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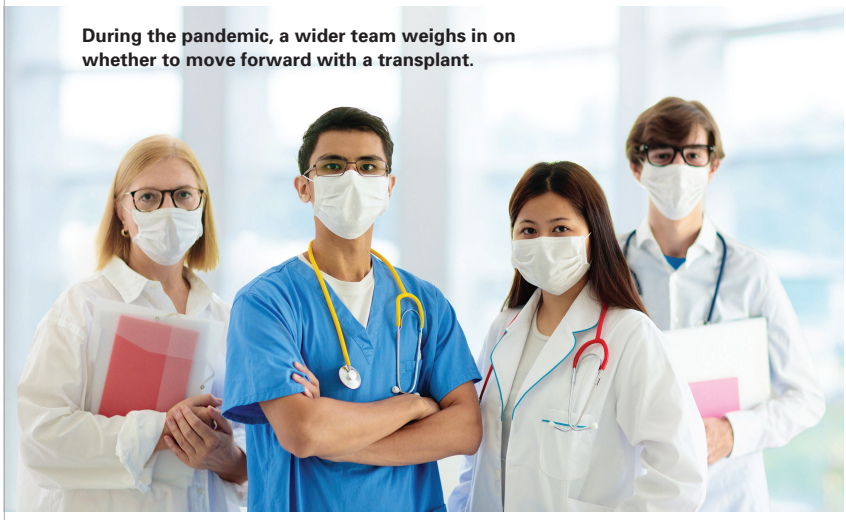
The AJT Report

News and issues that affect organ and tissue transplantation

The Role of Transplant During a Pandemic

The effect of the COVID-19 pandemic reveals the transplant community's unique role—and value—within the healthcare field



During the pandemic, a wider team weighs in on whether to move forward with a transplant.

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"Coronavirus is the scariest thing we have dealt with in a century," states Brendan Parent, JD, assistant professor of bioethics at New York University Langone Medical Center in New York City. The pandemic, he says, has brought with it the question of how best to triage critical lifesaving care, both related and unrelated to the COVID-19 crisis. In many cases, this means that transplants must be suspended.

"There is already some effort to delay transplantations that can be delayed," confirms James Benedict, PhD, scholar in residence at the Center for Healthcare Ethics at Duquesne University in Pittsburgh. Kidney transplants, in particular, have been put on hold throughout the country, because most waitlisted patients have the option of dialysis. The American Society of Transplantation COVID-19 Organ Donation and Transplantation Town Hall reports that transplant centers across the nation are taking a varied approach to the pandemic. In many cases, centers are making decisions about suspending transplantations based on the number of COVID-19 patients in their region.

Managing Scarce Resources

This is a time when the medical community can learn from the transplant community, which has had a lot of experience in making difficult allocation decisions in times of scarcity, such as considering the nuances of listing decisions in terms of comorbidity assessment. However, the transplant community can also learn from the general medical community, as everyone currently seeks ways to overcome resource challenges. "Transplantation extends lives and improves quality of life, just like treatments of COVID do," points out Dr. Benedict. Certainly, the pandemic helps to place transplant within the larger context of medicine and reminds the medical community of its priorities.

In the current climate, not only must transplant centers make decisions about whether to move forward with transplants, so too must patients and physicians, who might choose to reject an organ offer based on an unwillingness to risk COVID infection and the dearth of resources presented by the pandemic. For many patients and physicians, it may make sense to defer the transplant until after the threat has passed. Transplants are still going forward for those patients who would otherwise die, despite the additional risk of infection that transplant carries.

KEY POINTS

- **The rapid onset of the pandemic and its immediate strain on resources has led to an increase in delayed transplants.**
- **Because all health communities must make difficult decisions regarding allocation of limited resources, the pandemic places transplant within the larger context of medicine.**
- **Some transplant centers are making decisions about suspending procedures based on the number of COVID-19 patients in their region.**
- **The pandemic may ultimately give rise to a greater appreciation of the interconnective nature of health among individuals.**

As David Magnus, PhD, director of the Center for Biomedical Ethics at Stanford University School of Medicine in Palo Alto, California, suggests, organ supply may be more likely to decrease during the pandemic, because shelter-in-place directives tend to limit many of those traumatic events—such as automobile acci- →

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dents and gunshot wounds—that can result in brain death and organ donation. There is also concern about transplanting organs that are positive for SARS-CoV-2, which, combined with the current shortage of tests for individuals who are asymptomatic for COVID-19, means that organs from any deceased donor may be associated with unquantifiable risks for the recipients. In addition, the continued backlog in coronavirus test results has meant that potential organ donors are being kept on ventilators for long periods pending test outcomes. In regions where ventilators are a scarce resource, such a decision may not be justifiable. "There is such a different reality between different institutions and parts of the country," says Dr. Magnus. This variability raises the specter of geographic inequality and may force a reckoning with that reality in a postpandemic world.

