employed. However, a patient is not required to take part in a clinical trial if there is a possibility of shortened life or anticipated side affects (Rabbi Bleich and *Lev Aryeh Responsa*). Some allow experiments to take place on the Sabbath, even if doing so would cause the doctor and patient to violate the laws of the Sabbath.

The laws of *choleh sh'ain bo sakanah* slightly differ than those previously mentioned. Rabbi Menashe Klein and Nahmanides say that dangerous surgery or treatment is allowed for chronic pain based on a Tosafist commentary on the Babylonian Talmud, Tractate *Nazir* (59a). In contrast to the latter, the book *Mor U'Kitzeah* writes that it is not permissible to put oneself in a dangerous position, a "*makom sakanah*," to alleviate non-dangerous pain. According to the *Chazon Ish* (Rabbi Abraham Yeshayahu Karelitz) and the *Sefer Chasidim* (written by Rabbi Yehuda HaChasid), as long as a doctor's intention is to help the patient, and not to further his own career,

it is permissible to run clinical trials even for non life-threatening pain. 13

Dr. Eisenberg lists opposing views detailing success rates which would enable a patient to take part in a trial. For a *choleh she'ain bo sakanah*, it must be more likely that the person will be safe and cured of their particular ailment. In regard to overriding other commandments of the Bible, a trial for non-lethal sicknesses does not permit violating the Sabbath, eating non-kosher, or disregarding any biblical or rabbinic commandments.¹¹

Although Judaism places great value on assisting one's fellow man, halacha does not necessarily dictate that it is permissible for an adam barie to take part in a trial. According to Jewish law, it is completely forbidden for a doctor to conduct a dangerous trial that uses healthy candidates. The Jerusalem Talmud, Tractate Terumot (Chapter 8) says that a person must put himself in "possible danger" in order to save someone in "definite danger." The Babylonian Talmud, Tractate Sanhedrin (73a), however, says man is not obligated to do so. In fact, the Radbaz (Rabbi David ben Zimri) calls someone who puts himself in "possible danger" a "wise fool." Similarly, Rabbi Kook claims that someone who is healthy and participates in a dangerous trial is tantamount to someone who attempts suicide or kills. The Radbaz modifies his harsh words by adding

elsewhere, that if the possibility of danger in the trial is very small, one is allowed but never obligated to take part in the trial. If no dangerous side affects are expected, a healthy man is obligated to help under the prohibition of standing idle.

Within Judaism, Rabbi Shlomo Zalman Auerbach makes a distinction between "lifanav" and "lo lifanav." The first, translated literally as "before him", means that there is an identifiable person who can benefit from a trial. In contrast, the second person does not know the individual who will benefit from the trial. Rabbi Aurbach says that if a sick man is "lifanav", the healthy man may be experimented on, even if it is dangerous. He perceives that the Babylonian and Jerusalem Talmudic texts are not contradictory, but rather they refer to two different cases, one of "lifanav" and the other "lo lifanav".

In recent years, various national agencies have been established to monitor clinical trials in the United States. Periodically the FDA inspects institutions where clinical trials are being conducted. All trials whether federally funded or not, must comply with the FDA regulations. Federal regulators create standards for the IRB, Informed Consent, and other regulations that further protect human subjects in research studies. FDA's Office of Human Affairs also has a code of federal regulations. These regulations apply to any trial in which a new drug is being tested for approval by the United States government. The Office

for Human Research Protections (OHRP) is a part of the US Department of Health and Human Services, and is responsible for volunteers in all clinical trials that are federally funded. The OHRP enforces the Regulations for the Protection of Human Subjects. Other organizations that help protect the volunteers involved in clinical trials include: patient advocates in hospitals, peer review, Public Responsibility in Medicine and Research (PRIM&R), and Applied Research Ethics National Association

(ARENA).4

There are basic ethical requirements that must be adhered to in order to protect human trial participants. The most important is an Informed Consent form, a document signed by the subject stating that he or she fully understands the implications of their participation in the trial. Informed consent may not be given under duress, as detailed in the Belmont Document. The concept of "informed consent" originated during the Nuremberg codes. The Informed Consent document must include: a clear explanation of what will occur during the trial, the benefits and risks of participating, and an alternative to participating in the trial. In addition, participants must have the ability to withdraw from the trial at any time. ^{4,6}

Halacha's ideas about informed consent are slightly different and are in some ways stricter than those that American law requires. "Becoming informed and giving consent...are

required," according to Dr. Eisenberg. 14 Informed consent is not only a right that a patient has; rather it is also an obligation. The verses, "you shall live" and "you must truly guard your soul" indicate that every person must provide for himself life. Maimonides speaks at length about keeping oneself healthy. It is, therefore, only logical that a patient must know about all the aspects of the treatment before joining a trial so that medical decisions can be made responsibly. Rabbi Moshe Feinstein, a twentieth century foremost authority, says that a patient's input is "crucial to medical decision making."

There are some rabbinic authorities that claim that even if a trial is undoubtedly beneficial, verbal coercion may be employed. In such a case, the patient must provide verbal consent. If he cannot be convinced, he may not be experimented on against his will. Rabbi Moshe Feinstein insists that coercion may only be used in rare cases.

A doctor plays a major rule in Jewish consent because the doctor has a greater grasp on the patient's treatment options. Similarly, a researcher best understands the risks and benefits involved in a particular clinical trial. Both a researcher and a doctor must provide a patient with all the information he may need to make an educated decision.

More specific issues arise in dealing with children and people who do not have the mental capacity to make decisions for themselves. The National Commission for Protection of Human Subjects of Biomedical and Behavioral Research only allows children to participate in clinical trials, if they have an informed consent form from their parents or legal guardians. At age seven or older, the children themselves must assent to the trial. In addition the IRB must approve the trial for children. 4,6,15

There are many ethical issues involving patients that are mentally ill. The basic issue is whether a mentally ill person understands the legal ramifications of informed consent. ¹⁶ Some people believe that vulnerable people should not be included in clinical studies. Others believe if the study is more beneficial than the standard therapy, then they should be included in clinical trials. Precautionary measures have been set up to help address these issues. Some study coordinators may include a surrogate person not related to the patient, or having any interest in the trial, help make an informed decision for the patient involved. ^{15,16}

The standard of care and informed consent required by Jewish law as discussed in the Talmud date back to the revelation at Mount Sinai. The moral, legal and ethical principals of the Bible that have been debated and discussed over the centuries are the foundation for many of the laws and standards for human research and clinical trials that are in effect today.

Works Cited

- [1] "Declaration of Helsinki." World Medical Association. 9 Oct 2004. 23 Jan. 2005. http://www.wma.net/e/ policy/b3. htm>.
- [2] "International Ethical Guidelines for Biomedical Research Involving Human Subjects." Council for International Organizations of Medical Sciences. Nov. 2002. 21 Jan. 2005. http://www.cioms.ch/frame_guidlines_nov_2002.htm.
- [3] "Office of Human Subjects Research." The Belmont Report.
 National Institutes of Health. 21 Jan. 2005.
 http://www.nihtraining.com/ohsrsite/guidelines/belmont.html>.
- [4] "A Guide to Understanding Informed Consent." National Cancer Institute. 20 Jan 2005 http://www.nci.nih.gov/.
- [5] "History of Research Ethics." <u>IRB Training and Certification</u> for Researchers. 24 Jan. 2005. http://dor.ncat.edu/compliance-ed/ethics3.html.
- [6] "Resource Information." <u>ClinicalTrials.gov</u>. U.S.National Institutes of Health. 30 Jan. 2005. http://clinicaltrials.gov/ct/info/whatis#types.
- [7] "Background Information on Clinical Research."

