Standard Operating Procedure for doing transplants during the COVID 19 Pandemic

By

The State Appropriate Authority

Government of Maharashtra

Index & Acknowledgements

Acknowledgements:

The SOP drafted by:

Dr S K Mathur ,President ZTCC Mumbai ,Member State Advisory Committee on THOTA & Emeritus Prof G S Medical College Mumbai

Dr Akash Shukla, Jt Secretary,ZTCC Mumbai, Prof and HOD Gastroenterology, Seth G S Medical College & KEM Hospital, Mumbai

Inputs from:

1. Dr Bharat Shah Gen Sec ZTCC Mumbai, Hon Consultant Nephrologist , LTMM College & Hospital & Global Hospital
2. Dr Atul Mulay, Sec Gen ZTCC Pune , Consultant Nephrologist Pune
3. Dr G B Daver, Immediate past President ZTCC Mumbai, Member State Advisory Committee on THOTA , Former Dean GMC & JJ hospital Mumbai .
4. Dr Sudhir Kulkarni, President ZTCC Aurangabad , Urologist.
5. Organ Specific guidelines prepared by:

    A) Liver: Dr S K Mathur, Dr Ravi Mohanka, Dr Aabha Nagral & Dr Akash shukla

    B) Kidney : Dr Bharat Shah, Dr Rushi Deshpande, Dr Rasika Sirsat & Dr Kalpna Mehta

    C)Heart and Lung : Dr N K Kapadia, Dr Talha Meeran & Dr Unmil Shah.

Approved by:

Dr (Mrs) S. Tayade	Dr T P Lahane
Director Health Services	Director Medical Education & Research
State Appropriate Authority	Member Secretary MCFOT
Dr Satish Pawar	Dr Sudhir Raghuvanshi , OSD, DMER
Additional Commissioner NHM	Assoc.Prof. Pathology, JJ Hospital, Mumbai
Dr Arun Yadav	Dr Sunil Lilani, OSD,DMER
ADHS (THOTA), Dept of H & FW	Assoc.Prof. Microbiology,

General protocols to be followed by all hospitals doing

organ transplantation during COVID-19 pandemic

(To be read and interpreted with the SOPs for Deceased Donor & living Donor transplant)

INTRODUCTION

World Health Organisation (WHO) China country office on 31.12.2019 has informed of cases of pneumonia of unknown cause detected in Wuhan City, Hubei Province of China. The Chinese authorities identified a new type of corona virus, which was isolated on 07.01.2020 by laboratory testing. It is a new strain that had not previously been detected in humans is from the family of viruses that cause illness ranging from the common cold to more severe diseases such as Middle East Respiratory Syndrome (MERS - CoV) and Severe Acute Respiratory Syndrome (SARS - CoV). This “novel” corona virus is now officially named as Corona virus Disease 2019 (COVID-19 The Novel Corona virus (COVID-19) cases have been confirmed in large number of countries due to which the World Health Organisation (WHO) on 11.03.2020 has characterized COVID-19 as pandemic.

Organ transplantation for end stage organ failure is a life saving intervention and has not been stopped in any country during this COVID-19 pandemic.In USA Organ Transplantation comes under Essential Services,

However due to the risk of COVID-19 related risk of morbidity and mortality in the recipient and live donor,there is a need for assessing the risk vs. benefit of organ transplantation. **In general if risk of death within 6 months without organ transplant is more than 50% (applicable to liver, heart and lungs as per published literature, Annexure 5), which is much higher than the risk of contacting COVID-19, then that patient should get the benefit of organ transplantation.** However though renal transplant does not fall in this category, there are patients who require urgent renal transplantation due to various reasons (as defined by Renal Transplant experts Annexure 5).

Hence organ transplant for super-urgent and semi-urgent/urgent category/indications should be continued during COVID-19 pandemic.

However In case of Deceased Organ Donation, if no suitable willing recipient satisfying above Indications is available than in order to avoid wasting of organs, the same can be allocated by the organ specific subcommittee on case to case basis to other recipients in the waiting list.

While recommending organ transplantation during COVID-19 pandemic following general safeguards have to be ensured:

1) Safety of healthcare professionals(HCP) (doctors, nurses, transplant coordinators,technicians,wardboys,housekeeping staff involved in organ transplantation) by providing adequate PPE.

2) Prevention of transmission of COVID-19 from Patients (recipients & donors) to HCPs and vice-versa by having proper facilities for isolation in pre-transplant, during and post-transplant period.
3) Prevention of transmission of COVID-19 from patients(recipients & donors) or HCPs to other (non-transplant) patients and vice-versa by proper segregation of areas and personnel.
4) The Transplant should happen in a **Centre not earmarked for COVID care. However** due to prevalent circumstances, **if Hospitals having transplant facilities are also taking care of COVID patients then, these hospitals may opt to perform transplants if they can** ensure a complete segregation of COVID and transplant areas (including pre-, intra- and post-transplant care. The segregation shall also encompass HCWs, support staff, patient movements, patients' caretakers/visitors/accompanying persons & their movements, canteen, logistics, waste disposals, toilets, washrooms etc. **There should be complete physical and process segregation among covid & transplant areas of the hospital.**

5) The hospital head will have to give an undertaking that they have the facility & manpower to comply with the above and that they shall abide with the above and the implementation of this compliance shall be the sole responsibility of the hospital.

