Changes in this version

Specialist Nurse (SN) will upload completed FRM6439 to attachments for Transplant Clinicians to review.

Reference to national guidance removed with regard to living donors and routine screening (2.2.1 and 3.0)

Assessment and screening in potential recipients to be as per centre policy (6.0)

Executive Summary and Contents

- There is growing evidence on the use of organs from SARS-CoV-2 positive donors. Permissiveness for clinical teams to assess particular donor/recipient circumstances is important so that safe donation and transplantation procedures are not avoided solely on the basis of a positive screening SARS-CoV-2 result.
- There is growing experience in the use of organs from donors that are positive for SARS-CoV-2 ribonucleic acid (RNA). Thus far, transmission has only been described through transplantation of lungs where a lower respiratory tract sample was not tested during donor screening and was subsequently shown to be strongly positive for SARS-CoV-2 RNA.
- Patients with a diagnosis of COVID-19 and positive SARS-CoV-2 RNA results, where COVID-19 is felt to contribute to the cause of death, are currently **not being considered** for deceased organ donation.
- In potential deceased donors with **no diagnosis of COVID-19 (where COVID-19 is not felt to contribute to the cause of death)** and positive or indeterminate SARS-CoV-2 RNA tests, analysis of the patient's history and consecutive viral RNA results can help with interpretation of the likely stage of infection.
- Where positive screening results are compatible with recent, resolving, or **current** infection in the upper and/or lower respiratory tract, evidence thus far indicates that transmission of SARS-CoV-2 through the transplantation of (non-lung) organs leading to COVID-19 in the recipient is unlikely. **Non-lung organs from these donors will now be offered.**
- FRM6439 'SARS-CoV-2 Assessment and Screening' contains donor information on SARS-CoV-2-related issues and is completed for all potential deceased donors. Specialist Nurse (SN) will upload completed FRM6439 to DonorPath as an attachment (visible in DonorPath, TransplantPath and TissuePath). **Transplant clinicians must check this form when considering, or after accepting, an organ offer.**
- The following issues are also discussed in this policy document:
  - SARS-CoV-2 assessment and screening in potential organ donors (living or deceased) (section 2.0)
  - Potential living donors with positive SARS-CoV-2 RNA tests (section 3.0)
  - Potential deceased donors with negative SARS-CoV-2 RNA tests (section 4.0)
  - Potential deceased donors with positive or indeterminate SARS-CoV-2 RNA tests (section 5.0)
  - SARS-CoV-2 assessment and screening in potential recipients (section 6.0)

Policy

1.0 Introduction

1.1 This document provides guidance on the SARS-CoV-2 **assessment and screening** of potential solid organ donors in the UK. **Users must refer to www.odt.nhs.uk for the most recent version of this document and all linked documents.** Guidance on the consent of potential solid organ transplant recipients and living donors is given elsewhere[1].

1.2 There is growing experience in the US and Europe with the transplantation of organs **(other than lungs)** from selected donors that were **positive** for SARS-CoV-2 ribonucleic acid (RNA) in respiratory tract samples, without apparent transmission to recipients[2-13]. These experiences are reflected in the organ donation policies of other countries[11,14]. Transmission has only been described through transplantation of lungs where a lower respiratory tract sample was not tested during donor screening and was subsequently shown to be strongly positive for SARS-CoV-2 RNA, denoting infection at the time of donation[15].

1.3 In previous versions of this policy, organ donation from selected donors with positive (or indeterminate) SARS-CoV-2 RNA test results was thought reasonable, following virological advice, where resolved or resolving infection was deemed likely**.** Permissiveness for clinical teams to assess particular donor/recipient circumstances is important so that safe donation and transplantation procedures are not avoided solely on the basis of a positive screening SARS-CoV-2 result.

1.4 **FRM6439 'SARS-CoV-2 Assessment and Screening' contains donor information on SARS-CoV-2-related issues and is completed for all potential deceased donors. In all instances, transplant clinicians must check this form when considering, or after accepting, an organ offer. This form can be viewed in the attachments** (visible in DonorPath, TransplantPath and TissuePath).

1.5 Specialist Nurses in Organ Donation (SNODs) and National Organ Retrieval Service team members must adhere to local donor hospital policies on the use of personal protective equipment (PPE) when caring for patients with positive or indeterminate SARS-CoV-2 RNA test results.

