

NATIONAL TRANSPLANT SPECIFIC GUIDANCE FOR COVID-19

1. Deceased Donors

A rigorous epidemiological survey should be conducted among potential donors and their families.

Individuals who have been exposed to a confirmed or suspected COVID-19 patient within the last 14 days, who have returned from nations with more than 10 infected patients and those whose cause of death was unexplained respiratory failure should not be accepted as deceased donors.

PCR of airways specimens of donors with suspicion of COVID-19 should be undertaken.

The deceased donor programme may be temporarily suspended.

(Emergency teams are being created for the management of COVID 19 pandemic drawing health personnel from different sources and is a priority. Under the circumstances, it may be difficult to sustain dedicated transplant activity if health personnel are drawn for management of COVID-19 patients).

2. Living related Transplants

Individuals who have been exposed to a confirmed or suspected COVID-19 patient within the last 14 days or who have returned from nations with more than 10 infected patients should not be accepted as living donors or recipients.

PCR of airways specimens of donors with suspicion of COVID-19 should be undertaken. The living donor transplant programme may be temporarily suspended in line with the MoHFW's Advisory for Hospitals and Medical Institutions dated 03-03-2020, accessible at <https://www.mohfw.gov.in/pdf/AdvisoryforHospitalsandMedicalInstitutions.pdf>

3. Emergency life saving Transplantation

In case a transplant is to be done in an acute emergency setting, it should be performed with appropriate assessment and evaluation of COVID-19 infection in the donor as well as the recipient. Appropriate counseling of both the donor and the recipient as well as their families should be done and due informed consent taken before proceeding with the transplant.

A rigorous epidemiological survey should be conducted among potential donors and their families.

Living donor liver transplant as an emergency procedure may be considered for acute liver failure.

4. Transplantation Recipients

Similar to the general population, transplant recipients should strictly follow the travel advisories issued by the Ministry of Health & Family Welfare, Government of India.

Transplant Recipients returning from Abroad

All transplant recipients who have been exposed to a confirmed or suspected COVID-19 patient within the last 14 days or who have returned from nations with more than 10 infected patients should undergo testing for COVID-19 within 14 days of monitoring, isolation and quarantine. If any transplant recipient has fever or cough, they should immediately call their respective transplant centres. All transplant centres must have guidelines in place specifying which patients need testing and inpatient management and which patients can stay at home with close telephonic follow up. If they are advised to visit the hospital, they should wear a mask as soon as they enter the hospital premises. In case of a medical emergency like difficulty in breathing, they should present to the nearest emergency department.

5. Transplant related recommendations

- a) Transplant in the times of COVID is considered risky in view of the problems of donor selection, recipient selection and infection control risks
- b) Transplant can only be considered in emergent cases in centers which have dedicated facilities to ensure the safety of the recipient and the team
- c) The pre, peri and post transplant areas, including the operation theaters need to be specifically earmarked for this purpose.
- d) Staff involved in their care may not be involved in care of other patients.
- e) There has to be adequate availability of PPE specifically ear marked for their care
- f) The center should not be one earmarked for the treatment of COVID-19 patients and needs to have protocols for patient movement around the hospital to prevent nosocomial acquisition of COVID
- g) Transplant may be considered only after clear counseling on the risks involved due to COVID to recipient and donor.

6. Treatment and modification of immunosuppression

There is scarcity of data and consensus on effective treatments of coronavirus in transplant patients. Many centres have tried antivirals, hydroxychloroquine and macrolides in COVID-19 patients with variable results. However, as of now, there is no treatment approved by the Central Drugs Standard Control Organization (CDSCO) or Foods and Drug Administration (FDA) for COVID-19.

There is no consensus regarding modification in the immunosuppressive regimen of transplant recipients with COVID-19. The dose adjustment has to balance the infection control and the organ rejection.

Since no consensus exists as to the treatment and immunosuppression adjustment of transplant patients with COVID-19, the discretion and decision-making lies with the transplant physician incharge of the transplant patient care.