 <u>CenterWatch Clinical Trials Listing Service</u>. Thomson

 Centerwatch. 28 Jan. 2005. http://www.centerwatch.com.patient/backgrnd.html#Section1.
- [8] Aveener, Shlomo. "Genetic Testing, Free Choice, and Dangerous Human Experimentation." <u>Assia</u> 1998. 19 Feb 2005. www.medethics.org.il/articles/Assia61-62.04.doc.
- [9] Freedman, N.Z. "Scientific Tests with Humans." <u>Assia</u> (1979). 06 Mar 2005. www.medethics.org.il/articles/r001270. htm>.
- [10] Jakobovits, Immanuel. Jewish Medical Ethics. New York: Bloch Publishing Co., 1975.

- [11] Steinberg, Avraham. "Human Experimentation."

 <u>Encyclopedia of Jewish Medical Ethics.</u> Ed. Fred
 Rosner. Vol. 2. Jerusalem, Israel: Feldheim Publishers,
 2003.
- [12] Kopelman, Loretta M. "Research Methodology: Clinical Trials." <u>Encyclopedia of Bioethics</u>. Ed. Stephen G. Post. Vol. 4. New York: MacMillan Reference, 2004.
- [13] Avraham, A.S. "Medical Trials with Animals and People."

 Assia 5 (5746). 18 Feb 2005. www.daat.ac.il/daat/kitveyet/assia/nisyonot-2.htm.
- [14] Eisenberg, Daniel. "Dangerous Surgery to Save a Life." 2
 May 2004. 02 Mar 2005. https://www.aish.com/societyWork/sciencenature/Dangerous_Surgery_to_Save_a_Life.asp.
- [15] Levine, Carol. Ogletree, Thomas W. "Research Methodology: Subjects." Encyclopedia of Bio Ethics. Ed. Stephen G. Post. Vol. 4. New York: MacMillan Reference USA, Thomson Gale, 2004.
- [16] Youngner, Stuart J. and Gaines, Atwood D. "Online ethics.org: The Ethics of Research with Human Subjects Who are Mentally III." 24 Jan. 2005. http://www.onlineethics.org/reseth/mod/mentres.html

Reproductive Human Cloning

Shoshana Pinsky

On February 23, 1997, an article in *The Observer* revealed that Dr. Ian Wilmut of the Roslin Institute in Sweden was successful in cloning a sheep. This sheep, named Dolly, was born on July 5, 1996 and was the first mammal ever to be successfully cloned using the technique of somatic cell nuclear transfer (SCNT). Following the birth of Dolly, scientists acknowledged that it would only be a matter of time before technology advanced to the point where they would be able to clone humans. This announcement resulted in a tremendous upheaval and debate over the ethics of human reproductive cloning.

Cloning has a number of different definitions and can be accomplished in a variety of ways. At its most basic level, cloning is the process of asexual reproduction which can be defined as the creation of a new being without the union of male and female gametes.² This type of cloning occurs constantly in nature. One example is bacterial replication, where a bacteria replicates its DNA and undergoes binary fission to create a duplicate of itself. Both of the bacterial daughter cells contain the same one chromosome as the original parent cell.

Unlike bacteria, human reproduction is a sexual process which involves the fusion of male and female gametes. Somatic

cells within the human body contain forty six chromosomes, or twenty three pairs. Some of these cells are designated to undergo meiosis where the diploid cells undergo a series of divisions to produce four haploid cells, or cells with only one copy of each chromosome. These haploid cells are termed gametes; a male gamete is called the sperm and a female gamete is called the oocyte. Fertilization of the oocyte by the sperm results once again in a diploid cell; the two haploid cells fuse and the chromosomes become one diploid set. This diploid cell, now termed the zygote, undergoes numerous mitotic divisions to form a multicellular organism. The offspring's genetic material is thus a combination of the DNA of both parents; it contains one copy of each chromosome from the female parent and one from the male parent.²

Based on this understanding of how a multicellular organism is formed, one can appreciate how SCNT can be used to produce a human clone. The process involves transplanting the nucleus from a mature somatic cell into an enucleated oocyte. This method results in a diploid cell which contains genetic material from only one parent cell; the enucleated oocyte contributes no chromosomes while the transplanted nucleus provides the cell with two sets of each chromosome. Somatic cell nuclear transfer is a therefore a process of asexual

reproduction since a new organism is created without the union of two gametes.²

Oocytes are present in a female's ovaries from the time of birth. These oocytes are gametes that have been arrested in an early stage of meiosis. The first step of SCNT involves aspirating a number of oocytes from the woman's ovaries and culturing the cells until they have matured. While the length of time necessary for maturation varies according to the chemicals used and the reproductive status of the woman, it ranges from less than an hour to two days.²

The chromosomes of the oocyte are then removed so that the donor genetic material can be inserted. The most common technique for eliminating the DNA involves aspirating it out with a micropipette. Alternately, the DNA can be destroyed through the use of a laser. The nucleus of the donor cell must then be inserted into the oocyte. One method involves physically removing the donor nucleus from the somatic cell and injecting it into the cytoplasm of the oocyte. The more common technique, however, entails fusing the entire somatic cell with the oocyte. While this results in the mixing of the cytoplasm and organelles of the two cells, the oocyte is over one hundred times larger than the somatic cell and the cytoplasm and organelles of the somatic cell are greatly outnumbered by those of the oocyte.²

Being that an unfertilized oocyte is essentially a dead cell, once the donor DNA is inserted into the oocyte, the cell must then be "activated." In the normal process of sexual reproduction, an enzyme produced by the sperm activates the oocyte after the two have fused. This triggers various chemical processes within the cell and allows for the replication of the genetic material in anticipation of cellular division. Without activation by the sperm, an oocyte cannot proceed to become a functioning organism. As there is no fertilization of the oocyte in SCNT, scientists must artificially activate the oocyte, often through the application of a strong electric shock.²

The oocyte with the somatic cell DNA is then cultured in vitro for a few days until it is mature enough to be placed back into the reproductive track of a female. There, the cells continue to divide until they form a fully developed organism. In the hypothetical case of human reproductive cloning, the new human produced is the clone of the person from whom the donor nuclear DNA was extracted; the genetic material of the clone is essentially identical to the genetic material of the donor.²

While the DNA of the clone and the person cloned (termed the clonee) are almost identical, a common misconception is that a cloned person would be completely identical to the clonee. This assumption is faulty for a number of reasons. Firstly, the genetic material of the clone and the clone

would differ in respect to mitochondrial DNA. The mitochondrion is a small organelle within eukaryotic cells which is the center for cellular respiration. Each eukaryotic cell contains many mitochondria. Unlike other organelles, mitochondria contain small, circular chromosomes. In SCNT, the oocyte provides the cytoplasm for the clone. Even if the two cells were fused, the cytoplasm and organelles of the donor cells are insignificant when compared to those of the large oocyte. Thus, while the clone's nuclear DNA is practically identical to that of the clonee, the clone contains mitochondrial DNA from the donor of the oocyte and the clone and clonee are therefore not genetically identical.²

A second genetic difference between the clone and the clonee results from chromosomal mutations. All DNA occasionally undergoes mutations as a result of outside radiation and chemicals, as well as occasional mistakes in the transcription and translation process. Thus, the genetic material of the clone will almost certainly undergo mutations which can result in differences between the DNA of the clone and of the clonee. Since the DNA is a blueprint for the proteins that the person will produce, once it is mutated, the clone will produce different proteins than the one who was cloned which can result in phenotypic differences between the two.²

Lastly, the environment in which the clone is raised will result in differences between the clone and the clonee. While there is a debate as to whether nature (i.e. genetics) or nurture (i.e. environment) shape a person, few will argue that nurture has no role at all. Therefore, the clone will differ from the clonee as a result of his or her upbringing. Not only will being raised by different people in a different place result in differences, but the mere fact that the two will have been brought up at different points in time will cause significant variation in the development of the two people.²

