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Education

Max and Keira's law: a discussion surrounding the advantages, disadvantages and alternatives to an opt-out organ donation system in the UK

EDUCATION

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ABSTRACT

Relevance:

To increase the number of organ donors in England, the government will implement Max and Keira's Law: all adults over the age of 18 living in the United Kingdom become potential organ donors after their death, unless they choose to opt out. The law will be employed by spring 2020. Despite there being presumed consent for the retrieval of organs, families of the deceased will still be contacted to recheck consent, and ensure that family wishes are upheld.

Summary:

Despite definite implementation of the law, there have been concerns over the presumed consent given for retrieving organs from the deceased; ignorance and lethargy from certain members of the public may mean that true informed consent can never be obtained when collecting organs. To combat this, expensive national campaigns would need to be launched to make the public aware of the new process, as well as educating them on how to opt out of the process if necessary. Regardless of these challenges, there are many advantages to the new law. Advantages include an increase in successful organ donations and transplant, as well as potentially an increased availability of organs for use in medical research, drug development and university teaching.

Take Home Messages:

Based on the advantages, the move to the opt-out system appears to be a sensible method to increase the number of organs available for use in medicine. Proposed alternatives such as xenotransplantation and 3D bioprinting have the obvious benefit of providing an almost infinite supply of organs. However, these alternatives remain in the preclinical stages, with ethical challenges and infection risks that need to be overcome before they can be used in hospitals.

By Spring 2020, the UK government will implement 'Max and Keira's Law, commonly referred to as an opt-out system. Everyone over the age of 18 in England will be assumed to have agreed to be an organ donor when they die. (1) The new system would not presume consent for the retrieval of organs whilst a person is still alive; however, individuals may still opt to be a living donor. All adults living in England will be on the organ donor list unless they have opted out by recording their decision not to donate, or are a part of a group excluded from organ donors. Excluded groups would include those who have or are suspected of having conditions such Creutzfeldt-Jakob Disease (CJD), Ebola, an active malignancy or are HIV positive. (2)

Currently, all countries within the UK except Wales have an opt-in system, where people are not considered as organ donors unless they sign up to the register, and express consent to donate. The opt-out legislation, which was first proposed in 2015, has been supported by several health regulatory bodies in the UK, most notably from the British Medical Association (BMA), who have supported the change by advising local MPs through parliamentary briefings about the positive impact that this life-saving change in law could bring. (3) Those excluded from having given assumed consent include minors, those who lack the mental capacity to understand and act on the new law, visitors to England and those who have lived in England for less than 12 months prior their death. Moreover, if a deceased individual has not opted out, family members will still be contacted and asked if they knew of any unregistered objection. (4) If there is a known objection from the deceased, or it becomes clear that the individual would not have consented, the organ donation will not go ahead; donation despite objections would ruin the trust between a doctor and the family and could reduce donation rates in the long term. Organ donation involves legal consent from the donor, which can be obtained when the donor is alive or dead with the assent of their next of kin. (5) Donation may be for research or transplantation into another person as a part of an operation to either save or improve the recipient's quality of life.

The main aim of an opt-out system is to overcome the shortage of organ donors currently available for transplant operations in the UK. Statistics taken from the 31st March 2019 show that there were 6077 patients in the UK waiting for a suitable organ on the active transplant list, yet only 1600 deceased donors listed in the UK. A further 1039 living donors are also listed. (6) Although it is possible for a single donor to donate multiple organs, the demand for certain organs over others, such as a demand for kidney and liver donors, would limit the number of organs retrieved per donor. In cases where an organ is available, challenges such as family refusal, poor condition of a donated organ, incorrect blood type or tissue match and adverse immune reactions leading to the body's rejection of an organ, may prevent a successful transplantation.

The proposed system would generate a greater number of potential organ donors, leading to a larger selection of organs that surgeons can use in operations, thus increasing the likelihood of finding a suitable match for someone who needs a transplant. (7) This could lead to a reduction of complications post-surgery, which benefits both the patient's health and the NHS financially, as less money would be spent in treating the complications of surgery, providing alternative treatments or arranging palliative care for someone with a life-limiting condition. This paper aims to discuss some of the advantages, disadvantages and alternatives to the implementation of 'Max and Keira's Law' in England.

