

GUIDELINE ON ORGAN, TISSUE DONATION AND TRANSPLANTATION SERVICE IN MALAYSIA DURING THE COVID-19 PANDEMIC

1. INTRODUCTION

The COVID-19 pandemic had taken most of the world by surprise. To better manage hospital beds and resources, the Ministry of Health (MOH) ordered a temporary halt on its transplant services between March 2020 to June 2020 [*Surat Pemberitahuan Penangguhan Pembedahan Elektif Termasuk Transplan di Hospital Kementerian Kesihatan Malaysia (KKM) Semasa Wabak COVID-19 (20 Mac 2020)*, *Surat Penyampaian Perkhidmatan Transplantasi Kebangsaan Pasca Perintah Kawalan Pergerakan (PKP) (9 Jun 2020)*]. This allowed critical beds to be utilized for treatment of COVID-19 patients, while reducing the potential spread of COVID-19 amongst immunosuppressed transplant patients. With the controlled number of infections within the country and a better prepared health system, transplant services are poised to recommence. However, vigilance and caution need to be maintained to ensure the safety of recipients, donor, family, and healthcare workers. While the true risk of donor-derived transmission is unclear, patient-to-patient and patient-to-healthcare worker infection has been described and human-to-human transmission has been confirmed ^(1,2). As such, this guideline serves to ensure safe assessment, procurement and transplant activities. All activities related to transplant services will be assessed on a case-to-case basis taking into consideration the current local infection rate and related information issued by the MOH.

2. GENERAL GUIDELINES

2.1. Personnel safety

- 2.1.1.** All coordinators and procurement/transplant team members shall adhere to stipulated standard operating protocols (SOPs) when on duty while practicing strict hand hygiene and wear surgical mask when indicated.
- 2.1.2.** Team members who are symptomatic (URTI, fever or any symptoms related to COVID-19) shall not be allowed to participate in the procurement/transplant process. Refer Annex 1: Case Definition of COVID-19 in COVID-19 Management Guidelines in Malaysia.
- 2.1.3.** Team members, who are exposed to a positive COVID-19 case, shall notify the NTRC and practice self-quarantine for 14 days. When symptomatic the team member shall seek treatment at the nearest health facility.

2.2. Family conference/counselling

- 2.2.1. Appropriate clinical spaces for discussion/counselling shall be considered. This must adhere to physical distancing measures. Poorly ventilated and confined rooms shall be avoided.
- 2.2.2. Areas identified for family conference/counselling shall be equipped with hand sanitizers. All participants shall don surgical mask.
- 2.2.3. All participants shall be screened and complete the declaration form for COVID-19 screening (*Borang Deklarasi Saringan Penyakit COVID-19 as in Annex 8 of COVID-19 Management Guidelines in Malaysia*) and/or any related requirement according to local hospital SOPs prior to family conference/counselling.

2.3. Clinic assessment / Follow-up review

- 2.3.1. Where possible alternative methods of review / follow-up shall be considered. This includes the use of telehealth, encrypted video conferencing, electronic referrals and / or data capture.
- 2.3.2. The frequency of face-to-face clinic visits shall be limited where possible. This can be considered following a clinical assessment, and on a case to case basis.
- 2.3.3. All patients shall be screened and assessed prior to clinic arrival according to local SOPs.
- 2.3.4. All clinical areas/room shall be equipped with appropriate PPE for clinical staff and room/device disinfection protocol after clinical test/procedures.
- 2.3.5. For lung transplant referrals, where possible, in-hospital investigations such as chest x-ray, lung function may not be necessary if up-to-date information from referring hospital is available. Consider implementing home spirometry training and monitoring.

2.4. Procurement team travels

- 2.4.1. All procurement team members shall adhere to the SOPs and practise strict hand hygiene. Hand sanitizer shall be available during transport.

2.4.2. Procurement team members who present with URTI symptoms with or without fever or any symptoms related to COVID-19 shall not participate in the procurement.

2.4.3. When travelling by NTRC vehicle, a maximum of 5 team members shall be allowed in the vehicle at any time with surgical mask.

2.4.4. While travelling via commercial flight for the purpose of organ procurement may be the most time saving mode, flights during the Movement Control Order (MCO) are infrequent and may affect the cold ischaemic time of organs. MERCY flights shall be considered when necessary.

2.5. Operating theatre

2.5.1. Only 2 donor coordinators shall be allowed in the operating theatre at any one time.

2.5.2. Donor coordinators shall advise donor hospital operating theatre managers to limit the number of staff in the donor procurement theatre.

2.5.3. Procurement/Transplant team members shall observe and practice operating theatre SOPs according to local settings.

