

New report offers framework for research on organ transplantation

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The number of patients in the U.S. awaiting organ transplantation outpaces the amount of transplants performed in the U.S., and many donated organs are not transplanted each year due to several factors, such as poor organ function, says a new report from the National Academies of Sciences, Engineering, and Medicine. Increasing the quality and quantity of organs that can be recovered from deceased donors and successfully transplanted requires organ donor intervention research, which is conducted on donated organs prior to their transplantation.

This research tests and assesses clinical interventions—for example, medications, devices, and [donor](#) management protocols—aimed at maintaining or improving the quality of donated organs prior to, during, and following transplantation. Transplantation research previously has focused almost exclusively on recipients and post-[transplant](#) health outcomes.

Organ transplantation is the optimal treatment for many end-stage organ-specific diseases. In 2016, more than 27,000 organs were transplanted from nearly 10,000 deceased individuals, yet nearly 5,000 [donor organs](#) were not transplanted. Many factors affect the supply of organs such as willingness to donate one's organs or those of a family member upon death, inability to allocate an organ within the short time frame during which it is viable for transplantation, or organs being found unsuitable for transplantation due to the health of the deceased donor, cause of death, or functional or anatomical abnormalities in the donor or donated

organ. As of July 2017, more than 117,000 transplant candidates were awaiting an organ, 80 percent of which were kidneys.

"The very brief time frame in which donor [intervention](#) research must be conducted to maintain organ viability and ensure successful transport to the recipient, coupled with the fact that organs from a single donor may go to multiple recipients in different transplant centers throughout the United States, adds to the complexities of this research," said James Childress, John Allen Hollingsworth Professor of Ethics Emeritus at University of Virginia, and chair of the committee that conducted the study and wrote the report. "This report seeks to enable organ donor intervention research to move forward in a manner that ensures dignity and respect for deceased organ donors and their families and is within appropriate ethical, legal, and regulatory limits to save more lives, to improve the quality of lives, and to fully honor the gifts of organs for both current and future transplant recipients."

In order to improve coordination and sharing of information about donor preferences, all active U.S. donor registries should coordinate in order to create a single, unified, secure national donor registry that is easily accessible to organ procurement organizations (OPOs), the report says. All donor registry information collected by departments of motor vehicles should automatically feed into this single national registry.

To clarify legal guidance for authorization of organ donor intervention research, the committee recommended that the Organ Procurement and Transplantation Network (OPTN) and transplant community engage in public consultation and determine whether to revise the Uniform Anatomical Gift Act and state laws to either specify that when the decedent has authorized transplantation, this denotes authorization for research followed by transplantation, or to add the option to participate in organ donor intervention research to the list of choices for the donor.

There are no requirements currently for what information about donation options, including research, should be provided to individuals who are contemplating registering to be an organ donor, the report says. To improve transparency and public trust in the organ donation process involving research prior to transplantation, the OPTN, OPOs, Health Resources and Services Administration, advocacy organizations, and relevant professional associations should develop and test communication strategies and materials that explain organ donor intervention research and disseminate those resources—such as template language for donor registries—once effective messaging is identified.

When a post-mortem research intervention is administered prior to organ recovery and the intent is to have an effect on a specific organ—the target organ—the intervention could affect other organs from the same donor that may also be removed and transplanted after the intervention—non-target organs. As a result, many transplant recipients across multiple transplant centers could become human subjects in a single organ donor intervention research study.

The committee proposed a two-stage process for obtaining consent from transplant candidates who could receive a target or non-target research organ. In the first stage, which would be part of the clinical consent process that begins at the time of patient intake and continues through wait-listing, information on organ donor intervention research is provided and the transplant candidate is asked to decide whether they would consider receiving a research organ. The second stage would occur when an organ is being offered to the transplant candidate, following research informed-consent processes as determined by the single institutional review board for organ donor intervention research.

A major reason for the lag in organ donor intervention research, the committee found, is the lack of central oversight necessary to overcome the complexities of this geographically and clinically dispersed research.

Therefore, the report recommends the establishment of centralized management and oversight of organ donor intervention research in order to ensure equitable, transparent, and high-quality research.

The report also includes recommendations for creating electronic tools to ensure that organ donor intervention studies are listed on a publicly available website and for tracking and monitoring research outcomes.

More information: [www.nap.edu/catalog/24884/oppo ... g-lives-by-improving](http://www.nap.edu/catalog/24884/oppo...g-lives-by-improving)

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