Special Article

NOTTO COVID-19 Vaccine Guidelines for Transplant Recipients

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Abstract

In December 2019, novel coronavirus (SARS-CoV-2) infection started in Wuhan and resulted in a pandemic within a few weeks' time. Organ transplant recipients being at a risk for more severe COVID-19 if they get SARS CoV-2 viral infection, COVID-19 vaccine has a significant role in these patients. The vaccine is a safer way to help build protection and would either prevent COVID-19 infection or at least diminish the severity of the disease. It would also reduce the risk of the continuing transmission and enhance herd immunity. Immuno-compromised patients should not receive live vaccines as they can cause vaccine-related disease and hence the guidelines suggest that all transplant recipients should receive age-appropriate 'inactivated vaccine' as recommended for general population. Though trials have not been undertaken on transplant recipients, efficacy and safety of COVID-19 vaccine have been scientifically documented for few vaccines among the general population.

Keywords: *COVID-19 vaccine, guidelines, NOTTO, transplant recipients*

Introduction

With the use of COVID-19 appropriate behavior, in many countries, the incidence of COVID-19 is decreasing, though not with some degree in every country. With the development of safe vaccine against COVID-19, its global utilization is paramount. Transplant recipients being a high-risk group for COVID-19 infection, these vaccines are urgently required for these patients. The Centers for Disease Control and Prevention (CDC) suggests that COVID-19 vaccination will help in the prevention of COVID-19, is a safer way to help build protection, and will be an important tool to help in stopping the ongoing pandemic.[1]

Advantages of getting a COVID-19 Vaccine:[1-6]

1. Risk of acquiring COVID-19 infection goes down substantially.
2. Risk of having severe COVID disease even if one acquires the infection is substantially reduced.
3. The risk of continuing transmission to others will decrease
4. Vaccine will help in faster development of herd immunity.

Rationale and General Principle for the Vaccination

SARS-Cov2 infection has significantly impacted transplant recipients, with high morbidity and mortality (5%–35%%).[7-9] Vaccination for these high-risk patients is a priority.

1. Patients with immunosuppression may have reduced response to vaccination because of altered T lymphocyte functions. These patients may have lower antibody response compared to general population. Antibody response usually correlates with the degree of immunosuppression.
2. In general, in immunocompromised patients, live vaccines can cause vaccine-related disease, therefore patients with organ transplant should not receive live vaccines.[10-12] Kidney Disease: Improving Global Outcomes (KDIGO) and American Society of Transplantation- Infectious Disease Community of Practice (AST-IDCOP) guidelines suggest that all transplant recipients should receive age appropriate 'inactivated vaccine' as recommended for general population.[13,14]
3. Efficacy and safety of COVID-19 vaccine has been scientifically documented only for few vaccines and

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many are still under clinical trial.[15-18] Initial trial of COVID-19 vaccine had included healthy volunteers, and patients with comorbidity but trials on transplant recipients have not been done till the publication of these guidelines.

4. Participating recipients can have minor side effects as seen in many other vaccines like vaccine site pain, fever, fatigue, muscle and joint pain, and headache after administration of COVID-19 vaccine. These side effects do not mean vaccines are unsafe. Severe or long-lasting side effects are extremely rare. Also, COVID-19 vaccines are continuously being monitored for safety in post-marketing survey to detect rare adverse events.
5. In cases of any adverse event, the transplant patient is required to report to health care providers for appropriate management. After the completion of COVID-19 schedule, routine antibody testing is *not* required to confirm seroconversion. If needed for research, antibody testing can be done after 14 days of the second dose.
6. More studies are required to document energy, duration of immunity and requirement of booster dose in case no antibodies develop. Table 1 shows details of few common regulatory bodies' approved COVID-19 vaccine.

COVID-19 vaccine guidelines

1. We recommend that all transplant team members should support and encourage appropriate uptake of vaccine by counseling transplant recipients and addressing vaccine hesitancy.
2. We recommend using virtual platforms for information related to COVID-19 vaccine for all transplant team members, who are a major source of information for the transplant recipient community.
3. Based on other vaccine guidelines for solid organ transplant recipients,[11-15] we suggest that transplant recipients and their household members should get vaccinated against any COVID-19 vaccine that is authorized or approved by their health regulators/agencies. Transplant recipients scheduled for transplantation, should be given vaccine two weeks prior to surgery or one to six months post-transplant.[13,14] Even after vaccination, COVID-19 appropriate behaviors like wearing face mask, hand hygiene, cough etiquettes and social distancing should be continued by all recipients.
4. Transplant recipients who have previous COVID-19 infection and or, have antibodies against COVID-19 are also required to be vaccinated. There is no need of testing for antibodies against coronavirus before giving COVID-19 vaccination. Transplant recipients should undergo the entire schedule of vaccination with only one type of vaccine and different COVID-19 vaccines should not be used in the same patient. In case, a transplant recipient misses the second dose of COVID-19 vaccine at scheduled time, then the second dose is to be given as early as possible. Revaccination is not required.

Table 1: Types of COVID-19 vaccines[19-22]

Type of vaccine	Pfizer-BioNTech	Moderna	Oxford-AstraZeneca- SII	Bharat Biotech
Status in India	Pending approval	Not applied	CDSCO approved Emergency Use	CDSCO approved Emergency Use
Storage	70 Degree	-20 for 6 months	Regular fridge	Regular fridge
How it works	Messenger RNA	Messenger RNA	Recombinant Viral Vector Technology	Whole-Virion Inactivated virus
Efficacy	95%	95%	62-90%	Trial on going
Approved status outside India	FDA approved	FDA Approved	Approved in UK	Not applied
How many shots needed?	Two doses, 3 weeks apart	Two doses, 4 weeks apart	Two doses, a month apart	Two doses a month apart
What are the side effects?	Fatigue, headache, chills, muscle pain, especially after the second dose	Fever, muscle aches, headaches lasting a few days. Effects worse after second dose.	Fever, muscle aches, headaches lasting a few days.	Fever, muscle aches, headaches lasting a few days.
Recommendation	≥16 years	≥16 years	≥18 years	≥18 years

CDSCO=The Central Drugs Standard Control Organisation, SII=Serum Institute of India

5. Transplant patient with suspected or active SARS-Cov2 infection should NOT get vaccination. Vaccination should be deferred for 4-8 weeks after symptom resolution.
6. Please see the details of COVID-19 vaccine operational guidelines updated as on 28 December 2020.[2,3,22]

Disclaimer: COVID-19 pandemic is evolving in a dynamic manner, therefore, this COVID-19 vaccine Guideline is a live and dynamic document and will be updated as per the evolving situation. This is consensus Guidelines of National Organ and Tissue Transplant OrganisationIndian society of Organ Transplantation, Liver Transplant Society of India and Indian Society for Heart and Lung Transplantation as on January 19, 2021.

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Conflicts of interest

There are no conflicts of interest.

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