3. DONOR SELECTION

3.1. Donor screening (deceased)

3.1.1. All potential donors shall be subjected to the COVID-19 screening with detailed history taking regarding possible infection and exposure to COVID-19 ^(1,3,4) (Appendix 1).

3.1.2. Results of potential donor's COVID-19 test shall be made available to the recipient team as part of donor virology screening and to operating theatre staff upon donor admission and it shall be documented.

3.1.3. All potential donors shall be screened for COVID-19 using up-to-date recommended gold standards. Samples shall be taken from either:

- i. Lower respiratory tract samples (i.e., sputum or bronchoalveolar lavage) is preferred.
- ii. Upper respiratory tract sample (Nasopharyngeal and oropharyngeal swab).

- 3.1.4. All screening samples for COVID-19 for the purpose of organ and tissue donation shall be prioritised and laboratory request forms shall be labelled with “TRANSPLANT” on the top right corner of the form.
- 3.1.5. Where possible all screening of COVID-19 shall be conducted in the donor hospital. When needed, samples can be sent to the nearest hospital with available COVID-19 testing laboratory.
- 3.1.6. A positive screening result precludes organ donation.
- 3.1.7. When a lung donation is scheduled if the clinical condition permits, a chest computed tomography (CT) shall be performed to exclude viral pneumonitis.
- 3.1.8. In corneal donation, an ocular swab shall be obtained within 24 hours prior/after death.
- 3.1.9. Concerns or doubts regarding the eligibility of potential donor with regards to COVID-19 infection shall be discussed with either a microbiologist, infectious disease physician or the NTRC consultant and documented.

3.2. Donor exclusion criteria

3.2.1. General:

- i. Potential donors who are identified as confirmed, suspected, probable/ under surveillance (PUS) for COVID-19 infection are not eligible to donate organ/tissues.

3.2.2. Corneal donation shall be deferred, **refer appendix 2*

- i. If an international travel has occurred within the past four weeks.
- ii. If the donor has close contact with a confirmed/probable/suspected COVID-19 case within four weeks from time of contact.
- iii. If the donor was diagnosed with COVID-19 infection within the past 3 months.

4. RECIPIENT MANAGEMENT

4.1. Recipient selection

4.1.1. General:

- i. A stringent selection criterion shall be applied to ensure:
 - a. The best possible outcome for the recipient.
 - b. The best possible utilisation of a donated organ/tissue which is already a limited resource and will likely be even more limited due to the COVID-19 pandemic.
 - c. A reduced risk of prolonged ICU admission.
- ii. Where possible, potential recipient on active waitlist should practice self-quarantine whilst waiting for a potential transplant surgery. When going out, practice physical distancing and wear face mask.
- iii. Where possible, all potential transplant recipients shall be tested for COVID-19 before being mobilized to transplant centres.
- iv. To save time, testing for COVID-19 can be done at the nearest health facility with COVID-19 testing laboratory.
- v. All screening samples for COVID-19 for the purpose of organ and tissue donation shall be prioritised and laboratory request forms shall be labelled with “TRANSPLANT” on the top right corner of the form.
- vi. In the event where a potential recipient has a recent history of exposure to a confirmed, suspected, probable or PUS for COVID-19 and/or has compatible sign and symptoms regardless of known exposure, the case shall be discussed with a Microbiologist or Infectious Disease Physician prior to the scheduled transplant surgery ⁽³⁾.
- vii. Recipient candidates who test positive for the COVID-19 infection will not be eligible ^(3,5).
- viii. All potential recipients shall be informed that a negative test does not guarantee the absence of a COVID-19 infection.

4.1.2. Kidney recipient exclusion criteria:

- i. Patients with high immunological risk and anticipated to require thymoglobulin as an induction agent should be excluded.
- ii. Time required to arrive in transplant centre >12 hours (from time that patient instructed to travel)
- iii. Previous COVID-19 within 6 weeks of clearance of infection.

