



Considering a COVID-19 vaccine mandate for pediatric kidney transplant candidates

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Abstract

The world continues to face the effects of the SARS-CoV-2 pandemic. COVID-19 vaccines are safe and effective in protecting recipients, decreasing the risk of COVID-19 acquisition, transmission, hospitalization, and death. Transplant recipients may be at greater risk for severe SARS-CoV-2 infection. As a result, transplant programs have begun instituting mandates for COVID-19 vaccine for transplant candidacy. While the question of mandating COVID-19 vaccine for adult transplant candidates has garnered attention in the lay and academic press, these discussions have not explicitly addressed children who may be otherwise eligible for kidney transplants. In this paper we seek to examine the potential ethical justifications of a COVID-19 vaccine mandate for pediatric kidney transplant candidacy through an examination of relevant ethical principles, analogous cases of the use of mandates, differences between adult and pediatric kidney transplant candidates, and the role of gatekeeping in transplant vaccine mandates. At present, it does not appear that pediatric kidney transplant centers are justified to institute a COVID-19 vaccine mandate for candidates. Finally, we will offer suggestions to be considered prior to the implementation of a COVID-19 vaccine mandate.

Keywords Children · Kidney transplantation · COVID-19 vaccination · Mandate · Ethics

Introduction

The world continues to face the effects of a SARS-CoV-2 pandemic that has resulted in more than 290,000,000 confirmed cases and 5,446,753 deaths over the past 2 years [1]. COVID-19 vaccines have proven effective in protecting recipients, decreasing the risk of COVID-19 acquisition, transmission, hospitalization, and death. COVID-19 vaccines are safe, with generally mild and transient side effects for both adults and children. Despite the widespread availability of safe and efficacious vaccines in the US, Canada, and Europe, many eligible adults and

children remain unvaccinated. Solid organ transplant (SOT) recipients are known to be vulnerable to several respiratory viruses, including SARS-CoV-2, due to a weakened T-cell mediated immune response [2]. Vaccination prior to transplant offers the best opportunity to develop immunity [3]. This recognition has led some transplant centers to mandate COVID-19 vaccination prior to accepting a patient as a transplant candidate [4–7]. Others are considering similar mandates. While the question of mandating COVID-19 vaccine for adult transplant candidates has garnered attention in the lay and academic press, these discussions have not explicitly addressed children who may be otherwise eligible for kidney transplants [8–12]. Nevertheless, at least some pediatric kidney transplant centers have instituted COVID-19 vaccine mandates for children 5 years of age and older, excluding children whose parents refuse COVID-19 vaccination for their child.

A kidney transplant is clearly in the best interest of most children with kidney failure, offering them the best opportunity for growth, development, well-being, and survival compared to continued dialysis or compassionate conservative treatment [13–17].

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While it is desirable that all children with kidney failure and their caregivers receive the COVID-19 vaccine, the focus of this analysis is to examine the potential justification of a COVID-19 vaccine mandate for pediatric kidney transplant candidacy. The justification of policies mandating other vaccinations for transplant, while important, are beyond the scope of this paper. We also restrict our discussion to countries and jurisdictions where COVID-19 vaccines are freely available, recognizing that the resolution of current global inequities in vaccine access is another important ethical issue and key to the resolution of this pandemic [18].

Parental vaccine hesitancy and pediatric transplant

Parental vaccine hesitancy is common, longstanding, and complex [19–22]. Concerns about vaccine safety and effectiveness are especially common in communities that have a learned mistrust of the healthcare system [23]. Some vaccine-hesitant parents have children with organ failure who need a transplant. Despite recommendations for universal vaccination, non-vaccination and under-vaccination are common among pediatric kidney transplant candidates and recipients [24–26]. A 2011 survey of pediatric organ transplant centers found that 39% had experienced situations involving caregiver refusal of vaccination for nonmedical reasons [27]. Additionally, 10% of centers reported they would not accept a candidate with organ failure whose parents refused vaccines [27].

There is some evidence suggesting a higher risk of vaccine preventable diseases among pediatric transplant recipients. Feldman and colleagues analyzed nearly 7000 pediatric solid organ transplant recipients in the Pediatric Health Information System administrative database and found 16% of those children developed vaccine preventable diseases resulting in hospitalization, though kidney transplant recipients were the lowest risk group [28]. While that study was unable to assess vaccination status among recipients, Höcker and colleagues reported that vaccine-preventable diseases occurred in 5% of kidney transplant recipients who were unvaccinated and vaccine preventable diseases were four times more frequent in recipients who were unvaccinated than in those who were vaccinated [24].

