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Update on Coronavirus 2019 Vaccine Guidelines for Transplant Recipients

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ABSTRACT

The coronavirus disease 2019 (COVID-19) vaccine and its utility in solid organ transplantation need to be timely revised and updated. These guidelines have been formalized by the experts—the apex technical committee members of the National Organ and Tissue Transplant Organization and the heads of transplant societies—for the guidance of transplant communities. We recommend that all personnel involved in organ transplantation should be vaccinated as early as possible and continue COVID-19–appropriate behavior despite a full course of vaccination. For specific guidelines of recipients, we suggest completing the full schedule before transplantation whenever the clinical condition permits. We also suggest a single dose, rather than proceeding unvaccinated for transplant, in case a complete course is not feasible. If vaccination is planned before surgery, we recommend a gap of at least 2 weeks between the last dose of vaccine and surgery. For those not vaccinated before transplant, we suggest waiting 4 to 12 weeks after transplant. For the potential living donors, we recommend the complete vaccination schedule before transplant. However, if this is not feasible, we suggest receiving at least a single dose of the vaccine 2 weeks before donation. We suggest that suitable transplant patients and those on the waiting list should accept a third dose of the vaccine when one is offered to them. We recommend that organs from a deceased donor with suspected/proven vaccine-induced thrombotic thrombocytopenia should be avoided and are justified only in cases of emergency situations with informed consent and counseling.

SEVERE acute respiratory syndrome coronavirus 2 (SARS-CoV-2) has engendered the global coronavirus disease 2019 (COVID-19) pandemic, which has become a constant menace to solid organ transplantation (SOT) and waitlisted patients, because they are more vulnerable to COVID-19–associated morbidity and mortality [1–3]. The National Organ and Tissue Transplant Organization has previously published COVID-19 vaccine guidelines for transplant recipients and transplant-specific guidelines with reference to COVID-19 [4–7].

COVID-19 vaccination is the most promising way to tackle this pandemic, and because of a rapid change in our outlook about the vaccines, there is need for a revised consensus statement in the context of vaccination among SOT and waitlisted patients.

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With the decline in COVID-19 cases, the number of waitlisted patients ready for transplantation will consequently enlarge, and hence timely and concise guidelines for vaccination will aid transplant physicians in better decision making. Emerging data suggest that the benefits of the COVID-19 vaccine in SOT and waitlisted patients clearly outweigh the harm in the current pandemic [8] The COVID-19 vaccine will also prepare this high-risk population in case of a possible third wave. In general, COVID-19 vaccination should be given to all patients irrespective of previous COVID-19 history. Currently, ChAdOx1 nCoV-19/Oxford −AstraZeneca (Covishield, Serum Institute of India, Pune, India), BBV152 (COVAXIN, Bharat Biotech International Ltd, Hyderabad, India), Sputnik V, and Zydus Cadila's COVID-19 DNA vaccines are approved by the Drug Controller General of India for persons aged ≥18 years [9] and Zydus Cadila's 3-dose COVID-19 DNA vaccine is approved for emergency use in children aged 12 and older. The data for safety in pregnant women [10] and children [11] are also promising, and it is hoped that these groups will also be included in the near future.

VACCINATING UNIVERSAL HEALTH CARE STAFF AND TRANSPLANT TEAMS

The health care communities are at the highest risk of contracting COVID-19 because they are the most exposed. They can also be a source of disease spread and nosocomial infection. Evidence suggest that the severity of COVID-19 infection is reduced by vaccination. Therefore, vaccinating health care workers is of paramount importance and highest priority. There are enough studies to document safety and efficacy of COVID-19 vaccines in general [12−15]. However, there are also reports of breakthrough COVID-19 [16] cases with vaccines. But owing to the rarity of such instances, and the urgent need for developing an adequate response, immunizing all the staff is highly encouraged. This also calls for continuing the practice of COVID-19−appropriate behavior (eg, wearing face masks, hand hygiene, cough etiquette, and maintaining social distance). The future will unfold the efficacy of vaccines with different strains and mixing of vaccines, but currently, vaccinating all health care individuals should be the first step for restoring full-scale transplantation activities in the COVID-19 era.

