



Letter to the Editor

## Should COVID Vaccination Be Required in Heart Transplantation & Left Ventricular Assist Device Implantation?

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TO THE EDITOR: The COVID-19 pandemic has impacted global health like few other crises in human history. According to the World Health Organization, more than 230 million cases have been confirmed, resulting in more than 4.7 million deaths worldwide.<sup>1</sup> In the U.S. alone, over 43 million individuals have contracted COVID-19 with more than 700,000 deaths.<sup>1</sup>

The far-reaching effects of the pandemic have also substantially impacted solid organ transplantation. Organ donation rates have been reported to be decreased by as much as 50-90% across a wide region of countries.<sup>2</sup> Data from the United Network of Organ Sharing (UNOS) demonstrated a decline of more than 1/3 in the transplant rate in the early period of the pandemic, with a majority of UNOS regions reporting an increase in waitlist mortality.<sup>3</sup> A specific analysis of heart transplantation in the US demonstrated a 75% increase in waitlist inactivation, a reduction of 37% in waitlist additions, and a 26% decline in deceased donor recovery when comparing to pre-pandemic data.<sup>4</sup>

Beyond its impact on transplant trends, COVID-19 has been ruthless in its infection and spread, with many heart transplant recipients contracting the virus. Hospitalization rates for heart transplant recipients with COVID-19 infection have been reported to be as high as 80%, with a mortality approaching 30% in one multicenter European analysis.<sup>5</sup> A more recent systematic review, including 39 manuscripts and 415 patients, confirmed these findings with 77% of COVID positive heart transplant recipients requiring hospitalization resulting in an inpatient mortality of 25%.<sup>6</sup>



These disturbing statistics have spurred professional societies to urge vaccinations for not only those individuals who have received a solid organ transplant, but also those who are being considered for the transplant waitlist. Unique to individuals with end-stage heart failure, this also bears consideration for candidates being evaluated for durable mechanical circulatory support (MCS) or left ventricular assist devices (LVADs). The International Society of Heart and Lung Transplantation (ISHLT) and American Society of Transplantation recently issued a joint statement with the following recommendations:

- i. All solid organ transplant recipients should be vaccinated
- ii. All eligible household and close contacts should be vaccinated
- iii. Vaccination should occur prior to transplantation, with completion of the series 2 weeks before when possible

The ISHLT has further recommended vaccination for all MCS recipients, regardless of prior COVID-19 infection status. These recommendations are based on the tremendous efficacy of vaccinations in preventing COVID-19 related morbidity and mortality. Full vaccination has been demonstrated to be 89% effective at preventing COVID-19 infection leading to hospitalization.<sup>7</sup> This efficacy has been documented across age groups as well as with the most recent Delta variant.<sup>8</sup>

Despite the above data and recommendations, vaccine hesitancy remains a problem, and individual providers as well as institutions are likely to have varied perspectives and policies in regards to vaccination. We, therefore, sought to define provider opinions and current institutional practices amongst transplant and LVAD health care workers. This was achieved with a 5-question anonymous survey, distributed via electronic communications, from September 17 – September 24, 2021. A total of 121 responses were available for analysis. The majority of respondents (63%) were cardiologists involved in the care of heart transplant and LVAD patients. A sizeable proportion of respondents indicated that their program requires COVID-19 vaccination for patients to remain active on the transplant list or in order to be listed, 42.9% and 41.4% respectively. Only 23.1% reported a requirement for vaccination in patients awaiting LVAD implantation with even fewer required vaccinations for the primary caregiver to the patient (12.9% for transplant caregivers, 8.5% for LVAD caregivers). However, when asked for which populations they would be in favor of mandating COVID-19 vaccinations, there was overwhelming support for patients on the transplant list and those awaiting LVAD implantation, 90.9% and 77.7% respectively. The majority of respondents were also in support of a vaccine requirement for caregivers (80.2% for transplant caregivers and 71.7% for LVAD caregivers). Support for vaccination requirements in all four populations remained high when evaluating responses by role on the heart transplant team (Figure).

