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PERSPECTIVE

Putting ethics and clinical decision making before politics: requiring COVID-19 immunization for Solid Organ Transplantation (SOT) Candidates and their Support Team



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We recommend that vaccination for COVID-19 should be a requirement for waitlist activation for solid organ transplant (SOT). We also recommend that such vaccination be required of the primary member of the in-home support team. We argue that these requirements are consistent with current standard practices that draw on a well-established ethical framework. As a result, these recommendations should be easily received and are only controversial owing to the inflamed and politicized state of public discourse.

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The politicization of our current public health crisis has rendered controversial many simple measures to address the spread and effects of COVID-19. For instance, requiring vaccination of those who work with vulnerable populations (such as nursing home residents) or of professionals who have constant contact with the general public (such as police officers) is debated as if there are two, equally rational positions. But even a cursory reflection on the duties and established practices of health-care workers and public safety professionals makes clear that we should expect the practice of vaccination to be near universal among them because vaccination protects not only those professionals but also those they are committed to serve. The requirements should be set accordingly.

We believe that requiring vaccination against COVID-19 should not be controversial when we focus strictly on established frameworks and practices surrounding eligibility for wait-listing to receive a solid organ transplant (SOT). We recount those frameworks and practices in order to clear away the “controversy” and solidify this requirement as a best practice.

Ethical framework

The ethical framework behind listing a patient to become a solid organ transplant recipient is not essentially different from most clinical decision making.^{1,2} Respect for patient autonomy requires that patients be fully informed about their illness and treatment options. They are empowered to refuse or consent to proposed interventions. However, solid organs are scarce, often life-saving commodities gifted to the community of those in need. This context places heightened responsibility on the transplant team in the shared decision-making process.^{3,4}

Abbreviation: SOT, Solid Organ Transplantation

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Shared decision making in clinical medicine means that each party brings their expertise to the dialogue when more than one viable option exists. Patients know their values and preferences. Physicians and health-care professionals understand the treatment options and their general benefits and burdens. Health-care professionals offer options to the patient that have some chance of benefit. However, in decisions regarding solid organ transplantation, the transplant team adheres to a higher standard than merely some chance of benefit. The transplant team is the initial steward of the gift of the organ. The gift is made to the community of patients in need and good stewardship (sometimes called the principle of utility)⁵ requires that the organ is allocated in a way that is likely to result in significant benefit to the recipient. Thus, the transplant team uses its professional expertise to set screening protocols for potential recipients and requirements to promote behaviors that increase the likelihood of successful long-term transplant outcomes. Many of these are well-known such as requiring potential recipients of a liver transplant who suffer from alcohol substance use disorder to complete a treatment program for the disorder or for a cigarette smoker to demonstrate a sustained abstinence from nicotine before he is approved for a lung transplant.⁶ Such requirements seem common-sensical and typically generate little controversy.

Two other well-established considerations regarding good stewardship of donated solid organs are worth mentioning. First, traditional medical ethics embraces the principle of non-maleficence as embodied in the famous dictum, “*Primum non nocere*.” The physician is obligated to avoid harming the patient and when that is not possible in the course of treatment, to take appropriate steps to ameliorate that harm. Patients who receive SOTs are “harmed” by the physician in the sense that they will be subject to immunosuppression to prevent graft rejection. Being immunocompromised places a patient at increased risk of opportunistic infections. As a result, many transplant programs require the patient to be up to date on a range of vaccinations, such as those for hepatitis A and B, and to receive an annual seasonal flu vaccination. The patient may be required to receive all vaccinations that are proven to be efficacious against infectious threats that would significantly jeopardize the benefit of organ transplantation.

Additionally, it has long been precedent in allocating organs to require recipients to have social support that promotes the possibility of successful living post-transplant. The “support team” in the patient’s household and close contacts must also meet certain qualifications that correlate with successful outcomes. For instance, a potential lung transplant candidate can be ruled ineligible to be listed if their primary in-home support person is a tobacco smoker. While this may defy our American tendency toward individualism, it follows from the health-care team’s duty of stewardship and doing no harm to the patient.

Recommendations

The clinical ethics consultation service at Loyola University Health System (Neiswanger Institute for Bioethics)

was asked to analyze the ethical issues involved in requiring vaccination against COVID-19 as a condition of waitlist activation for SOT.