In summary, humans clones would differ from those who are cloned both in terms of genotype and phenotype. In fact, they would differ even more than monozygotic twins. While monozygotic twins have the same mitochondrial genetic material and are often raised in the same or similar environments, this would not be the case for clones. While all would agree that identical twins are two distinct people with different personalities, it should be noted that clones would be even more different.²

Despite the fact that clones would not be completely identical to the clonee, a number of potential benefits and uses for human reproductive cloning can be envisioned. Firstly, a human clone that is genetically related to a parent could be created for couples who cannot conceive a child through natural

means. The nucleus of a cell would be extracted from a somatic cell of one of the parents and transplanted into the oocyte of a woman. This technology could be used both for infertile and homosexual couples.²

Somatic cell nuclear transfer could also be used to clone a child who has died or is on the verge of death. Parents could preserve the nucleus from a somatic cell of their child and through somatic cell nuclear transfer, scientists could create a clone of their deceased child. Similarly, one can envision the use of nuclear transplantation to clone a deceased spouse.²

Another potential use of human reproductive cloning would be to create genetically compatible organs and tissues for a person who is ill and in need of a transplant. It is often very difficult to find a compatible organ or blood donor. Moreover, there is a shortage of people willing and able to donate organs when compared to the number of people in need of organs. By creating a clone of the person who is ill, another human could be created who is genetically compatible to the ill person in order to donate blood or an organ. Already there are stories of parents with an ill child becoming pregnant in the hope that the new sibling would be a compatible donor; through the use of somatic cell nuclear transfer, parents would be guaranteed that the siblings would be genetic matches.²

A last, but perhaps most controversial, benefit of human reproductive cloning would be the creation of clones to further scientific knowledge. The cloned individuals could be used as subjects in furthering research of somatic cell nuclear transfer. Additionally, the clones could be used to further understand the relationship between nature and nurture in the development of a person.²

While no known cases of human cloning are currently known, scientists agree that it is only a matter of time before the technology advances to a point where a human could be successfully cloned through SCNT. The question then arises as to whether it is ethically and morally acceptable to clone a person. Ethical concerns have been raised by both religious and secular groups alike. On February 24, 1997, one day after the announcement of the successful cloning of Dolly, the Clinton administration charged the National Bioethics Advisory Commission with investigating and analyzing the ethical implications of human cloning.1 President Clinton also placed a temporary ban on the use of federal money in cloning research and asked private research companies to voluntarily cease any research on human cloning.³ The National Bioethics Advisory Commission reported its findings in June of 1997, which were based on discussions with clergymen, ethicists, scientists, and physicians. The Commission concluded that a wide range of moral, legal, and ethical issues are involved in evaluating human reproductive cloning. Concerns that would seem to oppose using the technology for human reproductive cloning include issues of safety, the treatment of children as objects, the value of family structure, and individuality. On the other hand, ethical issues such as personal freedom and the right to conduct scientific research would seem to argue for the further development of technology. The Committee concluded that human reproductive cloning should be banned until further information about the safety of the procedure be determined. Furthermore, they advised that the ban on human reproductive cloning not be lifted unless experimental trials are regulated with independent review and informed consent.¹

The National Bioethics Advisory Committee acknowledged that a person's stance on human reproductive cloning will depend on one's religious perspective. Different religions have different views on the matter and even within a given religion, the opinions of individuals are often mixed.¹

Presently, the Catholic Church is the strongest opponent of cloning. Catholics give a number of reason for their strong opposition. Firstly, they believe that an embryo is considered a human and is imbued with the sanctity of life from the moment of conception. In the case of somatic cell nuclear transfer, once the donor nucleus is transplanted into the oocyte, the resulting

diploid cell would be given the status of life. Inevitably, such cells will be destroyed in the process of perfecting the technique of somatic cell nuclear transfer. As such, human reproductive cloning is not objectionable in itself but the process that would eventually result in successful clones can be equated with murder.²

Catholics also see the *actual* cloning of humans as unethical. The Catholic Church teaches that G-d implants a soul within each person at the time of conception. Catholics therefore believe that while cloning might result in a biological human, without the fusion of sperm and egg the spiritual component of a person is missing. The clone would have a physical form but lack a soul. Moreover, they feel that the creation of a new person by scientists steps over the boundary of what distinguishes man from G-d. While it is acceptable for humans to study medicine to *assist* in reproduction, the Catholic Church believes that the actual act of creating a person should remain solely in the hands of G-d.²

Lastly, Catholicism places a strong emphasis on the value of "common human experience." Therefore, the Catholic Church must also take into account the effect that cloning would have on society as a whole. The "natural law" or "moral law" of the world dictates that a traditional family, sexual relations, and procreation are all linked together.² SCNT would cause

confusion over the status of parents as the individual who donates his or her genetic material for cloning would technically be both a parent and a twin of the clone. The children produced from this technique would be the ones who would suffer as a result of this confusion.⁴ Cloning would place a strain on the "natural law," and therefore, on all of society.

While the Protestant Church opposes human reproductive cloning, their stand against it is not as strong as that of the Catholic Church. Protestants have mixed responses to the question of whether cloning poses a problem of "playing G-d." While all Protestants believe that G-d created the world, they differ in what they perceive as man's role in the universe. Some Protestants see man as partners with G-d in the maintenance of the world and believe that it is the job of humans to protect and guard the world which G-d created. In other words, G-d created the world and entrusted it to man to maintain. As such, cloning is extremely problematic as it allows man to create a new person and not just oversee that which was created by G-d. However, other Protestants view humans as "co-creators" with G-d. They believe that G-d created a world and gave it to man, and it is man's responsibility to improve the world and continue in the creative process. Those who accept this second view would not see cloning as an attempt to "playing G-d."2

However, even Protestants who see humans as "cocreators" would view human cloning as problematic for a number of other reasons. Much like Catholics, Protestants understand the Bible as valuing heterosexual marriages. Cloning allows for homosexual couples to raise a child genetically related to one of the partners as one of the partners could be the one to donate the DNA to be cloned. This ability for genetic bond could give rise to more homosexual unions, which Protestants feel would lead to a breakdown in the traditional family unit.² Furthermore, Protestants understand the Bible as placing tremendous value on human life and fear that "manufacturing" children through SCNT will detract from this important value if life can be created on demand in a laboratory. Secondly, Protestants worry that human reproductive cloning would take away from the concept that children are gifts from G-d. Lastly, as noted above, there would be loss of embryos in the experimental stages of human cloning. Like Catholics. Protestants also see embryos as imbued with life and in perfecting the technique of cloning humans, life would be lost.²

The Muslim perspective of human reproductive cloning is complex due to different values and principles within Islam; some of these tenets would seem to support cloning while others would oppose it. Therefore, it is not so clear as to whether Islam would support or oppose human reproductive cloning.

The Koran is the Muslim code of law and Muslims therefore look to it to formulate an opinion on the morality of cloning. The Koran states (23: 12-14):

We created a man of an extraction of clay, then We set him, a drop in a safe lodging, then We created of the drop a clot, then We created of the clot a tissue, the We created of the tissue bones, then We covered the bones in flesh; thereafter we produced it as another creature. So blessed be G-d, the

In these verses, the Koran makes it clear that humans are integral partners with G-d in the creation of man. Based on this idea, some Muslims see cloning as permissible as it is another way of creating man in which humans are involved.²

Best of creators!

