Received: 8 December 2021 | Revised: 24 January 2022 | Accepted: 25 January 2022

DOI: 10.1111/petr.14243

VIEWPOINT

WILEY

The case against COVID-19 vaccine mandates in pediatric solid organ transplantation

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Abstract

Background: The American Society of Transplantation in conjunction with the International Society for Heart and Lung Transplantation released a joint statement on August 13, 2021 in which they strongly recommend that solid organ transplant (SOT) recipients and their eligible household members and close contacts be vaccinated against SARS-CoV-2 with an approved COVID-19 vaccine. Some SOT programs have gone further and will refuse to list or transplant candidates unless the candidate and their household are vaccinated against SARS-CoV-2.

Methods: Two general pediatrician-ethicists use current best evidence and moral theory to argue why it is unethical to mandate COVID-19 vaccination for pediatric SOT candidates, their primary support person, and their households.

Results: Pediatric vaccine mandates are most justifiable when they prevent the harm of a serious vaccine preventable disease (VPD) in children in settings where transmission is highly likely and there are no alternatives that are effective in preventing transmission that intrude less on individual freedom. An additional justification for a vaccine mandate in the SOT context is stewardship of a scarce resource if there is significant risk of graft loss from the VPD to an unvaccinated SOT candidate or recipient. Current evidence does not support fulfillment of these criteria in pediatric solid organ transplantation.

Conclusions: Making SOT listing contingent on COVID-19 vaccination is problematic. Though there is some risk of harm to a pediatric SOT candidate in remaining unvaccinated, the risk of harm of not being listed and transplanted is greater and overriding.

KEYWORDS
ethics, parental dismissal, transplantation, vaccine mandates, vaccine refusal, waitlisting

The American Society of Transplantation in conjunction with the International Society for Heart and Lung Transplantation released a joint statement on August 13, 2021 in which they strongly recommend that all solid organ transplant (SOT) recipients and their eligible household members and close contacts be "vaccinated against SARS-CoV-2" with an approved COVID-19 vaccine, and "whenever possible, vaccination should occur prior to transplantation".[1] This statement did not call for compelling the administration of COVID-19 vaccines pre- or post-transplant; rather, it strongly recommended COVID-19 vaccination. Despite this, by early October, several transplant programs began requiring transplant recipients and living donors to be vaccinated against COVID-19.[2–4]

Abbreviations: AAP, American Academy of Pediatrics; SOT, solid organ transplantation; VPD, vaccine preventable diseases.

It appears that the transplant community is divided on the appropriateness of a COVID-19 vaccine mandate. Hippen has argued that a mandate may be narrowly defensible, but "may prove to be purchased at the expense of an attenuation of shared decision-making, proffering claims of risk reduction from a vaccine mandate beyond what the current evidence base supports, and unintentionally exacerbating durable inequities in access to transplantation".[5] In contrast, Kuczewski and colleagues argued in favor of mandating vaccination against SARS-CoV-2 as a condition of being listed for an organ; and to require vaccination against SARS-CoV-2 of the patient's primary person and eligible members of the SOT recipient's household.[6]

There are several arguments for and against a COVID-19 vaccine mandate for SOT candidates. Arguments in support of a mandate include 1) the benefits of the vaccine significantly outweigh the risks for the individual and the community, and 2) to transplant an unvaccinated SOT candidate places at risk the patient who is about to begin lifelong immunosuppression, other patients who may be unwittingly exposed during the course of their treatment, the transplant team, and the transplant program.[7] Arguments against a mandate include the serious and irreversible harm imposed on the unvaccinated if they are refused access to transplantation,[8] and the potential that a mandate will exacerbate health disparities to the extent that there is a higher proportion of vaccine refusers from marginalized groups[5,7,8] (though whether marginalized groups in organ failure will have lower uptake of the COVID-19 vaccine is unknown; the limited data that exist regarding routine vaccination of children in organ failure show low uptake equally in all racial and ethnic communities.[9]).

The debate to date has not yet included consideration of pediatric SOT recipients. Children, however, make up approximately 6%–7% of SOT recipients.[10] In this manuscript, two general pediatricians and ethicists, one (LFR) with expertise in transplantation policy[11,12] and one (DJO) with expertise in vaccine policy,[13–15] use current best evidence and moral theory to argue why it is unethical to require a vaccine mandate for pediatric SOT candidates, their primary support person, and their households.