Recommendations

- All personnel involved in organ transplantation should be vaccinated as early as possible.
- Continue COVID-19−appropriate behavior, despite full course of vaccination.
- In settings where vaccines are available to groups other than health care workers, but not to everyone, authorities are encouraged to prioritize transplant candidates, transplant recipients, transplant caregivers, or specific transplant subgroups (ie, lung transplant), after first vaccinating transplant staff.
- Educate transplant candidates regarding acceptance of the COVID-19 vaccine.

Additional Recommendations

- Encourage and prioritize vaccinations to patients on the waiting list and before planned living donor transplant whenever feasible. The emphasis should be on encouragement rather than enforcement.
- Counsel patients that the benefits and risks are uncertain in the transplant population and defer to patient preference, explaining the low risk of serious adverse events following immunization such as vaccine-induced thrombotic thrombocytopenia (VITT)/thrombosis with thrombocytopenia syndrome (TTS) associated with adenovirus vectored COVID-19 vaccines in the general population, as reported by Global Advisory Committee on Vaccine Safety [17].
- Request that patients inform the transplant center after receiving the vaccine and in the event of any reaction or adverse event following the vaccine or for any query in case of vaccine hesitancy. Any change in treatment, if required owing to adverse events, should be carried out in consultation with the transplant team.
- Ask all listed patients to update their transplant coordinator or transplant team members after vaccination for tracking vaccination status of candidates on the waiting list and also at time of organ offer; direct inquires by program staff may also be added.

EFFICACY OF VACCINATION IN WAITLISTED PATIENTS AND DONORS

Vaccination before commencement of immunosuppression is aimed at improving vaccine efficacy. The data about efficacy of COVID-19 vaccine in waitlisted patients showed a relatively ameliorated response compared with the general population, but a significant proportion of patients still develop a robust response (Table 1 [18−26]). The chances of acquiring COVID-19 and developing a severe disease is much higher in an unvaccinated waitlisted patient than in a vaccinated patient. A majority of waitlisted patients also have comorbid conditions such as hypertension and diabetes, which make them highly prone to developing severe COVID-19 infection [27]. Furthermore, some data suggest that SOT elicits an attenuated response; hence vaccinating the waitlisted patients will be a more fruitful effort in the context of transplantation. We currently recommend continuing safety measures in all waitlisted patients to prevent COVID-19 transmission. There is no universal or compulsory rule for vaccinating a waitlisted individual, and it is an individual decision, but in cases of nonurgent transplantation, transplant teams have to play a huge role in promoting the vaccination of waitlisted patients. A multidisciplinary approach is needed to inform benefits vs risk of vaccination. This is more important in case of deceased donation, because waitlisted patients will have a long waiting time, so they can theoretically get a full course before transplant. Nevertheless, there are no

Table 1. Summary of Major Studies Regarding Efficacy and Safety of Different Vaccines in Transplant and Waitlisted Patients