Each ZTCC will ensure the Compliance of documentation by hospitals in case of deceased organ donation and transplantation.

6) While carrying out transplant activity, the hospital has to ensure that there is **no compromise on the care of the covid patients.**

7) The ambulance/transport vehicle carrying the organ shall be completely sanitized with appropriate disinfectants prior to use for organ transport. All HCP including the ambulance driver should be in appropriate protective equipments.

8) **Must obtain COVID-19 specific written informed consent from recipient and living donor,** explaining the **risk of getting COVID-19** and extra mortality and false negative (-ve) test results.

Screening of Health care workers for COVID-19: (Separate form to be filled for each HCW)

1) All classes of HCWs should be screened only epidemiologically and clinically. If these are negative, no further testing is required, and this is as per international and ICMR recommendations for asymptomatic HCWs (detailed screening form in annexure 4) and may be updated in future.

2) HCWs found to have positive epidemiological or clinical screening, should not be part of the team for at least 2 weeks and sent for further appropriate testing.

3) All HCW involved in donor surgery, transportation of organ or recipient care should follow UP.

4) Those HCW who have recovered from CoViD 19 can resume duty after 2 swabs are negative followed by a period of 2 weeks before they can be part of the transplant team.

SOP for Deceased Organ Donation and Donor Screening During COVID-19 Pandemic

Deceased Organ Donation and Donor screening During COVID-19 Pandemic (To be read with General protocolof transplant during COVID-19)

During COVID-19 pandemic there is potential risk of COV infection transmission from the donor to recipient through organ transplantation, however Transmission of SARS-CoV-2 from donor to recipient has not yet been reported. The risk of virus transmission must be balanced against the risk to the recipient associated with not using the organ and losing an opportunity for transplant. None of the countries affected by COVID have stopped Organ transplantation from Deceased donors. In India,

On 31st March2020, NOTTO on its websie (https://notto.gov.in/news-events.html) published NATIONAL TRANSPLANT SPECIFIC GUIDANCE FOR COVID-19.1754068/2020/NOTTO-DGHS (Annexure-A, Renal Transplant Guidelines, Annexure-C and Guidelines for Liver Transplantation,Annexure – D)

However it has not given detailed protocol to be followed during Deceased Organ donation.The SOP has been prepared on basis of a) Published documents on Organ transplantation from other COVID affected countries and India ,b) general guidelines for Testing for COVID in India by ICMR and MoH&FW govt of India. **This SOP is subject to change as and when new evidence becomes available.**

Objective of SOP:

1. Screening of Deceased Donor for possible COVD 19 infection
2. Stratify donors into high, intermediate, or low risk for transmission of COVID-19
3. Recommendation based on stratification for Accepting or rejecting the donor

Responsibility of compliance: This lies with the hospital administration of the transplant centers and should be telephonically supervised by ZTCC.

Standard Operating Protocol:

1) Screening of Deceased Donor for possible COVD 19 infection

The optimal approach to donor screening may change over time as more data accumulates. At this time we suggest:

Screening to include following 4 Steps:

A) Epidemiologic screening for travel and potential exposures to COVID 19

B) Screening for symptoms suggestive of COVID-19 infection

C) Pulmonary Imaging (X-ray Chest and or CT Chest)

D) Laboratory screening by Nucleic acid testing of specimens

A) Epidemiologic Screening

Does the deceased donor meet any of the following criteria?

Ans. Yes, No or Unknown

1. H/O international travel in the in the preceding 28 days,
2. H/O Travel to or from a high-risk area where local COVID-19 transmission is occurring (As per GoI website- https://www.mygov.in/covid-19/?cbps=1 or a local government website like www.covid19.gangashankar.com) in the last 28 days
3. H/O Direct contact with known (laboratory confirmed patients) in the preceding 28days*
4. H/O Direct contact with suspected case of COVID-19 in the preceding 28days*
5. Confirmed Diagnosis of COVID-19 in the last 28 days

*this includes being within six feet of a person with suspected or proven COVID-19. Close contact can occur while caring for, living with, visiting, or sharing a healthcare waiting area or room with a COVID-19 case or having direct contact with infectious secretions of a COVID-19 case (e.g., being coughed on, sneezing, contact with saliva, feces etc)

Unknown should be considered yes for decision

B) **Clinical Screening**:

Has the deceased donor experienced any of the following symptoms* in the last 21 days?

