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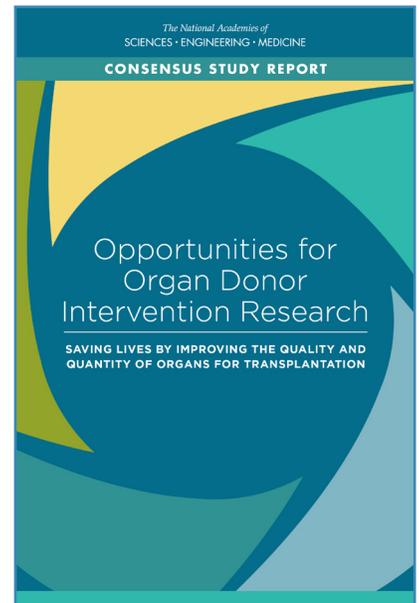
Opportunities for Organ Donor Intervention Research

Saving Lives by Improving the Quality and Quantity of Organs for Transplantation

The organ donation and transplantation system strives to honor the gift of donated organs by fully using those organs to save and improve the quality of the lives of their recipients. While most related research to date has focused on improving transplantation processes and health outcomes for recipients, the field of organ donor intervention research looks at ways to enhance the quality and increase the quantity of organs that can be recovered from deceased donors and then successfully transplanted. This valuable research—which tests and assesses medications, devices, and donor management protocols—can be done either while the organ is still in the deceased donor or after it is recovered from the donor but before transplantation.

This type of research is challenging to conduct under current policies and regulatory mechanisms concerning biomedical research. It also brings to the surface ethical questions about who should be considered a human subject in a research study, whose permission and oversight are needed, and how to ensure that such research does not threaten the equitable distribution of a scarce and valuable resource.

With support from an array of organizations, the National Academies of Sciences, Engineering, and Medicine assembled an expert panel to examine the ethical, legal, regulatory, policy, and organizational issues related to U.S. research involving deceased organ donors. The resulting report, *Opportunities for Organ Donor Intervention Research: Saving Lives by Improving the Quality and Quantity of Organs for Transplantation*, offers recommendations for conducting organ donor intervention research in a way that maintains high ethical standards, that ensures dignity and respect for deceased organ donors and their families, that provides transparency and information for transplant candidates who might receive a research organ, and that supports and sustains the public's trust in the process of organ donation and transplantation.



ABOUT ORGAN TRANSPLANTATION AND ORGAN DONOR INTERVENTION RESEARCH

In recent decades, the outcomes for transplant recipients have improved, and the number of organs transplanted has increased. Yet the growth in the number of patients awaiting organ transplantation has outpaced the growth in the number of organs being transplanted (shown in the figure below). As of July 13, 2017, there were 117,154 transplant candidates awaiting an organ. The supply of available organs can be affected by many factors, including the number of potential organ donors and the public's willingness to donate. Sometimes donated organs may not be used because of the condition of the organ or because it is not possible to allocate the organ within the timeframe of its viability for transplantation.

When a donor organ becomes available and a potential recipient is identified from a waiting list, the process moves swiftly: The decision to accept an organ deemed viable for transplantation is usually made within an hour of receiving the offer, and transplantation surgery proceeds as soon as possible thereafter. These processes are accomplished by an interdependent network of multidisciplinary, multi-institutional services that includes organ procurement organizations (OPOs), donor hospitals, and transplantation programs and centers.

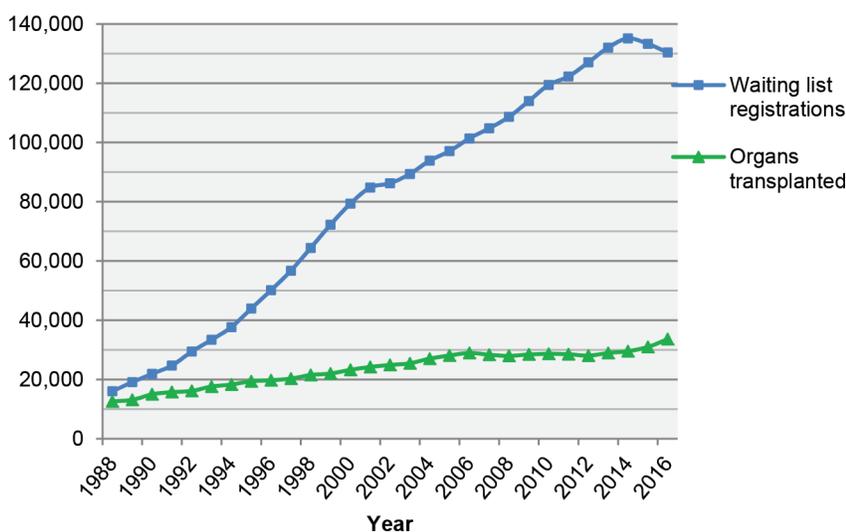
Organ donor intervention research, if authorized, takes place after the donor is declared deceased. The intervention would be administered to the deceased donor prior to organ recovery or to the target organ after the organ has been recovered but before transplantation. The committee's work focused on identifying next steps in overcoming challenges to this research (see Box) so that it can be conducted in the pursuit of enhancing the quality and increasing the quantity of organs available for transplantation.