Author	Study population (n)	Vaccine	Remarks
Rabinowich et al [18] April 2021	LT (n = 80)	Pfizer-BioNTech BNT162b2 SARS-CoV-2 vaccine	Only 47.5% developed antibody response in LT and lower mean antibody levels (95.41 vs 200.5 AU/mL in control participants, $P < .001$)
Korth et al [19] April 2021	KT (n = 23)	Pfizer-BioNTech, Kronach, Germany	Lower proportion of cases developed antibody response (22% vs 100%)
Grupper et al [20] April 2021	KT (n = 136)	BNT162b2 (Pfizer-BioNTech)	Lower proportion of cases developed antibody response (37.5% vs 100%); MMF, old age, and triple immunosuppression regimen were associated with decreased response
Havlin et al [21] May 21	LuT (n = 18)	Pfizer-BioNTech	None developed Anti−SARS-CoV-2 IgG response but 4 out of 12 developed T cell response
Miele et al [22] May 2021	KT (n = 5); LuT (n = 5); LT (n = 4); HT (n = 2)	Pfizer-BioNTech BNT162b2 mRNA vaccine	Studied T cell response; study showed lesser response in SOT
Sattler et al [23] June 2021	KT (n = 39)	BNT162b2	Studied both Humoral and T cell response; lower response in KT
Boyarsky et al [24] June 2021	SOT (n = 658)	SARS-CoV-2 mRNA vaccine	15% had antibody response after dose 1 and dose 2; 46% had no antibody response and 39% had no antibody response after dose 1 but subsequent response after dose 2
Broseta et al [25] June 2021	MHD (n = 205)	mRNA-1273 (Moderna) or BNT162b2 (Pfizer-BioNTech) SARS-CoV-2 mRNA vaccine.	97.7% response; 95.4% seroconverted
Grupper et al [26] April 2021	MHD (n =56)	BNT162b2 (Pfizer-BioNTech) vaccine	Relatively decreased response compared with control group of health care worker (96% vs 100%); lower age and lower lymphocyte count

HT, heart transplantation; KT, kidney transplantation; LT, liver transplantation; LuT, lung transplantation; MHD, maintenance hemodialysis; MMF, mycophenolate; SARS-CoV-2, severe acute respiratory syndrome coronavirus 2; SOT, solid organ transplantation.

norms for delisting a waitlisted candidate from deceased donor list based on vaccination status. The recommended minimum gap of 2 weeks between vaccine dose and surgery will also be a part of self-isolation for patients and donors, which is integral for transplantation in the COVID-19 era. Additionally, the living donor should be ideally vaccinated before transplant, because they may be a rare source of potential donor-derived infection. This will also negate the complications during transplant from rare but possible vaccine-related COVID-19. As of yet, there is no head-to-head trial of different COVID-19 vaccines in the transplant population suggesting one vaccine over the other for better safety and efficacy. Open, transparent, and evidence-based communication about the potential benefits and risks to recipients and the community is essential to maintaining trust.

Recommendations

- All waitlisted patients should be appropriately counseled about vaccinations.
- Maintain a gap of at least 2 weeks between the last dose of the vaccine and transplant surgery.
- Administer the second dose as per the Ministry of Health guidelines (ie, between 12 to 16 weeks for Covishield and 6 weeks for Covaxin after the first dose, which is similar to guidelines for the general population).
- Complete the vaccination schedule before transplant; however, if this is not feasible, we suggest the living donors receive at least 1 dose of the vaccine 2 weeks before organ donation.
- There should be no temporary de-listing of patients prior to vaccination or for any minimum time period after the first or second vaccine dose is administered.

Suggestions

- Proceed with the transplantation if a candidate or donor rejects the offer of vaccination.
- Complete the full schedule before transplantation whenever the clinical condition permits.
- In cases where complete vaccination course is not feasible, proceed with a single dose rather than proceeding unvaccinated for transplant.
- Proceed with any available vaccine, as there is no preference of vaccines for waitlisted patients or their living

donors in the absence of head-to-head analysis on safety and efficacy of vaccines.
- Accept organs for unvaccinated patients who are highly sensitized (calculated panel reactive antibodies ≥ 80), and vaccinate 4 to 12 weeks after transplant.
- Regarding candidate vaccination status, accept patients on living and/or deceased donor waiting lists who are not highly sensitized (calculated panel reactive antibodies < 80).
- Do not inactivate patients until they receive a partial and/or complete vaccine course; if a patient refuses vaccine after mandatory counseling of risks vs benefits, proceed with written informed consent for the same.
- For those not vaccinated prior to transplant, accept organs and suggest waiting for 4 to 12 weeks after transplant to receive the first dose of COVID-19 vaccination.
- Encourage the acceptance of organs for patients after the first vaccine dose, and delay the second dose of vaccine for 4 to 12 weeks posttransplant when feasible.
- Wait for 2 to 4 weeks after completion of a recipient's vaccination to schedule a living donor kidney transplant when feasible.