SARS-CoV-2 and kidney transplant recipients

A number of case series have suggested that adult kidney transplant recipients are at higher risk of severe illness and mortality due to SARS-CoV-2 infection [29–32]. In contrast, a recent metanalysis of SARS-CoV-2 infection among adult

solid organ transplant recipients found rates of lower respiratory tract infection, hospital admission, and ICU admission similar to that of the general population [33]. Despite the higher risk of SARS-CoV-2 complications, there appears to be consensus that for most adults with kidney failure who desire a transplant, the overall balance of benefits and harms favors transplant over continued dialysis or compassionate conservative care regardless of COVID-19 vaccine status [3, 8–11, 33, 34]. This is due to the reduced life expectancy and quality of life associated with the alternative treatments of kidney failure [3, 8–11, 33, 34].

Though the data is limited, reports of SARS-CoV-2 infection among unvaccinated pediatric kidney transplant recipients suggest that most are mild, with few patients requiring intensive care ($n=5$) or supplemental oxygen ($n=3$) and none requiring ECMO or resulting in allograft loss or death [35–38]. Multisystem inflammatory syndrome in children (MIS-C) has been reported in pediatric solid organ transplant recipients ($n=3$), but there is no evidence that it is more common in this population [38, 39]. New variants may change outcomes for these children, and the chronic outcomes from the disease (i.e., “long COVID”) have not been studied in this particular population to date.

The evidence in support of (or against) a COVID-19 vaccine mandate for pediatric kidney transplant candidates is limited and likely will remain so. It is certain that COVID-19 vaccination prior to transplant is preferable for the potential pediatric recipient, their family, the transplant community, and public health at large, but there is uncertainty about the degree of benefit vaccination provides and the magnitude of risks of harms from remaining unvaccinated. In the setting of clinical uncertainty, analysis of the permissibility of a COVID-19 vaccine mandate for kidney transplant has largely focused on balancing ethical principles [3, 8–12]. Proponents of vaccine mandates as a requirement for transplant appeal to the principle of beneficence in emphasizing the medical benefits of vaccination for transplant recipients, the principle of justice with its focus on the stewardship of scarce resources (donated organs) and maximizing the overall utility of transplantation (getting the most overall good from the limited supply of organs) [3, 10–12]. Those opposed to vaccine mandates raise concerns about non-maleficence (the harm done to a patient by denying them the opportunity of transplantation), the uncertain impact of the COVID-19 vaccine on transplant outcomes, worsening inequity, and the violation of patient autonomy [8–10, 12]. This conflict between principles that are not readily balanced suggests that principles may not provide a sufficient framework to provide ethical guidance in the case of vaccine mandates for transplant candidacy [40]. Recognizing the limitations of both the available data and a principle-based ethical analysis related to the COVID-19 vaccine and pediatric kidney transplant, further insight and guidance may be found by using a

casuistic approach, examining other situations in which there is at least modest consensus regarding the use of mandates. We will examine abstinence mandates for substance use disorder, hepatitis B immunity testing mandates, vaccine mandates for healthcare workers, primary care practice vaccine mandates, school participation vaccine mandates, and life-saving blood transfusion mandates. These analogous cases have been used by others to argue for vaccine mandates in organ transplant. Insight from these examples can help form recommendations for developing ethical policy about a vaccine mandate in the pediatric transplant setting.

