Since January 2020 Elsevier has created a COVID-19 resource centre with free information in English and Mandarin on the novel coronavirus COVID-19. The COVID-19 resource centre is hosted on Elsevier Connect, the company's public news and information website.

COVID-19 Vaccine Refusal and Organ Transplantation

Lainie Friedman Ross

For 2 years, the coronavirus disease 2019 (COVID-19) pandemic has wreaked havoc on our health systems. The pandemic has adversely impacted the transplant community—from organ procurement to outcomes. In the United States, the development and free distribution of several effective vaccines has not been the panacea that we had hoped for as uptake of COVID-19 vaccines has been mired in controversy. This has led to moral distress among transplant professionals about how to deal with vaccine refusers. Several programs have denied maintaining vaccine refusers on deceased donor organ waitlists.[1,2] Arthur Caplan, a renowned ethicist, published a commentary on a medical news website entitled "It's Okay for Docs to Refuse to Treat Unvaccinated Patients."[3] I argue it is not okay, not even when the treatment is a scarce resource and patients put the organ at risk because of their decision. And my argument holds for all transplant candidates irrespective of the organ needed.

The debate to penalize or exclude waitlist patients whose choices we disagree with is not new in the transplant world. For 30 years, some have argued to give those with alcohol use disorder lower priority on the liver transplant waitlist because they are (at least partly) to blame for their illness.[4,5] Others have argued for relative or absolute contraindications based on candidate behaviors (from smoking to lack of social support).[6] Most notable is the lack of consensus about these criteria for each organ.

Four arguments are advanced to exclude COVID-19 vaccine refusers from transplant waitlists. First, vaccine refusers are to blame for being at risk for COVID-19 because the vaccine is easily available and free. Second, vaccine refusal is a sign of nonadherence. Transplant recipients must follow a very strict regimen and if they are unwilling to get vaccinated despite repeated recommendations, they should be excluded. Third, transplanting an unimmunized candidate may "waste" the organ due to an early preventable patient death, and if it causes graft and patient outcome requirements at a particular transplant program to fall short of Centers for Medicaid & Medicare Services (CMS) requirements. it may place the transplant program's Medicare participation at risk. Fourth, unvaccinated transplant candidates pose an unacceptable risk to their providers and other patients.

Each claim can be refuted. First, whether patients are to blame for being at risk for COVID-19 is morally irrelevant; physicians have a fiduciary responsibility to act in patients' medical best interests. The transplant community has set thresholds of graft and patient survival thresholds above which candidates in organ failure are deemed to be able to benefit from organ transplantation and eligible for listing. Vaccine status can be considered one component of clinical risk that determines expected graft and patient survival over time.[7] Candidates whose expected outcomes meet the minimum CMS requirement threshold should be waitlisted, even if they fail to maximize their odds for the best clinical outcome. Although these candidates are making bad choices and they should be strongly counseled to get vaccinated, penalizing them is inconsistent with our fiduciary obligation of beneficence.

Second, vaccine refusal in and of itself is not proof of nonadherence. Most transplant programs strongly recommend but do not mandate vaccines for other vaccine-preventable diseases.[8] Although COVID-19 is more lethal than many of those other infections and we are in the midst of a pandemic, new effective treatments are being developed, although much still needs to be learned regarding safety and efficacy.

Third, the claim that transplanting unvaccinated candidates wastes organs and threatens a program's CMS status because of high mortality is problematic because there are ways to mitigate risk regardless of vaccination status (eg, social distancing, wearing of effective masks, avoiding indoor crowds). Although the risks from severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection in transplant recipients are serious, the vast majority of unvaccinated transplant recipients infected with SARS-CoV-2 recover. An early meta-analysis of global case series found that "a higher admission rate was noted but overall outcome was similar to the general population,"[9] although other meta-analyses have demonstrated both severity and mortality to be higher in transplant patients.[10] Even if unvaccinated candidates are at greater risk of mortality, the threat to a program's status is also true of other nonideal candidates (eg, older candidates). Candidates who meet graft and patient outcome thresholds adjusted for vaccine status should be offered an organ.

