Opt-in Vs. Opt-out of Organ Donation in Scotland: Bioethical analysis

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This paper looks at the ethics of opt-in vs. opt-out of organ donation as Scotland has transitioned its systems to promote greater organ availability. We first analyse studies that compare the donation rates in other regions due to such a system switch and find that organ increase is inconclusive and modest at best. This is due to a lack of explicit opt-out choices resulting in greater resistance and family override unless there are infrastructures and greater awareness to support such change. The paper then looks at the difference between informed consent of the opt-in vs. presumed consent in the opt-out approaches. Patient autonomy and dignity are better reflected with informed consent. Eighteen months have passed since the new organ donation policy has come into effect, this paper recommends more research into organ donors’ psychological motivations to help governments and the healthcare profession obtain more organs for transplantation.

KEYWORDS Organ donation, transplantation, opt-in, opt-out, informed consent, presumed consent

Introduction

In July 2019, the Scottish Parliament passed the Human Tissue (Authorization) (Scotland) Act 2019, which introduces a hard opt-out organ donation scheme within the Scottish Healthcare System from March 2021 onwards (The Scottish Parliament, 2018; National Health Service Blood and Transplant, 2020). The opt-out system for organ donation presumes consent instead of the traditional opt-in approach based on informed consent. Accordingly, when someone eligible to be an organ donor dies but has not registered or opted out, the new procedure will presume that the individual has consented to organ donation. ‘Soft’ opt-out means that the family still has the power to override such presumed consent as
opposed to ‘hard’ opt-out, where the family cannot override (Moore et al., 2018). The rationale for looking into opt-out systems in the United Kingdom (UK) is that they can potentially increase the supply of organs for transplantation, as demand is pressing due to an ageing population with a rising rate of conditions such as kidney and liver failure. As patients are dying on the waiting list, some scholars and clinicians believe it is imperative to switch to the opt-out approach to increase organ availability (Rieu, 2010; Saunders, 2012a).

This paper will first analyse the opt-out system’s effectiveness by exploring empirical data from Wales, Spain and other countries that have implemented opt-out consent for organ donation. We will then look at the traditional ethics of informed consent and the implications of presumed consent in the opt-out approach.

Does the opt-out system yield more organs?

The ethical rationale for organ donations for transplantation, especially in live donors whose future health may be affected, is based on goodwill, altruism, and promotion of the common good. Those who argue for live donation purely on utilitarian grounds that sacrificing a few for the benefit of the greatest number of those in need are not compelling (Dalal, 2015). According to Streat, utilitarianism fails to ‘adequately encompass interpersonal interactions during organ donation’ (Streat, 2004; p. 382). He suggests that the clinicians’ priority should lie in the person-centred end-of-life care of their patients rather than treating them as prospective organ donors.

We will analyse the evidence that switching to an opt-out system could generate greater organs availability. For this, we will primarily consider two places that have transitioned to the opt-out system: Wales, which is culturally, geographically, policy-wise close to Scotland and England; and Spain, the nation with the highest organ donation rates (Rieu, 2010; English et al., 2019).

Noyes et al. (2019a) look at the short-term impact of the soft opt-out launch in Wales by comparing the figures before and after the Human Transplantation (Wales) Act passed in 2013 and implemented in 2015. The consent rate for organ donation was between 48.5% and 53.6% in the three consecutive years before implementation. Eighteen months after the Act, the rate was 61%. Due to a similar trend of rising rates in the rest of the UK during this period, the authors conclude that the increase cannot be attributed to legislation change. Even though the soft opt-out method received public support, as the potential donor never explicitly opted to donate their organs or discussed it with their families, there is often a substantial family override. The rate of family overruling three years before the implementation ranged from 5% to 7.2%; and rose to 15.1%, 18 months after implementation. The reasons for family override are ‘complex and numerous.’ They include different religious beliefs and younger minorities not adhering to their parents’ cultural rules (p. 4). These statistics show that family honouring the deceased’s decision is critical for the soft opt-out system to work. It reveals the value of potential donors making explicit choices about organ donations.
beforehand (Noyes et al., 2019a). However, it should also be noted that prior to the opt-out legislation in Wales, a ‘soft opt-in’ system was in place where family members could still override a donor’s decision to donate. This shows that even in an opt-in system, there are circumstances where the wishes of the donor are not honoured.

Madden et al. contend that the opt-out structure has had a definite impact on the surge in Wales’s consent rates compared to England’s opt-in system. The consent rate was determined by the proportion of relatives of possible donors who gave approval after being contacted about organ donation (Madden et al., 2020). There was a considerably greater rate of organ donation after brainstem death in Wales compared to England. The authors, however, acknowledge that the short-time interval since the law came into effect limits the significance of this finding (Madden et al., 2020; p. 1151). The study also fails to consider the impact of public media campaigns and the clinicians’ additional training during the law’s enactment in Wales. They might have raised awareness and, therefore, rates of organ donation consent during that brief period (English et al., 2019; Noyes et al., 2019a).