Looking Forward

"The big lesson is recognizing the way in which all of our systems are tied together," says Dr. Magnus. He also explains that the pandemic will provide an opportunity for the surgical field in general to focus on how to draw the line between essential and nonessential procedures. "It's not just where we are right now, but what happens at the end of this," he says.

Some members of the transplant community have begun to explore the possibility of using organs from patients who are positive for SARS-CoV-2. The idea might seem risky right now, notes Mr. Parent, but it might not in the future. Other viruses infect donors and donor organs, and while such viruses may make these organs marginal, they do not necessarily preclude transplant. Moreover, respiratory viruses

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–David Magnus, PhD

tend not to be a problem for kidney, heart and liver transplants. If the medical community develops a successful approach to managing COVID-19 and/or vaccinations become available, it is possible that organs from patients who are positive for SARS-CoV-2 will become transplantable after such patients are effectively treated.

The pandemic may also create a greater sense of interconnectivity for society in general, and may motivate the healthcare community to make some positive changes. As Dr. Benedict notes, for the transplantation community, a growing understanding of health as a shared resource could translate into an increase in organ donation. He points out that although obesity, smoking and climate change are actually likely to cause more deaths overall, it is coronavirus that has alarmed people the most in terms of health. He attributes this intense fear reaction partially to the rapid onset of the pandemic and its immediate strain on resources. "The pandemic is revealing to us," reflects Dr. Benedict, "that health is a common good. Your health matters to me and my health matters to you… It matters to me if the guy making my fast food has sick leave." AJT

Proposed New OPO Performance Metrics

JULIA KHIMICH / SHUTTERSTOCK.COM

On December 17, the Centers for Medicare & Medicaid Services (CMS) issued a proposed rule that would update the Organ Procurement Organization (OPO) Conditions for Coverage that OPOs must meet to receive Medicare and Medicaid payment. The intention of the revision is to increase both donation and organ transplantation rates, and the proposed rule would revise the outcome measures used for assessing OPO performance to ensure that they are transparent, reliable and enforceable.

Current federal law dictates that the CMS must conduct reviews of OPOs and certify them every four years based on whether they meet the Conditions for Coverage. Facilities must correct any problems cited in the reviews, also known as surveys, to continue to receive payments for services from Medicare and Medicaid. The proposed changes affect these reviews and are intended to improve the quality of OPO services and hold underperformers accountable.

The proposed rule redefines donors as individuals who provided at least one organ that was transplanted. This stands in contrast to the current definition of donors as individuals who have provided an organ that has been procured. This change would mean that OPOs would no longer be allowed to count organs procured for research as part of their organ count for performance. The rule also proposes that, in addition to the current CMS recertification inspections that occur every four years, the CMS would provide a review of OPO performance every 12 months. All OPOs would need to meet at least the donation and transplantation rates of the top 25% of OPOs.

The proposed rule received 834 comments. (Comments were due on February 21, 2020.) One of those comments from Arnold Ventures (AV), a philanthropic organization based in Houston that researches healthcare issues, concluded as follows: "Therefore, AV supports, without qualification, the strong performance standard proposed by CMS for OPOs to maintain contracts, which requires OPOs to maintain performance that is not statistically significantly different from the top 25% of OPOs, in order to maintain their certifications. With 1,000 patients removed from the organ waiting list every month because they have died or become too sick to transplant, we urge CMS to enforce OPO decertifications of poor performing OPOs without delay."

Diana H. Buck, MEd, MBA, CTBS, chairperson of the American Association of Tissue Banks (AATB) Board of Governors, wrote in the AATB response, "In light of the interaction between tissue and organ donation, the AATB urges CMS to provide further rationale for setting a required performance threshold at the top 25%, especially given that it redefines above-average performing OPOs (as a matter of math) as 'low performing' and automatically puts the majority of OPOs at risk of decertification without opportunity to present mitigating factors or an improvement plan. As a result, the proposed measure if implemented could result in a large number of OPO decertifications, which could significantly disrupt the existing system for tissue donation and procurement. The AATB is concerned that this type of destabilization to the existing system of OPOs may create an immediate and unnecessary shortage of tissue grafts available to heal people in need." AJT