Ans. Yes / No / Unknown

1. Fever (>38ºC or 100.3ºF or subjective fever)
2. Malaise or flu like symptoms, + /- myalgias
3. New cough
4. Shortness of breath
5. Any Other*

Unknown should be considered yes for decision

*(*for detailed list refer to Annexure 1)*

C) **Pulmonary Imaging : X-ray / CT Chest findings :**

A thoracic CT imaging may show signs of SARS-CoV-2 infection even in absence of symptoms and negative testing and hence may be useful in donor assessment.(Ref8)

CT chest is essential before accepting a donor even if X-ray chest is normal.

Are the CT Chest Findings suggestive of COVID-19 ? (Annexure 2)

Ans: Yes/No

1) Multifocal lower lobar or multi lobar bilateral Lung GGOs (Ground glass Opacities) having rounded morphology with Peripheral and posterior distribution and with or without consolidation

2) Absence of Mediastinal Lymphadenopathy and Pleural effusion is important negative finding.

D) Laboratory screening: RT-PCR testing of specimens:

<u>This is mandatory for all deceased organ donors.</u>

Recommendation for sample to be tested:

i) **Must : -** Swabs from Nasopharynx , Oropharynx and Endotracheal Secretion

ii) Optional: BAL

- A Blood sample: to be preserved for future testing for serology (Covid 19 specific IgM/IgG)

2) Deceased Donor Risk Stratification based on above four Steps A-D (Refer to Flowchart)

i) High Risk Donor :

-If answers to one or more of both A (Epidemiologic) + B (Clinical) screening are yes

- If answer to A + C or B+C is Yes even if COVID-19 test is negative

- In presence of A/B + Positive COVID-19 test

- Positive COVID-19 test

ii) Intermediate Risk Donor:

-If answers to one or more of either A (Epidemiologic) or B (Clinical) screening are yes

And C & D are Negative

iii) Low Risk Donor:

If Answers to all A, B, C and D are Negative

3. Recommendation for Donation : Accepting / Rejecting/ Optional:(Figure 1)

In general Organ Donation Contraindicated if donor has recently had COVID-19 infection or PCR Test positive for COVID-19 as part of the donor evaluation

i).High Risk Donor : Organ Donation Contraindicated

ii) Intermediate Group:

Decision to be taken jointly by the treating team and the recipient patient depending on

urgency of transplant.

Decision to be informed in writing to the respective ZTCC

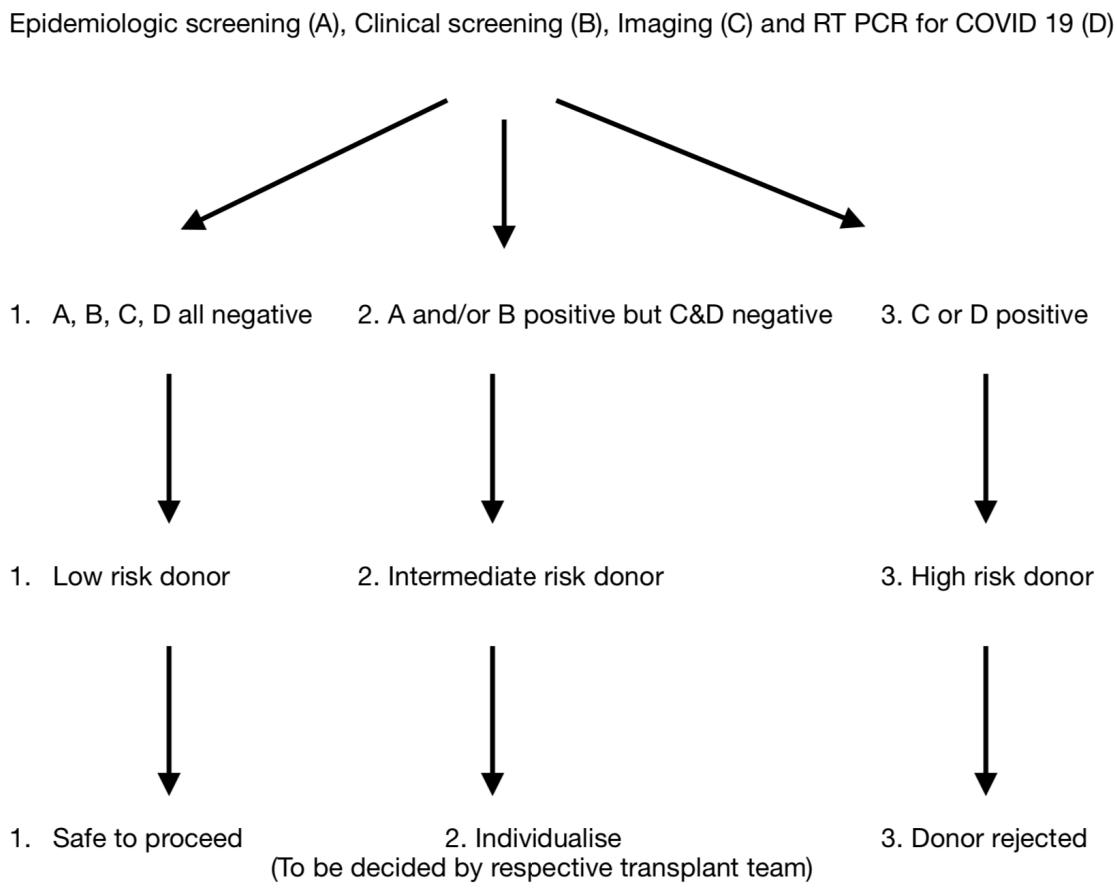
Recipient counseling documentation about false –ve test results and COVID-19 specific Informed Consent must be documented.