The opt-out organ donation system has already been trialed in several European countries, including Austria, France, Greece, Italy, Spain and Sweden. Spain has the highest rates of organ donation in Europe, due to their implementation of presumed consent, along with additional non-legislative measures, such as financial incentives for those who do not choose to opt out. (8) Overall, when other determinants of donation rates are accounted for such as GDP per capita, literacy rates, religion and causes of death of donors, presumed consent countries have roughly 25–30% higher organ donation rates than opt-in countries. (9, 10)

Not all these countries have opt-out organ donation systems. Some countries such as Israel use a donation-allocation system to motivate individuals to donate organs. Israel's Organ Transplant Act 2008 introduced a priority point system, rewarding those who are willing to donate an organ with preferential status as a recipient of a donated organ. A person can gain priority points by signing a donor card, making an organ donation during their lifetime, being a first-degree relative of someone signing a donor card or by consenting to donate organs after death. (11) The act has led to a record number of signed donor cards and there has been a significant increase in the numbers of transplants in Israel.

Perhaps the greatest advantage to an opt-out system is that an increase in donated organs available for transplant would lead to more successful operations. Successful transplant allows patients to have a greater quality of life and return to their normal routine prior to their illness. For example, if someone required a kidney transplant, but was unable to find a suitable donor, they would have to undergo haemodialysis for multiple hours weekly. The average patient receives dialysis 18 hours a week, which extrapolates to the patient losing one month of every year out of their normal routine on dialysis alone. (12) Exhausting processes such as dialysis, can be eliminated through successful organ transplantation, and significantly improve patients' quality of life.

Organ donation may provide closure and consolation for the family of someone who has passed away suddenly or in a tragic manner. Normally, families would only be contacted if the deceased had signed up to the organ register; however, an opt-out system would mean that if the deceased's organs were needed, the family would be contacted in order to seek consent for the organs to be used.

Opening this new avenue for families who had not previously considered organ donation may provide some relief and alleviate their own guilt, as they know that their relative's death was not in vain.

Further satisfaction could be received as the family of the lost individual may also have the chance to connect to new individuals who were saved due to the organs of their loved one. A 1987 descriptive study that examined donor families' overall feelings about their organ donation experience found that of the 83% of families who returned a survey, a majority of donor families had positive feelings about organ donation because of their desire to help someone else and make something good come from their loss (13). It is important to note that not all families would feel consolation knowing that their loved ones' organs are being used to treat another individual. Families may grieve in different ways and the idea of organ donation may prolong the family's grieving period. In such cases, it would be important for clinicians to provide social and emotional support for families experiencing the organ donation process, and communicate sensitively when asking for consent. (14, 15)

An opt-out system would increase the number of organs collected for medical research or teaching purposes—when an organ is unsuitable for transplant or if a specific tissue type of organ is desired for research. Organ use in research could contribute to providing vital information about the pathology of a disease; and assist in the development of more efficacious drugs with improved safety profiles, as they would be tried on a donated organ before risking the safety of a participant in a trial. (16) Moreover, due to higher volumes of organs available, medical students have the potential to learn anatomy and human physiology using human specimens. Thereby allowing medical students to forge stronger links between anatomy and the pathologies observed during clinical placements. (17)

One of the main reasons for organ shortage is due to insufficient education on organ donation. (18) An opt-out system may engage the public on the issues surrounding organ donation, as the government would accompany the new law with a large awareness campaign to educate and assist people in making an informed choice. A study analyzing 383 medical students showed that prior to a specific lecture on organ donation, the request for further information about organ donation was significantly higher amongst students without a donor card compared to card carriers ($P < 0.0001$). However, after the lecture, the number of students requiring further information decreased to just 19% of the cohort ($P < 0.0001$). (19) Exposure to donated organs during teaching, and a specific lecture about donation significantly decreases the request for further information on organ donation and improves students' attitude to organ donation. With such teaching, students could share the information with friends, families and colleagues, thus helping to reinforce a positive attitude to organ donation from the general public. Hence, contribute to fewer people opting-out. (19)

Though a majority are in favour of organ donation, (20) the proposed system relies on the assumption that the public are informed about the process, and can decide what happens to their organs after death. This ignores the possibility that some members of the public remaining ignorant or lethargic with regards to finding out about donation; some would still be accustomed to a process where consent is given actively, rather than as a result of inaction. (21) This would ultimately result in several organs being retrieved without true informed consent, which may compromise the trust patients have in doctors and the NHS.