EFFICACY OF THE COVID-19 VACCINE IN SOT

Transplant teams should continue encouraging SOT patients to accept the vaccine, because the myths and hesitancy in this ongoing pandemic can hinder the acceptance rate of the vaccines. The efficacy of different COVID-19 vaccines in SOT is less (up to 65%) compared with the general population and information about the risk and severity of a postvaccination COVID-19 is scarce in these patients [28−30]. The detailed summary of high evidence data regarding vaccination in SOT recipients/waitlisted patients is described in Table 1. The reported efficacy of vaccines is further reduced in lung and heart recipients compared with liver recipients because a higher immunosuppression usage occurs with these organs. Hence, checking antibody response after the doses in these organ recipients could be considered**.** The protective level of antibody response in SOT is unknown and limits the utility of antibody testing. Generally, measuring the humoral antibody response or cellular response in all SOT as a guide for dosing is not recommended and currently should be done in research settings. Vaccines are generally safe for SOT as per the current evidence. Other societies have recommended similar intervals between vaccine doses in SOT [31].

Recommendations

- Complete the entire schedule in SOT, preferably before transplant or 4 to 12 weeks after transplant.
- There is no change compared with the general population in the duration between first and second doses for Covishield, which is 12 to 16 weeks apart, and Covaxin, which is 4 to 6 weeks apart.
- Do not change the immunosuppression regimen, either in the form of induction or maintenance, with respect to vaccination.
- There should be a gap of 12 weeks for vaccination in cases of COVID-19 infection, which is similar to the general population.
- There should be a gap of 4 weeks after recovery from any febrile illness (non−COVID-19).
- There should be a gap of 4 weeks after transplant surgery, in a previously unvaccinated patient irrespective of the induction used.
- There should be a gap of 4 weeks after antirejection therapy like rituximab or thymoglobulin or plasmapheresis.
- Do not change the schedule of COVID-19 vaccine with respect to other vaccine schedules.
- Any available vaccine should be administered, and there is no preference of vaccines for SOT.
- All the transplant teams should systematically collect data regarding the vaccine response and adverse events that would prove as a data repository for future studies.
- Further research is needed for dosing, duration, and type of vaccine for SOT, because currently available data have proven lower efficacy in SOT than the general population.

OPTIMUM GAP BETWEEN 2 DOSES/NEED OF A BOOSTER DOSE

A preliminary report concluded that extending the second dose beyond 45 weeks [32] resulted in higher antibody response, and a third dose given at 45 weeks further enhanced the antibody response. The United Kingdom has planned a booster dose—a strategy for a vulnerable group to tackle the subsequent waves [33]. A study reported that a booster dose in SOT will develop augmented antibody response [34]. There are ongoing randomized controlled trials studying the effect of a third dose in SOT [35]. SOT with organs like lung and heart should be the prioritized candidates for a booster dose, but further studies are warranted. France has approved giving a third dose of a COVID-19 vaccine to certain patients who are immunocompromised. As of August 12,2021, the US Food and Drug Administration (FDA) authorizes an additional vaccine dose for certain immunocompromised people and recommends that other fully vaccinated individuals do not need an additional vaccine dose right now [36]. The results from the first COVID-19 vaccine booster trial in transplant recipients show a third dose is safe and highly immunogenic. There is a future need for individualized decision for a third dose in SOT recipients and waitlisted patients who have shown inadequate antibody response after the second dose in research settings. More data are required to suggest administering a booster dose. Booster dose can be given if there is a documented inadequate antibody response in research settings.

Recommendations

- Complete the 2 doses of vaccine in all SOT and waitlisted patients. If the second dose is missed at the scheduled time, then the second dose can be given at any time.

