ISOT Position Statement For Transplantation In Era Of COVID-19

Introduction

The optimal approach to corona virus disease (COVID-19) screening in organ recipients and donors may change over time as more data accumulate. Organ transplantation for end stage organ failure can be a life saving intervention in certain patients with organ failure and can be performed electively in other types of organ failure for example kidney failure (with few exceptions). Some countries have stopped living donor organ transplants (with exception for life saving measures) and some continue with deceased donor organ transplantation. However due to risk of COVID-19 related morbidity and mortality in the recipient and living donor, there is need for assessing the risk v/s benefit of organ transplantation and if in certain organs the risk of death is higher due to waiting than that patient should be considered for organ transplantation.
All transplant teams can quickly build up a registry and assess regarding number of patients currently contactable, their ability to procure and take medicines in the current lockdown and connectivity with their doctors, number of patients who developed COVID-19 and their outcome. This will help each of the regions to set up support systems for the new transplants. At this time, as the situation improves, there may need to be a phased increment in transplantation services.

While recommending organ transplantation during COVID-19 pandemic following GENERAL SAFE GUARDS have to be ensured by each hospital:

a) Safety of health care professionals (doctors,nurses, coordinators,technicians,wardboys,house keeping staffs involved in organ transplantation) by providing adequate PPE
b) Prevention of transmission of COVID-19 from patients (recipients & donors) to health care Professionals (HCP) and vice-versa by having proper facilities for isolation in pre and post-transplant period.
c) Prevention of transmission of COVID-19 from patients (recipients & donors) or health care professionals to other (non transplant) patients and HCP and vice-versa by proper segregation of areas and personells.

1. Before restarting transplant program in the era of COVID-19, **we recommend** that each transplant hospital does a detailed assessment of epidemiology, **current trends, surge capacity and impact** of COVID-19 as well as assessment of ICU facility and team. Thereafter, transplants can proceed with caution if the above concerns have been addressed.

2. Before restarting the transplant program, w**e suggest** to initiate assessment of existing transplant recipients for their access and compliance to drugs. Patients transplanted in COVID-19 pandemic should have the same stringent follow up as they would have got prior to it.
3. **We suggest** a team of health care workers (HCW) (transplant coordinators and transplant team members) should be designated to care **EXCLUSIVELY** for transplant cases (**COVID FREE safe transplant pathway**) to reduce the risk of transmission. When feasible all transplant teams should define two teams which are separate and not working together and which should have independent transplant surgeon, physician and intensivist so that all surgical and medical problems can be handled if one team gets quarantined or exposed. This would require that the retrieval of organs to implant should be the responsibility of one team and the other team does not get involved and stays away totally from that patient. The teams can alternate for each patient.
4. **We recommend** routine **CLINICAL** and **EPIDEMIOLOGICAL** screening for COVID-19 in donors, recipients, HCW and care takers (4-6) **(Table 1 , 2)**.
    a. **CLINICAL** screening: fever (>38ºC or 100.3ºF or subjective fever) and or respiratory symptoms: cough, anosmia, shortness of breath, wheezing or chest tightness, sore throat, flu like symptoms.
    b. **EPIDEMIOLOGICAL** screening for travel and potential exposures: travel to or residing in an area in the preceding 21 days, where local COVID-19 transmission is occurring, confirmed diagnosis of COVID 19 in the last 28 days, direct contact with known or suspected case of COVID-19 in the preceding 21 days.
5. **We recommend** routine **LABORATORY** screening with COVID-19 real time polymerase chain reaction (PCR) test of airway specimen for both **donor and recipient** with the testing occurring as close as possible prior to surgery within 24–72 hours in all living and deceased donor organ transplants along with chest CT scan prior to transplantation If suggested by transplant team (7-8).
6. Living donor with previous COVID-19 positive should not donate for at least 3-6 months until the knowledge gaps are filled on whether there can re-infection or persistent virus in the body for longer than a month despite clinical and laboratory recovery and or presence of IgG antibody. However in case of life saving transplants, w**e suggest** donor with a previous diagnosis of COVID-19 requires **two negative** COVID-19 tests and complete symptom **resolution** for 28 days before being considered for donation and another negative test at the time of donation (documentation required).
7. **We recommend** all transplant recipients and donors should sign the fully documented standard written informed **CONSENT** accepting **EXTRA risk** of COVID-19 infection during hospital stay and after transplant. It should include risk and benefit of transplantation vs available alternative treatment such as dialysis.
8. **We recommend** adequate storage and supply of personal protective equipment **(PPE)** (i.e., triple layer masks, N95 respirators, gloves, gowns, eye protection) as per **GOVERNMENT** guidelines and PPE should be easily accessible to HCW
9. **We recommend** routine training of HCW on use of PPE and screening of COVID-19 infections in addition to general measures **(Table 1-3).**
10. **We recommend** ensuring HCW and cleaning personnel should receive **training** on standard, contact, droplets, and airborne precautions (including correct use of PPE, donning and doffing, masks tested for fitting, hand hygiene, respiratory hygiene, and social distancing etc.)