THE COMMITTEE'S RECOMMENDATIONS

Broadly, the committee's recommendations address the legal, regulatory, and policy frameworks as well as the approval, implementation, and oversight of organ donor intervention research. **To see all of the recommendations, please visit nationalacademies.org/OrganDonorResearch.**

Legal, regulatory, and policy frameworks for organ donation and research participation

Trust in the U.S. donation and transplantation system is essential. Yet there are no universal requirements for what information about organ donation options—including research—should be provided to people who are contemplating registering to be an organ donor. Furthermore, state laws vary regarding authorization for research followed by transplantation, and there is no standard practice for recording a person's preferences for donating organs for the purpose of research.



National transplant waiting list registrations for all organs (as of December 31 each year) and organs transplanted (living and deceased donors) by year.

Steps can be taken to improve transparency and public trust in the process for research followed by transplantation. For instance, communications strategies and lay-friendly materials should be developed that explain donor intervention research and put it in the wider frame of improving opportunities for organ transplantation.

To streamline and improve information sharing about donor preferences, the committee recommends that all active U.S. donor registries coordinate to ensure a single, unified secure national donor registry that is easily accessible to OPOs. This national registry should receive all donor registry information collected by departments of motor vehicles.

Additionally, legal and policy guidance on organ donation for the purpose of research followed by transplantation needs to be clarified, including through revisions to the Uniform Anatomical Gift Act.

For organ recipients, careful consideration must be focused on effectively informing transplant candidates about organ donor intervention research. Transplant candidates receive a wealth of information from the time of intake through the time of discussing a transplant organ offer, and they need

enough time to fully learn about organ donor intervention research and make a decision about whether they would consider receiving a research organ. The committee recommends developing and implementing a two-stage process that would begin with educating potential transplant recipients early and at regular intervals throughout the time they are on the transplant waitlist, and then at the time an organ is offered, would provide details on the research and would follow the process approved by the single institutional review board for informed consent for research participation.

Research approval, implementation, and oversight

One major reason for the lag in organ donor intervention research is the lack of central oversight that is needed to overcome the complexities of this geographically and clinically dispersed research. Promising research is not likely to proceed at the volume, quality, and pace needed without a central organization to coordinate and facilitate cooperative research among a large number of institutions. The complexity and urgency involved in conducting organ donor intervention research, paired with the need for adherence to the relevant ethical, legal, and regulatory policies, point to the need for a more centralized research system—a centrally administered standing committee focused on organ donor intervention research, a single institutional review board, and a study-specific data safety monitoring board, which is recommended by the committee. Such a system would work to ensure equitable, transparent, and high-quality research.

CONCLUSION

Increasing the number and enhancing the quality of organs available for transplantation can save lives and improve quality of life. The committee's recommendations aim to strengthen the conduct of organ donor intervention research, helping to maximize the gifts of donated organs.

CHALLENGES IN DECEASED ORGAN DONOR INTERVENTION RESEARCH

In addition to challenges faced in many areas of biomedical research, this research faces additional challenges, including:

- *Rapid decision making*—Decisions must be made in a short timeframe on whether or not to accept an organ that has been part of a research intervention.
- *Target and non-target organs*—The intervention may have the potential to affect not only the target organ of the intervention but also the non-target organs if administered prior to organ recovery.
- *Numerous potential organ recipients*—Specific recipients that need to consent to research are unknown at the outset of the research.
- *Numerous and geographically dispersed research sites and organizations*—Specific organ procurement organizations, donor hospitals, and transplant centers to be involved are unknown at the outset of the research.
- *Fairness*—Donated organs are a scarce and valued national resource, and sustaining the fair and equitable system for organ allocation is of paramount importance.

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To read the full report, please visit
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