



Implementing Presumed Consent for Organ Donation in Israel: Public, Religious and Ethical Issues

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Some of the most important advances in medicine over the last 30 years have been in the field of organ transplantation. Huge efforts and vast resources are being invested to improve surgical methods and histocompatibility examinations and to combat rejection of the implants. As a result, the success rate of transplantations – represented by lives saved and improved quality of life after the procedure – has risen [1]. Yet, despite medical progress, the supply of organs (the main source of which is human cadavers) does not meet the demand [1]. This is reflected by the constantly growing number of patients on waiting lists for transplantations. In Israel, according to data from the National Center for Transplantations (updated January 2007), more than 800 people are awaiting organ transplantations while the number of transplantations performed during the past year was less than 300 [3]. In the United States the number of people awaiting organ transplantation exceeds the annual supply of organs by a factor of 10 [2]. For patients in need of an organ the shortage is a matter of life and death; for medical practitioners whose patients await an organ it is a source of profound professional frustration; for health systems struggling with the problem of limited resources this shortage is considered a financial burden [1,4]. Over the years, numerous proposals to increase the organ supply have been made – by medical practitioners, administrators and ethicists.

Current Israeli policy regarding cadaver organ donation

The constant organ shortage has raised a debate on the harvesting policy of cadaver organs. In many countries, such as the U.S, Great Britain, Canada and Australia, procurement of an organ requires explicit consent of the donor prior to his or her death [5]. This policy, known as the “expressed consent” or “opting-in” system, is also customary in Israel [3]. According to this policy, if a person wishes to donate his organs upon death, he must

specify as such by signing a donor card. Ethically, this policy relies on the assumption that “express or explicit consent is always prospective informed consent” [6]. In other words, a person who has registered as a donor is fully informed regarding organ donation and all its aspects and is therefore allowed to give his or her consent to this procedure. This clear, active consent is derived from the full autonomy a person has over his body [7]. However, the fact that a person has “opted in” is not sufficient for organ procurement to take place. The agreement of the next of kin is also needed. Refusal of the deceased person’s family will thus prevent the donation, even if the person has signed a donor card during his or her life [2,7].

According to the Israeli National Center for Transplantation, only 4% of the Israeli population has signed an organ donor card (known as an “Adi” card). As for the families, less than 50% of them are willing to donate their relatives’ organs [3]. These refusal rates of families are similar to the data reported in the U.S. [5].

In contrast to countries in which the expressed consent policy is anchored in legislation, in Israel the situation is completely different. The law relating to the organ donation issue is the Law of Anatomy and Pathology. Section 6 of that law states that a doctor is allowed to operate on a body and use any part of it in order to save life. This is subject to one condition: namely, three doctors qualified for this task must sign a document declaring that the operation is indeed being performed for the purpose of saving a life. The law states that, by definition, cornea, kidney and skin transplantations are also considered life-saving procedures. The law does not require the approval of either the donor or the family. However, there is the obligation to notify the family before the operation takes place [8]. Clearly, not only does the law ignore the question of expressed consent, it also leaves the individual with no option of objecting to the harvesting of his or her organs upon death.

An attempt to implement the above law was made at the Soroka Medical Center in Beer Sheva in 1993, when the organs of a deceased individual were taken before his family’s permission had been given. This event led to a major crisis in the delicate

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relationship between doctors and the public; it also caused a sharp decrease in the rate of donor card signing that year [9]. For that reason, organ procurement in Israel *de facto* is conducted according to the expressed consent policy.

What is presumed consent?

One of the strategies conceived to increase the number of available organs is the presumed consent doctrine. This policy is based on the assumption that “everyone, as a matter of course, would agree to have her or his organs harvested upon death” [1]. Hence, a qualified doctor or a clerk can determine that the organs of a person who died in a hospital can be taken for the purpose of transplantation or research [7]. Despite the above, an option is granted to any person to object to the removal of his/her organs, whereby the individual’s name is added to a national “opt-out” registry. In this manner, a well-documented pool of donor-objectors is created and maintained by the responsible authority [2,7]. Procurement coordinators are obliged to check this registry when facing a potential deceased donor in the hospital [2]. A person who had not opted out in advance is considered upon death as a donor, and for that reason the doctor has no obligation to receive family authorization for the procurement process [1,10].