On the other hand, some Muslims quote different verses from the Koran (75: 37-38) as proof that Islam is opposed to human cloning:

Was he not once a drop of a sperm that had been split, and thereafter became a germ-cell-whereupon He created and formed [it] in accordance with what [it] was meant to be, and fashioned out of the two sexes, the male and the female? These two verses seem to support the view that G-d is the Creator of man and that humans are the agents involved in the process. Given this view, humans would not be allowed to create

man on their own through the process of somatic cell nuclear transfer.⁴

In addition to these verses from the Koran, three recurring themes that can be traced through Islamic law which would influence a Muslim's decision on the permissibility of cloning. The first theme is the value placed on scientific knowledge. Since scientific study can further one's awe of G-d and the brilliance of His universe, Muslims believe that scientific study is a form of divine worship. This would seem to support the advancement of human cloning as long as the knowledge acquired in studying cloning is used to benefit mankind. Furthermore, most Muslims claim that G-d desires the creation of life. Therefore, any scientific knowledge used to create more life would certainly be acceptable.²

A second theme in Muslim law is the emphasis on the importance of heterosexual marriages. The Koran states (51: 49): "And of everything We have created pairs that you be mindful." This verse is interpreted by Muslims as a command for heterosexual marriages. As such, Muslims would oppose human reproductive cloning if it would lead to an increase in homosexual marriages. Furthermore, human reproductive cloning would appear troublesome even for heterosexual couples given the fact that only one parent is genetically involved in creating the clone.²

Thirdly, Muslims believe at that the fetus is infused with a soul six weeks after conception. Cloning would therefore be problematic since embryos often die before birth when using somatic cell nuclear transfer. If the fetus was to die after six weeks of gestation, there exists the possibility that human cloning could be considered murder.²

These seemingly conflicting views and themes within Islam are cause for a lot of discussion as to the morality of ethics of human cloning. While no one position is clear, there is much heated debate within the Islamic community concerning the ethical considerations involved in human reproductive cloning.

Judaism's stance on cloning is somewhat hard to define. On one hand, Judaism preaches restraint before committing an act which may be prohibited according to Jewish law or which may result in negative consequences which could not have been predicted. On the other hand, cloning could be viewed as permissible and even commendable if it would help a person fulfill an obligation they would otherwise be unable to fulfill.⁶ Rabbi Israel Lipschuetz, a German rabbi who lived during the late eighteenth to early nineteenth century, wrote *Tiferes Yisroel*, a commentary on the Babylonian Talmud. Amongst his comments on Tractate *Yadayim*, he explains that "anything which we have no reason to prohibit is permitted, without having to find a reason for its permissibility. For the Bible does not

mention every permissible thing, but rather only those which are forbidden." Given this principle, Judaism views human reproductive cloning as permissible unless an aspect of the technology or its ramifications violates a law or principle already laid out in the Bible.⁶

Within Jewish law, there exists an obligation for men to have children. The biblical obligation to have one son and one daughter is derived from the verse in the Bible where G-d commands Adam "peru u'revu"- be fruitful and multiply (Genesis 1:28). The question then arises as to what is required of a man in order for him to fulfill this obligation. Is the obligation for procreation satisfied by the contribution of genetic material to form a new being or must this be accompanied by the combination of his genetic material with that of a woman's? If the former suffices, a man could fulfill his obligation to father children through SCNT if he is the one to donate the genetic material. Therefore, if cloning allows an infertile male to have children and fulfill a biblical commandment which he would otherwise be unable to satisfy, one could see the case for considering cloning permissible. However, cloning could at most be considered a good deed but not an obligation as males are only required to procreate through natural means. There does not exist any obligation for a man to engage in any

reproductive technology if he cannot have children through normal sexual intercourse.⁵

However, if the commandment of procreation requires the *combination* of male and female genetic material, the obligation of procreation is not fulfilled through cloning. All of the primary genetic material in somatic cell nuclear transfer comes from one person. If this is the case, the cloning of humans would not be looked upon as favorably by Jewish authorities.⁵

It is important to note that Jewish biblical law only obligates a male to have children and does not place this commandment upon women. Therefore, if the genetic material being cloned is taken from a somatic cell of a woman, no biblical commandment is fulfilled. Furthermore, while most Jewish authorities do not see any transgression of Jewish law in the process of SCNT itself, a violation of Jewish law could occur if the gestational mother of the clone is married. Some authorities maintain that a married woman is prohibited from serving as a gestational mother for a child other than her husband. They hold that such an action would fall under the prohibition of adultery. Thus, Judaism advises against creating a clone from a woman's genetic material as it would not fulfill any biblical commandment and at the same time, could lead to a transgression of biblical law.5 The question then arises as to whether cloning violates any fundamental Jewish beliefs. According to Jewish

tradition, there is no issue of "playing G-d" involved in human cloning. Rabbi Yehudah Loew of Prague (the *Maharal*) explains that G-d created the world in six days but allows man to be part of the creative process and continue to create anew. Man was commanded by G-d with "*umilu es haaretz vekivshuha*" – fill the earth and conquer it (Genesis 1:28). Commentators have explained this verse to mean that man not only has permission, but even has a responsibility, to continue to develop the world and be involved in the creative process as long as no violation is transgressed in the process. Nachmanides, a Jewish sage who lived in the fifteenth century, goes even further to explain that within this commandment lies permission for man to utilize the various fields of science to "conquer the world."

Furthermore, Judaism distinguishes between *yesh me'ain*, creating something from nothing and *yesh me'yesh*, creating something form from previously existing matter. While man is allowed to create something new from matter that already exists, Judaism believes that the creation of something completely new is a power reserved for G-d. Cloning through the method of SCNT is clearly *yesh me'yesh*, creating a new person from genetic material that already exists in the world. As such, human reproductive cloning does not appear to infringe on the powers reserved for G-d.⁶

Jewish authorities agree that a clone would have the status of a full-fledged human who possesses a soul. Jewish tradition indicates that throughout history, sages have created golems, artificial beings formed from dust. These beings had the ability to move and act on their own but as they did not have the capability of speech, an ability that distinguishes man from animals, they were considered to lack a soul. Jewish authorities have determined that since human clones would have the capability for speech, they would be considered humans with souls. Jewish authorities have also stated that a creature is considered a human if its mother is a human. As the Babylonian Talmud in Tractate Niddah (23b) points out, "an animal-like creature born of a human mother is regarded as a human being." Moreover, an organism gestated within and born from a human mother is considered to posses a soul. As such, a clone is not only considered human but also considered to posses a soul like every other human being does. Furthermore, Jewish authorities have also determined that a standard for distinguishing between humans and animals is whether the creature is capable of advanced thought. As a clone is clearly an intelligent being, he or she would be considered a human.6

Some object to human cloning on the basis that children may be exploited if they are created to fulfill a specific purpose, such as acting as a source for organs. Not only is creating a

clone in order to procure organ and blood donations not considered an exploitation of a human, but it may in fact fulfill an obligation. Jews are obligated in the commandment of "verappo ye-rappe" (Exodus 21:19), which translates as "and you shall surely heal." This phrase obligates Jews to heal those who are sick, using all of the technology and medical knowledge available.⁷ It would seem to follow that if the technology of cloning can be used to help heal one who is ill, Jews may be obligated to use this technology as long as no other prohibitions are transgressed in the process.

In summary, Jewish law does not see cloning as the ideal method of procreation. However, if the technology advances to the point where creating human clones is a possibility, Jewish law can foresee the possibility that cloning might not only be permissible but also advisable in certain cases. As Rabbi Broyde, a contemporary Orthodox Jewish authority explains, "One is inclined to state that *halacha* (Jewish law) probably views cloning as far less than the ideal way to reproduce people. However, when no other method is available it would appear that Jewish law accepts that having children through cloning is perhaps a commandment in a number of circumstances and is morally neutral in a number of other circumstanced."

