Dutch law approves opt-out system

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The law for an opt-out organ deceased donor system has been approved by the Dutch Senate on February 13th 2018 with a narrow margin (38-36). In 2016, the law had passed the lower house with an even smaller margin (75-74). With the new legislation, residents over the age of 18 who have not yet documented their choice regarding organ donation in the National Dutch Donor Registry will receive a request to state if they wish to donate or if they wish that the next of kin or a designated person will decide. Those who do not respond will receive a follow-up letter mailed after six weeks, registering them as having no objection to organ donation. This communication will be documented in the Donor Registry and confirmed by a letter. Of note, the organ donor status can be changed at any time. Notably, even with those legal changes, the next of kin will still be able to oppose a documented organ donation status.

Some historical background: The Dutch Organ Donation Act was implemented in 1998. This law had four objectives: (1) to provide a legal framework to all involved in organ donation, (2) to increase the supply of donor organs and tissues, (3) to ensure a fair allocation of donor organs and tissues, and (4) to prevent commercialisation and organ trade. Notably, although an increase in the supply of donor organs and tissues had been a key objective, registrations had not exceeded 40% of the population and there had not been a substantial increase of transplants. Ten years later (in 2008), the Organ Donation Masterplan was then initiated with the objective to achieve an increase of deceased donor transplants by 25% over the next five years (to 800 transplantations). New approaches included an improvement of donor identification, support of hospital-based donation coordinators and donation intensivists, improved communication skills and training sessions for medical professionals, improvement of donor organ quality by establishing dedicated organ procurement teams, and active outreach activities. In addition, actions were taken to improve possibilities and practices of living donation. Despite these interventions, the goal of increasing the transplant volume was not met. The Masterplan had considered the opt-out legislation as an important step to meet the demand for organ transplants. Notably, The Netherlands had traditionally low deceased donors rates (14,3 per million pmp in 2017). In contrast, living kidney donor rates have been very high with a rate of 33,7 pmp. Thus, organ donation appears to resonate in the population, however, less so as a deceased donation. Of interest, 75% of the population would like to receive a donor organ, and 61% have been in favour of changing the legislation towards an opt-out system. At the same time, only 40% of the population are registered and only 58,7 % of those with a consent for donation.

The opt-in system that has been in place until recently and will remain active until 2020, thus leaving the final decision in an emotionally stressful situation with next of kin if a decision has not been
registered before. Moreover, in the current situation, the next-of-kin may assume that the lack of registration may indicate an objection to organ donation. In 2016, for example, refusal rates had been 68% for organ donation (annual report NTS 2016 3 table 8.3) and 84% for tissue donation (annual report NTS 2016 3 table 8.5) in the absence of a registered determination to donate. The opt-out approach is thus not only aiming to increase donations and transplantations but also to relieve pressure on family members who must decide on organ donation at a very difficult time. Moreover, an opt-out system is also expected to support the conversation of intensive care physicians and transplant coordinators who deal with grieving families.

By March 1, 2018, there have been 1,086 people waiting for organ transplantation in The Netherlands 7. Approximately, 150 patients die on the waiting list every year and 100 patients are removed from the list with worsening conditions. Changing donation legislation is a key health policy question going far beyond transplantation since it also involves ethical, social and religious beliefs. More countries have changed recently from an opt-in to an opt-out consent system 8. International comparisons demonstrate that opt-out consent may lead to a relative increase in the total number of organs transplanted 8-10. Within the UK, Wales has recently (in 2016) changed from an opt-in to opt-out consent with an increase in registered donors, fewer families refusing donation and more living donations 9,11. However, the change does not always translate to increased donor rates as recently seen in Brazil12 and it may take a long time before changes in donation rates are noted. Challenging in objectively assessing the impact of opt-in versus opt-out systems are differences across countries: some countries, (Singapore and Austria) have a ‘hard-opt-out system’ where the registration will be followed regardless of the families’ wishes. In other countries, (Spain and Wales) families of potential organs are always given the chance to refuse. Moreover, countries with high donor pmp rates combined the opt-out approach with an improved infrastructure, increased funding for transplant programmes and staff and public relation campaigns. In addition, Spain the country with the world’s highest deceased donation rates has significant regional differences.

Important issues which came up in the public debate (in the Netherlands) referred to mentally challenged individuals or those who are functionally illiterate. Moreover, there had been concerns that the information on a new legislation will not reach everyone. Those aspects will require special attention in the implementation process. As reflected by the narrow votes, many political parties were internally divided about changing the law. Arguments included that the proposed change implies that ‘our bodies belong to the State as soon as we pass away’ and that people’s beliefs and wishes may not be sufficiently respected. Moreover, there are also religious or cultural based beliefs on the relevance of bodily integrity. At the same time, there remains distrust in the diagnosis of
brain death by some. Notably, in the immediate aftermath following the approval of the opt-out law, an immediate and temporary registration of objections was noted in the Netherlands.

The law is expected to be effective by July 1, 2020. Communication campaigns are planned to provide information in a precise, understandable and accessible way for everyone, with special attention to the mentally challenged or functionally illiterate. Donation professionals will receive training to inform and prepare them on practical implications. In addition, protocols for professionals involved in deceased organ donation will be updated. The practice in communication around donation will be adapted. Along with changing the law on organ donation, all interventions already made to improve the organisation of donation in hospitals will be continued. A close follow up after implementation is warranted to monitor whether the law indeed has positively changed organ donation rates.

Authorship statement:

- Marlies E. J. Reinders: Participated in the writing of the paper and Final approval of the version to be published
- Jeantine M. M. P. J Reiger-van de Wijdeven: Participated in the writing of the paper and Final approval of the version to be published
- Jeroen de Jonge: Participated in the writing of the paper and Final approval of the version to be published
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