

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

Approved by ZTCC Executive Committee on 1s April 2020

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.

Deceased Organ Donation and Donor screening During COVID-19 Pandemic

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 March 2020, NOTTO on its website (<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.

ZTCC Mumbai was created by Govt of Maharashtra through its GR dated 9th July 1999 and given responsibility of Distribution of Deceased Donor organs to appropriate recipients and provide Technical advice .

In Mid March, Mumbai ZTCC introduced deceased donor screening policy as follows (all through whats App discussions among experts):

- 1) 16th March: Epidemiological and Clinical Screening based Deceased Donor risk stratification and Decision to accept or reject Donor (this was based on publication by American Society of Transplantation dated 11h March and ICMR's general guidelines for testing for COVID-19)
- 2) 24th March: Epidemiology+ Clinical Screening and COVID-19 testing was introduced

Subsequently ZTCC Mumbai has prepared a Standard Operating Protocol (SOP) to be followed for screening and based on results, assessing the risk of transmission (risk stratification) through Deceased Organ Donors during this Pandemic of COVID19 .

(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 MHFW 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 COVID 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

Standard Operating Protocol:

1) Screening of Deceased Donor for possible COVID 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
- B) Screening for symptoms suggestive of COVID-19
- C) Pulmonary Imaging (X-ray Chest and or CT Chest)
- D) Laboratory screening: (Nucleic acid testing of specimens)

A) Epidemiologic Screening

Does the deceased donor meet any of the following criteria?

Ans. Yes, No or Unknown

- H/O international travel in the in the preceding 28 days,
- H/O Travel to or from a high-risk area where local COVID-19 transmission is occurring (As per Gol website- <https://www.mygov.in/covid-19/?cbps=1>) in the last 28 days
- H/O Direct contact with known (laboratory confirmed patients) in the preceding 28days*

- H/O Direct contact with suspected case of COVID-19 in the preceding 28days*
- 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)

B) Clinical Screening:

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

Ans. Yes, No or unknown

- Fever ($>38^{\circ}\text{C}$ or 100.3°F or subjective fever)
- Malaise or flu like symptoms, + /- myalgias
- New cough
- Shortness of breath

*(*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 if X-ray chest is normal.

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

Ans: Yes/No/Equivocal

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:

This is mandatory for all deceased organ donors.

Recommendation for sample to be tested:

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

- A Blood sample: to be preserved for future testing for serology (Covid 19 specific IgM/IgG) (will need 5 ml of blood collected in RED top vacutainer.

The serum (at least 2 ml) will have to be separated and stored at -20 (minus 20)degree Centigrade)

ii) Optional: BAL

2) Deceased Donor Risk Stratification based on above four Steps A-D:

i) High Risk Donor :

- If answers to one or more of both A (Epidemiologic) + B (Clinical) screening are yes
- If answer to C (CT Chest) and or D (COVID-19 test) is 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

ii) Intermediate Risk Donor:

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

In general Organ Donation Contraindicated if donor :

- Has active COVID-19 infection
- 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.

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

iii) Low Risk Group: Organ Donation Acceptable,

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

- 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

Precautions and care for :

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, 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 and clinician (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.

Reference:

- 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 Transplantation and COVID-19 (Coronavirus) Infection. 1754072/2020/NOTTO-DGHS (Annexure – D)
- 10) GoI website <https://www.mygov.in/covid-19/?cbps=1>

Contributions:

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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%)

Annexure2:

***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 without consolidation
- 2) Absence of Mediastinal Lymphadenopathy and Pleural effusion is important negative finding.