1 | NEW VACCINE, OLD ISSUE

The issue of under-vaccination of pediatric SOT candidates is not new. In 2005, Campbell and Herold, two pediatric infectious disease specialists, stated unequivocally, "Under no circumstances should transplantation be delayed to accommodate vaccinations. Children in whom primary vaccinations are incomplete prior to transplantation should have immunizations administered post-transplantation" [[16] at p. 658]. The article was clearly written under the assumption that the incomplete vaccine status was due to medical concerns. Similarly, Benden and colleagues elaborate: "Vaccinations are often incomplete in very young children who undergo lung transplantation, as caregivers are unsure whether vaccination is safe for children with advanced lung disease. Children who are frequently admitted to the hospital often have incomplete vaccination because of fractured well-child care" [17 at p. 883]. Both Campbell and Herold as well as Benden and colleagues asserted that vaccination should not be limited to the pediatric transplantation candidate, but the "immunization status of all household contacts should be reviewed and updated" [16 at p. 658–9; [17] at p. 883].

In the intervening 15 years, however, the proportion of parents refusing to vaccinate their children has increased,[18] and the American Academy of Pediatrics (AAP) changed its policy regarding vaccine refusals and patient dismissal. The AAP initially encouraged its members to respect parental vaccine refusals, accommodate parents who refused or delayed vaccines for their children in their practices, and dismiss these patients from their practice only as a last resort.[19] More recently, AAP policy is more permissive of dismissal.[20]

How to approach parental vaccine refusal has not only played out in the primary care office but also in transplant programs. In 2011, Ladd and colleagues surveyed transplant programs to determine their approach to transplantation of pediatric candidates who were incompletely vaccinated using hypothetical scenarios. While most programs (82%) would list a child not vaccinated for medical reasons, less than half (47%) would list a child whose parents refused vaccination. Only five respondents (4%) reported that their programs had written policies regarding parental refusal of vaccination.[21]

Pre-COVID, Feldman and colleagues argued for the need for transplant programs to develop vaccine policies because vaccine-preventable diseases (VPD) are responsible for considerable morbidity and mortality among SOT recipients.[22] In a study conducted pre-COVID, Feldman and colleagues showed that 1092 of 7000 (15.6%) pediatric SOT recipients were hospitalized with a VPD in the first five years post-transplant, with an overall case fatality rate of 1.7%.[22] However, the researchers acknowledge that interpretation of these results are limited by their inability to determine "whether individuals hospitalized for [VPD] had received vaccines against the infection for which they were hospitalized nor to know whether their immunity had waned secondary to immunosuppressive medications"[22 at p. 266].

Data available on risk of harm to pediatric SOT candidates from SARS-CoV-2 are sparse. The few available studies of COVID-19 disease among pediatric SOT recipients do not show any meaningful difference in severity of illness, hospitalization or mortality with their immunocompetent peers.[23–25] Paradoxically, listing and transplanting children who are unvaccinated may be life-saving. Several studies suggest that children in organ failure pre-transplant may be at greater risk from COVID-19 than children post-transplant.[26–28] Though there are several factors that may be contributing to this difference that require further study (e.g., different likelihood of getting tested for COVID-19, different likelihood of exposure), the data to date nonetheless challenge the claim that listing a pediatric SOT candidate who has not received a COVID-19 vaccination amounts to poor stewardship of a scarce resource.

2 | VACCINE MANDATES AND CHILDREN

Another compelling argument against making COVID-19 vaccination required for waitlisting or transplanting a pediatric SOT candidate is that such a mandate penalizes a child for a parent's bad decision.

Children do not choose whether or not to get vaccinated, nor do they choose their primary person nor their household members. To suggest that children will not be waitlisted because their parents make bad choices is punishing children for actions beyond their control, a scenario at odds with what is supported by many theories of justice: children in organ failure are among the worst off[29] and should have priority on the waitlist.[11,30,31]

This is not to say that vaccine mandates for children are never justifiable. Mandates represent a restriction of parent choice or freedom and must be balanced against the broad authority we grant parents in the United States regarding how they raise their children, including the right to make health-care decisions on their behalf.[32] Public health ethics principles are most commonly used to justify infringing upon personal liberty to prevent harm to others while prioritizing strategies that minimize this infringement.[33] Accordingly, when vaccines effectively prevent harm to others by reducing transmission of highly infectious agents capable of infecting others through ordinary close contact in settings that facilitate this type of contact, and the alternatives that are less restrictive on individual freedom are also significantly less effective in preventing transmission, then vaccine mandates are justifiable. School vaccine mandates for most routine vaccines meet these criteria. However, there are a number of reasons why a vaccine mandate for listing pediatric SOT candidates may not. One reason, from a public health ethics standpoint, is that transplant center personnel have access to many other alternatives to vaccines, such as personal protection equipment, hand hygiene protocols, and infection prevention programs, that can effectively reduce the risk of exposure and transmission of VPD in the hospital and transplant setting. A second reason is that all patients, whether vaccinated or unvaccinated, can be required to employ some of these mitigation strategies for the period of time in which they are in a clinic or hospital room. In contrast, many of these alternative risk mitigation strategies are not as accessible or sustainable in schools, creating the potential for increased risk of disease transmission.