The Spanish model has been widely recognized as a model of the opt-out system’s success because of its high donation and transplantation rates (Rudge, 2018; Ahmad et al., 2019; English et al., 2019). Between 1989 and 1999, the number of deceased organ donations more than doubled from 14.3 to 33.6 per million population (Ahmad et al., 2019). The opt-out scheme was credited as a factor for this upturn (Rieu, 2010). Nevertheless, Rudge (2018) maintains that the Spanish success was more due to the founding of a national transplant organization in 1989 that employed medically qualified donor coordinators in every hospital. This success was complemented by necessary infrastructures crucial to facilitate Spain’s opt-out system. Other factors that contribute to the high donation rates in Spain may be the ‘strong and sustained investments in public education’ and ‘special training for intensive care nurses and doctors’ (English et al., 2019, p. 4973). The director of the Organización Nacional de Trasplantes, R. Matesanz, claims that instead of presumed consent, the key to Spain’s success was constructing a positive social climate that fosters donation and generates trust (Fabre et al., 2010).

Given the importance of infrastructures and media in Spain’s transition to opt-out, it would be important to compare with the policies in Wales and Scotland. Fernandez-Alonso et al. (2020) partly attribute the success of the Spanish programme to the role of nurse transplant coordinators. Both Wales and Scotland rely on a similar figure of a Specialist Nurse in Organ Donation (SN-OD). Their role is to identify, confirm consent from potential donors, and support their families. Outside the clinical setting, SN-ODs are also involved in the ‘liaison and education of staff within the critical care and emergency care areas’ (p. 2021) (Tocher et al., 2019). SN-ODs involved in the Welsh transition consider it a success but are unsatisfied with gaps in media campaigns and challenges with changes of responsibilities (Noyes et al., 2019b).

The opt-out procedure did not bring an increase in donation rates in all countries that attempted it. Brazil and France were met with a decrease in organ donation
after adopting the opt-out system (Bruce and Koch, 2017; Moore et al., 2018). Prabhhu (2019) also highlights that although some opt-out countries, such as Belgium and Spain, have the highest donation rates, other opt-out nations such as Luxemburg and Bulgaria are among the lowest.

Given the limited evidence to date from Wales and the fact that Spain does not attribute its success to the opt-out policy per se, the switch to opt-out donation is not a panacea for the organ shortage crisis. Fabre et al. stress the value of familial involvement throughout the process of organ donation (2010). When there is trust between the physicians and the donor’s family, they can more readily acknowledge the patient’s death and consent to giving. It will be interesting to see if the infrastructure of SN-ODs and medical staff can adapt their communication with patients and prospective donors regarding the changing Scottish law and whether a greater involvement of the mass media would affect its effectiveness.

Informed versus presumed consent

Given the analysis above, it appears that both patient and familial consent is crucial to organ donation outcomes. A significant difference between the opt-in and opt-out systems is that the former relies on conventional informed consent while the latter is based on presumed consent. The two approaches are based on different modes of ethical reasoning.

Informed consent is a gold standard in Western medicine. There are nuances to its application under diverse contexts, be they in public health, clinical research, or the bedside. Since the 1960s, the backbone of informed consent in research has been firmly enshrined. Its formulation and justification have evolved since the Nuremberg code and the Universal Declaration of Human Rights (United Nations, 1947, 1948). In medical research, we find guidelines on informed consent in numerous international documents1 (The National Commission for the Protection of Human Subjects of Medical and Behavioral Research, 1978; UNESCO, 1997; Council of Europe, 1999; UNESCO, 2005; The World Medical Association, 2008; CIOMS, 2016).

One of the Belmont Report’s principles is respect for persons, stating that humans are autonomous beings who have the right to choose specific treatments, medications or give permission to undergo experiments (Beauchamp and Childress, 2001; Page, 2012; Miracle, 2016). Autonomy and informed consent mean individuals can ‘opt-in’ as an organ donor. They do this by signing a donor registration form beforehand.

Under the UK’s opt-in system, a 2000 British Medical Association report showed that 70-90% of adults felt positive towards becoming organ donors (British Medical Association, 2000). A more recent survey in Northern Ireland confirms the preceding statistics, with 84% of respondents endorsing organ donation (Public Health Agency, 2013). However, in the BMA 2000 opinion poll, when

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1 These documents include: the Belmont Report, Council of Europe’s Oviedo Convention, The Universal Declaration on the Human Genome and Human Rights and constant updates from Council for International Organizations of Medical Sciences (CIOMS), World Medical Association’s Declaration of Helsinki and the UNESCO Declaration on Bioethics and Human Rights
the deceased had not opted in as a donor, there was a 45% family refusal rate. The discrepancy between general support for organ donation and the high familial rejection creates an obstacle for organ procurement. People probably favour organ donation as a broad concept but become more hesitant when the decision becomes personal for them or their loved ones. It also explains why only 36% of eligible adults have registered through the UK’s opt-in approach (Prabhu, 2019).

Rieu (2010) further maintains that under the UK opt-in system, the number of patients who would potentially benefit from transplantation is underrepresented. Doctors are hesitant to put new patients on the waiting list because they might never get the organs in time because of the lengthy delay. The unavailability of organs exacerbated by the low registration rate and high family refusal with the opt-in system led clinicians and legislators to contemplate the opt-out alternative.