7. Post-transplant follow up measures

Transplant patients might be at risk for COVID 19 due to immunosuppressed state. They may not manifest symptoms like general population. Fever may be absent in all cases as reported from study from China. Transplant units are advised to consider ways to limit hospital attendance for patients, such as:

- a) rescheduling non urgent out-patient appointments
- b) virtual or telemedicine or telephonic appointments
- c) home delivery of immunosuppression if feasible but not mandatory
- d) Patients with stable graft function and adequate drug supply can avoid routine follow up visits to transplant hospitals

8. Tissue Transplantation

At present, there is no evidence to suggest the spread of Corona viruses by blood transfusion or tissue transplantation.

Disclaimer:

The current outbreak is unpredictable. If widespread community-transmission occurs, healthcare infrastructure and capacity issues may have further impact on donation and transplantation. These recommendations will be regularly updated to account for the changing epidemiology and new information regarding treatment and testing. All transplant units must be aware of national and local guidance for managing patients with COVID-19.

No suit or legal proceedings shall lie against any person for anything done or intended to be done in good faith under this suggestions/advisory unless proved otherwise.

Information correct as of 30th March 2020.

- Please refer to below links for more information:-

- ❖ <https://tts.org/23-tid/tid-news/657-tid-update-and-guidance-on-2019-novel-coronavirus-2019-ncov-for-transplant-id-clinicians>
- ❖ <https://www.mohfw.gov.in/pdf/AdvisoryforHospitalsandMedicalInstitutions.pdf>
- ❖ <https://www.fda.gov/emergency-preparedness-and-response/mcm-issues/coronavirus-disease-2019-covid-19#fastfacts>
- ❖ <https://www.gaeba.org/2020/alert-coronavirus-2019-ncov-and-ocular-tissue-donation/>
- ❖ Guidelines for Liver Transplantation and COVID-19 Infection, as received from the President, Liver Transplant Society of India (LTSI) via official correspondence on 23-03-2020.

FAQS FOR ORGAN TRANSPLANT PATIENTS DURING COVID-19

1. How is SARS CoV-2 (the virus responsible for COVID-19) transmitted?

The transmission of SARS CoV-2 infection occurs from infected individuals through droplet spread or through fomites. A fomite is any inanimate object that, when contaminated with or exposed to SARS CoV-2 can transfer disease to a new person. For humans, common fomites are skin, hair, clothing, etc. On different fomites, virus can survive for different periods of time. The incubation period for COVID-19 in most of the population is 2-14 days.

2. Are transplant recipients at greater risk for acquiring COVID-19?

Risk of acquiring COVID-19 is same in organ transplant patients as any other person in society. However, due to the immunosuppressive drugs given to transplant recipients, their propensity to develop severe COVID-19 is higher as compared to other immunocompetent persons or non-transplant persons. and more likely to require ICU Care as compared to the general population.

However, a report from Lombardy province in Italy suggests that transplanted patients are at not any additional risk as the innate immunity is not altered by immunosuppressive medicines.¹

3. Do transplant recipients have to follow specific travel restrictions?

The Ministry of Health and Family Welfare, Government of India has recommended the countries to which travel should be avoided during the COVID-19 pandemic. These are updated regularly as the outbreak is evolving and can be accessed at https://www.mohfw.gov.in/travel_ad.html. It is also advisable for immediate household contacts of transplant patients to not travel to these high risk areas, as they will be a risk to transplant patients in their home environment, when they return from the epicenters/high incidence countries of the COVID-19 pandemic.

4. Is it advisable for transplant recipients to wear a mask or avoid crowded places?

Generally, as such, transplant patients should avoid being in crowded public places. Whether wearing masks outside the hospitals will provide protection from viral transmission is still controversial. In crowded places, it will be advisable for them to wear simple triple layer surgical mask. However, it is advised that transplant recipients should maintain social distancing and follow frequent hand washing or use hand sanitizer to prevent infection.

5. What should the transplant patient do if they suffer from flu like symptoms?

If any transplant recipient has fever or cough, they should immediately call their respective transplant centres. If they are advised to visit the hospital, they should wear a mask as soon as they enter the hospital premises. In case of a medical emergency like difficulty in breathing, they should present to the nearest emergency department.