Abstinence mandates for substance use disorder: encouraging pro-social behaviors

Some have suggested substance use abstinence policies prior to transplantation as analogous to possible vaccine mandates [3, 11, 41]. Many liver transplant programs have policies or mandates requiring a period of alcohol abstinence before accepting a transplant candidate with liver failure due to alcohol-use disorder [42–45]. One justification for such a policy is pragmatic. Some patients with alcoholic liver disease will recover liver function and not need a transplant if they are able to achieve abstinence [44]. The ethical basis for abstinence mandates rests on the argument that if abstinence has not been achieved, the graft will be endangered by future substance abuse, and the life of the graft will be shorter. By not optimizing the conditions under which a transplant occurs, the duties of stewardship of scarce resources and utility would be violated. This argument relies to some degree on conjecture about future events that are inherently uncertain. Some patients with acute liver failure due to alcohol use disorder have received successful transplants without previously achieving abstinence [42–46]. This calls into question the assumption that abstinence is required for a successful liver transplant. Furthermore, abstinence mandates may instead reflect a hidden bias about whether a candidate with alcohol-use disorder, who has contributed to their liver failure through what some consider to be socially-undesirable behavior, deserves a transplant [45, 47]. Such a position may be grounded in flawed assumptions about the degree of choice that exists with addiction and the availability of affordable and accessible efficacious treatments for substance use disorder, and overlooks the role of genetic susceptibility to substance use disorder [45, 47].

Like adults with liver failure due to alcohol-use disorder, it does not appear that early outcomes following kidney transplant for children or adults who are unvaccinated for SARS-CoV-2 are as bad as initially feared [33, 35–38]. In contrast to the lack of resources available to treat substance abuse disorder, COVID-19 vaccines are widely available and accessible in high-income countries. Like those with

liver failure due to alcohol-use disorder, those who refuse COVID-19 vaccine could be viewed as less deserving of a limited resource by refusing to participate in the pro-social behavior of vaccination to promote herd immunity than a potential candidate whose parents consented to the COVID-19 vaccine. It is possible that mandates reflect a desire of transplant teams to impose pro-social behavior that benefits public health and may benefit other vulnerable transplant recipients. Two years into the pandemic, it is common to hear anger and frustration towards the unvaccinated from exhausted health care teams, and mandating against the unvaccinated might be, in part, an emotional response to this difficult situation.

If vaccine mandates are truly an attempt to increase immunity among transplant candidates, then they should not be based on merely receiving the vaccine, but on mounting a sufficient immune response to it [8, 9]. After all, the goal of vaccination is immunity, at least sufficient to reduce serious illness and reduce spread to others. It has been established that patients with kidney failure do not respond as robustly to vaccine and some do not respond at all [48–50]. A very small proportion of children may have anaphylaxis or other issues which would be valid medical exemptions to vaccination. If the purpose of a mandate were strictly based upon medical benefit to the candidate or avoiding harms to other transplant recipients, such children should be also excluded from transplant. If, however, the purpose of the mandate were to promote socially desirable behavior such candidates should be included as they performed or were exempted from performing such action. The more important question is whether the promotion of socially desirable behavior is a sufficient reason to deny a transplant.

Pragmatically, the current literature suggests the socially desirable effects of mandating COVID-19 vaccine for pediatric kidney transplant candidates are likely to have a limited positive impact on overall public health. For the unvaccinated child, however, the potential harm of denying a transplant is substantial. When considering justifications for a COVID-19 vaccine mandate, pediatric kidney transplant centers may be better served focusing on the medical benefits and harms to the candidate or to other transplant recipients than focusing on promoting pro-social behaviors.

Mandated hepatitis B immunity testing and hemodialysis units: protection of others

Like the transplant clinic, in-center hemodialysis places multiple vulnerable patients and staff in close proximity. Historically close proximity and exposure to blood products contributed to outbreaks of hepatitis B in hemodialysis units [51]. As a result, it is standard practice in hemodialysis units to test for hepatitis B immune status in all patients at onset of therapy

and regularly as part of the Conditions for Coverage for End-stage Renal Disease Facilities in the USA [51, 52]. The primary purpose of this requirement is the protection of others (staff and other patients) rather than the patient themselves. Patients who do not demonstrate vaccine responsiveness are educated and respectfully persuaded to undergo repeat vaccination. Despite mandated testing, those who fail to demonstrate immunity and refuse vaccination are not excluded from receiving hemodialysis treatment. The reasons for this practice are recognition of the extreme harm (e.g., death if life-sustaining dialysis is denied) to the patient and that other steps can be taken to ensure the safety of staff and other dialysis patients, including universal precautions, not reusing dialyzers, and isolation of the unvaccinated patient [51]. While such accommodations utilize additional limited resources, they do permit relatively safe dialysis for the unvaccinated patient, other hemodialysis patients, and staff.