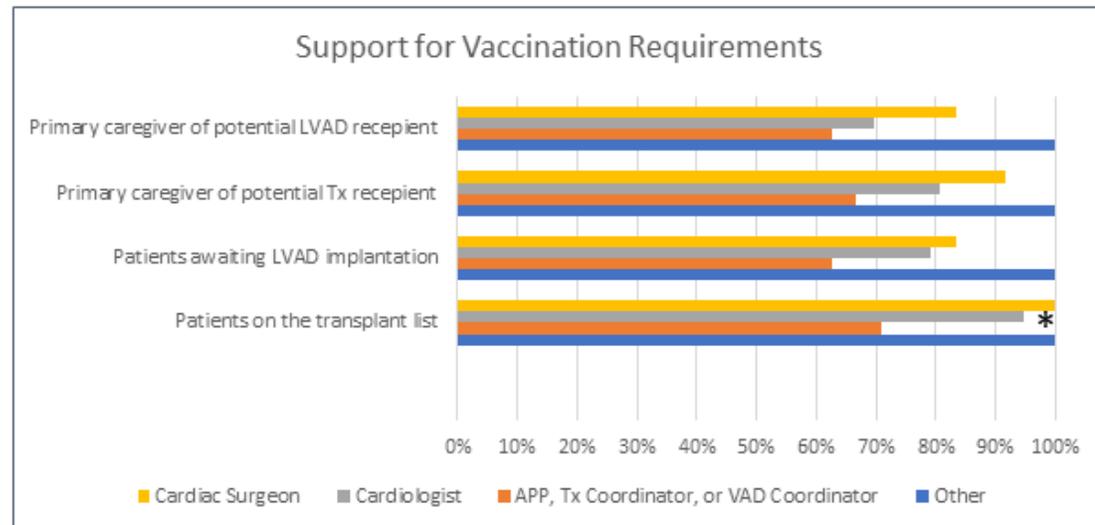


Figure. Support for vaccination requirements by population and provider role. LVAD = left ventricular assist device, Tx = transplant, APP = advanced practice provider, \* = p-value < 0.05

While there is largely agreement amongst providers that vaccinations should be mandated for individuals who are awaiting advanced heart failure therapies, that perhaps should extend to their caregivers; however, implementing such a policy would be challenging. The ethical concerns include complex considerations regarding the principles of autonomy, beneficence, and nonmaleficence, an endeavor fraught with concerns and considerations. While mandates may embrace the ethical principles of beneficence and nonmaleficence by promoting societal well-being, reducing virus transmission risk, and protecting health care workers and the sparse resource of a donated organ, it would undermine autonomy. Furthermore, such a requirement would undoubtedly impact other policy considerations in regard to both vaccinations as well as care giver behaviors and expectations. Beyond this, a more challenging question which arises with vaccination mandates may be the implications of such a change in policy to those patients already listed. If programs and providers proceed to de-list individuals who refuse to be vaccinated, how one addresses these vaccine hesitant candidates would potentially disrupt the fairness and equity of the evaluation and listing process. Finally, the possibility of having different expectations for transplant candidates as compared to LVAD candidates, regardless of the intended implant strategy for the latter, would be yet another policy and ethical conundrum.

While there are inherent limitations to any data acquired by survey, we feel that these data provide a useful snapshot of perspectives among the transplant community. Additionally, we were unable to distinguish whether or not more than one respondent from the same institution answered the survey. As such, we cannot yet conclude that most institutions require or wish to require vaccination.

The ethical and practical implications of vaccine mandates is certainly an area which requires thoughtful and meticulous discussion as well as research.



Differences in patient outcomes and factors such as patient satisfaction and patient provider trust between institutions that mandate the vaccine and those that do not would be key determinants in shaping policies surrounding vaccine requirements. Tailored surveys deployed to program leadership as policies evolve in this dynamic milieu, in addition to guidance from legal counsel, ethic committees and professional societies will be instrumental in approaching this challenge. In the interim, advanced heart failure providers should continue to broach the subject of vaccination with their patients. Too often patients and providers fail to engage in this exercise over concerns of the politicization and cultural perceptions of such conversations. While we struggle with the challenges of policies and mandates, we can always foster meaningful discussions with our patients and their caregivers.



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