Recommendation 1 - Requiring vaccination against COVID-19 as a condition of being listed to receive a solid organ transplant is ethically justified by the principles of sound clinical ethics.

A requirement for full vaccination against COVID-19 prior to transplantation is consonant with the value of responsible stewardship of a donated solid organ as this immunization would substantially increase the opportunity for ongoing successful utilization of the graft in a time of pandemic. As a result this recommendation is also supported by the duty of beneficence to the patient. Furthermore, requiring vaccination to become a transplant candidate is entailed by the health-care team’s duty of non-maleficence to the patient. Successful transplantation requires continuous immunosuppression of the patient making them more susceptible to infections such as COVID-19 and less likely to benefit from vaccination post-transplant. Vaccination prior to transplant is an effective and efficient means to minimize this induced vulnerability. Perhaps of the greatest importance is that the requirement is consistent with other requirements to which transplant candidates must agree in order to increase the opportunity for successful outcomes. Thus, it respects the integrity of the shared decision-making process and fundamental medical ethical principles.

Recommendation 2 – Requiring vaccination against COVID-19 of the patient’s primary support person and eligible members of the recipient’s household is consistent with current requirements of those roles.

The eligibility of the patient for listing is currently dependent on the willingness of these persons to meet significantly more difficult or onerous requirements, e.g., the primary support person of a lung transplant recipient cannot be an active smoker. Thus, this requirement is consistent with the current standard of care and respects the integrity of the shared decision-making process. Nevertheless, this conclusion is more provisional in nature and is strongest in this time of ongoing pandemic.

Discussion

The COVID-19 pandemic has had devastating implications for the health of persons nationally and worldwide. At this writing, more than 700,000 fatalities in the United States alone have resulted and the resources of the health-care system have been taxed by high volumes of patients requiring the support of intensive care. The pandemic has been especially injurious to populations with significant co-morbidities. Graft recipients have been vulnerable to the worst effects of the pandemic, with likelihood of mortality many times higher than that of the general population and with increased incidence of graft dysfunction after COVID-19 infection in heart transplant and lung transplant recipients.⁷ Requiring this vaccination is entirely consistent with the

well-developed ethos of transplantation programs that require SOT candidates and their support team to take reasonable steps to increase the chance of a successful outcome in the short and longer-term. Furthermore, the immunosuppression required by the graft means that vaccination post-transplant may not be as effective and requires a longer series of immunizations.⁸ It is reasonable that physicians decline to place patients in this position of vulnerability unless they are willing to use the simple and safe remedy at hand to ameliorate the situation, i.e., the vaccines.

The recommendations are based on a combination of enduring ethical principles and their application in the current context. The application of these principles is done in accord with established standards involving other requirements. The COVID vaccines are highly effective against the current variants prevalent in the pandemic such as the Delta variant.⁹ As a result, vaccination is clearly required by the principle of stewardship and/or utility. The requirement for vaccination of the SOT candidate should probably continue in perpetuity, provided that the available vaccines are highly effective against prevalent variants. However, should a newly-prevalent variant escape the immunity offered by the vaccines, the requirement should be reassessed for its congruence with developed norms. For instance, the 2008 to 2009 seasonal flu vaccine was not required for SOT candidates because it was not believed to be effective against the Pandemic Influenza A H1N1 virus.¹⁰ However, with the advancement in vaccines, the vaccination protocol for heart transplant candidates was updated in 2016 to require pre-transplant vaccination for heart transplant candidates.¹¹

Similarly, should the COVID-19 pandemic come under control in subsequent years with the risk of community transmission lowered to insignificant levels, programs may consider whether the requirements for the patient's household be continued or would be better construed as recommendations.¹² Such an ongoing reassessment of this requirement would maintain good faith with keeping the requirement in line with the stewardship and/or utility standards of other requirements for the patient's household.

It is worth noting that this policy would be unlikely to be controversial but for the current inflamed and politicized state of public discourse. That is, the COVID-19 vaccines are highly effective and present few likely burdens to the recipient beyond short-term discomfort. Their utilization is highly recommended from a medical and public health perspective. However, as the current debate has been distorted by misinformation and partisan politics, some strongly resist vaccination. Nevertheless, such distortions cannot and should not be allowed to override the long-established ethical standards of patient care.

Disclosure statement

The authors have no financial conflicts of interest to disclose.

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