While strongly encouraged, hepatitis B immunity is not required in dialysis centers because other measures can be taken to protect staff and patients. Similarly, accommodations can be made to promote the safety of a pediatric kidney transplant recipient who is unvaccinated and decrease the risks of spread of SARS-CoV-2 to other transplant recipients and staff including use of universal precautions, masking, separate waiting areas to avoid comingling of unvaccinated recipients with others, and physical distancing. An additional relevant factor is that vaccination against SARS-CoV-2 does not guarantee immunity and while it does offer the recipient protection against serious illness in most cases, it does not necessarily prevent infection and the ability to spread the disease to others. Thus, other protective measures are still essential for all patients, including vaccinated patients, in order to avoid spread of SARS-CoV-2 to others. Recipients whose parents refuse vaccination despite education and respectful persuasion should be instructed to take every possible action to protect themselves and others [3]. While an important component of reducing spread of SARS-CoV-2, vaccination does not preclude the use of other protective measures, and we do not believe the added benefit it offers to the protection of others in the clinic justifies the severe harm of denying a kidney transplant to a child whose parents refuse to consent to the COVID-19 vaccine.

Vaccine mandates of healthcare workers: professional obligations

The example of successful vaccine mandates for health care workers has been offered as an analogy by some in support of a COVID-19 vaccine mandate for transplant recipients [10]. For example, COVID-19 vaccine mandates have been imposed upon healthcare workers by many hospitals and a number of states resulted in healthcare worker vaccination rates near 100% [10, 53, 54].

The purpose and context of these mandates is not clearly analogous to the transplant candidate. Proponents of mandates for healthcare workers argue that mandatory vaccination promotes a safer working environment by protecting staff and patients from nosocomial vaccine preventable disease [55–59]. Healthcare workers and institutions are public health agents with professional codes and obligations, particularly towards the vulnerable who cannot protect themselves, including an obligation to “do no harm” [10, 11, 55–57]. Children with kidney failure and their parents have not chosen kidney failure and have no similar codes or professional duties and obligations, even if some would argue they still have ethical duties to others. Consequentially, these claims are significantly weaker than those on healthcare workers and do not seem to justify denial of transplant candidacy.

Primary care practice vaccination mandates: protecting other children and the patient–parent–physician relationship

Like some transplant centers, some pediatric primary care practices have imposed vaccine mandates for patients and families to receive medical care. Advocates for primary care vaccine mandates have provided many reasons for their stance, but most relevant to this discussion are two arguments. First, that pediatricians have an obligation to make their clinics as safe as possible for their patients and staff, and that requiring vaccination protects patients in the waiting room from vaccine preventable diseases [22, 60–62]. Second, that vaccination refusal reflects a rupture in the patient–parent–physician relationship and predicts nonadherence with other therapies [22, 60, 62].

Critics of dismissal policies have questioned these arguments, noting that other interventions such as masking, sequestering sick children, or preventing unvaccinated children from comingling with others in the waiting room may also mitigate risks to other vulnerable patients and staff [22, 63, 64]. Concern that vaccine refusal reflects a complete breakdown of trust in the patient–parent–physician relationship suggests that parents must always agree to physician recommendations regarding child health (e.g., healthy diet, parental smoking cessation, firearm ownership) which reflects an overly paternalistic interpretation of the patient–parent–physician relationship and does not reflect the true nature of pediatric practice [22, 63, 64]. There is no evidence that vaccine refusal by itself predicts non-adherence with other aspects of medical care. Dismissal policies do not benefit the child whose parents refuse to consent for vaccination and may reduce opportunities for that child to receive needed medical care [63]. Dismissal policies do not benefit overall public health and may instead worsen public

health if they result in clustering of unvaccinated children in one or a small number of practices [22, 63–66].