11. **We recommend** routine education of HCW, donors, recipients and care takers on COVID-19 prevention.
12. **We recommend** following haemodialysis unit preparedness checklist developed based on the Government of India guidelines for dialysis to deliver safe dialysis before transplant (9,10).
13. **We suggest** practicing social distancing for 14 days prior to surgery for both donor and recipient and using home-made reusable face-cover / facemask when going out in public or in instances where social distancing may be challenging.
14. **We suggest** to submit self-attested documents by email/ WhatsApp and virtual meetings for authorization committee permission if allowed by competent authority.
15. **We suggest** making an **early offer** to hospitals with availability to perform a transplant procedure and increase **local** retrieval for all organs if feasible. Recent data shows that asymptomatic individuals can spread the virus. N95 masks should be used for healthcare workers while travelling for organ retrieval.
16. **We recommend** minimizing the use of energy devices during procedures when possible. When energy is needed, we recommend avoiding the ultrasonic scalpel and lower energy settings to minimize surgical smoke
17. **We suggest** induction and other immunosuppressives drugs should continue as being practised before COVID-19.
18. **We suggest** avoid moving and transporting patients out of their room or area unless there is a medical necessity. Use designated portable X-ray equipment and/or other designated diagnostic equipment. If transport is required, use predetermined transport routes to minimize exposure for staff, other patients, and visitors, and have the patient use a medical mask if tolerable or reinforce respiratory hygiene. Ensure that HCWs who are transporting patients perform hand hygiene.
19. **We recommend** limiting visitors to those essential for patient support. Ensure visitors adhere to droplet and contact precautions and remain at least 6 feet away.
20. **We suggest** maintaining a record of all persons entering the patient's room, including all staff and visitors.
21. **We suggest** managing laboratory specimens, laundry, food service utensils, and medical waste following safe routine procedures according to infection prevention control guidelines.
22. **We recommend** ensuring equipment is either single-use and disposable or if equipment (e.g., stethoscopes, blood pressure cuffs, thermometers, food trays) needs to be shared among patients, clean and disinfect between use for each patient (e.g., by cleaning with ethyl alcohol 70% or 1% sodium hypochlorite or bleach solution).
23. **We recommend** routine cleaning and disinfecting surfaces with which the patient is in contact with 1% sodium hypochlorite solution.
24. **We suggest** management of recipient and the donor if become COVID-19 positive as per **government protocol** for COVID-19 patients.There is no consensus regarding modification in immunosuppressive regimen. Transplant team should make a **CASE BY CASE** evaluation for dose adjustment to balance infection control & rejection.
25. **We suggest** telemedicine encouraging social distancing when feasible. Telemedicine consultation is not a substitute to in-person consultation where clinical examination is required. https://www.mohfw.gov.in/pdf/Telemedicine.pdf ; https://tsi.org.in/
26. **We suggest** taking extra care of the elderly, HCW, recipients and keep them very safe from COVID-19, increasing immunity with healthy lifestyle for all, helping poor patients transplants,

using Government Aarogya Setu App, respect Corona warriors and strict adherence to universal precautions all the time to mitigate the spread of COVID-19.