- Further research is needed to establish the protocol for third dose of the vaccine in this group of patients.
- A third dose of the vaccine (when one is offered to them) to suitable transplant patients and those on the waiting list, to ensure continued and adequate protection against COVID-19.

THROMBOSIS WITH TTS/VITT IN SOT RECIPIENTS AND WAITLISTED PATIENTS

A very rare new type of adverse event called TTS, involving unusual and severe blood clotting events associated with low platelet counts, has been reported after vaccination with COVID-19 vaccines Vaxzevria and Covishield. A specific case definition for TTS is being developed by the Brighton Collaboration. This will assist in identifying and evaluating reported TTS events and aid in supporting causality assessments. The Global Advisory Committee on Vaccine Safety noted that an investigation has been initiated into the occurrence of TTS after the Johnson & Johnson vaccine administered in the United States. Countries assessing the risk of TTS after COVID-19 vaccination should perform a benefit-risk analysis that takes into account local epidemiology (including incidence and mortality from COVID-19 disease), age groups targeted for vaccination, and the availability of alternative vaccines [17]. The Global Advisory Committee on Vaccine Safety supports further research to understand age-related risk because, although available data suggest an increased risk in younger adults, this requires further analysis. On the issue of sex-related risk, although more cases have been reported in women, it is important to underscore that more women have been vaccinated and that some TTS cases have also been reported in men. Typically, the onset is between 4 to 20 days after adenovirus vectored COVID-19 vaccination. At the minimum, countries should encourage clinicians to measure platelet levels and conduct appropriate radiologic imaging studies as part of the investigation of the thrombosis event. Clinicians should also be aware that although heparin is used to treat blood clots in general, administration of heparin in patients with TTS may be dangerous, and alternative treatments such as immunoglobulins and nonheparin anticoagulants should be considered. There may be a geographic variation in the risk of these rare adverse events.

VITT is extremely rare (1.67/100,000), and SOT recipients and waitlisted patients are not a proven risk factor. This association was mostly linked to Oxford/AstraZeneca and Johnson & Johnson's vaccines [37,38]. There is uncertainly in estimating the high-risk individuals in whom VITT can occur. Patients on hemodialysis awaiting kidney transplant had a frequent history of thrombosis or HIT, but these do not make them prone to increased risk of VITT. At this point, there is no evidence that waitlisted patients or SOT patients are at increased risk for VITT. On suspicion, laboratory investigations, including low platelet counts, high D-dimer, low fibrinogen, and high platelet factor 4 antibodies [39], guide toward diagnosis along with computed tomography and magnetic resonance imaging findings of thrombosis. No specific treatment is available, but intravenous immunoglobulin has shown good results [40]. There is also no evidence for the use of prophylactic anticoagulation to prevent such episodes. The risk of VITT is far more with the first dose compared with the second. The second dose, in cases of VITT, could be continued with a different vaccine, as administering of a different vaccine to the same individual has been safe in preliminary studies.

Recommendations

- Fear of VITT/TTS should not be a reason for hesitancy in vaccination.
- In the case of organs from deceased donors with VITT/TTS, we recommend notifying the district medical officer in charge of vaccinations regarding an adverse event after immunization and following recommended protocols of the Ministry of Health and Family Welfare, including postmortem as is indicated for causality analysis. Organs from such donors are best avoided and may be justified only in cases of emergency situations with counseling of the benefits vs risks by experts followed by written informed consent
- An expert committee preferably comprising a virologist and a hematologist should decide about suggesting use of organs from potential donors with suspected or confirmed VITT.

DISCLAIMER

Transplant recipients and patients waiting for a transplant and their close contacts must continue to follow the latest government advice to reduce the risk of infection, even when vaccinated.

Updated as on July 2021. Further advice and information are available at: https://www.mohfw.gov.in/covid_vaccination/vaccination/index.html.

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