

Medicine and Society

Can presumed consent overcome organ shortage in India: Learning from the Belgian experience

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INTRODUCTION

The past quarter century has witnessed rapid advancement in the field of transplantation medicine. Various methods have been used that facilitate organ preservation, decrease organ rejection, improve organ matching, and, in general, augment the success rates of transplantation. Using the best of transplantation techniques, physicians and surgeons are trying both to overcome organ shortage and improve graft outcomes. To this end, many organ recipients are put on more effective immunosuppressant medication. Steroids, which have long been responsible for complications, are used less frequently today. This makes transplant surgery relatively safe. Minimally invasive techniques, such as laparoscopic donor nephrectomy, are used, swap transplants are encouraged and extended donor criteria are used more often now than ever before. Counselling is now an essential part of any successful transplantation programme and it is hoped that this will increase not only the quality, but also the quantity of organs available for transplantation. Despite all these efforts, waiting lists keep growing. Futuristic solutions that are looked forward to include the availability of hybrid organs^{1,2} that would diminish the risk of post-transplant organ rejection, as well as 3D organ printing.³ The large-scale application of such technologies, however, is still in the realm of science fiction.

Many patients die waiting for a transplant because of organ shortage. Behind these shortages lie stories of loss of life that cause immense grief to families and friends. Some countries have introduced a system of presumed consent (opt out) in an attempt to decrease the shortage of organs. They assume that every citizen who does not opt out agrees to deceased donor organ donation.⁴ Belgium introduced the system of presumed consent in 1986.

In India, the introduction of a deceased organ donation programme was initiated with the Transplantation of Human Organs Act (THOA) in 1994. Yet, 18 years after the law was passed, deceased organ transplantation is still in its infancy.⁵ Meanwhile, only a minuscule number of patients who have end-stage renal or liver disease have been able to get a transplant. The rising incidence of diabetes and hypertension in India is likely to further increase the organ failure rate and the demand for organs. Given this situation, the country needs to promote the deceased organ donation programme, as well as to consider other means of increasing the donor pool. An option that has been discussed among policy-makers and the medical community is the system of presumed consent.^{5,6}

Our close association with counsellors of the Mohan Foundation in Chennai and Hyderabad, which works towards deceased organ donation, and our knowledge of the implementation of presumed consent in Belgium allow us to reflect on whether such a model could be feasible in India. In response to those who advocate the implementation of a policy of presumed consent, we ask whether 'transplanting' the policy from one cultural context to another would work. Indeed, this year Belgium witnessed a major turnaround in public opinion regarding organ transplantation regulations and has reconsidered the option of presumed consent, looking at it more critically.⁷ Examining another country's experience with presumed consent would be a good starting point to understand the pros and cons of the policy and discuss its potential impact on healthcare in India. We also highlight areas of concern that are likely to play a role in the implementation of such a policy, given the socioeconomic and political context of the country.

INDIA AND BELGIUM: A COMPARISON OF TRANSPLANTATION POLICY

In India, the THOA was an attempt put a stop to the sale of organs. The policy-makers followed an economic rationale—reduce the financial gains from illegal sales by meeting the demand for organs.⁸ It was hoped that a national programme that promotes harvesting of healthy organs from brain-dead patients could be put in place using the opting-in system. This would require an explicit consent from either the patient, who may be carrying a donor card or might have asserted a will during his or her lifetime, or the patient's family so that organs could be retrieved after brain death was diagnosed. Some proponents of presumed consent have argued that it would be a more suitable way to address the shortage of organs in India.⁶ The argument is based on the 'widely spread premise' that a system of presumed consent leads to the retrieval of a higher number of organs. The proponents also argue that to bridge the gap between the need for and the supply of organs, an organ donation law based on presumed consent would be justified as being in the interest of society.⁶ Such a law could bypass the bureaucratic roadblocks that obstruct physicians from legally acting on someone's wish to be an organ donor. The increase in organ procurement that would result from such a law would also fortify the efforts to counter the black market in organs.⁶

Yet, as Coppen and others found, against all assumptions, the implementation of presumed consent offers no guarantee of achieving higher rates of organ donation.⁹ Most previous studies have pointed out that, in fact, it does not.¹⁰ This is possibly because even when presumed consent is in place, family consent is often sought. The mortality rate would also be a crucial factor in determining the rate of organ retrieval.⁹ Even if presumed consent would alleviate the shortage of organs, research would be needed