1.5.1 As regards to proceeding donors who test positive (or indeterminate) for SARS-CoV-2 RNA, members of the organ transport teams and healthcare workers at implanting centres do not need to take any additional PPE precautions.

1.5.2 Vaccination against SARS-CoV-2 is recommended for all healthcare workers.

2.0 General approach to SARS-CoV-2 assessment and screening in potential organ donors (living or deceased)

2.1 Deceased donors. See Table 1 for a summary of the approach to potential deceased organ donor characterisation in relation to SARS-CoV-2 status.

2.1.1 All potential deceased organ donors in the UK have nose and throat swabs and endotracheal aspirates tested for SARS-CoV-2 RNA preferably within 24 hours (and no longer than 48 hours) of organ retrieval.

2.1.2 NHSBT does not currently recommend the routine use of SARS-CoV-2 antibody results for donor characterisation purposes. When available, a complete set of molecular and serological tests can be used to inform assessment of specific cases.

2.1.3 NHSBT does not recommend the routine use of chest computed tomography (CT) for donor characterisation purposes or clinical decision-making on suitability to be an organ donor due to insufficient sensitivity and specificity[16,17].

2.2 Living donors.

2.2.1 Screen potential living kidney donors according to local hospital screening policies for elective surgery. At present, NHSBT does not recommend routine screening of living donors prior to surgery.

3.0 Potential living donors with positive SARS-CoV-2 RNA tests

3.1 Planned living donors found to be **positive** for SARS-CoV-2 RNA pre-operatively must be assessed for suitability to proceed to donation according to local hospital policies. Clinical decision-making needs to be made in the context of emerging evidence and experience.

4.0 Specific issues in potential deceased donors with negative SARS-CoV-2 RNA tests

4.1 Unless COVID-19 is suspected, a single set of negative nose & throat and endotracheal aspirate results for SARS-CoV-2 RNA preferably within 24 hours (and no longer than 48 hours) of organ retrieval is sufficient to complete potential deceased donor SARS-CoV-2 characterisation. These results will be in addition to hospital and intensive care unit admission screening.

4.1.1 This does not completely exclude SARS-CoV-2 infection, but experience to date illustrates the utility of this strategy. Thus far, there have been no reported cases in the UK of proven donor-derived transmission of SARS-CoV-2 in relation to deceased donor organs, tissues and cells where there were negative nose & throat and endotracheal aspirate results for SARS-CoV-2 RNA within 48 hours of organ retrieval[15,18].

4.2 Potential deceased donors who have been a close contact of someone who has had a positive SARS-CoV-2 test result[20] in the previous 10 days, but with no clinical suspicion of COVID-19 and negative SARS-CoV-2 screening RNA tests, can go forward for assessment of suitability for donation of **all organs**.

4.3 Other clinical scenarios for potential deceased donors with **negative** respiratory tract SARS-CoV-2 tests at the time of donor assessment, and the implications for organ offering, **are shown in Table 1 and Figure 1.**

4.4 In rare circumstances, it is possible (e.g., where there is a late revision of an initial result by the laboratory or the result on a sample taken prior to donor characterisation becomes available), that the deceased donor tests SARS-CoV-2 RNA negative during donor characterisation but positive results are retrospectively found. If this happens after organs have been transplanted, OTDT Directorate will contact recipient centres to discuss the possible clinical significance and any potential implications. The event will also be investigated by the OTDT Clinical Governance team. If this happens before organ recovery or implantation, results must be reviewed urgently in order to provide up-to-date information to transplant centres.

5.0 Specific issues in potential deceased donors with positive or indeterminate SARS-CoV-2 RNA tests and no COVID-19

5.1 Patients with a diagnosis of COVID-19 and positive SARS-CoV-2 RNA results, where COVID-19 **is** felt to contribute to the cause of death, are currently **not being considered** for deceased organ donation (Table 1).

5.2 In potential deceased donors with **no diagnosis of COVID-19 (those where COVID-19 is not felt to contribute to the cause of death)** and positive or indeterminate SARS-CoV-2 RNA tests, analysis of consecutive viral RNA results can help with interpretation of the likely stage of infection. Molecular tests are very sensitive and positive or indeterminate results can be obtained even when there is no replicating virus in the sample; sometimes this can continue for weeks or months. A positive or indeterminate SARS-CoV-2 RNA result will not always indicate current infection, and clinical, epidemiological and virological information must be used for a more accurate interpretation and assessment. Polymerase chain reaction cycle thresholds (Ct) may correlate with ability to recover viable virus from the sample, but care must be exercised when interpreting Ct results, especially as values vary between assays and samples. Ct trends interpreted in clinical context are often more valuable than single results.