Given that human reproductive cloning appears to be permissible in certain cases, Judaism must address the question of the relationship of the clone to the various people involved in his or her creation. This is especially important since according to Jewish law, a person's religious identity is established by one's mother. Only if a child's mother is Jewish is the child considered to be Jewish. Thus, it is very important to define the parents of a clone. Additionally, Jewish law places restrictions on the sexual relations a person can have with certain of his or her relatives. It is therefore important to define the relatives of as clone to ensure that no incestual relationships take place accidentally.⁵

According to Jewish law, it appears that the gestational mother is considered to be the legal mother of a child. While motherhood is conferred to the woman in which conception occurred, children who are conceived in a laboratory are considered to be the child of the woman into whom they are later transplanted. Therefore, most Jewish authorities maintain that a child created through SCNT would be considered the child of the gestational mother, not the egg donor.⁵

The question then arises as to the relationship between a woman who donates her nuclear genetic material for cloning (the clonee) and the clone. Given that the mother of a child normally contributes half of the genetic material to the child, it would appear logical that a woman who contributed all of the genetic material also be considered the child's mother. Accordingly, there are certain authorities who maintain that according to Jewish law, if the genetic material to be cloned is taken from a woman's cell, that woman would be the child's mother. Even according to those authorities who maintain that only the gestational mother is the legal mother of the child, the woman donor would be considered a possible mother and any sexual prohibitions that apply between a child and his or her mother's relatives would be applied to the relatives of the donor mother.⁵

Rabbi J. David Bleich mentions that some prominent Jewish authorities, including Rabbi Shlomo Zalman Auerbach, maintain that a child can have more than one mother. These authorities would then hold that both the gestational mother as well as the woman who donates the nuclear genetic material would be considered the mothers of the child. It would also be possible to make a case that the child would have three mothers since the woman who donates the enucleated egg is also considered instrumental in the child's creation.⁵

There is equal uncertainty surrounding the father of the clone. If the donor of the nuclear genetic material is a man, it is reasonable that this male would be considered the father of the child. Just as in determining the mother, if paternity is determined in sexual reproduction by the contribution of half of

the genetic material, it would follow that if a man contributes *all* of the nuclear genetic material, he would be considered the legal father of the clone. However, certain prominent authorities, such as Rabbi Waldenberg, maintain that in the case of human reproductive cloning, there is no legal father. Rather, paternity is only conferred in the case of sexual relations between a man and woman. Most Jewish authorities do not hold by this position and agree that if a male donates the genetic material, he is the father. Only if a female donates the genetic material is there no father of the clone.⁵

In summary, if the genetic material is donated by a male, he is considered by most authorities to be the father of the child and to have fulfilled the commandment of procreation. The mother of the child is less certain; most authorities maintain that the gestational mother is the legal mother while others hold that in a case where the woman donates the genetic material, she is the mother. Yet others hold that a child can have more than one legal mother according to Jewish law and if such is the case, the gestational mother, the genetic donor, and possibly the egg donor would be considered the clone's mother.

Given that the clone and clonee have almost identical genetic material, some question whether the two should be classified as siblings (more precisely, as twins), rather than as parent and child. However, Jewish law defines siblings as

individuals who share one or two parents. Since the clone and clonee have different mothers and different fathers, the two cannot be regarded as siblings according to Jewish law.⁵

Human reproductive cloning is a very sensitive issue and people of different religious groups feel that a government endorsement or ban on the practice limits their religious freedom. However, the current Bush administration has come out against human cloning. In 2002, the President's Council on Bioethics issued a report that supported a ban on human cloning; this ban would not only prohibit the creation of any cloned embryos but also would prohibit the transfer of a cloned embryo into a woman.⁸ However, as science and technology continues to advance and human cloning becomes more of a reality, the issue of human reproductive cloning is likely to be revisited and reevaluated once again.

Works Cited

- [1] "Cloning Human Beings: Report and Recommendations of the National Bioethics Advisory Commission." 23 Nov. 2004. http://bioethics.gov/reports/past_commissions/ nbac cloning.pdf>.
- [2]Lauritzen, Paul, Mackinnon, Barbara, Seidel Jr., George E., Stewart, Nathaniel. "Cloning." <u>Encyclopedia of Bioethics.</u> 3rd Edition. Ed. Stephen G. Post. Vol. 1. USA: Macmillian Reference, 2004.
- [3] "Ethical Implications of Cloning." <u>Today's Science</u>, April 1997. <u>FACTS.com</u>. Facts On File News Services. Hedi Steinberg Library, Stern College for Women, New York, NY.

- [4] McGee, Glenn, Ed. <u>The Human Cloning Debate</u>. California: Berkeley Hills Books, 2002.
- [5] Broyde, Rabbi Michael J. "Cloning People and Jewish Law: A Preliminary Analysis." <u>Journal of Halacha and Contemporary Society</u>. 34 (1997): 27-65.
- [6] Wahrman, Miryam Z. <u>Brave New Judaism: When Science and Scripture Collide.</u> New Hampshire: Brandeis University Press, 2002.
- [7] Loike, John D. and Steinberg, Avram. "Human Cloning and Halakhic Perspectives." <u>Traditions</u>. 32.3 (1998): 31-46.
- [8] "Human Cloning and Human Dignity: An Ethical Inquiry." 30 Jan. 2005. http://www.bioethics.gov/reports/cloningreport/pcbe cloning report.pdf>.

Organ Donation

Rebecca Sinensky

Today, organ donation is a common practice in the United States. When an individual with specific organs that are still healthy organs is on the verge of death, his or her family must make a decision as to whether they want to donate the organs of the sick relative. If the organs are donated, another sick individual who would die without a transplant is given a new chance at life and hope for survival.

Despite the frequency of organ donation today, there is a dire need for more organs. It is currently estimated that while about seventy people receive an organ transplant each day, approximately sixteen people die waiting for a transplant. Thus, close to twenty percent of people on transplant waiting lists die without receiving the transplant necessary to keep them alive. As of January 20, 2005, there were 87,205 people on transplant waiting lists. Given the above statistics, about seventeen thousand of these people will not receive a transplant, the only cure that can grant them the lives they are rapidly losing.

Secular ethics dictates that organ donation is not only permissible, but possibly also morally obligatory. Because the donor will die anyway and according to many standards is considered dead, it appears logical that he or she donate organs while the organs are still viable for transplantation. Most organs are only viable for transplantation for a short time after death. Therefore, it would appear that the right course of action for the relatives of a dying individual on life support would be to disconnect the dying person from life support and quickly harvest the organs to allow for transplantation.

When the ethics of organ transplantation first became an issue, Islam opposed organ donation. However, the Muslim Religious Council changed its stance and now encourages organ donation as long as the donor consents to the procedure in writing. One caveat to the Muslim view is that the donation must happen immediately after the organs are harvested; they cannot be stored in an organ bank for future use.³

The Roman Catholic Church is a strong proponent of organ donation and portrays it as a good deed, an act of charity and brotherly love. Former Pope John Paul II declared:

Those who believe in our Lord Jesus Christ, who gave His life for the salvation of all, should recognize the urgent need for a ready availability of organs for transplants a challenge to their generosity and fraternal love.

Roman Catholic leaders, however, have cautioned that the organs must be taken only after the donor's death and that the donor's wishes must be taken into account and treated with utmost respect.³

Similarly, the Lutheran Church is also a firm supporter of organ donation. In 1984, the Lutheran Church in America (LCA) publicly acknowledged its support of organ donation. The statement said that as organ donation is an act of brotherly love, members of the Lutheran Church should make arrangements accordingl, so that their organs can be harvested. The Church, however, was wary about organ trafficking.³

Many religions echo the Roman Catholic position and agree that while organ donation is permissible, the donor's wishes must be the crucial factor which determines whether his organs will be donated. Followers of the Presbyterian Church, Mormons, Hindus, and Buddhists all concur with this position. While there is nothing in their religious beliefs that should prevent organ transplantation, they respect the right of an individual to make a personal decision about the fate of his or her own body.³

Judaism takes a very interesting stance on organ donation. The main question of whether one can donate organs is related to both respect of the dead and the definition of death in Jewish law. The former sphere of respect of the dead related laws poses several problems to the permissibility of organ donation. *Nivul hamet* is a prohibition that forbids unnecessary mutilation of a dead body. Autopsies, under normal circumstances, are therefore forbidden. Rabbis do permit an

autopsy to be performed under certain circumstances, such as a case in which determining the cause of death may result in saving other lives. Therefore, it can be concluded that the rabbis agree that saving lives, *pikuach nefesh*, overrides the prohibition of *nivul hamet*. *Halanat hamet* is a prohibition that forbids the delay of the burial of the dead. All rabbis agree that *pikuach nefesh*, saving lives, overrides this prohibition as well. *Hana'at hamet* is a prohibition that forbids one from deriving any benefit from a dead body. All rabbis agree that *pikuach nefesh* overrides this prohibition as well. Consequently, since organ transplants save lives, all of these prohibitions can be suspended.⁴

However, it is not as clear that the laws pertaining to the definition of death can be disregarded. One is not permitted to kill one life to save another. Therefore a determination must be made as to whether death occurs only when the heart irreversibly ceases to beat or when there is no irreversible cessation of all brain activity, including the brain stem, even though the heart continues to beat. Harvesting of most organs must be completed while the heart is still beating. If it is determined that death is the cessation of the heartbeat, then most critical organs would not be able to be harvested. But if Jewish law determines that death is the cessation of brain activity, then one would be able to donate such organs.