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to better estimate how societies respond to legislative changes of this nature¹⁰ as there may be other factors that make the implementation of presumed consent favourable or unfavourable in a particular sociocultural setting. However, Abadie and Gay argue that once the other determinants of organ donation are accounted for, cadaveric donation rates are 25%–30% higher on an average in countries that have implemented presumed consent.¹⁰ They suggest that though presumed consent laws may alleviate organ shortages, contextual factors need to be taken into account while estimating whether this actually happens. Among the countries where presumed consent is in force are Austria, Bulgaria, Croatia, Cyprus, Czech Republic, Estonia, Finland, France, Denmark, Singapore, Greece, Hungary, Israel, Italy, Latvia, Luxemburg, Norway, Turkey, Poland, Portugal, Slovak Republic, Slovenia, Spain and Sweden.^{6,10} Along with Austria and Spain, Belgium is often stated to be a ‘success story’ in presumed consent.⁶ It would be interesting to take a closer look at the Belgian case for some clarifications.

In Belgium, those who do not explicitly withdraw consent while alive automatically become organ donors at the moment of their death.⁴ The main difference between the opting-in and opting-out systems is that the ‘default’ position is reversed. Opting-out systems change the leverage point for those people who follow the ‘path of least resistance’ or do not know what to decide. It is often said that a system of presumed consent releases a patient’s family from the burden of decision-making at a difficult time. They may be content with the decision having been taken out of their hands—the State has decided for them. One could refute Kaushik’s contention that presumed consent would violate autonomy⁶ by saying that there is the possibility of opting out. In fact, in Singapore, where presumed consent has been in effect since 1987, upon reaching the age of maturity, all residents receive a letter that informs them of this law, so as to facilitate their involvement and increase their awareness of the subject.^{11,12} The case of Singapore shows that in order to fully respect the principle of autonomy in systems of presumed consent, priority should be given to informing all citizens about the law and how they can opt out if they so wish. Yet, while it is argued that opting-out systems offer a way to overcome bureaucratic failures to retrieve information, we believe that opting-in systems also have this advantage. The danger in the case of opting-in systems lies in the failure to transmit and make known people’s choice to donate, rather than their unwillingness. Here, too, written directives may not be available in the brief period when decisions on the use of organs need to be made. The State needs to protect citizens by providing a means to register an objection and making it available at the time when it is required—this is essential for the success of any policy.⁶ It also depends on the trust that the civil society has in the government and the medical establishment, a factor that is often neglected in such discussions.

There are two kinds of opting-out systems: those that only take into account the will of the deceased, if it was registered before his death, and those that also take into account the possible refusal of the relatives of the deceased.⁶ In Belgium, for example, where presumed consent exists, relatives may take the initiative to refuse organ donation. Their power to object does not imply any legal obligation, however, as their consent is not required.⁴ The choice that was made in Belgium is based on the idea of compromise, since it was thought that any transplantation would inevitably require a negotiation between the interests of different people and groups of stakeholders: the donor, donor’s family, potential recipient and her/his family and the medical profession.⁴ This is

where Foucault’s ‘bio-politics’¹³ provides an insight into the relations between individual bodies and the State.¹⁴ The importance of bio-politics becomes clear, for example, when discussing a conscription system, under which neither the consent, nor the refusal of a patient or her/his family can affect cadaveric organ harvesting. In this system, the State has unambiguous authority to take decisions on harvesting and bodies are treated as public property.⁶ This shows that apart from the concern with augmenting the number of available organs, there are other values in society that may limit the range of possible methods to fulfil this purpose. It is to negotiate these that public debate is vital. The responses to this topic may vary in accordance with the cultural context.