The presumed consent policy has proved to be an effective manner of organ procurement

Implementing the presumed consent doctrine in different countries

The policy of presumed consent can be implemented either stringently or leniently. In the former (the stringent manner), the doctor is granted two discretionary options: the first is the power to provide the consent for organ donation of every deceased person who has not “opted-out” formally in advance. The second is the ability to procure the organs despite an objection of the donor’s next of kin. In the lenient manner, in the absence of any documentation the default option would still be to procure the deceased’s organs (this is in complete contradiction to informed consent). Nevertheless, in contradiction to the stringent interpretation, here the donor’s family does have the right to participate in the process and to prevent the donation [2,7].

Currently, the European countries that have adopted the Presumed Consent policy are Austria, Belgium, Finland, France, Italy, Norway, Spain, Sweden and Switzerland. Countries that act according to the Expressed Consent policy are Australia, Canada, Denmark, Germany, Ireland, Israel, The Netherlands, Great Britain and the U.S. Among those countries that have embraced the Presumed Consent policy, Austria is the only one in which the policy is implemented in its stringent sense; in the other

countries mentioned above the lenient interpretation was applied [2].

In recent years, attempts have been made to evaluate the efficiency of the presumed consent policy in organ procurement. In general, it was found that cadaveric organ donation rates were 25–30% higher in presumed consent countries [5]. In a comparative study conducted among six European countries in 1990, organ transplantation rates were significantly higher in Belgium, France and Austria which operate under the opting-out system, as compared to Great Britain, Germany and The Netherlands that operate under a system of opting-in. In Belgium for instance, an increase of 140% in the number of available organs was reported that year, following its transition from expressed to presumed consent [11]. Another example of the influence of presumed consent is seen in two transplantation centers in Belgium – one in Leuven and the other in Antwerp. Leuven shifted to presumed consent as soon as the law was passed in Belgium, and within 3 years the donation rates in that center climbed from 15 to 40 donors per million people. In contrast, Antwerp, which did not change its procuring policy, showed no change in donation rates [12]. More examples can be found in Spain and Italy [2,4,7].

There are several ways in which presumed consent laws can generate higher donation rates. The first, and most obvious, is that these laws allow for the next of kin’s wishes to be ignored during the procurement process. However, this explanation can only be true for Austria, where the policy is implemented in the stringent sense. This is clearly not the case for other countries. Another way in which presumed consent laws may be influential is by functioning as a “signaling device to the population at large and next of kin in particular” [2]. The existence of a presumed consent law shifts the question that the donors and their families face. Instead of asking families if they have a reason to believe that the deceased would have agreed to donate, they are asked whether they think the deceased would have *objected* to the donation. Moreover, with regard to public opinion, presumed consent laws and changing the default from “No” to “Yes” actually reflect a social norm concerning the expected course of action, although the right to refuse the donation still exists [2]. This last assumption regarding the social norm has been proven correct; in contrast to the U.S and Great Britain where about 40–50% of the families refuse the donation of their beloved ones’ organs, in France the rate of family refusal is about 30% and in Spain as low as 20% [5,13].

An international survey of transplantation professionals showed that 75% of the responders supported presumed consent legislation and 39% acknowledged this kind of legislation as the most efficient means of increasing organ donation rates, thus placing it first among all other methods proposed in the survey [5].