6. What if transplant patients exhaust their medicines?

In view of lock down in various cities in India (Now in whole country), it is advisable to store your medicines for a sufficient period, which at present should be approximately two months. It is necessary to electively organise your medicines. If medicines are not available, it will be best to contact your treating hospital and may be they can help.

Reference:

1. D'Antiga, L. (2020), Coronaviruses and immunosuppressed patients. The facts during the third epidemic. Liver Transpl. Accepted Author Manuscript. doi:10.1002/lt.25756

- **Please refer to below links for more information:-**

<https://www.mohfw.gov.in/>

<https://www.myast.org/coronavirus-disease-2019-covid-19-frequently-asked-questions-transplant-candidates-and-recipients>

<https://www.cdc.gov/coronavirus/2019-ncov/infection-control/control-recommendations.html>

Renal Transplant Guidelines With Reference to COVID-19 Infection

These guidelines have been prepared by expert group of Indian society of Organ Transplantation (ISOT) and members of Covid-19 Working Group of Indian Society of Nephrology. In view of rapidly changing scenario of COVID-19 infection in India, these guidelines may be revised/updated time to time.

Organ transplant recipients are at a risk for more severe COVID-19 if they get SARS CoV-2 viral infection. Further, there is potential risk of infection transmission from the donor to recipient through organ transplantation. Also, there are issues in recipient and donor selection for transplant. In view of these issues' organ transplant at the time of COVID-19 pandemic should be undertaken with caution and should be done only at the centre where facilities of management of COVID-19 patients are available.

1. The pre, peri and post-transplant areas, including the operation theaters need to be specifically earmarked for this purpose.
2. Staff involved in care of transplant patients may not be involved in care of other patients.
3. There has to be adequate availability of PPE for care of these patients
4. The center should not be one earmarked for the treatment of COVID-19 patients and needs to have protocols for patient movement around the hospital to prevent nosocomial acquisition of COVID

1. Deceased Donors Transplants

Following individuals, having any of the following criteria, who are potential deceased donor should NOT be accepted as deceased donors:

a. **Epidemiological criteria –**

- International travel in last 14 days before onset of current event leading to brain stem death
- Contact in last 14 days before onset of current event leading to brain stem death with a confirmed case of COVID-19 or a healthcare worker with direct patient contact

b. **Clinical criteria –**

- Where the cause of death was due to unexplained respiratory failure
- where there was history of Fever or Acute respiratory infection (e.g. shortness of breath, cough, sore throat) with or without fever.
- Severe bilateral community-acquired pneumonia in absence of any other cause

c. **Laboratory criteria -**

- Confirmed Covid-19 positive case or test found positive while donor work-up is being done

1754071/2020/NOTTO-DGHS**Routine testing of deceased donors**

Routine COVID-19 (SARS-CoV-2) viral testing should be undertaken in all potential deceased donors within 72 hours prior to donation, both for assessment of donor fitness as well as for improving safety of staff involved in transplantation

Even though the potential deceased donor is fit to donate organs, every hospital and organ transplant system must balance between care of other COVID-19 positive patients in their health care setting against the organ transplant vis-a-vis availability of resources for safely conducting the organ transplant.

2. Living related Transplants

The living donor transplant programme may be temporarily suspended in line with the MoHFW's advisory for Hospitals and Medical Institutions dated 3rd March 2020, accessible at <https://www.mohfw.gov.in/pdf/AdvisoryforHospitalsandMedicalInstitutions.pdf>

However, if transplant is being done in view of emergency medical need of recipient, following individuals, who are living donor should NOT be accepted as donors:

a. Epidemiological criteria –

- International travel in last 14 days
- Contact in last 14 days with a confirmed case of COVID-19 or a healthcare worker with direct patient contact

b. Clinical criteria –

- History of Fever or Acute respiratory infection (e.g. shortness of breath, cough, sore throat) with or without fever.

c. Laboratory criteria -

- Confirmed Covid-19 positive or test found positive while donor work-up is being done

RT-PCR test of potential donors should be undertaken as suggested for deceased donors

Emergency lifesaving Transplantation

In case a transplant is to be done due to emergency need of recipient, it should be performed with appropriate assessment of COVID-19 infection in the recipient. Further, appropriate counseling of both the donor and recipient as well as their families should be done, and a high-risk informed consent taken before proceeding with the transplant.