Though the law of presumed consent was designed not only to increase donation rates but also to discourage organ donation by living donors, such donation did not become illegal in Belgium under the law of 1986.⁴ Encouraging deceased donation discouraged living donation, which could no longer be lucrative.^{15,16} It is somewhat surprising then that in recent discussions in Belgium, the idea of re-promoting living donation has been mooted. Though the current law allows the use of living donor organs only if cadaver organs are not available and if there is an acute threat to life, Vankrunkelsven reasons that when an organ is needed, we can always speak of a case of ‘life threat’. Hence, organs of living donors ought to be considered immediately and should regain their status as a primary option along with cadaver organs.¹⁷ Vankrunkelsven’s article, published in a Belgian newspaper in 2009,¹⁷ suggests that Belgium ‘lags behind’ in the area of living donors and that it is an ‘outmoded’ politic to consider organ retrieval from living donors only after it has been found that the organ of a brain-dead patient is not available.¹⁷ The campaign to legitimize the donation of organs by living donors also opens the door for discussions on compensating such donors. These discussions do not go as far as proposing the legalization of the sale of organs, but centre around meeting the costs incurred by a living donor in the process of donating, as well as compensating him/her for the income loss suffered as a result of it.¹⁷ In fact, similar issues are under discussion in the Indian context, and it is being considered whether certain non-monetary ‘benefits’ could be given to living donors.

Another argument takes into account the quality of the organs available for transplantation. Because of an increase in the average age of cadaver donors, it is argued that the organs available for younger patients on the waiting lists are of poorer quality. The quality of a kidney obtained from a living donor is often better than that of one obtained from a brain-dead donor, while the survival rates of living kidney donors are quite high.¹⁷ Yet, in Belgium, kidneys from living donors currently account for only 8% of transplants, compared to 29% in Scandinavia, 41.5% in the USA⁷ and over 95% in India. The Council of Europe’s data from 2007 mention that there are 3.9 living kidney donors per million population in Belgium, compared with 7 in Austria and 2.3 in Spain.¹⁸ The downside of the strategy to foster living donation is that the organs which can be retrieved from living donors are limited to the kidney and, in some cases, a part of the liver. It, therefore, does not cover the shortage of organs such as the heart, lungs and pancreas. Moreover, while donor mortality may be statistically low, it is equally necessary to take into account such mortality as mortality due to the shortage of organs.

What is important for us to note is that in Belgium, even the introduction of a law on presumed consent was not enough to overcome the shortage of organs. While many hold up Belgium as ‘an example’ in the area of presumed consent, others call it

'backward' in relation to living donation. Such evaluations may change over time, as is evident from the fact that living donation has moved alternately in and out of favour with policy-makers. Over and above of all this, however, certain bio-ethical considerations are recognized in the discussion on the issue and provide guidance on how to organize living donation. In Belgium, 2 such considerations are autonomy and the will of the family (interestingly, these are not considered contradictory). What, then, might be some of the principles that are worthy of being upheld as 'sacred' in policies on organ donation in India? After determining which policies should be implemented, it is important to consider how they will be implemented and which particular format will be adhered to while adapting a policy to a local setting.

DISCUSSION

In India, in the discussion on implementing presumed consent to overcome the shortage of organs, there have often been proponents arguing in favour of such a law. They recognize the importance of infrastructure to support a law on presumed consent, as well as the necessity to first increase awareness of organ donation and address religious and cultural questions that may be raised. Yet, they often take it for granted that opting-out systems will lead to an increase in the number of organs available. It is possible that a higher availability of organs would be followed by an increase in the number of referrals.¹⁰ Belgium, having banned living organ donation in 1986, is re-legalizing it seeing that cadaver organ donation alone, even under a law of presumed consent, cannot meet the requirement of organs. Looking at this issue from an anthropological perspective, Nancy Scheper-Hughes feels that the idea of organ scarcity is linked to the more general idea of 'shortage' which has ruled medical discourses ever since the first experiments took place.¹⁴ She urges us to reconsider what 'scarcity' and 'need' mean, and how these terms may blind us to alternative ways of dealing with the current issues of importance in the field of organ transplantation. The question of whether the shortage of organs can be resolved is crucial. After all, the assumption that it can underpins all current measures to counteract the illegal sale of organs. It is thought that a rise in the supply of organs would lead to a situation in which the supply meets the demand and the prices in the 'black market' will fall. If it were impossible to eradicate the shortage of organs forever, this linkage would not seem to be as straightforward as is often imagined, and societies might want to look for other strategies to fight the sale of organs.