27. **We recommend** this guidelines and checklist should be used in conjunction with local policies and official guidance from health authorities or hospitals as per changing situation.
28. Please ensure HCW asks the patient if there is any suspicion of COVID-19/ could this be COVID-19?
29. If there are any relevant ' YES' response indicating possibility of COVID-19 to any of the response, inform transplant director/ hospital in charge .

Futuristic approach for COVID-19 testing protocol for planned surgery based on IgM/IgG antobody detection via serology and PCR: The patients should get admitted in isolation 24 hours before planned surgery (11)

a) PCR negative and IgG positive: may be taken for transplantation, no testing during hospital stay and exit test (the statement assumes : IgG is universally protective and specificity of the antibody test is 100% or close to it)
b) PCR-negative and IgM/IgG negative: No infection- Go for transplantation, PCR testing every 6-7 days of stay and exit PCR test
c) PCR-positive and IgM negative: defer transplantation till PCR negative and IgG appears, activate national COVID-19 protocol

At present, there is no recommendation for prophylactic medications such as hydroxychloroquine or vaccinations for transplant patients. However, newer medications against COVID-19 are likely to be available soon.

Conclusion

Given that the epidemiological situation is constantly evolving, it is recommended that each transplant team assess the scenario that best describes their local situation (4,12). Any transplant program should make a CASE BY CASE evaluation when assessing the convenience of carrying out a transplant based on: availability of health care resources including ICU; risk/benefit of exposing an immunosuppressed patient to the risk of infection by COVID-19 (according to the number of cases and the possibility of admission under ideal isolation conditions) versus the need for transplantation (clinical situation of the patient).

V2 version of ISOT Position Statement for Transplantation in Era of COVID-19 as on 28th April 2020

TABLE 1-3: Transplant unit preparedness checklist developed to deliver safe transplant during and after COVID-19 pandemic

TBALE 1 CHECKLIST FOR	DONOR	RECEPIENT
1) EXTRA risk of COVID-19 consent : have transplant recipient and donor signed an informed consent accepting an EXTRA risk of COVID-19 infection in hospital and after transplant	Yes/No	Yes/No
2) COVID-19 DIAGNOSIS		
I. EPIDEMIOLOGICAL screening for travel and potential exposures	Yes/No	Yes/No
a) Travel to or residing in an area in the preceding 21 days, where local COVID-19 transmission is occurring	Yes/No	Yes/No
b) Direct contact with known or suspected case of COVID-19 in the preceding 21 days	Yes/No	Yes/No
c) Confirmed Diagnosis of COVID 19 in the last 28 days	Yes/No	Yes/No
Be aware that patient and donor may conceal history of exposure to COVID-19 in order to receive transplant	Suspect/not suspect	Suspect/not suspect
II. CLINICAL screening for COVID-19 symptoms	Yes/No	Yes/No
a) fever (>38ºC or 100.3ºF or subjective fever) and or	Yes/No	Yes/No
b) Respiratory symptoms: cough, shortness of breath, wheezing or chest tightness, sore throat, flu like symptoms. Consider excluding symptoms attributable to other causes and allergies	Yes/No	Yes/No
c) Fever (thermal screening)	Yes/No	Yes/No
III. LABORATORY screening with COVID-19 RT-PCR test of airway specimen **(1-3 days before transplant)**		
Date and time		
Specimen used: nasopharyngeal, oropharyngeal swab, bronchoalveolar lavage, endotracheal aspirate or a combination		
Results	+ve/ -ve	+ve/ -ve
3) SOCIAL DISTANCING: Practicing social distancing for 14 days prior to surgery to avoid unnecessary exposure	Yes/No	Yes/No
4) **HEALTH EDUCATION** on COVID-19 prevention	Yes/No	Yes/No
5) OTHER OPTIONAL TESTS IF SUGGESTED		
a) CT chest (if required by transplant team)	Yes/No	Yes/No
Date and time		
Results : normal /ground glass opacity/infection		
b) LABORATORY screening (COVID-19 RT-PCR test of airway specimen) (second test if required by transplant team such as in hot spot)		
Date and time		
Specimen used		
Results	+ve/ -ve	+ve/ -ve
c) PCR every week during their stay and before discharge		
d) COVID-19 IgM/IgG antibody rapid test if approved by Goverment	+ve/ -ve	+ve/ -ve
e) Pro-calcitonin (PCT)		
f) Highly reactive C reactive protein (HSCRP)		
g) Complete blood count: lymphocyte count		