Transplant programs also have a duty to reduce the likelihood of disease spread among their patients and staff, and they have taken steps to decrease risks to immunosuppressed transplant recipients coming to clinic. Practices such as universal masking, separate waiting areas, or moving high-risk or vulnerable patients directly to examination rooms decrease the risks posed by a transplant recipient who is unvaccinated. As previously stated, COVID-19 vaccination does not guarantee that a patient will not get infected and spread the disease to others, so other measures remain necessary. A strong and trusting patient–parent–medical team relationship is required for a successful transplant recipient, but, as in primary care, parental agreement with every recommendation made by the transplant team is not required. Like some primary care pediatricians, some transplant clinicians have raised concern that vaccine refusal is a marker for future nonadherence with transplant medications, testing, or follow-up, though there is little data to support this [3, 10]. This perspective is also inconsistent with OPTN guidance that certain pretransplant behaviors like dietary indiscretion or missing dialysis may not be true indicators of post-transplant adherence behaviors [67]. These behaviors instead reflect differences in values or available resources. Others have argued that it is incongruous to refuse vaccination but agree to immunosuppressive medications [3, 10, 27]. This may seem correct, but such incongruity may reflect different understandings of medicine and different values, and may not be sufficient to deny a child a beneficial kidney transplant. A parent who refuses to vaccinate their child because they do not think the vaccine is beneficial or moral may willingly administer immunosuppressive medication necessary to maintain the desired transplant that the parent views as beneficial.

Individual transplant center vaccine mandates raise equity concerns similar to those presented by pediatric practice policies. The potential harms to the child whose parents are vaccine-hesitant are different if the nearest transplant center willing to accept the child is a few miles away versus several hundred miles away. Like individual pediatric practice vaccine mandates, individual transplant center mandates could further burden those centers willing to accept patients whose parents refuse to vaccinate due to the additional risks from clustering unvaccinated recipients.

Additionally, vaccine hesitancy in the general pediatric population has complex interactions with social disparities and trust of the medical system. Data on COVID-19 vaccine uptake confirms that the groups most likely to suffer worse outcomes from COVID-19, like Black Americans, are also more likely to be hesitant about accepting the vaccine for themselves or their children [23, 68]. As Lauren Bunch explains, “there have... been events in the course

of medical history in the United States that have, very reasonably, engendered fear and mistrust among Black Americans.” This can extend to mistrust of a new vaccine, even when the science to support it is strong [69]. We also know that there are persisting disparities in access to and benefit from kidney transplantation for children in racialized communities [70]. Denying organ transplant to children whose parents refused vaccination because of mistrust earned from historic mistreatment of marginalized communities can increase inequities in transplant and exacerbate transgenerational traumas [3, 9, 23]. If vaccine mandates are considered or implemented, transplant clinicians must pay attention to these issues of trust, and redouble efforts to engage parents who may be vaccine hesitant, listen to their concerns, and partner with them on strategies to get their children vaccinated with parental confidence.

Public school vaccine mandates: balancing school safety and public goods

Like a potential COVID-19 vaccine mandate for pediatric kidney transplant, school vaccine mandates require obtaining certain vaccinations prior to school enrollment. These programs have effectively decreased outbreaks of vaccine preventable diseases at school [71–76]. School vaccine mandate requirements may be less than the overall recommended vaccine schedule (such as the ACIP recommended vaccine schedule). This narrowness is not because of rejection of the recommended vaccine schedule, but due to the need to balance the benefits of vaccination against the harm of denying a public good that an unvaccinated child would otherwise be entitled to [74]. Children have a right to receive public education and use of school attendance as a mechanism to promote vaccination must be carefully justified.

In Washington state, the State Board of Health immunization advisory committee (IAC) developed 9 standard criteria to assess whether mandating a childhood vaccine for school participation is justified [74, 77]. These criteria include vaccine safety, effectiveness, cost-effectiveness from a societal perspective, increase in safety of school environment, vaccine effectiveness in preventing diseases with significant morbidity or mortality, reduction in risk of person-to-person transmission, vaccine acceptability to the medical community and the public, and reasonable burdens of vaccine delivery, tracking, and parental adherence [74, 77]. As of January 2022, COVID-19 vaccination has not yet been mandated for public school participation in the USA or Canada. The COVID-19 vaccines appear sufficiently safe for those over 5 years of age and effective at limiting severe disease for children, though due to the relatively low prevalence and severity of disease due to SARS-CoV-2 infection in healthy children, the major benefit of vaccinating children

is accrued by higher-risk adults rather than the children themselves [73]. A recent analysis concluded that too little is known about the performance of any of the COVID-19 vaccines or the epidemiology of SARS-CoV-2 in children to make any firm judgments of whether a COVID-19 vaccine mandate for school participation could be justifiable [73].