iii) Low Risk Group: Organ Donation Acceptable,

Recipient Counseling documentation about false –ve test results and COVID-19 specific Informed Consent must be documented.

• Organs from deceased donors who have recovered from COVID-19 and have resolution of symptoms greater than 28 days prior to procurement and repeated negative testing are likely safe to use. However, more data is being generated on re-infection/ persistence of COVID 19.

Figure 1: Flow chart for stratifying risk of COVID 19 in and decision making for acceptance/rejection of a deceased donor



Precautions and extra care :

1)Transplant programs accepting organs from these donors:

a. Must obtain COVID-19 specific written Informed Consent from Recipient

b. should consider placing recipients in contact isolation and airborne isolation

c. Observe 'Universal Precautions' for all Healthcare personnel involved in Pre,Intra and Post Operative care

2) COVID 19 related Donor questionnaire to be filled by Clinician I/C or Intensivist and signed by Relative of Patient, clinician and hospital administration (Annexeure Table 1 & 2)

3) Recipient sample should be sent for COVID-19 testing.

The decision to wait or not to wait for the report to come before going ahead with transplant will be of individual Transplant teams and the hospital and the recipient. **ZTCC will ensure Compliance of documentation of all SOP by the hospitals.**

References:

1) ICMR Revised Strategy of COVID19 testing in India (Version 3, dated 20/03/2020).

2) American Society of Transplantation;COVID-19 (Coronavirus): FAQs for Organ Donation and Transplantation Updated: March 11, 2020

3) CDC: https://www.cdc.gov/coronavirus/2019-nCoV/summary.html

4) • World Health Organization: https://www.who.int/emergencies/diseases/novel-coronavirus-2019

5) In Canada: https://www.canada.ca/en/publichealth/services/diseases/2019-novel-coronavirus-infection.html

6) NHSBT COVID-19 Bulletin 17th March 2020. https://www.odt.nhs.uk/deceased-donation/covid-19-advice-for-clinicians/

7) Coronavirus Disease 2019 (COVID-19): A Systematic Review of Imaging Findings in 919 Patients.Sana Salehi et al. AJR Am J Roentgenol. 2020, 1-7

8) ISHLT Guidance for Cardiothoracic Transplant and Ventricular Assist Device Centers regarding the SARS CoV-2 pandemic. REVISED: March 21, 2020

9) https://notto.gov.in/news-events.html. NATIONAL TRANSPLANT SPECIFIC GUIDANCE FOR COVID-19.1754068/2020/NOTTO-DGHS (Annexure-A) , Renal Transplant Guidelines With Reference to COVID-19 Infection 1754071/2020/NOTTO-DGHS(Annexure-C) and Guidelines for Liver Trans-

plantation and COVID-19 (Coronavirus) Infection.1754072/2020/NOTTO-DGHS (Annexure – D)

10) GoI website https://www.mygov.in/covid-19/?cbps=1

Annexure 1:

CLINICAL FEATURES

(Adapted from Report of the WHO-China Joint Mission on Coronavirus Disease 2019 based on 55,924 cases and a study on 1099 cases by Guan et al published in N Eng J Med)

• Fever (87.9%),

• Dry cough (67.7%),

• Fatigue (38.1%),

• Sputum production (33.4%),

• Shortness of breath (18.6%),

• Sore throat (13.9%),

• Headache (13.6%),

• Myalgia or arthralgia (14.8%),

• Chills (11.4%),

• Nausea or vomiting (5.0%),

• Nasal congestion (4.8%),

• Diarrhea (3.7%), and

• Hemoptysis (0.9%), and

• Conjunctival congestion (0.8%)

• ARDS (3%)

• Abnormalities on chest X-ray (59%)

• Radiological findings on chest CT scan (86%)

Annexure 2:

***Report of HRCT Chest Findings:**

1) Presence of GGOs without consolidation

2) Presence of GGOs with consolidation

3) GGOs with peripheral distribution

4) GGOs with posterior distribution

5) GGOs with rounded morphologies

6) Multilobar/Multifocal involvement

7) GGOs with reticular changes

8) Vascular enlargement

9) Interlobular septal thickening in a crazy pavement pattern

10) Other findings

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1) Multifocal lower lobar or multi lobar bilateral Lung GGOs (Ground glass Opacities) having rounded morphology with Peripheral and posterior distribution and with or with-out consolidation

2) Absence of Mediastinal Lymphadenopathy and Pleural effusion is important negative finding.