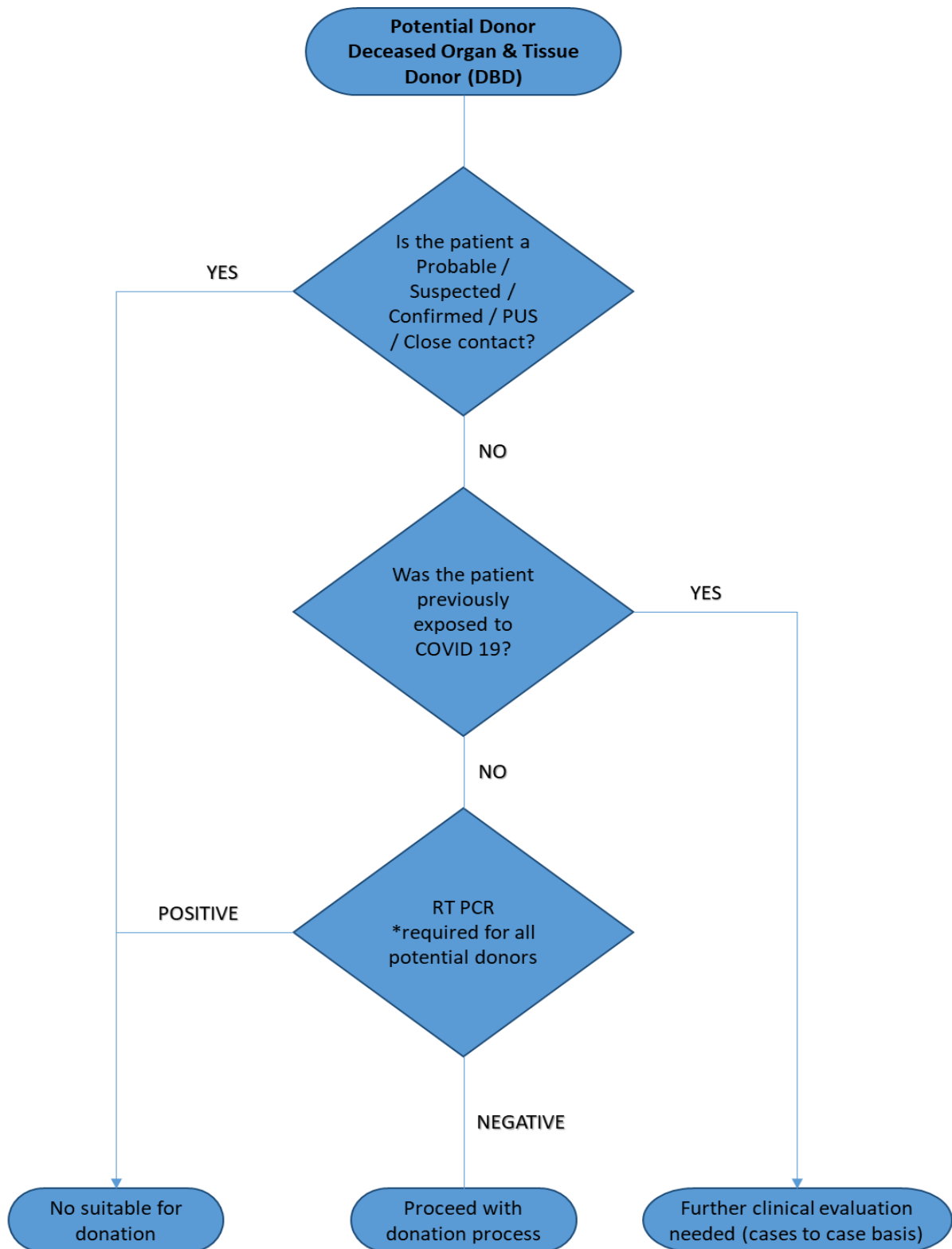
4.2. Admission protocols for potential recipients

4.2.1. General:

- i. All potential recipients shall be screened and complete the declaration form for COVID-19 screening or comply to local SOPs for admission.
- ii. Surgical mask is recommended for all potential recipients in hospital setting (if not contraindicated)
- iii. Personal transport to the transplant centre is preferred. If this is not possible, transport of recipients to the transplant centre shall be done via hospital ambulance. Potential recipients using air transport must adhere to SOPs and comply to the stipulated time frame for arrival.
- iv. Centres are encouraged to consider direct admission of patients to limit contact and therefore reduce transmission of COVID-19.