Like public school policy makers, transplant centers must balance the benefits that vaccination provides against the harm of denying a public good (an allograft) that a child with organ failure would otherwise be entitled to the opportunity to receive. In the case of pediatric kidney transplant the calculus may be different than the general population of school-age children. Children with kidney failure may be more vulnerable to severe infection from SARS-CoV-2 and these risks may rise further during the immune suppressed state following transplant. A pediatric kidney transplant recipient is also exposed to other immunosuppressed children increasing the risk of spread to other vulnerable patients. Thus, the medical benefit of COVID-19 vaccination may be higher for a child with kidney failure than a healthy child seeking to attend public school. The harms experienced by children may also be different between public school and transplant center vaccine mandates. Denying participation in public school does not deny a child all access to education. A child could attend private school or be home-schooled at greater expense or burden to the family and potentially less benefit for a child. Similarly, a child with kidney failure whose parents are vaccine-hesitant denied as a transplant candidate is not denied access to all kidney replacement therapy. Such a child could still receive dialysis therapy. Yet, the harms of denying kidney transplant are higher than denying public education to a child whose parents are vaccine-hesitant—while not life-saving, kidney transplant is clearly life-improving and life-prolonging.

Refusal of a life-saving transfusion on religious grounds: seeking state intervention to prevent severe harms

Some have suggested that parental refusal to consent to vaccination for a child with organ failure is similar to cases in which other parents refuse to consent for a life-saving blood transfusion on religious grounds [3, 78]. In the blood transfusion example, seeking state intervention to provide consent for a transfusion over parental objection is justified because parental refusal violates the harm principle constituting medical neglect [79]. The child is expected to die due to parent refusal of blood transfusion. Blood transfusion is life-saving, safe, and efficacious. There are no less intrusive alternatives and there is general public support for state intervention. If COVID-19 vaccine refusal similarly violated the harm principle, a mandate would clearly be justified [3, 78].

The harm principle requires consideration of eight conditions to justify state interference with parental decision-making. The first and most important condition asks if parental refusal to provide consent places the child at “significant risk of serious harm” compared to the alternative [79]. This is similar to claims supporting a vaccine mandate on the basis of nonmaleficence directed toward the patient [10, 11]. While the vaccine is very strongly recommended, at this stage of the pandemic, it is not clear that parental refusal to consent for COVID-19 vaccination places the child with kidney failure at “serious risk of serious harm.” As already noted, reports of severe morbidity or mortality from SARS-CoV-2 infection among unvaccinated pediatric kidney transplant recipients during the first years of the pandemic have been rare [35–38].

At present, it does not appear that parental refusal of COVID-19 vaccination violates the harm principle justifying state intervention to provide consent for vaccination. This does not necessarily mean transplant centers must not institute mandates, but rather a mandate cannot be justified solely on the basis of harm to a child whose parents refuse to consent for the COVID-19 vaccine.

Transplant centers could still be justified instituting mandates on the basis of insufficient benefit to the transplant candidate, risks to other transplant recipients, or concerns of the overall transplant system [3, 9, 11]. When weighing these other concerns, it is worth considering whether there are features that might lead transplant centers to consider children and adults differently.

Are children with kidney failure different than adults?

Many adult transplant centers have already instituted COVID-19 vaccine mandates for kidney transplant candidates [4–7, 9]. While the actions of adult kidney transplant centers are beyond the scope of this paper, there are some potential reasons why a COVID-19 vaccine mandate for pediatric transplant candidates may not be justifiable even if one is justified for adult candidates. When considering relative medical benefit, it is likely that the risks of morbidity or mortality to an unvaccinated transplant recipient from SARS-CoV-2 infection are lower for pediatric than adult recipients as the risks from SARS-CoV-2 infection are generally lower in children than adults [35–37, 80]. Furthermore, infectivity of a child with SARS-CoV-2 infection is lower than that of an infected adult [80]. On the other hand, one could note such differences are much less substantial when comparing an adolescent kidney transplant candidate to young adults, who would both be at lower risk than older adult recipients.

Another difference between unvaccinated pediatric and adult candidates is developmental. Adults are assumed to have capacity and, in most circumstances, are responsible for making autonomous medical decisions consistent with their own values. In contrast, children are assumed to lack capacity and decisions must be made for them usually by their parents. In the case of vaccine refusal, it is the parent who has refused the vaccine on behalf of their child. Children whose parents refuse to consent to a vaccine are arguably less responsible for the refusal than an autonomous adult who refuses to provide consent. There have been reported instances where adolescents whose parents have refused to consent for vaccination have sought vaccination without parental consent. If the adolescent desires vaccination steps should be taken to support that decision [81, 82].

