Changes in this version

In potential deceased donors **without a diagnosis of COVID-19 (where COVID-19 is not felt to contribute to the cause of death)** SARS-CoV-2 RNA positivity is no longer a contra-indication for full assessment and donation of non-lung organs, even when results are consistent with a current infection. It is no longer essential to have an interpretation of test results from the testing laboratory virologist in all potential donors with positive SARS-CoV-2 screening tests. Executive summary added. Updated references. Table 1 modified. Figure 1 added.

Executive Summary and Contents

- This version of the guidance aligns donor and recipient assessments with the evolving pandemic situation and the 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. **Transplant clinicians must check this form when considering, or after accepting, an organ offer.** This form must be requested from OTDT Hub Operations.
- 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 and transplant recipients 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. **This version now aligns donor and recipient assessments with the evolving pandemic situation and the 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.

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 must be requested from OTDT Hub Operations.**

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 Screening of potential living donors for SARS-CoV-2 infection, the need to check for symptoms of and exposure to COVID-19, and duration of SARS-CoV-2 protective behaviour pre- and post-donation must be in line with national guidance.

3.0 Specific issues in potential living donors with positive SARS-CoV-2 RNA tests

3.1 Planned living donors found to be **positive** for SARS-CoV-2 RNA in nose & throat swabs pre-operatively must be assessed for suitability to proceed to donation.

3.1.1 Where a current infection is certain or likely, donation is not recommended until it is deemed to have resolved. Whenever possible, a period of at least 10 days from onset of symptoms or from first testing positive for SARS-CoV-2 RNA (if asymptomatic) should be observed. This period can be reduced following individual assessment of the donor and recipient circumstances.

3.1.2 Where ongoing SARS-CoV-2 RNA positivity is indicative of a resolved infection, and pending specialist virologist consideration of the planned living donor's history, donation may be possible.

3.1.3 Decisions on when a potential living donor donates after recovering from COVID-19 (or an asymptomatic SARS-CoV-2 infection) must involve discussion with the wider multi-disciplinary team (including an anaesthetist) and the potential donor. There may be additional risks to the living donor from having a general anaesthetic within 7 weeks of being diagnosed with COVID-19 or an asymptomatic SARS-CoV-2 infection,

and other organisations have produced guidance around the timing of elective surgery in these scenarios[18].

3.2 If a living donor tests positive for SARS-CoV-2 RNA within two weeks of donation, NHS Blood and Transplant Organ and Tissue Donation and Transplantation (OTDT) Clinical Governance must be informed on www.odt.nhs.uk (https://www.odt.nhs.uk/odt-structures-and-standards/governance-and-quality/tell-us-about-an-incident/). Within this timeframe, it may be difficult to distinguish between infection acquired pre- or post-donation. Notification to OTDT allows safety monitoring of living donors and recipients, particularly where the recipient of the living donor's organ is not being cared for by the same team (e.g., donation from a non-directed altruistic donor, or through the UK Living Kidney Sharing Scheme).

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[15,19].

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 must be requested from OTDT Hub Operations.

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 Potential transplant recipients must be carefully questioned for symptoms consistent with COVID-19 and for contact with persons with confirmed or suspected COVID-19. Ideally, this would happen before the patient is admitted to hospital. Patients with a significant contact history, or where clinical suspicion of COVID-19 is present, must be discussed with a consultant in virology or infectious diseases.

6.2 Undertaking transplant surgery on an **asymptomatic** patient during the incubation period of COVID-19 is thought to carry significant risks of early post-operative mortality. NHS England and NHS Improvement currently advise that all non-elective admissions to hospital have nose and throat swabs tested for SARS-CoV-2 – clearly that would include those admitted for potential transplantation. For transplant patients, the same position has been taken by the Scottish Government and the Northern Irish Department of Health.

6.3 Units must adhere to protocols for SARS-CoV-2 nose and throat swab testing of potential transplant recipients and should be aware of the following:

6.3.1 Immediate pre-transplant recipient screening for SARS-CoV-2 has become universal practice in the UK. **Negative RNA test results (where neither clinical nor epidemiological suspicion of SARS-CoV-2 infection exist) are not absolute prerequisites to proceeding with transplantation** and, as for donors, interpretation must be aligned with all other relevant information. This includes history of, or results compatible with, infection in the recent past, where detection of residual viral RNA is unlikely to be of clinical significance.

6.3.2 Positive or indeterminate pre-transplant SARS-CoV-2 RNA swab results require prompt review with virologists. Detailed interpretation of a positive or indeterminate result is required. Analysis of a complete set of virological results (molecular and serological), together with clinical and epidemiological information, can help in the assessment.

6.4 Some units have used chest CT to screen potential transplant recipients for **asymptomatic** COVID-19 at admission for transplantation. The use of chest CT as a COVID-19 screening test has largely been supplanted by rapid turnaround time SARS-CoV-2 nose and throat swabs[16,17].