A vaccine mandate for listing pediatric SOT candidates may be less justifiable than for school attendance from a clinical ethics perspective as well because the consequences of each mandate are measurably different. To require parents who do not comply with a school vaccine mandate to find alternative educational opportunities for their children may be expensive, time-consuming, and/or the education may be of lower quality. Children in end-stage organ failure, however, may not have an alternative to transplantation.

3 | THE ENFORCEMENT PROBLEM

It is important to also consider how a COVID-19 vaccine mandate for pediatric SOT candidates, their primary support person, and their households would be enforced. If parents refused to vaccinate their child against COVID-19 at a center in which vaccination was mandatory, an option would be to take temporary medical custody of the child and to vaccinate the child on the grounds that it is in the child's best interest.[34] There is precedence for this, such as medical custody for blood transfusions in young children when parents refuse to consent.[35] However, this does not resolve the issue of how to implement a vaccine mandate for the primary caregiver and the other household members.

Policies to mandate vaccination of household members for SOT candidates were not common pre-COVID. While transplant programs strongly recommend that candidates' household members and support persons get vaccinated, very few programs had vaccine mandates for these third-parties because there are often less intrusive mitigation strategies that offer reasonable alternatives to mandates. In addition, enforcement of such mandates likely would involve excessive intrusion into the daily life of these third parties.

In the COVID-19 era, Kuczewski and colleagues support dismissal of candidates from the transplant waitlist if household members are not vaccinated.[6] Kates and colleagues disagree: "transplant centers are not empowered to require caregivers to be vaccinated without imposing consequences harmful to candidates. Because caregiver vaccination status is not readily modifiable by the candidate, it is a less appropriate listing criterion than the candidate's own vaccination status, although both could be expected to improve candidate health, public health, and net utility from transplantation".[36] We agree with Kates and colleagues. In addition, mandating the vaccination of household members is especially hard to justify in the pediatric setting given the early data that show that pediatric transplant recipients have low morbidity and mortality from COVID-19, similar to healthy children.[23–25]

Alternatively, one could argue that if parents and household members refuse to be vaccinated, that the child should be removed from parental custody and placed in a vaccinated household to make the child eligible for waitlisting and transplantation. This also raises serious ethical issues given that the risk of COVID-19 can be minimized by other less intrusive means such as masking, physical distancing, and early treatment with monoclonal antibodies if infected. While parental refusal is not in the child's medical best interest, removing children from an otherwise loving family is not in the child's best interest, all things considered.[37]

4 | WHERE WE NEED TO FOCUS

Policies to reduce unintentional under-vaccination of transplant candidates and their families are needed. The transplant community should prioritize all vaccinations in both pre- and post-transplant care for which all candidates, children and adults, are eligible. Feldman, Feudtner and Kempe proposed three initiatives which we support: (1) improve education of primary care physicians and parents about vaccination practices unique to the transplant population; (2) improve tracking of vaccinations through centralized registries; and (3) educate subspecialists regarding vaccine timing and encourage them to vaccinate in order to avoid missed health-care opportunities.[38] Making SOT listing contingent on COVID-19 vaccination, however, is problematic. We must continue to collect more safety and efficacy data about COVID-19 vaccines in children,[39] and

more specifically, to collect better safety and efficacy data in immunocompromised children. We also need to consider the severe harm that will be incurred by pediatric SOT candidates whose parents will not comply with vaccine mandates. There is some risk of harm to a pediatric SOT candidate in remaining unvaccinated, but the risk of harm of not being listed and transplanted is greater and overriding.

ACKNOWLEDGMENTS

none.

CONFLICTS OF INTEREST

The authors report no conflicts of interest.

AUTHOR CONTRIBUTIONS

Dr. Lainie Ross conceived of the commentary and wrote the first draft as well as numerous revisions. Dr. Doug Opel provided significant intellectual content and made significant revisions to multiple drafts of the manuscript. Dr Ross and Opel approved the final version of the manuscript.

DATA AVAILABILITY STATEMENT

This commentary is based on public data. No independent data were collected or used.

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How to cite this article: Ross LF, Opel DJ. The case against COVID-19 vaccine mandates in pediatric solid organ transplantation. *Pediatr Transplant*. 2022;00:e14243. doi:10.1111/petr.14243