5.2.1 Where positive screening results are compatible with recent, resolving or **current** infection in the upper and/or lower respiratory tract, current evidence indicates that transmission of SARS-CoV-2 through the transplantation of (non-lung) organs, leading to COVID-19 in the recipient is unlikely.

5.2.2 At present, there is no clear evidence on the frequency, timing or route of SARS-CoV-2 infection of organs outside the respiratory tract. In blood donors, low levels of SARS-CoV-2 RNA has been detected from the plasma of those in the pre-symptomatic phase, though this is a rare occurrence with uncertain significance; to date, no SARS-CoV-2 transmission via blood components has been reported worldwide.

5.2.2.1 SARS-CoV-2 RNA has been found within the gastrointestinal tract and is detectable in stool. Significance in terms of active sites of viral replication outside the respiratory tract remains unknown and no transmission involving non-respiratory routes has ever been reported. The risk of transmission from small bowel and solid organ pancreas transplants is not known at present. These organs can be offered, as per Table 1 and Figure 1, so that transplant centres can apply individualised assessment for their specific patients.

5.3 SNODs must complete FRM6439 for all potential deceased donors. All available SARS-CoV-2 test results must be collated and entered in this form during donor characterisation. The virologist in the testing laboratory may be consulted in specific cases and their views noted on the form. It is not essential to have a written, signed interpretation of test results in all potential donors with positive SARS-CoV-2 screening results. **In all instances, transplant clinicians must check FRM6439 when considering, or after accepting, an organ offer.** This form can be viewed in the attachments (visible in DonorPath, TransplantPath and TissuePath)

5.4 Selection of recipients for organs from deceased donors who test positive or indeterminate for SARS-CoV-2 RNA.

5.4.1 Transplant clinicians must consider perceived organ quality and the potential recipient's clinical urgency. Likely waiting times (and clinical outcomes) if the offer is declined must also be taken into account. Recipient history of SARS-CoV-2 vaccination and/or past infection may be desirable but is not mandatory. The possibility of long-term effects of SARS-CoV-2 infection on the donated organ remains unknown but favourable outcome data are emerging on recipients of organs from SARS-CoV-2 positive donors. Discussion of these issues within a multi-disciplinary transplant team is recommended. At present, there is insufficient evidence to further guide selection of potential recipients for these organs.

5.4.2 There is no evidence to support the **need for routine prophylactic** use of antiviral agents and/or monoclonal antibodies directed against SARS-CoV-2 solely on the basis of having received organs from these donors.

5.4.3 At present, there is no evidence to indicate that change in immunosuppression regimens in recipients of such organs is required.

5.4.4 Standard infection prevention and control measures within transplant units must be followed, according to local and national policy.

5.4.5 Post-transplant screening swabs for SARS-CoV-2 should be performed no less than once a week during the post-transplant hospital admission or for a minimum of 14 days post-transplant (whichever is longer). Lateral flow tests for patients discharged home can be utilised but molecular-based tests are preferred for inpatients and at outpatient visits, particularly during the immediate post-transplant period.

5.4.6 Although donor-derived transmission of infection from non-lung organs is not expected from these donors, **at present, these donors can be considered as non-standard infectious risk, hence recipient follow-up (as per 5.4.5) is essential and reporting of infection is mandatory.** Monitoring for early post-transplant SARS-CoV-2 infection, regardless of route of acquisition, is important. In those recipients that test positive for SARS-CoV-2, early intervention with antiviral agents and/or monoclonal antibodies directed against SARS-CoV-2 may be appropriate and must be discussed promptly with specialist virologists. If an organ transplant recipient tests positive for SARS-CoV-2 RNA within two weeks of transplantation, OTDT Clinical Governance must be informed via the incident reporting site on www.odt.nhs.uk.

6.0 SARS-CoV-2 assessment and screening in potential recipients

6.1 Transplant centres are encouraged to refer to their own policies with regards to SARS-CoV-2 assessment and screening in potential recipients.