6.5 There must be a low threshold for SARS-CoV-2 swab testing in patients on the transplant list who develop symptoms consistent with COVID-19 or have had a known exposure to SARS-CoV-2. Those with proven SARS-CoV-2 infection should be suspended for an appropriate period according to the clinical context.

6.5.1 The appropriate time for reactivation should be tailored on an individual basis. Urgency of transplantation, clinical status and stage of infection are some of the issues for multidisciplinary discussion. Time to recovery, in symptomatic cases, will vary and can be brief. For reasons covered elsewhere in this guidance (see 3.1.2), negative SARS-CoV-2 RNA is not a criterion to be used in isolation, when assessing this issue.

6.6 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. Within this time-frame, it is difficult to distinguish between nosocomial spread, pre- or post-transplant community acquired disease, or donor-transmitted disease. Transplant clinicians are encouraged to ask their virology department to retain the positive sample(s) and submit it for viral genetic sequencing; this is particularly relevant in the context of using donors with current SARS-CoV-2 infection and the potential ability to use molecular epidemiology to rule out a donor-derived infection. In rare circumstances, it is possible (e.g., where there is a late revision of an initial result by the laboratory), that the recipient initially tests negative for SARS-CoV-2 RNA on pre-transplant tests, but later is found to be positive after the transplant has been undertaken. A recipient who has tested negative pre-transplant and who is already going through the incubation period of a recently acquired infection may test positive fairly soon after the transplant.

6.6.1 Notification to OTDT will help facilitate investigation of possible donor-transmitted disease, and ensure appropriate notification of other clinical teams as appropriate (e.g., those caring for other recipients of organs from the same deceased donor, or a living donor in another centre). Importantly, notification of relevant information through the routine recipient follow-up forms will help building the long-term outcome picture for these recipients.

6.6.2 This must also be reported to the OTDT COVID-19 registry.

6.6.3 Clinical management of the recipient will be as per clinical need, in line with local and national guidance[21]. SARS-CoV-2 anti-viral or monoclonal antibody treatment, including prophylactic or pre-emptive, must be in accordance with up-to-date guidance or as part of a research study. Their utility is maximised if considered very early in the course of infection; low threshold for testing is essential.

7.0 References

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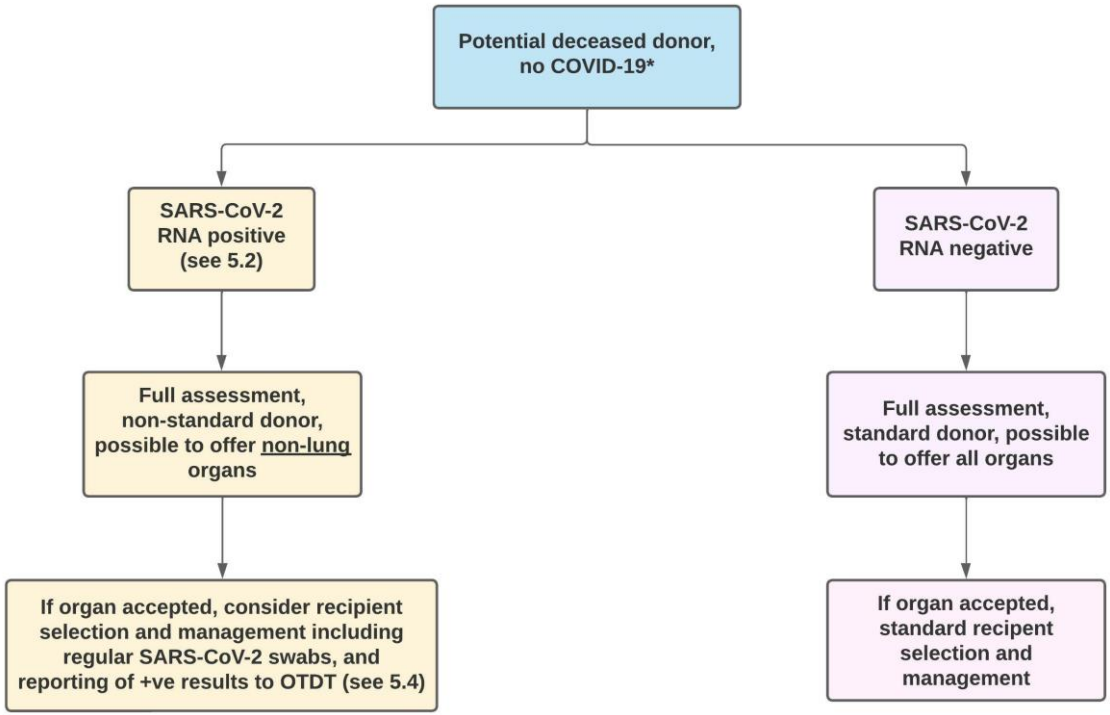
Table 1: General approach to potential deceased organ donor characterisation and organ offering in relation to SARS-CoV-2 status

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.