Some feel that this policy change could better reflect the public opinion by shifting the default position from presumed unwillingness to presumed willingness (Rieu, 2010; p. 535). However, Saunders argues that although approval can be given both explicitly and implicitly, it is an action, not a mental attitude. Therefore, it cannot be presumed when action has not been taken. He proposes that rather than presumed consent in the opt-out approach, tacit approval is indicated by patients’ inaction to opt-out. Consequently, the patients ‘by their silence—actually consented’ (Saunders, 2012a; p. 69).

Other authors find presumed consent problematic since the absence of objection or silence is not the same as consent. “Not saying no” does not equate to saying “yes” (Bruce and Koch, 2017; p. 3262). Furthermore, they contend that cases of clinicians abusing presumed consent could lead to ‘public distrust by exacerbating fears of ‘organ poaching’ from unwilling donors’ (Bruce and Koch, 2017, p. 3262; Dyer, 2019). The likely breakdown of trust between clinicians and patients and their families would be a high price to pay (Dinç and Gastmans, 2013; Kelley et al., 2015). Accordingly, strict adherence to informed consent towards organ donation may better protect potential donors’ individual rights. It prevents physicians from entering into conflicts and legal disputes with donor families under the opt-out system.

Hence, conventional informed consent in the opt-in scheme where patients decide to donate is more respectful of patients’ autonomy. For the opt-out system to work, one cannot merely presume consent but will need to communicate better with patients and their families about organ donation after death (Rieu, 2010; Noyes et al., 2019a).

**Psychological motivations of organ donation**

In order to address the deeper issues of consent, it will be useful to investigate why patients donate and the family dynamics. Several studies look at the psychological motivations to donate organs. Saunders (2012b) explores the motives of organ donation by differentiating altruism from solidarity. He claims that solidarity for a specific group could be more potent than altruism because it invokes feelings of attachment particular to an individual. He reasons that solidarity is a limited
form of altruism that stems from extended self-interest or an instinctual desire for genetic propagation. For example, parents are more willing to donate organs to their children. Saunders connects this desire to Dawkins’ idea of the selfish gene (Dawkins, 2016). Hill analyses attitudes towards organ donation amongst college undergraduates and their registration intentions and status. He finds altruism an important element in the personality of donors (Hill, 2016).

Other research in this area includes Abraham Maslow’s Hierarchy of Human Motivation that categorises human needs in levels according to physiological, safety, love, esteem, and self-actualization needs (Maslow, 1943; McLeod, 2018). Maslow’s theory could possibly give insight into the motivations of organ donors. Using this theory, Dar (2016) investigates case studies in Indian society to evaluate people’s motives to sell or donate organs owing to economic and legal concerns. Katz et al. (2018) use a survey to explore reluctance to register for organ donation with the sense of control over one’s future.

Recent literature on behavioural ethics could shed more light on these questions. Max Bazerman and Tenbrusel (2011) write about the blind spots of people when they make decisions. Most of the time, we make choices based on gut feelings that are not rational. Their book describes how such judgments often suffer from bias, short-sightedness, and memory revisionism. Thaler and Sustein (2008) illustrate how institutions or governments can ‘nudge’ their members towards better decisions in health and happiness matters. Their suggestion to rearrange ‘choice architectures’ would be applicable in bridging the gap between the general approval of donating organ and the lower donor registration numbers. Well-thought-out changes could make the process less cumbersome, and the message more nuanced and easily understood. For example, the latter could be done with websites that outline key information about the new law. While these are still theories that need further deliberations and empirical verifications, such works are the first steps towards further exploration to increase organ donations. For instance, Moorlock and Draper (2018) investigate social media use to increase living organ donation and find that institutionally organized personal case-based campaigns aimed at promoting specific recipients seem to yield the best results.

**Conclusion**

This paper has assessed the bioethical consequences of informed and presumed consent with the switch from opt-in to opt-out systems. The numbers from Wales and Spain show that the opt-out method on its own may not necessarily increase organ availability. While Welsh statistics show a moderate increase in the short term, Spanish data shows that countries could boost organ donation by building infrastructure that endorses and stimulates organ donation through qualified clinicians and the mass media. Countries that introduced the opt-out approach occupy both the top and the bottom levels of organ donation. A unidimensional switch from one system to another cannot automatically resolve the problem of organ shortage.

Informed consent is the time-honoured mechanism that protects patients’ dignity and autonomy. Our analysis reveals that presumed consent favoured in an opt-out
approach can hypothetically sow mistrust between clinicians and the patients and their families due to potential conflicts of interest. It may lead to people opting out of organ donation and cause an increase in family overrides. While we still need more research on organ donor’s psychological and ethical motivations, it appears that an automatic switch over to opt-out may not be the best solution to increase organ availabilities.

For places like Scotland, where the opt-out method has been implemented, it will be necessary to support clinicians and administrators with a proper infrastructure that encourages donation through education and effective communication strategies.

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