Ethical issues embedded in presumed consent

The Presumed Consent doctrine, efficient as it is in increasing organ procurement, is the subject of major public and ethical debates. The core argument of the opponents is that presumed consent would constitute a brutal violation of the

right of autonomy over one's body. When discussing the ethical validity of presumed consent, Kluge [1] writes in her article: "if logic of the presumed consent option were to be applied consistently, it would mean that someone who did not want to be interfered with physically, whether that be sexually or in any other fashion, would have to inform potential trespassers to the individual's person of that fact. That would reverse the polarity of the right to inviolability. The individual's body would become public property unless a right of dominion was claimed by the individual person." Nowadays, since the respect for the individual's autonomy is a cardinal guideline in medical ethics and treatment, it is morally forbidden either to treat or to invade a person's body in a way he or she would not wish it to be treated. This is a necessary consequence of the informed consent principle [14]. The opting-out system, which presumes consent on the basis of the individual's silence and lack of objection to the organ donation, stands in complete contradiction to the above mentioned principle of informed consent. In an article opposing presumed consent, Wright [15] claims that it may bring about a great reduction in donation rates in countries where autonomy is highly prized and that even a strategy using financial incentives is preferable to this. Silence, or the fact that there is no positive indication of the deceased's wish to donate his/her organs, can merely be a sign of ambivalence and confusion. Interpreting this as willingness to donate has been described as "presumptuous and disrespectful" [16,17].

Another question that evokes tremendous controversy is that of "body utility." Objectors to presumed consent protest the notion that dead people have no use for their organs. They argue that this cannot be true since the person is perceived according to modern ways of thinking as an embodied being whose body is an integral part of his identity. What happens to the body after the person dies cannot be separated from the person's wishes [1].

A fundamental concern expressed by the objectors relates to public education and knowledge regarding organ donation. In light of the pressing need for organs, they claim, under presumed consent legislation there might be a hidden motive in avoiding discussion of the question of organ donation with patients and their families, out of fear that they might object. This refraining from informing and educating patients about the procedure and significance of organ donation may result in public mistrust of health systems. In the long run, this approach may cause a decrease in organ retrieval and the number of available organs for transplantation [18].

Opponents of the presumed consent policy strongly object to the claim that it might help create greater communal bonding and solidarity. They insist that only through active and voluntary compliance to donate will true communal attachments be fostered [19].

We shall now turn to the arguments raised by the proponents of the presumed consent policy. A common and frequently made claim is that many people who support organ donation find it hard to envision their own deaths. For that reason they have difficulties contemplating the donation of their organs [20].

Surveys conducted in the U.S and Great Britain in the 1990s show that 70% of the people are willing to donate their organs – an astounding revelation which proves that the scarce resource of organs is not optimally utilized [14,16]. Based on these polls, it is clear that implementation of the presumed consent policy would fulfill the wishes of at least 70% of the public, and even more as long as a well-publicized opting-out option exists. This key argument of the proponents is also referred to as the "Fewer Mistakes Claim." It means that an opting-out system would constitute an increase in the number of deceased whose wishes are being respected, over the current system. The "Fewer Mistakes Claim" can be considered as a derivative of inheritance laws. For instance, in the absence of a will, we generally assume that the person would have wanted to leave his or her possessions to the immediate family. We assume that since this is the choice of most people with regard to assets, this is the policy that leads to the smallest number of mistakes. The decision whether to remove organs from a deceased person parallels the decision of how to handle other properties of the deceased after his or her death [14].

Public awareness to the issue of organ donation should be increased through the media

A much-discussed issue among those who support presumed consent is autonomy. In theory, a policy of expressed consent defends the autonomy of individuals by requiring those who wish to become donors to sign a donor card. However, this opting-in policy actually violates the individual's autonomy as procurement coordinators seek permission from the deceased's next of kin. This raises the question of whose rights and autonomy should we respect – the donor's or the family's? The procedure of asking for family permission is not only time consuming (which may result in damage to the donor's organs), it may also result in the deceased's wishes being overlooked. Under such a system there is hardly any incentive for a person to register as a donor, knowing that his or her family's wishes would take preference. A policy of presumed consent can therefore protect the wishes of both those who want to become donors and those who refuse to donate their organs [13,21]. This would also remove a great burden from the families – the burden of deciding the fate of their beloved one's organs, an almost impossible decision to make, particularly at a time of sorrow and grief [13,21,22].