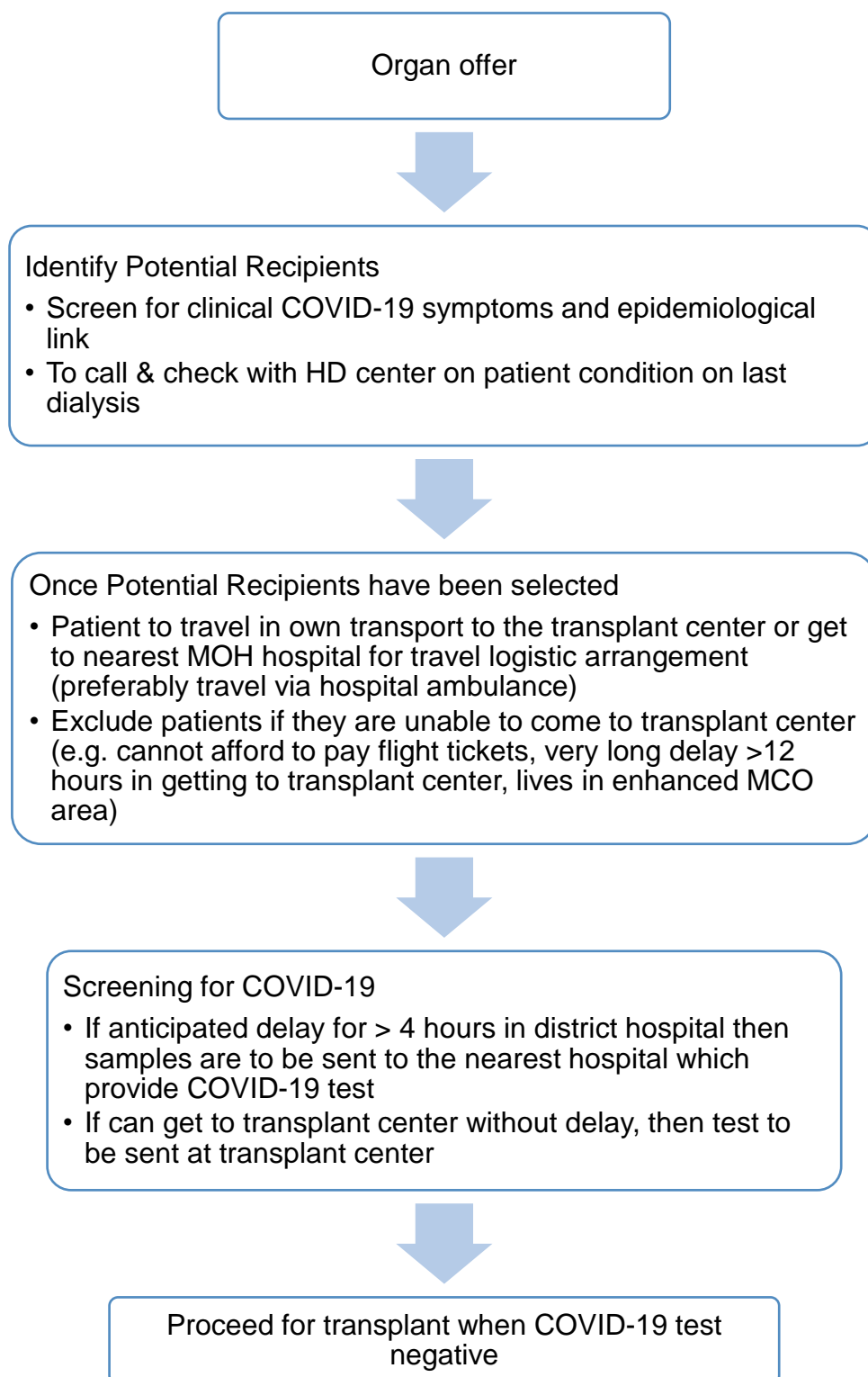
4.2.2. Kidney: refer appendix 3

APPENDIX 1 : Flow Chart for Deceased Organ Donation



APPENDIX 2: Eligibility for Ocular Tissue Donation during COVID-19 Outbreak

RT-PCR SARS-CoV-2 (< 24 hours prior/ after death)	COVID-19 signs	COVID-19 symptoms	Plausible alternative etiology	Close contact	Eligibility
Positive	Yes/No	Yes/No	Yes/No	Yes/no	NO
Negative (post mortem/recent premortem)	Yes	Yes/No	Yes	Yes/No	Medical director review
			No	Yes/No	NO
	No	Yes	Yes	Yes/No	Medical director review
			No	Yes/No	NO
		No	Not applicable	Yes	Medical director review
				No	YES
Not done	Yes	Yes/No	Yes/No	Yes/No	NO
	No	Yes	Yes	Yes	NO
			No	Medical director review	
		No	Yes/No	Not eligible	
		No	Not applicable	Yes	NO
		No	Not applicable	No	YES

APPENDIX 3: KIDNEY TRANSPLANT RECIPIENT MANAGEMENT

5. REFERENCES

1. Guidance on Coronavirus Disease 2019 (COVID-19) for Transplant Clinicians Updated 8 June 2020
2. Clinical features of patients infected with 2019 novel coronavirus in Wuhan, China.
3. Reopening of transplant programmes: issues for consideration
4. Spanish recommendations to manage Organ Donation and transplantation regarding the infection associated with the new coronavirus (SARS-CoV-2) producer of COVID 19.
5. Guidance for Cardiothoracic Transplant and Ventricular Assist Device Centres regarding the SARS CoV-2 pandemic; ISHLT; REVISED: March 21, 2020.