7.0 References

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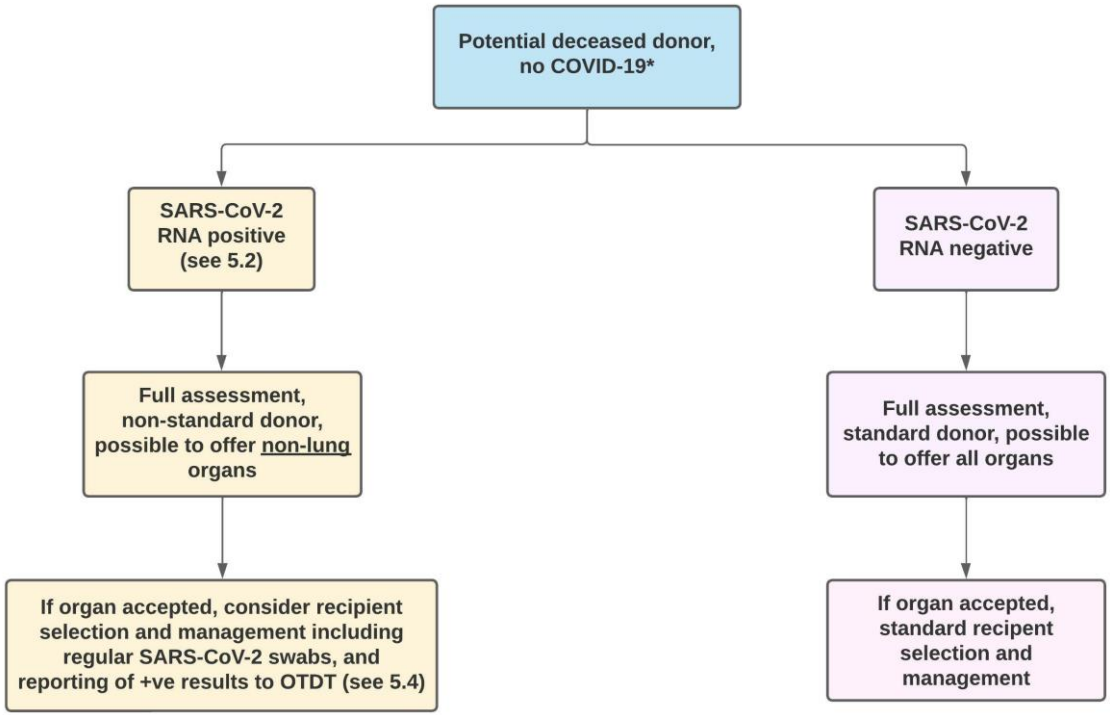
Table 1: General approach to potential deceased organ donor characterisation and organ offering in relation to SARS-CoV-2 status

Potential donor's SARS-CoV-2 status	SARS-CoV-2 RNA results	Implications for donor assessment	Implications for organ offering
No COVID-19*	Donor hospital NTS negative Donation NTS and ETA negative	Can proceed with donor assessment Can complete donor assessment	Assess suitability of all organs
No COVID-19* and documented exposure to SARS-CoV-2, regardless of the timing of exposure	Donor hospital NTS negative Donation NTS and ETA negative	Can proceed with donor assessment Can complete donor assessment	Assess suitability of all organs
No COVID-19* and previous asymptomatic SARS-CoV-2 infection	Donor hospital NTS negative Donation NTS and ETA negative	Can proceed with donor assessment Can complete donor assessment	Assess suitability of all organs
No COVID-19* and previous resolved COVID-19	Donor hospital NTS negative Donation NTS and ETA negative	Can proceed with donor assessment Can complete donor assessment	Assess suitability of all organs
No COVID-19*, but with incidental positive SARS-CoV-2 RNA result(s)	NTS or ETA samples are **positive or indeterminate**	Collect another set of samples for confirmation. The history and pattern of results may aid interpretation by a clinical virologist in the testing laboratory and transplant centre. **In the absence of COVID-19*, offer of non-lung organs from these non-standard donors is possible.** Positive results can be due to a variety of reasons (see Figure 1), and donation teams must provide as much information to transplant teams as possible.	Assess suitability of **non-lung organs**
COVID-19 is a contributory cause of death	NTS or ETA samples are **positive**	**Not** suitable for donor assessment	**A contra-indication to donation**

*COVID-19 **not** felt to be a contributory cause of death; ETA – endotracheal aspirate; NTS – nose and throat swab.

Figure 1: Summary of management pathways with respect to potential deceased donor SARS-CoV-2 status



*COVID-19 **not** felt to be a contributory cause of death.