The position of *Halakhah* (Jewish law)

Organ donation is an extremely controversial subject in *Halakhah*, regardless of the consent argument discussed above. Studies suggest that almost 45% of Israeli families who refuse to donate their beloved one's organs attribute this refusal to the claim that it is forbidden to harvest a dead person's organs according

to Halakhah [23]. Briefly, there are three major approaches in Halakhah concerning the question of determining death. The first (the more conservative) relates to the pulse as the ultimate measurement of determining life. As long as there is a pulse the person is still alive, even if the brain has ceased functioning. The second approach claims that brain death can be accepted as the criterion for determining death. Yet, supporters of this approach believe that in Israel there are currently no ways to determine complete brain dysfunction without breaking the Jewish prohibition against carrying a dying person. Finally, the third approach accepts brain death as the ultimate determinant of death, since the breathing center in the brainstem no longer functions and the person cannot breathe on his own. According to this stance, the tests that doctors perform to determine clinical death are valid. This last stance was adopted by the Rabbinat of Israel in 1982; therefore, according to Halakha, organ transplantation is permissible [23,24].

Jewish law refers to organ donation as a moral obligation and its stance is similar to the opting-out policy

Let us now return to the foremost question: what does Halakhah say with regard to presumed consent? In religious and Halakhah databases there is no mention of or reference to the policy of presumed consent. However, there is a very clear acknowledgment of organ donation as a moral obligation. In his article "Donating organs of the dead – consent of the deceased and the position of the family," Rabbi Shaul Israeli (former member of the Israeli Rabbinat) states that if a person consults his rabbi in the matter of whether or not to allow procurement of his organs for transplantation after his death, he should be encouraged to do so since it is a moral obligation (a *mitzva* in Jewish terms). This only refers to cases in which the transplantation is "life saving" [25]. In another article, "Organ donation for life saving," Rabbi Shlomo Goren (former Chief Rabbi of Israel) refers to cadaver kidney and cornea donation. He claims that provided these organs are donated in order to be transplanted to people who need them (and not for creating "an organ bank"), not only is it allowed it is a *mitzva*, since it is life saving [26].

Despite the above, there is a difference between performing a voluntary *mitzva* of organ donation and procuring the organs of every person who had not stated otherwise. What does Halakhah say about that? In his article, Rabbi Israeli makes several salient comments. The first is that once a person has agreed to donate his organs, his family has no right to refuse the donation. The deceased's agreement does not have to be explicit, that is, signing a donor card. It is enough that the family has no reason to believe that he would object to the donation. If the deceased had expressed his objection to his family, then his wishes would be respected and his organs would not be removed [25]. It appears that the position of Halakhah is in fact quite similar to the

opting-out policy: in the absence of any explicit direction given by the deceased, the organs should be removed. The objection of the family has no validity. In the same article, Rabbi Israeli relates to a completely different aspect of organ donation – the signing of a donor card. He asserts that the mere dealing with the subject of accidents and sudden death may bring a disaster upon an individual. For that reason, one should refrain from signing a donor card [25]. Presumed consent thus provides the solution to another aspect of organ donation that is considered problematic with regard to Halakhah – it averts the need of actually signing a donor card as a means of stating one's wish to become a donor. In conclusion, with regard to Jewish Law, presumed consent might even be preferable to the current system of expressed consent.

Is Israel heading towards the presumed consent policy?

In January 2007, a new law on organ retrieval was proposed in the Israeli Knesset. According to this proposal, every deceased person over the age of 18 would be considered a donor unless he or she had signed a special objection form. Family refusal would still be accepted; no organs would be removed from donors whose families expressed their objection. In other words, the intention is to apply the presumed consent policy in its lenient sense. Today this suggested law is still a subject of debate in the Knesset and continues to make headlines in the newspapers because of the huge organ shortage in Israel.

Conclusions

Examining the literature and the data from different countries, we have come to realize that one of the most crucial factors for this kind of policy to succeed is how it is captured in the public eye. A great concern for health systems and doctors in presumed consent countries is that they not be seen as "organ vultures" and that they maintain the public's trust. To avoid misinterpretation, public education and media coverage would be needed on a large scale. The nature of the media coverage for presumed consent could determine how the public responds. Campaigns should be undertaken to raise awareness about the organ shortage, the medical criteria for death, and the stance of different religions. Still, extensive research is needed to find the best ways to educate the public about this organ donation policy.

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