Fourth, the risk the unvaccinated transplant patient poses to other patients and to the transplant community is real, but much lower if the transplant team is vaccinated and we adopt other mitigation strategies in our hospitals. Vaccine refusers among organ candidates will be the exception. Before we threaten unvaccinated candidates with delisting, we must acknowledge that only 73% of health care workers were vaccinated by September 2021, even though we were given first dibs.[11] Many health professionals do not get annual flu shots, exposing our patients to risks. Making COVID-19 vaccine refusal an absolute exclusion for waitlisting is too severe.

The main moral problem with a policy to refuse to transplant unvaccinated candidates, then, is an equity

concern. Under the National Organ Transplantation Act[12] and reaffirmed by the Final Rule,[13] the transplant community is charged not only with ensuring "best use of organs" but also with the responsibility to balance equity and efficiency. COVID-19 vaccine refusers are not a random group, with higher vaccine hesitancy in communities of African ancestry and Hispanic ethnicity,[14] who are already disadvantaged by many transplant allocation policies and practices.[15,16] Although the racial and ethnic gap of COVID-19 vaccine uptake has largely disappeared, the gap still persists for booster shots among those who are eligible.[17] Given the structural racism that undergirds medical history in the United States,[18] and the call to promote racial equity in organ transplantation,[19] we must consider the unintended consequences that a policy to exclude the unimmunized from the waitlist will cause. A mandatory policy may exacerbate racial and ethnic disparities. Rather than penalize, we must take the time to hear the concerns of the unvaccinated and to work with them to overcome misinformation and mistrust.

Even if transplant programs are within their legal right to discriminate against candidates who refuse the COVID-19 vaccine, one must ask how far the community is willing to go. Will transplant teams mandate testing to ensure that the vaccine recipients mounted an effective immune response, or will they mandate multiple boosters? If the patient is a minor, what will the transplant team do if they are not vaccinated because of age or because of parental concerns? One must also wonder what will happen if the transplant candidate's designated caretaker or other family members refuse to be vaccinated. Will the transplant community demand that candidates find another support person, and what will we do if the candidate cannot?

The desire to exclude those patients whose primary support person refused vaccination is not hypothetical. The clinical ethics consultation service at Loyola University Health System recommended such a policy to its transplant programs, arguing "it has long been precedent in allocating organs to require recipients to have social support that promotes the possibility of successful living post-transplant."[20] This precedent may be a major source of inequity. In 2019, Ladin et al[21] conducted a survey to determine how many patients are excluded from organ waitlists owing to lack of social support. They noted that "subjective criteria such as social support are especially susceptible to implicit bias, exacerbating concerns about inconsistent use and disparities."[21] They also noted that Canada and the European Union recently removed social support considerations owing to these concerns.[21]

I totally support recommending, encouraging, and even nudging transplant candidates and their social support person and other household members to get vaccinated for COVID-19. This is one of those health care situations in which directive counseling is not only morally permissible but, one could argue, morally obligatory. COVID-19 vaccination of transplant candidates promotes the medical interests of the patient, because of the risks of immunosuppression post-transplantation; the best use of organs, by reducing the risk of unnecessary graft loss or recipient death due to COVID-19; the safety and well-being of the transplant team who cares for the patient, by protecting them from unnecessary exposure; and the safety and well-being of other immunocompromised patients who may come in contact with the individual in the outpatient transplant clinic or the hospital setting. Directive counseling can take many forms: educational programs provided in virtual group pretransplant sessions and/or written educational materials that address vaccine concerns for candidates and families, a peer educator program of vaccine advocates, and tailored conversations as part of outpatient appointments.[7] Our responsibility does not end if they initially refuse. A vaccine refusal at 1 time point does not take the conversation off the table, because recent data show increasing vaccination among previously hesitant individuals. Respectful conversations within a trusting doctor-patient relationship in which patients and their families do not fear being penalized for their ambivalence are integral to increasing vaccination acceptance over time. As part of medicine's fiduciary obligation, we must not abandon the unvaccinated patient, but instead must work harder to build trust and to educate and enable all of our patients to choose wisely.

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