To ensure that most organs are donated with true informed consent, the government would have to spend more educating the public via national campaigns. In 2016-2017, the NHS Blood and Transplant (NHSBT) spent approximately £5 million on campaigns encouraging mainly those who are less aware of the need and the opportunity to save lives to donate. (22) A change in systems would mean that the NHSBT would have to spend a greater sum annually to address the entire population, rather than just targeted groups. The public would need to be informed that they are organ donors by default, and would need to be given the relevant information on how to remove themselves from the register if they choose to opt out. This information is too vast to be conveyed solely via social media; more expensive traditional media campaigns and expensive television and print advertising would be required. Therefore, requiring a larger budget to be allocated to the NHSBT from the government.

Another concern regarding the shift to an opt-out system is that an increased rate of organ donation does not necessarily equate to a proportional increase in successful organ/tissue transplants. Conditions such as osteopenia, obesity (due to inactivity/diet changes), cancer and autoimmune tissue rejection could develop in individuals after a transplant, and would negatively impact an individual's quality of life. (23) A study measuring the incidence of malignant tumours post-transplant operation showed that out of 674 solid-organ-transplant recipients (305 renal, 307 heart, 54 lung, 8 heart/lung), 79 malignancies were detected, representing an overall cancer frequency of 11.7% in recipients of organs which would further complicate their health. (24) Therefore, it could be argued that rather than shift to an opt-out system, the NHS should instead focus on preventing post-operation complications, and providing further care for organ recipients post-transplant.

As the opt-out system has already been accepted and will be enforced in the UK, future discussions will likely turn to how the new law can be successfully implemented, rather than whether the law is needed in the first place. Nonetheless, it is still worth exploring some of the more unfamiliar alternatives to organ donation such as xenotransplantation, genetic engineering and

3D Bioprinting organ tissue. All three alternatives offer an almost unlimited source of organs. Scheduling transplant surgery would no longer be dependent on the unpredictable availability of a donor human organ. This would allow clinicians to intentionally time the harvesting of an organ for immediate transplantation, as well as allocate immunologic pre-treatment of the recipient if necessary. (25)

Xenotransplantation involves transplanting tissues or organs between members of different species. Most xenotransplantation activity is still in the preclinical stage. Currently, there are significant ethical concerns surrounding xenotransplantation as it could mean livestock would be reared solely for organ harvesting, as well as the threat of spread of infectious diseases. Xenotransplantation would be accompanied with heavy immunosuppressive therapy, which can lead to fatal infections such as Hepatitis B and HIV in patients. (26) These challenges would have to be overcome before xenotransplantation can compete with organ donation.

A printed organ is an artificially constructed structure designed for organ replacement, produced using 3D bioprinting techniques. 3D bioprinting seems to be a feasible alternative compared to xenotransplantation. However, 3D bioprinting is relatively expensive due to a lack of equipment and resources, and needs to be further developed before it can be commonly used in hospitals. Another option is genetic engineering. Genetic engineering involves the modification of the phenotype of a living organism by manipulating its genetic material. The exact tissue type and blood type of an organ can be engineered, resulting in a much lower chance of rejection by the body of the recipient. (27) Since no humans or animals are used to obtain the organ, there are fewer ethical difficulties that need to be overcome when using genetic engineering. However, practicality and expense still remain an issue.

The UK's move to an opt-out system in 2020 means that all adults over the age of 18 living in the UK become potential organ donors after their death. Despite there being presumed consent for the retrieval of organs, families of the deceased will still be contacted to recheck consent and ensure that family wishes are upheld. Challenges to this new system include the possibility of true informed consent never being fully achieved. Advantages include an increase in successful organ donation and transplantation, as well as potentially an increased availability of organs for use in medical research, drug development and medical teaching. Based on the potential benefits, as well as the fact that proposed alternatives to organ donation are still in the preclinical stages, the move to the opt-out system appears to be a sensible method to increase the number of organs available for use in medicine.

Summary:

- The opt-out system will be implemented in Spring 2020 by in England.
- Those over 18 will be assumed to have given consent to be an organ donor unless they have opted out or are part of a group excluded from organ donation.
- The main aim of an opt-out system is to increase the number of organ donors available for transplant in UK.
- Countries with opt-out systems have around 25-30% higher donation rates than opt-in countries.
- Opt-out systems may also help facilitate research and teaching, providing information about pathology of a disease and drug development.
- Challenges of an opt-out system involve lack of true informed consent due to members of the public remaining ignorant or lethargic with regards to finding out about donation.
- Increased rate of organ donation does not always mean the number of successful organ and tissue transplants increase.
- Alternatives to an opt-out system include xenotransplantation, genetic engineering and 3D printing.

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