These SOPs are subject to modification in future as more knowledge is available in this rapidly evolving field

Organ transplantation for end stage organ failure is a life saving intervention and has not been stopped in any country during this COVID-19 pandemic.In USA Organ Transplantation comes under Essential Services,
However due to the risk of COVID-19 related risk of morbidity and mortality in the recipient and live donor,there is a need for assessing the risk vs. benefit of organ transplantation. **In general if risk of death within 6 months without organ transplant is more than 50% (applicable to liver, heart and lungs as per published literature, Annexure 5), which is much higher than the risk of contacting COVID-19, then that patient should get the benefit of organ transplantation.** However though renal transplant does not fall in this category, there are patients who require urgent renal transplantation due to various reasons (as defined by Renal Transplant experts Annexure 5

Hence organ transplant for super-urgent and semi-urgent/urgent category/indications should be continued during COVID-19 pandemic.

General protocols to be followed by all hospitals doing organ transplantation during COVID-19 pandemic

While recommending organ transplantation during COVID-19 pandemic following general safeguards have to be ensured:

1) Safety of healthcare professionals(HCP) (doctors, nurses, transplant coordinators,technicians,wardboys,housekeeping staff involved in organ transplantation) by providing adequate PPE.

2) Prevention of transmission of COVID-19 from Patients (recipients & donors) to HCPs and vice-versa by having proper facilities for isolation in pre-transplant, during and post-transplant period.

3) Prevention of transmission of COVID-19 from patients(recipients & donors) or HCPs to other (non-transplant) patients and vice-versa by proper segregation of areas and personnel.

4) The Transplant should happen in a **Centre not earmarked for COVID care. However** due to prevalent circumstances, **if Hospitals having transplant facilities are also taking care of COVID patients then, these hospitals may opt to perform transplants if they can** ensure a complete segregation of COVID and transplant areas (including pre-, intra- and post-transplant care. The segregation shall also encompass HCWs, support staff, patient movements,

patients' caretakers/visitors/accompanying persons & their movements, canteen, logistics, waste disposals, toilets, washrooms etc. **There should be complete physical and process segregation among covid & transplant areas of the hospital.**

5) **The hospital head will have to give an undertaking t**hat they have the facility & manpower to comply with the above and that they shall abide with the above and the implementation of this compliance shall be the sole responsibility of the hospital.

6) While carrying out transplant activity, the hospital has to ensure that there is **no compromise on the care of the covid patients.**

7) The ambulance carrying the organ shall be completely sanitized with appropriate disinfectants prior to use for organ transport. All HCP including the ambulance driver should be in appropriate protective equipments.

8) **Must obtain COVID-19 specific written informed consent from recipient and living donor,** explaining the **risk of getting COVID-19** and extra mortality and false negative (-ve) test results.

Screening of Health care workers for COVID-19: (Separate form to be filled for each HCW)

1) All classes of HCWs should be screened only epidemiologically and clinically. If these are negative,no further testing is required, and this is as per international and ICMR recommendations for asymptomatic HCWs (detailed screening form in annexure 4) and may be updated in future.
2) HCWs found to have positive epidemiological or clinical screening, should not be part of the team for at least 2 weeks and sent for further appropriate testing.
3) All HCW involved in donor surgery, transportation of organ or recipient care should follow UP.
4) Those HCW who have recovered from CoViD 19 can resume duty after 2 swabs are negative followed by a period of 2 weeks before they can be part of the transplant team.

Standard Operating Protocol for Living Donor Transplantation:

Objectives of SOP:

1. Screening of recipient and living donor for possible COVD-19 infection.
2. Stratify donors into high or low risk for transmission of COVID-19.
3. Recommendation based on stratification for accepting or rejecting the recipient or living donor.

Timing of Screening of Live Donor and Recipient:

Super-urgent: Liver

1. Only one set of full screening with testing both for recipient and donor.
2. Donor to be kept in isolation room till discharge.
3. Authorization committee to be approached after full screening and special covid-19 consenting is over.

Emergent / Urgent: (Liver,Kidney)

1) Both donor and recipient should be isolated (home or hospital) and observe practicing social distancing for 14 days prior to surgery and use facemask when going out in public.
2) Pre and post-transplant recipient and donor should not be residing in hotspot or containment zones for COVID-19.
4. Timing of screening for recipient and living donor: 1st screening to be done at initial evaluation i.e.day zero and 2ndscreening after 7 to 21 days, within 48hrs of date of transplantation.
5. Authorization committee to be approached for provisional permission after 1st set of screening and final permission after 2nd set of screening except for super-urgent where only one-time permission will be needed.

1.Screening of Recipient and Living donor for possible COVD-19 infection :

The optimal approach to donor screening may change over time as more data accumulates.