The Babylonian Talmud, Tractate *Yoma* (85a) rules that if a building collapses on the Sabbath when no work is permitted, and there is a chance of survivors, people can violate the Sabbath and dig for survivors. The question is raised of how far one is allowed to continue to dig to see if the last person is in fact dead. The discussion proceeds by attempting to determine whether a person's breath or heartbeat is the key indicator of life. In the discussion, the Bibilical verse (Genesis 7:22) "kol asher nishmat ruach chaim biapav" (all, in whose nostrils, is the breath of the spirit of life) is quoted to express that the neshama (the soul) is based in the breath. Therefore, it can be concluded that one is only allowed to continue to dig until he reaches the nostrils. This would imply that the indicator of life is respiration.

Rabbi Bachya ben Asher (commonly referred to as Rabbeinu Bachya) states on his commentary to Deuteronomy (6:5) that the heart is the sanctuary of the *neshama* and it is the first thing to be created and the last thing to die. This means that the time of death is determined by the cessation of the heartbeat. Maimonides (2:19) and the *Shulchan Orach* (Code of Jewish Law) (329:4) disagree and believe that the lack of respiration determines death. They derive this from the Talmud that states that one can dig until he reaches the nostrils.⁵

Maimonides (4:5) brings another example to prove that the determination of death is not clear-cut. If a person is actively dying one is supposed to let him die and in certain instances, not artificially prolong life in a state of suffering. The question is raised of how one can be 'dying' because if lack of respiration or a cessation of heartbeat is death then someone is either dead or alive and cannot be in a stage between death and life. How can one be in a quasi state of living? Rabbi Moses Isserlis in his commentary on the *Shulchan Aruch* (330:5) further proves this point. If a woman dies in childbirth one can attempt to save the baby. This is problematic, however, because it is difficult to determine at what moment the mother dies and thus at what moment one can save the baby. If too much time passes then the baby will also die. If respiration is the death indicator then Rabbi Isserlis would not have asked his question because it would be clear when the mother died. Therefore, lack of respiration may not be the indicator of death.

The Babylonian Talmud, Tractate *Ohalot* (1:6) states that a person is not *tameh* (impure) until his soul leaves him. This principle applies to animals as well. When an animal is decapitated, it is dead even though it is still moving; these movements are merely spasmodic and do not stem from the one central source, the brain. Life exists solely in the brain. ⁵

Research has proven, contrary to the conclusion of prior sources, that it is brain activity which serves as the indicator of life and not respiration alone. Thus, when the Talmud states that

one can continue to dig until the nostrils to determine if the victim is alive, it using respiration as a test to determine if there is life but not as the actual determination of life.

Rabbi Moses D. Tendler, a rabbinic authority and bioethicist, maintains that brain death determines death. Therefore, once someone is placed on a respirator and all brain activity has ceased, his organs can be harvested because he is already dead. However, there are rabbis who disagree with Rabbi Tendler and believe that death occurs only upon termination of heart activity and, therefore, organs cannot be donated. Organ donation is a complex issue and therefore, a Jew is advised to consult a rabbi before making such a decision.

WORK CITED

- [1] "Organ Life: Make Organ and Tissue Donation Your Way of Life." 12 Dec. 2004. http://www.organdonor.gov>.
- [2] "The Organ Procurement and Transplantation Network." 29 Dec. 2004. http://www.optn.org>.
- [3] "Tissue Donation: Statements from Various Religions." 5 Dec. 2004. http://www.redcross.org/donate/tissue/relgstmt.html.
- [4] "Halachic Organ Donor Society" 19 Dec. 2004. http://www.hods.org/index.html.
- [5] Fink, Rabbi Reuven. "Halachic Aspects of Organ Transplantation." The Journal of Halacha and Contemporary Society. 5(1983): 45-64.

Artificial Insemination

Rachel Yamnik

Artificial insemination is usually utilized by couples who are having difficulty conceiving children largely but not exclusively because of male infertility. It is a procedure that involves semen being deposited into or near the cervix of a woman's uterus using a syringe. There are two categories within artificial insemination: Artificial insemination by husband (homologous insemination, AIH) and artificial insemination by donor (heterologous insemination, AID). Although this procedure enables otherwise infertile couples the chance of having children, it raises a myriad of ethical issues for Christians, Muslims, and Jews.

According to the Lutheran Church there are few ethical problems when it comes to AIH. However, Lutherans believe that the marriage bond and reproduction are intertwined. Therefore AID is not ethically permitted because this procedure violates the significance of sexual intercourse within marriage and the importance of parenthood. This separation violates the Divine institution of marriage.² Helmut Thielicke, author of *The Ethics of Sex*, also regards AID as ethically unacceptable for similar reasons. He asserts that the problem is presented when the third party (donor) who is introduced into the marriage relationship interferes with the sacral unity of the couple's

relationship. In accordance with these standards, facing the reality of being childless or adoption is preferable to AID, even with the husband's consent.³

Ethicist Joseph Fletcher expresses a dissenting view within the Lutheran Church. He argues that what is important is the personal relationship present in a marriage. Since a donor is not entering into an intimate relationship, AID is permissible. In addition, he says that parenthood is not just a physiological relationship but also a moral relationship with a child. Even though there are dissenting views within Lutheran Church, the main approach to AID is that of contempt.⁴

The Roman Catholic Church similarly has accepted AIH, while its core rejects AID. Pope Pius XII first formulated opposition to heterologous insemination in 1949 both outside and even inside the boundaries of marriage. Regardless of whether the husband agrees to this procedure, the Roman Catholic Church condemns AID for virtually the same reasons as the Lutheran Church.⁵

According to Islam, AIH is permissible as long as it involves only the husband and wife and it takes place within the confines of the marriage. Additionally, masturbation must be avoided when obtaining the semen because it is *haram* (forbidden) in Islam.⁶ AID is unacceptable according to Islamic law. It is not considered adultery, but morally it is viewed as

reprehensible as adultery. This procedure is also punishable but not as severely as adultery. The child that results out of this procedure is considered illegitimate.⁷

Within Judaism, there are many issues regarding artificial insemination, especially when the semen inserted into the woman does not belong to her husband. There is a strong consensus that artificial insemination by the husband is allowed as a last resort for reproduction. In addition, there must be a considerable amount of time that the couple has tried to become pregnant independently. Some rabbis also impose that AIH should not be done during the period of the ritual impurity of a woman. Finally, in order to obtain the sperm of the husband the preferred method is through a condom and all cares should be taken to avoid masturbation. Such unanimity does not exist when a donor contributes the semen. Should this type of conception be viewed as an act of adultery and is the child now viewed as a mamzer (an illegitimate child)?

