



# Organ Transplant Candidacy and COVID-19 Vaccination Status

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A series of recent media reports have highlighted a current policy among at least some transplant centers to deny potential transplant patients the ability to be waitlisted for an organ due to COVID-19 vaccination status (see Business Insider, Washington Post, and Healthline). Transplant centers generally devise their own policies and consider both medical and nonmedical criteria when selecting potential candidates to add to the waitlist for an organ transplant (i.e., listing). Transplant centers can rule out a candidate when transplantation is not considered the best treatment option for the particular patient. However, the larger underlying issue in listing decisions is a lack of organ supply. The demand for organs far outweighs the available supply. For instance, in 2020, 91,099 individuals were in need of a kidney, while 22,817 kidneys were received. This lack of supply tends to be a key factor in the nationwide allocation of organs to ensure that organs go to individuals with the most need and to individuals who will ensure optimal stewardship of this scarce resource.

All transplant centers are members of the Organ Procurement and Transplantation Network (OPTN), a program to coordinate organ allocation authorized by the National Organ Transplant Act of 1984 (NOTA; P.L. 98-507, as amended) and administered through contract by the Department of Health and Human Services (HHS), Health Resources and Services Administration (HRSA).

Multiple congressional committees have jurisdiction over the OPTN and oversee its activities. These include House Energy and Commerce and Senate Health, Education, Labor, and Pensions. Other committees also have jurisdiction over certain activities related to the OPTN, such as Senate Finance due to the Centers for Medicare and Medicaid Services' role in regulating members of the OPTN.

This Insight provides background information on the organ donation and transplantation system, describes transplant center listing criteria, and outlines the current recommendations of relevant professional organizations.

# Background

Organ donations and transplantations are coordinated through the OPTN, a nationwide network of all organizations (e.g., transplant centers, organ procurement organizations [OPOs], laboratories) involved in the process. OPTN is administered by the United Network for Organ Sharing (UNOS), a private

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https://crsreports.congress.gov IN11848 organization under contract with HRSA. UNOS has held the contract to administer OPTN since it was established NOTA.

OPTN administers a series of policies intended to allocate organs with consideration of both the limited number of organs and their short shelf-life, among other considerations. OPTN also issues white papers that highlight a variety of topics for OPTN members, including ethical considerations.

#### **OPTN Considerations for Transplant Candidacy**

The OPTN does not issue policies requiring transplant centers to use specific criteria when determining whether patients would be suitable candidates for transplantation. Nor does the OPTN require transplant centers to have a specific selection process. The OPTN encourages transplant centers to develop their own guidelines for transplant consideration, noting that each potential transplant candidate should be examined individually and all guidelines should be applied without bias. The OPTN has noted that "listing decisions are complex and that transplant clinicians try to work with patients to identify and mitigate risk factors for negative outcomes and foster positive ones."

In "General Considerations in Assessment for Transplant Candidacy," OPTN explores a number of nonmedical criteria that are commonly used by transplant programs in listing decisions. Two of those criteria relevant to this topic are "potentially injurious behavior" and "adherence." Potentially injurious behavior may include nonadherence to medical recommendations among other behaviors. The adherence criterion, in this context, is "understood to be a bi-directional, proactive process of discussion and agreement between the patient and the medical team, on a course of therapy or management." This criterion specifically references the ability of the potential candidate to adhere to a medical regimen post-transplant.

A refusal to adhere to medical recommendations pre-transplantation could be considered a potentially injurious behavior. It could also provide insight into the potential candidate's ability to adhere to post-transplant medical regimens. OPTN maintains "that evaluation and listing decisions should be driven primarily by medical benefit, and that potentially injurious behavior should not be considered a sole basis for excluding transplant candidates unless [it] outweighs the benefit." OPTN states in the white paper that a history of consistent and documented treatment of nonadherence should be considered by the transplant team.

#### **Transplant Center Listing Criteria and Processes**

Transplant centers do not have uniform selection criteria or processes nationwide. Policies vary by transplant center. OPTN bylaws require all transplant centers to develop candidate selection procedures, but provide no additional requirements for development of those procedures. According to a 2011 study of liver transplant selection committees at four transplant centers, each transplant center conducted weekly selection committee meetings to select candidates for listing. These meetings included transplant coordinators, surgeons, hepatologists, and social workers. Other attendees varied depending on the transplant center. For instance, some included ethicists, and some included experts in neuropsychology, chemical dependence, and finance. In others, social workers assumed these roles.

Selection committees decide to list the patient, defer pending further review, or rule out. The 2011 study found that justification for "rule out" decisions were as follows: (1) the patient was too well; (2) comorbidities or advanced age; (3) the patient was too sick; (4) recent or active substance abuse; and (5) other psychosocial barriers, including psychiatric disease, lack of or inadequate social support, noncompliance or failure to complete testing, and inadequate insurance.

## **Professional Organization Recommendations**

The American Society of Transplant Surgeons (ASTS) has issued a position statement on the role of COVID-19 vaccination for transplant candidates and recipients. In addition, the American Society of Transplantation and the International Society for Heart and Lung Transplantation (AST and ISHLT, respectively) issued a joint statement on the COVID-19 vaccine. Both statements recommend vaccination against COVID-19 for transplant candidates. ASTS notes that this is consistent with their preexisting "routine standards of care" to mitigate known infectious disease prior to organ transplantation. AST and ISHLT specify that household and close contacts of the transplant recipient should also be vaccinated when eligible and that all vaccination should occur prior to transplantation whenever possible.

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