At this time, we suggest that screening to include following 4 steps

A. **Epidemiologic screening** for travel and potential exposures

B. **Clinical screening** for symptoms suggestive of COVID-19

C. **Pulmonary Imaging** (X-ray chest and / or CT Chest)

D. **Laboratory screening:** testing of specimens by SARS COV2 RT-PCR, IgM & IgG antibodies

Note: Details to be filled in Screening Forms separately for Donor and Recipient (Annexure 3):

A. Epidemiologic Screening

Does the Recipient and Living donor meet any of the following criteria?

Ans. Yes, No or Unknown#

1. H/O international travel in the preceding 28 days,
2. H/O Travel to or from or residing in high-risk area(Hot spot) where local COVID-19 transmission is occurring (As per GoI website- https://www.mygov.in/covid-19/?cbps=1, or a local government website like www.covid19.gangashankar.com) in the last 28 days
3. H/O Direct contact with known (laboratory confirmed patients) in the preceding 28days
4. H/O Direct contact with suspected case of COVID-19 in the preceding 28days*
5. Confirmed Diagnosis of COVID-19 in the last 28 days

B.

'Unknown' should be presumed as 'yes' for decisions

*this includes being within six feet of a person with suspected or proven COVID-19.

Close contact can occur while caring for, living with, visiting, or sharing a healthcare waiting area or room with a COVID-19 case or having direct contact with infectious secretions of a COVID-19 case (e.g., being coughed on)

B. **Clinical Screening**:

Has the Recipient / Living donor experienced any of the following symptoms* in the last 28 days?

Ans. Yes, No or unknown

1. Fever (>38ºC or 100.3ºF or subjective fever)
2. Malaise or flu like symptoms, + /- myalgias
3. New cough
4. Shortness of breath
5. Any Other *(*for detailed list refer to **Annexure 1**)*

C) Pulmonary Imaging : X-ray / CT Chest findings (Annexure 2):

CT chest is essential before accepting a donor if X-ray chest is normal.

Are the CT Chest Findings Normal or Abnormal ?

D) Laboratory screening: SARS COV2 RT-PCR testing of specimens:

a.This is mandatory for all Recipients and living organ donors.

b. Recommendation for sample to be tested twice at minimum 48hrs interval:

i) Specimen **: -** Swabs from Nose , Oropharynx

ii) Endotracheal Secretion for Recipients if intubated

iii) Optional: BAL

Once the recipient and donor evaluation are complete, separately completed screening forms for recipient and living donor to be submitted to authorization committee.

Transplant should not be performed if donor is positive by RT-PCR

Annexure 3: Screening form for COVID-19 for Recipient / Living donor

Hospital Name : _____

Name of Patient : _____

Age: _____Gender: Male / Female. Bed Number: _____Hospital ID

_____

Address of the patient:

_____

_____

History given by patient or relative*

*Name of relative and relationship with patient who gave history:

_____

Places where patient travelled in the last 28 days before admission/ assessment:

_____

_____

A. **Epidemiologic Screening**	
Does the recipient / living donor meet any of the following criteria?	Yes, No or Unknown**
1. H/O international travel in the in the preceding 28 days	Yes, No or Unknown
2. H/O Travel to or from or residing in a high-risk area(hotspot) where local COVID-19 transmission is occurring in the last 28 days (As per GoI website- https://www.mygov.in/covid-19/?cbps=1)	Yes, No or Unknown
3. H/O Direct contact with known (laboratory confirmed patients) COVID-19 in the preceding 28 days*	Yes, No or Unknown

4. H/o Direct contact with suspected case of COVID-19 in the preceding 28 days*	Yes, No or Unknown
5. Confirmed Diagnosis of COVID-19 in the last 28 days	Yes, No or Unknown
*this includes being within six feet of a person with suspected or proven COVID-19. Close contact can occur while caring for, living with, visiting, or sharing a healthcare waiting area or room with a COVID-19 case or having direct contact with infectious secretions of a COVID-19 case (e.g., being coughed on) **For purpose of decision-making unknown to be considered as yes	
B. Clinical Screening	
1. Has the Recipient/Living donor experienced any of the following symptoms* in the last 28 days?	Yes, No or Unknown**
2. Fever (>38ºC or 100.3ºF or subjective fever)	Yes, No or Unknown
3. Flu like symptoms and/or myalgias	Yes, No or Unknown
4. New onset cough	Yes, No or Unknown
5. Shortness of breath	Yes, No or Unknown
6. Any Other Symptom	Yes, No or Unknown
****For purpose of decision making unknown to be considered as yes.**	

C. **Pulmonary Imaging**			
• Is X-ray chest normal	Yes / No	Date of Imaging	
• Is HRCT chest normal	Yes / No	Date of Imaging	

D. Laboratory screening: (RT-PCR testing of specimens)		
• **1st set sample:**Nasopharyngeal /oropharyngeal swab / endotracheal secretion / BAL / serology for antibodies*	Positive / Negative	Date of testing
• **2ndset sample:**Nasopharyngeal /oropharyngeal swab / endotracheal secretion / BAL / serology for antibodies*	Positive / Negative	Date of testing
*Please tick mark & Attach the report		
Acceptable to proceed for donation & transplant		Yes / No