A further potential difference between pediatric and adult candidates is the requirements of a committed caregiver. While all transplant recipients require some level of social support and care beyond what is offered by the transplant program, children are reliant to an even greater degree upon their caregivers. If caregivers have refused to consent for their child to be vaccinated, it is likely that they will remain unvaccinated as well, potentially posing a greater infectious risk to other transplant recipients in waiting rooms or other shared spaces [81, 82]. Any potential vaccine mandate must also consider the vaccination status of the caregivers who accompany and care for the pediatric kidney transplant recipient [9, 11].

Gatekeeping and a COVID-19 vaccine mandate

Organs are a limited resource and must be rationed. Transplant teams are tasked with determining the “best use” of those organs. Organ stewardship requires that an organ be allocated in a way that is likely to result in significant medical benefit to the recipient, not merely for the recipient to have any chance of benefit [11]. One approach to transplant gatekeeping is to consider “best use” of an organ by a patient-centered approach focused on identifying the medically suitable candidate and an assessment of whether the potential recipient would benefit sufficiently relative to the burdens that transplant would pose [83]. In their classic text, Fox and Swazey described this goal of gatekeeping by transplant professionals as “to optimize the patient’s chances for survival and to offer him as enduring, active, and meaningful a post-transplant life as possible without undue physical, psychic, or social harm to himself, the donor, or their families” [83]. Such an approach would focus on the absolute risk that COVID-19 vaccine status confers on a pediatric kidney transplant candidate. A different approach is to consider the likelihood of medical benefit to a potential

transplant recipient relative to another hypothetical patient in need of the allograft, focused on comparing relative benefit and prioritizing the “better” candidate [84]. In one example of this approach, some have suggested the use of a standardized benchmark for transplant candidacy based on a minimal acceptable outcome of $\geq 50\%$ 5-year survival [85, 86]. Conceivably, a similar claim could be made to justify a COVID-19 vaccine mandate if outcomes of pediatric kidney transplant recipients who are unvaccinated were substantially worse than recipients vaccinated prior to transplant. This claim is unlikely to prove successful. While data is limited, studies to date do not suggest notably poorer patient or graft survival [35–37]. Furthermore, average graft and patient survival among pediatric kidney transplants at baseline is significantly higher than the proposed minimal acceptable outcomes. In the USA, the 5-year average graft survival was 84% among deceased donor pediatric kidney transplant recipients from 2013–2014 and 5-year patient survival was 97% [87]. Using either approach, it seems clear that for a child with kidney failure, receiving a kidney transplant is clearly in the child’s best interest regardless of vaccine status.

If the effect of a COVID-19 vaccine mandate is to exclude vulnerable children from a treatment that is in their best interest, then the burden of proof must be on those pursuing steps to exclude them. That solid organs are scarce, life-improving commodities gifted to the community of those in need does not change this [3, 11]. While one could argue that everyone with organ failure is inherently vulnerable, children are doubly so. While a kidney transplant may impose additional risk of morbidity or mortality from SARS-CoV-2 infection in an unvaccinated child due to the impact of immunosuppression, this has not been clearly demonstrated in children. In contrast, the survival, quality of life, and developmental benefits of kidney transplant over dialysis have been clearly demonstrated.

Mandates for potential transplant candidates are coercive. They deny a choice (to receive a transplant) that a child or parent is otherwise entitled to by threat of harm. Harm of denial of a transplant is real and significant. Coercion is sometimes justifiable (such as seat belt or driving while intoxicated laws), but this is justified by preventing clear and significant harms to the person or to others. While we agree that every eligible child (and adult) should be vaccinated against the SARS-CoV-2 virus, the limited evidence to date suggests a transplant is clearly in the best interest of a child with kidney failure regardless of COVID-19 vaccine status. Without clearer evidence, it is difficult to claim a mandate for COVID-19 vaccine among pediatric kidney transplant candidates meets a similar threshold of clear and significant harms. While a kidney transplant is not lifesaving, it is clearly life improving compared to remaining on dialysis and unvaccinated. Furthermore, other less drastic opportunities

exist to mitigate risks of harm to the unvaccinated transplant recipient and to other patients and staff. Finally, pediatric kidney transplant recipients form a small portion of kidney transplant recipients and a tiny portion the overall population, while it would be ideal for all transplant recipients to be vaccinated prior to transplant, such a practice is unlikely to dramatically impact overall public health in a large country with significant vaccine resistance. It is not clear that a COVID-19 vaccine mandate for pediatric kidney transplant would enhance net utility, but there is clear concern it would harm vulnerable children otherwise expected to benefit from transplant.