3. Transplantation Recipients

Similar to the general population, transplant recipients should also strictly follow the travel advisories issued by the various ministries of Government of India from time to time. They should take extra precaution as they have risk of developing severe COVID-19 disease, if they acquire SARS CoV-2 viral infection.

4. Transplant Recipients returning from abroad

All transplant recipients who have been exposed to a confirmed or suspected COVID-19 patient within the last 14 days or who have returned from nations with COVID-19 outbreaks should undergo quarantine and isolation for 14 days and should be tested for SARS CoV-2 infection.

If any transplant recipient has fever, cough or breathing difficulty, they should immediately call their respective transplant centres. All transplant centres must have guidelines in place specifying which patients need testing and inpatient management and which patients can stay at home with close follow up with various means like mobile and email etc.

If they are advised to visit the hospital, they should wear a mask while coming to hospital premises. In case of a medical emergency like difficulty in breathing, they should report to the nearest emergency department.

5. Treatment and modification of immunosuppression

There are two issues of management of organ transplant patients with COVID-19

a. Management of COVID-19 in transplant patient.

There is scarcity of data and consensus on effective treatments of COVID-19 as such and more so in transplant patients. Few centres have tried antivirals, hydroxychloroquine and macrolides in COVID-19 patients with variable results. However, as of now, there is no treatment approved by the Central Drugs Standard Control Organization (CDSCO) or Foods and Drug Administration (FDA) for COVID-19.

b. Handling of immunosuppressive medicines with COVID-19

There is no consensus regarding modification in the immunosuppressive regimen of transplant recipients with COVID-19. The dose adjustment has to balance the infection control and the organ rejection. However, there is overall agreement of stopping antimetabolite drugs and decrease calcineurin inhibitors by 50%. Steroid should be continued on same doses. (Massachusetts General Hospital COVID-19 Treatment Guidance).

6. Post-transplant follows up measures

Transplant patients are at risk for severe COVID 19 if they acquire infection due to their immunosuppressed state. They may not manifest symptoms like general population. Fever may be absent as reported from study from China. Transplant units are advised to consider ways to limit hospital attendance for patients, such as:

1. Rescheduling non urgent out-patient appointments
2. Virtual or telemedicine or telephonic appointments
3. Home delivery of immunosuppression if feasible

1754071/2020/NOTTO-DGHS

Patients with stable graft function and adequate drug supply can avoid routine follow up visits to transplant hospitals.

7. Tissue Transplantation

At present, there is no evidence to suggest the transplant of Coronaviruses by blood transfusion.

Tissue and Eye Donation Criteria:

Deferral will be based upon infection status in the last 28 days before donation:

- Positive test for COVID-19
- Symptoms consistent with COVID-19 infection (e.g., unexplained fever, cough, shortness of breath) in a patient with suspected COVID-19 infection
- Donor defined as a Person under Investigation (PUI)
- Fever with severe acute lower respiratory illness (e.g., pneumonia, ARDS)

Additionally, deferral will be based upon exposure in the last 28 days before donation:

- Close contact with a person who has confirmed COVID-19
- Close contact with a Person under Investigation (PUI) for COVID-19
- International travel

8. Personnel Precautions working in the program:

The health and safety of all the healthcare worker in the transplant program is of paramount importance. Transplanting hospitals are advised not to expose any of their staff if there is even the slightest risk of virus transmission from both epidemiological and clinical criteria.

It is likely that this pandemic may require the current resources to be utilized elsewhere, hence there is even more reason to practice caution when deciding on proceeding with donation and transplantation. It is with this in mind that all elective live living kidney and liver transplant should be postponed.