Doctor's signature

Name

Designation

Signature of patient's relative

Name

Relationship

Date / Time Date / Time

Place Place

Annexure 4: COVID-19 screening form for healthcare workers (HCWs)

Hospital Name : _____

Name of HCW :

_____

Age : _____ Gender : Male / Female

Designation : _____ Screening result: positive / negative

Address of the HCW:

_____

_____

Places where HCW travelled in the last 28 days:

_____

A. **Epidemiologic Screening**	

Does the HCW meet any of the following criteria?	Yes, No or Unknown**
1. H/O international travel in the in the preceding 28 days	Yes, No or Unknown
2. H/O travel to or from or residing in a high-risk area(hotspot) where local COVID-19 transmission is occurring in the last 28 days (As per GoI website- https://www.mygov.in/covid-19/?cbps=1 or a local government website)	Yes, No or Unknown
3. H/O direct contact with known (laboratory confirmed patients) COVID-19 in the preceding 28 days*	Yes, No or Unknown
4. H/Odirect contact with suspected case of COVID-19 in the preceding 28 days*	Yes, No or Unknown
5. Confirmed diagnosis of COVID-19 in the last 28 days	Yes, No or Unknown
*this includes being within six feet of a person with suspected or proven COVID-19. Close contact can occur while caring for, living with, visiting, or sharing a healthcare waiting area or room with a COVID-19 case or having direct contact with infectious secretions of a COVID-19 case (e.g., being coughed on) **For purpose of decision-making unknown to be considered as yes	
B.Clinical screening	
1. Has the HCW experienced any of the following symptoms* in the last 28 days?	Yes, No or Unknown**
2. Fever (>38ºC or 100.3ºF or subjective fever)	Yes, No or Unknown
3. Flu like symptoms and/or myalgias	Yes, No or Unknown
4. New onset cough	Yes, No or Unknown
5. Shortness of breath	Yes, No or Unknown
6. Any Other Symptom	Yes, No or Unknown
****For purpose of decision-making unknown to be considered as yes.**	

Form filled and signed by:

HCW's signature	Signature of I/C of hospital
Name	Name
Date / Time	Date / Time

Place

Place

Annexure 5: Indications for transplant for various organs during COVID-19 (Only life threatening)

1. **Liver Transplantation Indications during COVID-19**

Indications for super-urgent / urgent Liver transplantation during COVID-19: both for living and deceased organ donor:

A. Super-urgent foracute liver failure(ALF) (as defined by King's college criteria and NHSBT updated), primary non-function (PNF), hepatic artery thrombosis (HAT) within 21 days with failed attempt at radiological or surgical revascularization, post-live-liver donation ALF

B. Acute Budd-Chiari syndrome (BCS), autoimmune hepatitis (AIH), Wilson's disease and acute hepatitis B (HBV) presenting as acute liver failure

C. Urgent:

    a. Estimated 3-month mortality > 50%

    b. Acute on chronic liver failure (ACLF)grade 2 and 3

    c. Hepto-renal syndrome (HRS)type 1 &2

    d. Hyponatremia:Serumsodium < 130 or 125 (despite volume correction) + Childs (CTP) score >=10

    e. Refractory ascites (TIPPS contraindicated) with severe hepatic dysfunction

f. CTP Score >= 13 Or model for end-stage liver disease (MELD) score >25

g. Grade 3 or 4 hepatic encephalopathy (HE)

D. Hepatocellular carcinoma (HCC) within university of California San Francisco (UCSF) criteria with decompensated cirrhosis (CTP Score >=8) and not suitable for locoregional therapies

E. Hepatoblastoma

F. Any other cases, to be decided on case to case basis by each transplant team and approval by appropriate authority

Indications for emergent kidney transplant during COVID-19

There is a potential for recipient to be COVID-19 positive and for COVID-19 to be transmitted during transplant either from health worker or from donor. The extent of this risk is not clear, and we are not aware of any reports of transmission. If it is not urgent, better to defer transplant.

Indications for urgent / semi-urgent renal transplantation (both living and deceased donor)

1. Those dialysis patients who are not getting adequate dialysis due to failure of all accesses (vascular and peritoneal)

2. Highly sensitized patients on waiting list for deceased donor kidney transplant

Kidney transplant should be performed after confirming that the benefit of transplant is greater than risk and with adequate resources are allocated without jeopardizing pandemic preparedness.