A particular text in the Babylonian Talmud, Tractate *Chagiga* (14b-15a) sheds light on this weighty query. Ben Zoma (a Talmudic sage) was asked whether a high priest is allowed to marry a pregnant virgin. A priest is not permitted to marry a divorcee, a female offspring of an impermissible marriage of a priest, and a prostitute. The high priest is further restricted and can only marry a virgin (not even a widow). Ben Zoma answered

that this is a rare, yet feasible case, as it is possible for a woman to become pregnant and still remain a virgin as demonstrated in the *Midrashic* legend of Ben Sira. This *Midrash* suggests that Ben Sira was biologically the son of the prophet Jeremiah and his daughter. Jeremiah was in a bath when he was attacked and taken away causing him to ejaculate into the warm waters of the bathtub. Jeremiah's daughter, unaware of what had happened earlier, bathed in her father's bathwater. Her father's semen entered her vagina while she bathed and impregnated her with Ben Sira.

Some rabbinic authorities, including Rabbi Moses Feinstein, are of the opinion that the arrival of sperm into a woman's body in an act other than intercourse, as in the story above, does not constitute adultery. Therefore the child produced by this procedure is not a *mamzer*. Consequently, he believes that artificial insemination using a donor, even if the source of the sperm originated from a non-religious or non-Jewish person, may be permissible according to Jewish law.⁹

However, other rabbis, such as Rabbi Eliezer Waldenberg, holds that artificial insemination using a donor is forbidden according to Jewish law. He claims that one cannot compare the passage in the Talmudic passage regarding the birth of Ben Sira to artificial insemination because that situation is very rare. Furthermore, getting pregnant by semen that was in a

bathtub constitutes no act of insertion in contrast to artificial insemination, which involves the active insertion of the sperm into the woman. Since AID is a virtual act of intercourse, it can be considered questionable adultery and the child produced is a questionable mamzer. In a sense, a questionable mamzer is worse than a bona-fide mamzer, because while a mamzer is allowed to marry a convert or another mamzer, a questionable mamzer is not permitted to marry anyone. Rabbi Waldenberg also opposed this procedure for fear of its negative impact on society. He was concerned that heterologous insemination will not only be utilized by married women but also by unmarried woman who now can circumvent marriage and have children. This would tremendously weaken the institution of marriage. Therefore, he concluded that not only is AID forbidden, but it is an act of debasement as well.

However, if a person is of the opinion that AID is permissible, the integral question of paternity must be answered. Determining the legal status of the father is important for legal support and inheritance. In addition, if the father (donor) is unknown, there is a problem for the child's future marriage. There could be a potential for incest if such a child marries an incestual relative as defined by Jewish law.

According to Jewish law, the concept of severing a tie with a biological father is only applied to cases of conversion

and intermarriage. When someone converts to Judaism, he or she is considered reborn and therefore all ties to his biological parents are severed. In the case of intermarriage, Jewish law does not recognize the paternity of a man over his child born to another religion. Thus, if a Jewish man marries a non-Jewish woman the law does not recognize his status as the father of the child and therefore the child is considered a non-Jew. This is so because he is considered to have been *mafkir zerah*, given up his sperm. Conversely, if a Jewish woman marries a non-Jewish man, the law does not recognize the paternal right of the non-Jewish father and the child is considered Jewish. The same is true with the sperm of a donor. When the donor is donating his sperm he is doing it with the intention of giving it up.¹¹

The next problem that arises is the marriage options of a child conceived by AID. Rabbi Waldenberg and others, who are opposed to AID, declare that this child has no options—he may not marry. However, adherers to Rabbi Feinstein's opinion believe that AID is permissible and the child is treated as a normal Jew for all intents and purposes, including marriage. However, to avoid incest it is necessary to use a non-Jewish donor because then other children of the donor are not considered related to this child even if they were to convert. The identity of the donor's religion is determined by the religion of the majority of the men in the community that the child is

conceived in. If most of the males in that community are not Jewish then it is presumed that the sperm used from the sperm bank in that community is from a non-Jewish donor.¹²

In conclusion, the common literature out today and the dominant opinion among Jewish authorities seems to be in concurrence with Rabbi Waldenberg in believing that AID is impermissible according to biblical and rabbinic law. Two events that occurred bolstered this position. By the late 1960s and early 1970's, AID was made available to married as well as to unmarried woman. In addition, sperm banks were now allowing the option of knowing who the donor of the sperm was and therefore there was no longer a severance between the mother and the donor father. As a result Rabbi Feinstein's interpretation of the donor's sperm as *mafkir zerah* is no longer applicable. Even though the dominant opinion is that AID is not allowed, a Jew must consult his or her rabbi if ever faced with this quandary.

Works Cited

- [1] Rosner, Fred and Bleich, David J. <u>Jewish Bioethics</u>. New Jersey: KTAV Publishing House, 2000.
- [2]Ramsey, Paul. <u>Fabricated Man: The Ethics of Genetic Control.</u> New Haven and London: Yale University Press, 1970.
- [3] Thielicke, Helmut. The Ethics of Sex. Trans. John W Doberstein. New York: Harper & Row, 1964.

- [4] Fletcher, Joseph. Morals and Medicine. New Jersey: Princeton University Press, 1954.
- [5] Schneider, Edward D. "Procreation Ethics Series: Artificial Insemination." Journal of Lutheran Ethics. Volume 1 Issue 1. 5 Jan 2005. www.elca.org/jle>.
- [6] Ebrahim, Abul Fadl Mohsin. "Biotechnical Parenting." 5 Jan 2005. http://muslim-canada.org/biotechnical.htm>.
- [7]"Artificial Insemination." 5 Jan 2005. http://islamet.com/bioethics/obstet/artifi.html
- [8] Jakobovitz, Immanuel. <u>Jewish Medical Ethics: A Comparative and Historical Study of the Jewish Religious Attitude to Medicine and its Practice.</u> New York: Block Publishing Company, 1997.
- [9] Broyde, Michael J. "The Establishment of Maternity and Paternity in Jewish and American Law." 28 June 2005. http://www.ilaw.com/Articles/maternity2.html>.
- [10] Steinmetz, Chaim. "Single Motherhood and Artificial Insemination." 5 Jan 2005. http://www.myjewishlearning.com/ideas_belief/bioethics/Bioethics_Fertility_TO/Bioethics_AI/Bioethics_SingelAI.htm.
- [11]Weiner, Rebecca. "Who Is A Jew?" 5 Jan 2005. http://www.jewishvirtuallibrary.org/jsource/Judasim/whojew1.html.
- [12] Finklestein, Baruch, and Michal Finklestein. <u>The Jewish</u>
 <u>Couple Third Guide To Fertility Key.</u> Jerusalem: Feldheim Publishers, 2005.
- [13] Peck, Peggy. "InsemiNation." 5 Jan 05. http://www.medicinenet.com/script/main/art.asp?articlekey=50877>.

Do Not Resuscitate in Slow Motion: A Jewish Perspective

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One of the most tense and intense clinical experiences in medicine is the participation in cardiopulmonary resuscitation (CPR). While the primary goal is to restore adequate circulatory and respiratory function, maintaining proper dignity of the patient is another extremely worthy consideration. One specific form of CPR which is not formally taught in medical schools or described in textbooks is referred to as a 'slow code'. Actually, within the medical community this procedure bears a number of terms of endearment, such as - light blue, Hollywood codes, partial codes, and show codes. The 'slow code', as referred to in this text, is designed to go through the motions of resuscitation but without the normal aggressiveness of routine CPR. It is performed with the hope and intent of failing to restore a heartbeat and/or spontaneous respiration. For example, during chest compressions, one normally attempts to compress the sternum to a depth of 1.5-2.0 inches. In a slow code, the depth of compression might be much shallower than that. Certain drugs might not be utilized that otherwise usually are. The duration of the entire code may be shortened, and the overall enthusiasm, attentiveness, and urgency on the part of the staff diminished. The question is: why would hospital staff who are trained to help

patients and who dedicate their lives in doing so, perform halfhearted resuscitative procedures?