General principles for handling SARS CoV-2 infection in transplant centre

1. Personnel should follow all hospital-based protocols for the isolation and management of COVID-19 patients.
2. Any questions or concerns about the infectious status of a potential donor should be referred to your Medical Director / Organ sharing body for further guidance.
3. If a donor is being ruled-out due to hospital considerations, local or national health authorities be sure to record the information. It is important that this information be documented clearly and accurately. Documentation should include transmittable disease status, COVID-19 testing status/high risk suspicion and/or individual organ suitability.
4. Screening questions should reflect updated COVID-19 national guidelines

Please refer to below links for more information: -

- ❖ Coronavirus (SARS-CoV-2) causing COVID-19: Information for donation and transplant professionals Version 1 dated 18-3-2020 – BY Donate Life & The Transplant Society of Australia & New Zealand

1754071/2020/NOTTO-DGHS

- ❖ <https://tts.org/23-tid/tid-news/657-tid-update-and-guidance-on-2019-novel-coronavirus-2019-ncov-for-transplant-id-clinicians>
- ❖ <https://www.mohfw.gov.in/pdf/AdvisoryforHospitalsandMedicalInstitutions.pdf>
- ❖ <https://www.fda.gov/emergency-preparedness-and-response/mcm-issues/coronavirus-disease-2019-covid-19#fastfacts>
- ❖ <https://www.gaeba.org/2020/alert-coronavirus-2019-ncov-and-ocular-tissue-donation/>
- ❖ Guidelines for Liver Transplantation and COVID-19 Infection, as received from the President, Liver Transplant Society of India (LTSI) via official correspondence on 23-03-2020.

Disclaimer:

The current outbreak is unpredictable. If widespread community-transmission occurs, healthcare infrastructure and capacity issues may have further impact on donation and transplantation. These recommendations may require regular updation to account for the changing epidemiology and new information regarding treatment and testing. All transplant units must be aware of national and local guidance for managing patients with COVID-19.

No suit or legal proceedings shall lie against any person for anything done or intended to be done in good faith under this suggestions/advisory unless proved otherwise

26th March, 2020

Guidelines for Liver Transplantation and COVID-19 (Coronavirus) Infection

These guidelines have been prepared by expert group of Liver Transplant Society of India (LTSI). In view of rapidly changing scenario of COVID-19 infection in India, these guidelines may be revised/updated time to time.

COVID-19 is caused by the novel coronavirus named Severe Acute Respiratory Syndrome Coronavirus-2 (SARS-CoV-2) that emerged in Hubei, Wuhan province of China in December 2019.

Covid-19 is now declared as a **Global Pandemic**, and cases in India are rising rapidly. Immunocompromised patients are at a greater risk, and there is an immediate need of guidelines for liver transplantation in India, both in deceased donor (DDLT) and living donor (LDLT) Centres.

The infection is spread by droplet and possibly airborne route as well, and CDC has recommended use of airborne precautions. Health care transmissions of COVID-19 have occurred and given the potential for greater infectivity, strict isolation precautions should be followed for anyone with suspected SARS-CoV2.

Guidelines for Issues specific to liver transplant in India

A. Status of doing Liver Transplant

1. Moratorium on all non-urgent transplants for 2 weeks
2. Acute liver failure (ALF) - can be done as usual after medical therapy has failed.
3. Acute on Chronic Liver failure (ACLF with organ failure – decision for transplantation should be based on individual's centre's discretion

B. Deceased donor liver transplant

Elective DDLT should be done only if donor is COVID-19 negative, and recipient is from the same city. Air travel should be avoided.

C. Living donor liver transplant should be done for urgent cases after thorough counselling as LDLT imposes a risk on the healthy donor with hospital admission and contact risks

D. Testing for COVID-19

All donors (deceased and living donor) and recipients should be tested for COVID-19 at the time of urgent transplant.

E. Immunosuppression strategy

Standard immunosuppression should be followed. No evidence exists as of now to modify immunosuppression due to COVID-19.

F. Follow up post transplant

1. Patients should follow up with their respective centres as usual. All routine follow up visits to be done online via telemedicine.
2. However, those patients with post-transplant emergencies should attend hospital as usual.

G. Care of sick recipients on waitlist

The management of recipients for various medical complications to be continued in the hospital, including ICU admissions

H. Prophylactic medications for COVID-19

At present, there is no recommendation for prophylactic medications or vaccinations for transplant patients.

I. Advisory for transplant recipients for COVID-19

All transplant recipients should be sent an advisory from the respective transplant centre regarding various do's and don'ts for prevention of COVID-19 infection.

J. Testing of Transplant professionals

This should be done selectively if there has been a positive case of COVID-19 in the concerned hospital