Post-transplant care

1. Both recipient and donor should be managed in isolation room
2. Staff involved in their care should not be involved in care of other patients.
3. The staff taking care should use PPEs
4. Immunosuppression can be the same as used routinely
5. Following discharge, video consultation can be offered
6. If recipient needs readmission, it should be in isolation room

Indications for super-urgent / urgent heart transplantation during COVID-19

Indication for heart transplant will be patient on extracorporeal membrane oxygenator (ECMO) / temporaryventricular assist device (VAD)
As far as possiblewe must choose an emergencycase based on clinical criteriawith possiblegood outcome and relativelyyoung patients below 55
As per he ZTCC cardiac and lung transplant sub-committee guidelines for emergent/ urgent cardiac transplant listingto be decided on case to case basis

Indications for super-urgent / urgent lung transplantation during COVID-19

In view of COVID-19 pandemicfollowing cases should be considered under emergent criteria for lung transplant:

1. Patients on ventilator and/ or ECMO
2. Patients in respiratory exacerbations with type 2 respiratory failure, on NIVs
3. Patients with end stage lung diseases with complications like pneumothorax, severe hemoptysis, etc.
4. Patients with refractory right heart failure with abnormal ECHO / right heart cathparameters
5. Patients with significantly high oxygen requirement secondary to respiratory failure
6. Any other cases, to be decided from case to case

Annexure 6: COVID-19 Consent Form for organ transplant

Name of patient

Age/Sex

Hospital ID

Dr_____ of _____ hospital has explained to me the additional risk that are associated with transplant during the CoViD 19 pandemic. I understand fully that despite all the best intentions, adequate testing and precautions, there is a risk of peri-operative transmission of the CoViD 19. I have also been explained that with the currently available data, it is difficult to exactly quantify this risk. I am also aware that the donor will be screened for this infection but despite a negative screening , there is a small risk of transmission due to false negative test. Understanding all the potential benefits of the transplant despite the risk associated with CoViD 19, I have agreed to undergo _____ transplant. If despite following the SOP, CoViD 19 infection is transmitted, I will not hold the organ distributing agencies (ZTCC/ SOTTO/ ROTTO/NOTTO) or the transplant teams or Hospital responsible.

Name of the Patient

Signature

Name & Signature of two independent witnesses

1.

2.

Date

Place

Name & Signature of the doctor administering consent

Date

Place

Format 1 for undertaking by Hospitals doing deceased organ donation

Date:

To,

General Secretary,

ZTCC, Mumbai /Pune/Aurangabad/Nagpur

CC State Appropriate Authority (DHS), Govt of Maharashtra

Subject: To conduct deceased organ donation and Retrieval of organs from deceased donor

Dear Sir,

Our_____ Hospital is willing to conduct deceased organ donation and Retrieval of organs from deceased donor in our hospital ifthere is a potential donor any family consents for Organ Donation.

We understand that special care must be taken in view of recent COVID 19 pandemic.

I.....Head of Hospital herewith give this undertaking on behalf of the Hospital that we have complied with all the guidelines specific for COVID 19 and shall abide by all the orders, guidelines and rules of the state appropriate authority. I shall also ensure that, there shall be no compromise on managing patients with COVID while carrying out donations.

Thanks & Regards,

Signature of Head of Hospital
Date .....Place.....

Name of Head of Hospital

Designation

Format 2 for undertaking by Hospitals performing transplants

Date:

To,

General Secretary,

ZTCC, Mumbai /Pune/Aurangabad/Nagpur

CC State Appropriate Authority (DHS), Govt of Maharashtra

Subject: Regarding Deceased donor and Living donor organ transplants at _____ hospital

Dear Sir,

Our _____hospital is willing to do Deceased donor organ (specify if all organs or a particular organ) and/or Living Donor transplants during COVID-19 pandemic. We understand that special care must be taken in view of recent COVID 19 pandemic.

I.....Head of Hospital herewith give this undertaking on behalf of the Hospital that we have the capability to be compliant with all the conditions of Standard Operating Procedures (SOPs) of State Appropriate Authority (DHS) of Govt of Maharashtra to carry out transplants during the corona pandemic. I take the responsibility that we will follow all the guidelines specific for COVID 19 and shall abide by all the orders, guidelines and rules of the state appropriate authority, especially with regards to the transplants during the Covid 19 pandemic. I shall also ensure that, there shall be no compromise on managing patients with COVID while carrying out transplants.

Thanks & Regards,

Signature of Head of Hospital
Date .....Place.....

Name of Head of Hospital

Designation

Format 3 for undertaking by Hospitals opting not to performing transplants during COVID 19 pandemic

To,

General Secretary,

ZTCC, Mumbai.

CC. State Appropriate Authority (DHS) Govt of Maharashtra

Dear Sir,

Kindly note Deceased donation and transplantation program is on hold in our hospital ____(hospital Name)_____ due to COVID-19 pandemic.

I understand that during this period patients already registered for transplantation from our hospital will be put on hold by the ZTCC .

Hospital will inform all the Registered recipient from the hospital about the decision and give them option to move any other hospital for transplantation and inform ZTCC about their reply.

Hospital will inform ZTCC in writing once it restarts the Deceased donation and transplantation program.

Thanks and Regards,

Signature of Head of Hospital
Date .....Place.....

Name of Head of Hospital

Designation