Some articles have also referred to examples of situations in which systems of presumed consent have failed, if not to provide organs, then from a social point of view. Nagral argues that there is a need for discussion on India's acceptance of a model that is of western origin.⁵ Reflecting on the Belgian experience, we would add that considering the seemingly temporal character of certain convictions underlying organ transplantation regulations, governments ought to be less concerned with promoting a policy under the banner of 'development' and should focus more on finding the best solution in keeping with the country's socioeconomic and political context. It is important to take into account the potential dangers posed by the interaction of a system of presumed consent with the current social and healthcare scenarios in India.⁵ It is not enough, Nagral says, to take into account the needs of those on the waiting list. The regulations must also address the needs of other people who are structurally disadvantaged by the imbalances in the social and healthcare systems.⁵ Moreover, infrastructural concerns open the debate on whether government institutions can cope with the current

complexities entirely, the role private institutions can play and whether to deny or limit any possible input by private institutions. Nagral goes on to say that any chosen strategy would need to be accompanied by the utmost care to ensure an equitable distribution of organs based on survival needs rather than the ability to afford.⁵ He sums up his concerns in a question: 'Are the proponents of this system willing to go beyond availability and simultaneously look at making transplantation accessible, equitable and ethical?'⁵

Also, as we have seen, systems of informed consent are often praised for transferring the burden of consent from the family of a brain-dead relative to the physician. However, it is significant that in India, the civil society has shown a considerable lack of trust in the medical establishment over the past few years. Scandals related to the sale of organs that received media attention have brought harm to the often taken-for-granted status of physicians. During field research in India, one of the authors heard people express the concern that if a patient were to be in possession of a donor card, doctors would declare him/her brain dead sooner than necessary so as to retrieve organs and commercialize these. If this is the case with informed consent, we can expect that in the case of presumed consent, the fear that the necessary care would be withdrawn too early from a relative in intensive care would increase. Therefore, we believe that the primary need is to address the issue of trust. For this, it is necessary to tackle corruption so as to support the governmental regulatory framework that is elementary to the implementation of organ transplantation regulations. Building trust will take time, yet it is vital for the law of presumed consent to be accepted by patients, families and the civil society at large.

Lastly, the question can be raised whether positive motivation—a deliberate choice—for donation may contribute to a long-term positive experience for all stakeholders. We wonder if putting in place a system of presumed consent could diminish such proactive opportunities. Although we acknowledge that systems of presumed consent do not take away autonomy *per se*, they limit it to the option of withdrawal rather than an assertion of will. Until now, the discourse in organ donation has been dominated by the issue of increasing the availability of organs. However, equal importance should be given to the type of choice-making that results in the long-term social and emotional well-being of donors and/or their families. The case of Singapore shows how governments can work to instil positive motivations even in systems of presumed consent, by being sensitive while negotiating the bio-political matrix that knits together the State and its citizens. To optimize the power of different stakeholders, on the lines of the practice of presumed consent in Belgium, we believe it would be good to hold in-depth public debates before taking any decision on the implementation of a law of presumed consent.

CONCLUSION

Attempts at organ regeneration to overcome the shortage of organs are still in their infancy. In India, as in other countries, the rising incidence of diabetes and hypertension has led to end-stage organ damage in an increasing number of patients. Policy-makers need to explore newer strategies to implement the deceased donation programme. Presumed consent is often mentioned as one possible way of giving a kick-start to such a programme, as well as overcoming the shortage of organs. However, the experience of Belgium, which has had a system of presumed consent for many years, shows that this does not guarantee the end of organ shortage. It is crucial to implement the law effectively and in harmony with the sociopolitical, economic and cultural context.

It is also important to take into account the extent to which the public can proactively embrace a decision to put in place a system of presumed consent, and whether the system can rely on sufficient trust among the public, the medical establishment and the government.

The law of presumed consent in Belgium was meant to discourage living donation. Yet, Belgium is today struggling to implement a living donor programme, as the shortage of organs is still a challenge. We argue that we need to examine the reasons for the shortage of organs, as well as the limitations of the concept of presumed consent. If the shortage of organs cannot be alleviated, it may call into question some of the basic assumptions of the THOA, which aims to eradicate organ markets by increasing the supply of organs.

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