Avoiding a mandate

An all or nothing approach makes an issue adversarial when a more nuanced approach may be more helpful. Trust between patients, parents, and the medical team is critical for a successful transplant. Parents and children frequently come to COVID-19 vaccine decisions with different understandings of the mechanisms, safety, efficacy, and nuances of COVID-19 vaccines than those of the transplant team [10, 23, 88]. They may feel strongly that vaccine refusal is in the child's best interest. Efforts should be made to educate and promote trust rather than erode it with an ultimatum. Vaccine refusal may be a modifiable behavior with several evidence-based strategies available for increasing vaccine acceptance within the patient–parent–clinician relationship [3, 89, 90].

A framework for a COVID-19 vaccine mandate for pediatric kidney transplant

It is clear that all eligible children with kidney failure and their caregivers should be educated and respectfully persuaded to obtain the COVID-19 vaccine. Centers should make every reasonable effort to encourage, promote, and help transplant candidates achieve full COVID-19 vaccination. As with all decision making in children, transplant teams should aim to understand the values of parents and children, hear their concerns, and develop shared expectations of what can, and should, occur during the transplant workup and post-transplant care. Transplant workup may need to be delayed while working through concerns with vaccination. Mandates for adult candidates may potentially be justified, but a mandate that would exclude children who are unvaccinated from transplant eligibility entirely does not seem ethically justifiable at the present time.

Our understanding of the current pandemic and impact of SARS-CoV-2 continues to evolve. It is possible that future

studies may identify clearly increased harms related to SARS-CoV-2 infection among pediatric kidney transplant recipients who are unvaccinated. It may be necessary to impose a mandate. With this in mind, we propose the following suggestions to be considered prior to the implementation of a COVID-19 vaccine mandate:

- The vaccine must be demonstrated to be safe and efficacious, and approved by a national or international regulatory agency. Currently, there are transplant candidates who are too young to receive the vaccine at all, or for whom the vaccine has only emergency (rather than full) approval.
- The vaccine mandate must provide *clear* benefit to either the potential transplant recipient or other recipients or the transplant system as a whole. Using a vaccine mandate for transplant candidacy solely to support general public health policy is potentially coercive, unlikely to achieve a goal of improved public health, and certain to harm children whose parents refuse to consent to vaccinate.
- Vaccine mandates should be explicit, evidence-based, and developed with diverse stakeholder and community input. Suggested models to develop vaccine mandate policy have been proposed elsewhere and may provide more specific guidance [3, 77].
- Any vaccine mandate should apply universally (nationally). While transplant centers are permitted to develop their own policies and criteria for evaluation of candidates for transplant, we agree with others and encourage any vaccine mandate to be developed on a national or regional level [3, 9]. A national policy allows for a consistent, fair, and standard approach to transplant candidates who are unvaccinated.
- Any mandate must consider the implications for those who receive the vaccine, but lack measurable antibody response or who cannot receive the vaccine for reasons such as anaphylaxis [8, 9].
- Any vaccine mandate must consider caregiver vaccination status as well.
- A mandate should not reinforce inequity in transplant access. A COVID-19 vaccine mandate risks disproportionately impacting children from historically marginalized groups who may have good reason to mistrust vaccine recommendations. This is an empiric question and the impact of a mandate on marginalized groups must be studied. If such a policy results in an unacceptable impact on transplant equity, it must be paused [8, 10].
- Any vaccine mandate should be continually reassessed for effectiveness and necessity [8–11]. With improvement in the pandemic or improved antiviral treatments, the relative benefit of vaccination may fall, and a mandate should be discontinued. In contrast, if the pandemic were to worsen with a newer more virulent strain, such a mandate might remain in place.

Declarations

Competing interests The authors declare no competing interests.

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