h) Stool PCR for COVID-19 in confirmed COVID-19 cases with 2 negative NP swab before transplant	+ve/ -ve	+ve/ -ve
6) COVID-19 assessment **ACCEPTABLE TO PROCEED** for surgery	Yes/No	Yes/No
a) Date and time of proposed surgery		
b) Is laboratory testing compatible with proposed transplant date and time?	Yes/No	Yes/No
Remark		
Date: Name /Signature		
This checklist should be used in conjunction with local policies and official guidance from health authorities or hospitals		

TBALE 2: CHECKLIST FOR HCW & Care Giver	HCW	**Care Giver**
1) Health education on PPE and COVID-19	Yes/No	Yes/No
2) SOCIAL DISTANCING : Practicing social distancing for 14 days prior to surgery to avoid unnecessary exposure	Yes/No	Yes/No
3) COVID-19 DIAGNOSIS		
I. **EPIDEMIOLOGICAL** screening for travel and potential exposures	Yes/No	Yes/No
a) Travel to or residing in an area in the preceding 21 days, where local COVID-19 transmission is occurring	Yes/No	Yes/No
b) Direct contact with known or suspected case of COVID-19 in the preceding 21 days	Yes/No	Yes/No
c) Confirmed Diagnosis of COVID 19 in the last 28 days	Yes/No	Yes/No
II. **CLINICAL** screening for COVID-19 symptoms	Yes/No	Yes/No
a) Fever (>38ºC or 100.3ºF or subjective fever) and or	Yes/No	Yes/No
b) Respiratory symptoms: Cough shortness of breath, wheezing or chest tightness, sore throat, flu like symptoms. Consider excluding symptoms attributable to other causes and allergies	Yes/No	Yes/No
c) Fever (thermal screening)	Yes/No	Yes/No
4) OTHER OPTIONAL TESTS if suggested by transplant team		
a) LABORATORY screening (COVID-19 RT-PCR test of airway specimen) **(** eg**.** If the hospital is a COVID facility **)**		
Date and time		
Specimen used: nasopharyngeal (NP), oropharyngeal swab, bronchoalveolar lavage, endotracheal aspirate or a combination		
Results	+ve/ -ve	+ve/ -ve
b) CT chest		
Date and time		
Results : normal /ground glass opacity/infection		
c) COVID-19 IgM/IgG Antibody Rapid Test	+ve/ -ve	+ve/ -ve
d) PCT, HSCRP,CBC		
e) COVID-19 assessment acceptable to proceed for transplant	Yes/No	Yes/No
Remark		
Date: **Name /Signature**		