CPR was developed in 1960 at the Johns Hopkins Medical Center. As a new therapy, it was assumed to be appropriate for all types of patients, and was administered to anyone who experienced cardiac arrest. Based on observations overtime, the medical community developed the perspective that CPR was not beneficial to all patients, and was even harmful to some. In certain patients, it is felt, successful CPR will not improve the overall condition of the patient. Specifically, the quality of life of patients who, for example, are in the end stages of terminal illness or suffer from advanced dementia, will not be enhanced.2 The basic argument thus being, that such a procedure is qualitatively futile by not having the potential of improving the patient's quality of life. In fact, it is the belief of many, that CPR in some patients prolongs their agony and may actually increase the level of discomfort, thus resulting in a decrease in quality of life. Quality of life is a fundamental principle in bioethics, but is rather difficult to precisely define and evaluate.

According to the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, "quality of life is an ethically essential concept that focuses on the good of the individual, what kind of life is possible given the person's condition, and whether that condition

will allow the individual to have a life that he or she views as worth living."³

Some factors that may be relevant to quality of life determinations from an objective perspective include: physical mobility, freedom from pain and distress, the capacity to perform the activities of daily life and to engage in social interactions. Patients who authorize a Do-Not-Resuscitate order (DNR) exercise their legal right of self-determination and autonomy. In many clinical cases, hospital staff are faced, from their perspective, with a dilemma when such an order was not officially authorized by the patient, family, or health care proxy. In these cases, a segment of the staff may strongly feel that the patient would be ill served with resuscitative efforts. They maintain, furthermore, that they are not required to provide treatments that are futile, and as such, inappropriate. On the other hand, however, without a valid DNR, they are generally obliged to provide CPR and have a responsibility to adhere to the patients implicit or explicit wishes. Hence, the unofficial development of the 'slow code' to attempt to satisfy both sides of the dilemma. The slow code, it is argued, respects the wishes of the patient and family and avoids subjecting the patient to the detrimental consequences of what is believed to be an inappropriate intervention. Slow codes are not formally ordered by physicians. They are not discussed with the patient or family

in advance. They are simply implemented by unofficial internal discussions among staff who sincerely believe that this is the best clinical choice given all the considerations. Such decisions are clearly laden with serious ethical implications. For example, does the slow code respect patient autonomy and his/her right to make medical decisions or is it actually an act of disregard for patient autonomy, and designed to placate the family and circumvent legal implications? Should the performance of a procedure (in this case CPR) which is deemed medically futile be left to the sole discretion of medical staff, and can medical staff be obligated to provide care they feel is unwarranted and possibly harmful? If medical futility based on quality of life determinations are truly within the decision making domain of medical staff, does the staff have the right to substitute a meaningless and physiologically futile procedure in its stead. Two specific ethical issues regarding slow codes which this writer would like to address are: deception and dignity. The perspective of both general bioethics principles and of halacha (Jewish law) will be considered.

The Ethics Manual for the Ethics and Human Rights Committee of the American College of Physicians states:

Intervention in the case of a cardiopulmonary arrest is inappropriate for some patients, particularly those with terminal irreversible illness whose death is expected and imminent. Because the onset of cardiopulmonary arrest does not permit deliberative decision making, decisions about resuscitation must be made in advance... Because it is deceptive, physicians or nurses should not perform half-hearted resuscitation efforts ("slow codes").⁴

Dr. Gail Gazelle correctly points out that, "No clinical intervention performed in a secretive manner will be one that enhances a patient's right to self-determination."

The above point of view seems straightforward and logical. Deceiving a patient is inherently unethical, and is in direct opposition to fundamental principles of patient self-determination and informed consent. It is, therefore, most interesting to note the following response to Dr. Gazelle's article.

The slow code should not be seen as an attempt to cheat the patient, or more frequently his or her family, but rather as a way of allowing the family to accept that the outcome of death was inevitable, even though aggressive measures were used....the slow code can be seen as a ritualistic comforting hand on the shoulder of a grieving family member.....".

While the notion of comforting a family and facilitating their acceptance of the death of a loved one can be very healthy and well placed, other more direct and compassionate methods than

one that misleads and ignores direct communication should be utilized. 6

Deception in Jewish law is considered a serious offense. According to the Babylonian Talmud, Tractate Chulin (94a) it is forbidden to deceive any human being, and such deception (referred to as g'neivat da'at-stealing one's knowledge) constitutes a violation of the biblical command not to steal. The prohibition is defined as giving the impression that one is doing something beneficial specifically on behalf of another person, when in reality one is not (Shulchan Arukh, Code of Jewish Law, Choshen Mishpat, 228:6). The misimpression can be conveyed by speech or action (Maimonides, Mishneh Torah, Laws of Sales, 18:1). Consequently, the performance of a slow code may very well be a violation of deception according to Jewish law as the impression is clearly being conveyed that something beneficial is being done for the patient, when in reality the procedure is of little or no benefit. While the patient is unaware of what is presently transpiring, he/she may have previously been under the impression that a full effort of CPR would be performed at some point in the future if needed. In addition, family members who assume routine resuscitative efforts will be, or were, performed are implicitely or explicitly being misled. Dr. Avraham Steinberg states unequivocally, "Sometimes a partial CPR ("slow code") is performed without the use of medications or a respirator. Such a partial CPR is unethical since its only purpose is to show the family that CPR was attempted or to avoid a lawsuit."

A second factor that should serve as an additional motivation against the performance of slow codes is the dignity of the patient. Judaism places an extremely high value on proper respect of the deceased. A deceased individual is considered intrinsically sanctified, comparable to a Torah scroll. As such, Rabbi Yehiel Mikhel Tukechinksy explains in his book, Gesher H'Haim (Bridge of Life), that any procedure performed on the deceased which disrupts the body structure is prohibited. As Dr. Gazelle indicates, slow codes are not necessarily benign procedures, and may be invasive and traumatic. 1 It is this writer's impression, for example, that with certain patients even shallow chest compressions may fracture, or crack, the sternum. If the person experienced a cardiopulmonary arrest, and is not resuscitated, then that person is considered dead from the moment of arrest-not from the time the slow code is called off. Even without alteration of the physical body of the person, CPR without any realistic goal of resuscitation is in disregard for and disrespect to the very same human dignity that the staff may be trying to preserve.

Based on the above reasons, this writer feels that Judaism cannot condone the slow code. In spite of generally well

intentioned medical staff that sincerely care about the welfare of the patient, the approach of the slow code is not the answer to a difficult dilemma. This article is not designed to resolve that dilemma, but to sensitize the reader to the need of the comprehensive care of the patient-including the actual moment of death. Appropriate care and concern must continue at all times.

Works Cited

- Gazelle, Gail. "The Slow Code-Should Anyone Rush to its Defense?" <u>New England Journal of Medicine</u>, 338:467-469, 1998.
- [2] Burns, Jeffrey P. "DNR', <u>Encyclopedia of Bioethics.</u> 3rd Edition. Ed. Stephen G. Post. Vol. 1. USA: Macmillian Reference, 2004.
- [3] Beauchamp, Tom L. and Childress, James F. <u>Principles of Biomedical Ethics</u>, 5th ed. New York, 2001.
- [4] Snyder, L. and Leffler, C. Ethics Manual:5th ed. Annals of Internal Medicine, 142:7, 2005.
- [5] Segal, Eran. "The Slow Code," <u>New England Journal of Medicine</u>, 338:1921-1923, 1998.
- [6] Greenfield, L. John. "The Slow Code," <u>New England Journal of Medicine</u>, 338:1921-1923, 1998.
- [7] "G'neivat Da'at." Encyclopedia Talmudit. Ed. S.J. Zevin. Vol. 6. Jerusalam: 1965.
- [8] Steinberg, Avraham. <u>Encyclopedia of Jewish Medical Ethics</u>. Vol. 3. Jerusalem, Israel: Feldheim, 2003. Translated by Fred Rosner.