TBALE 3: CHECK LIST TRANSPLANT COORDINATORS OR TRANSPLANT TEAM MEMBER	
Is there enough stock of PPE and drugs?	Yes/No
Are all HCW using N 95 mask or three-layer surgical facemask and all patients, donors, attendants and caregivers wearing a three-layer surgical facemask/home-made reusable face cover inside the pre and post-transplant area?	Yes/No
Is training for use of PPE including donning, doffing and proper disposal completed?	Yes/No
Are all HCW following hand hygiene between patients?	Yes/No
Have HCW received training in updated clinical knowledge of COVID-19, & guidelines from government, academic society, and hospital authority, cough etiquette, hand hygiene, social distancing, PPE and universal precautions?	Yes/No
Have HCW received training for clinical, epidemiology, laboratory screening of patients, donors, care takers and COVID consent process?	Yes/No
Have HCW self-monitored their symptoms and informed transplant program head in case they or their family members develop symptom(s) suggestive of COVID-19?	Yes/No
Is list of staff recorded and be retained by transplant team head?	Yes/No
Have HCW meals at different time after hands washed with flowing water?	Yes/No
COVID FREE SAFE PATHWAY FOR TRANSPLANT	Yes/No
Is there a designated entry and exit for patients and HCW involved in transplant?	Yes/No
Is there a dedicated area for pre-transplant evaluation to maintain distance between patients, donors and health workers, and is it cleaned between sessions?	Yes/No
Is cleaning and disinfection time table of pre-transplant area displayed at entry gate?	Yes/No
Is organ allocation policy followed in deceased donor transplant?	Yes/No
PRE AND POST-TRANSPLANT OPD AND WARD	Yes/No
Is there an alcohol-based hand sanitizer at entry?	Yes/No
Are the following equipment either used separately for each patient OR disinfect between the shifts?	Yes/No
a) Stethoscopes (diaphragms and tubing cleaned with an alcohol based disinfectant)	Yes/No
b) BP cuffs (NIBP cuffs can be cleaned by alcohol or 1% sodium hypochlorite)	Yes/No
c) Oxygen saturation probes	Yes/No
d) No sharing of thermometers	Yes/No
Are posters displayed on education and preventions of COVID-19 (hand hygiene, social distancing, COVID-19 symptoms and testing and universal precautions)?	Yes/No
Transplant infectious disease assessment if required	Yes/No
Transplant psychiatry assessment if required	Yes/No
Is disinfection, environmental cleanliness, and good air conditioning & ventilation conditions instituted?	Yes/No
Is safe distancing followed? Do not touch patients or use stethoscope unless essential.	Yes/No
Are all frequently touched surfaces inside the transplant unit, cleaned and disinfected frequently and duty list maintained?	Yes/No

Is pre-transplant dialysis as per the Government of India guidelines for dialysis to deliver safe dialysis?	Yes/No
Transplant OT	Yes/No
Is there dedicated transplant OT and HCW?	Yes/No
Is there cleaning and disinfection of OT and timetable?	Yes/No
POST-TRANSPLANT	Yes/No
Post-transplant patient and donor in single rooms with an attached bathroom	Yes/No
Are visitors limited to one visitor for 10 minutes a day at a distance of 1 to 2 metres away, wearing appropriate protection such as a surgical mask and a gown?	Yes/No
Determine approaches to minimize exposure to the healthcare setting for non-essential services	Yes/No
Is telemedicine and emergency consultation contact number available?	Yes/No
Recipients should avoid travel to area with COVID-19 cases	Yes/No
Can patients find information about the latest developments regarding COVID-19 on the hospital and government website? visit https://www.mohfw.gov.in/	Yes/No
Remark :	
Date: Name /Signature	

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Disclaimer

These recommendations/suggetions may require regular updation to account for the changing epidemiology and new information regarding treatment and testing.

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Draft copy of ISOT Position Statement for Transplantation in Era of COVID-19 was emailed to ISOT executive mebers and all ISOT members for opinion and suggetions which are discussed by ISOT COVID-19 team to include all practical suggetions in final document

Final document prepared by ISOT COVID-19 team