Changes in this version

Circumstances are described where organ donation from selected donors with positive (or indeterminate) SARS-CoV-2 RNA test results **may** be reasonable, following virological advice, and where evolving infection (and therefore the risk of infectivity to recipients) is deemed unlikely. Introduction of contextual interpretation of positive and indeterminate SARS-CoV-2 RNA results in potential deceased donors and potential living donors.

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.**

1.2 Also note that guidance on infection prevention and control measures in potential solid organ donors and transplant recipients are retained within the original documents (POL296 'Re-opening of Transplant Programmes: Issues for Consideration' and POL301 'COVID-19 – Second Surge Planning'). Guidance on the consent of potential solid organ transplant recipients and living donors is given elsewhere[1].

1.3 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.

1.4 In previous versions of this policy, negative SARS-CoV-2 RNA results were required to proceed to deceased donor characterisation and organ offering. However, SARS-CoV-2 RNA positivity alone does not define infectiousness and cannot be interpreted in a binary fashion. **This updated policy now sets out the circumstances where organ donation from selected donors with positive (or indeterminate) SARS-CoV-2 RNA test results may be reasonable, following virological advice, and where evolving infection (and therefore the risk of infectivity to recipients) is deemed unlikely.**

1.5 Please note the use of the following terms in this document:

1.5.1 **Date of disease onset:** the date of onset of COVID-19 symptoms.

1.5.2 **Asymptomatic infection:** detection of SARS-CoV-2 in an upper or lower respiratory tract sample without signs or symptoms compatible with COVID-19.

1.5.3 **Mild COVID-19:** detection of SARS-CoV-2 in the respiratory tract with symptoms consistent with COVID-19 and with no need for hospitalisation for COVID-19 (or

hospitalisation without the need for ventilatory support, which some groups define as moderate COVID-19).

1.5.4 **Severe COVID-19:** detection of SARS-CoV-2 in the respiratory tract with symptoms consistent with COVID-19 and the need for hospitalisation for COVID-19 with ventilatory support.

1.5.5 **Resolved COVID-19:** recovery from COVID-19, with no fever for a minimum of 48 hours and resolution of other symptoms (apart from cough or anosmia, as these can last for several weeks).

1.6 **After accepting the offer of an organ from a potential deceased donor, transplant clinicians must check FRM6439 'SARS-CoV-2 Assessment and Screening' and any additional virological details to assess donor information on SARS-CoV-2-related issues. This must be requested from ODT Hub Operations.**

1.7 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.

1.7.1 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.

1.7.2 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 general 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[15,16].

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[17].

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, **and from the perspective of the risks of transmitting SARS-CoV-2 with the donated organ,** a period of at least 10-14 days from onset of symptoms or from first testing positive for SARS-CoV-2 RNA (if asymptomatic) needs to be observed.

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 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]. 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.

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 will help facilitate investigation of possible donor-transmitted disease to the recipient, allow safety monitoring of living donors and ensure appropriate notification of clinical teams if 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 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 results.

4.1.1 This does not completely exclude evolving 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[19].

4.1.2 In the event of specific concerns about SARS-CoV-2-related risks of a potential deceased donor, donation teams must provide information to the virology laboratory performing the SARS-CoV-2 RNA screening tests so that interpretation and advice can be given.

4.2 Potential deceased donors with significant, well-documented exposure[20] to SARS-CoV-2 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 Tables 1 and 2.**

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 management options. 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 as positive results may alter suitability for donation.

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

5.1 Patients with symptoms of COVID-19 and a positive SARS-CoV-2 RNA are currently **not being considered** for deceased organ donation (Table 1).

5.2 In selected potential deceased donors with **no symptoms of COVID-19** and positive or indeterminate SARS-CoV-2 RNA tests, a more detailed analysis of viral RNA results is required in order to interpret their significance in relation to infectiousness. 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 Organs (other than lung) from selected potential deceased donors with positive or indeterminate SARS-CoV-2 RNA tests and no COVID-19 symptoms may be deemed appropriate for offering **after risk assessment by a clinical virologist in the testing laboratory. If results indicate current infection which is likely to be resolving or not to be evolving, non-lung offering is possible following detailed assessment (Table 2).** No test or opinion can be 100% accurate and any interpretation will be given based on the information available.

5.2.2 At present, there is no strong 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 amplified 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. The risk of transmission from small bowel and solid organ pancreas transplants is not known at present. These organs can be offered in selected potential deceased donors, as per Tables 1 and 2, but additional caution is recommended.

5.3 Where a potential deceased donor in one of the clinical scenarios in Table 2 has a positive or indeterminate SARS-CoV-2 RNA test, **SNODs must seek advice from the clinical virologist in the testing laboratory**. On receipt of all relevant information from the SNOD, including the completed FRM6439, the virologist will aim to provide an interpretation of the results obtained. This can be used to inform **(non-lung)** organ offering according to NHSBT policies. **The relevant information and discussions / decisions are available on request via ODT Hub. After accepting the offer of an organ from a potential deceased donor, transplant clinicians must check FRM6439 'SARS-CoV-2 Assessment and Screening' and any additional virological details to assess donor information on SARS-CoV-2-related issues. This must be requested from ODT 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 as well as the potential recipient's history of SARS-CoV-2 vaccination and/or past COVID-19 infection, and their clinical urgency. Consider also the possibility of end-organ damage due to possible long-term effects of SARS-CoV-2 infection on the donated organ. Likely waiting times (and clinical outcomes) if the offer is declined must also be taken into

account. 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 See 6.1.7 regarding routine screening for SARS-CoV-2 IgG of patients on transplant wait-lists.

5.4.3 There is no evidence to support the **prophylactic** use of antiviral agents and/or monoclonal antibodies directed against SARS-CoV-2 in recipients of organs from these donors.

5.4.4 At present, there is insufficient evidence to guide immunosuppression regimens in recipients of such organs

5.4.5 Standard infection prevention and control measures within transplant units must be followed, including routine post-transplant screening swabs for SARS-CoV-2. Screening swabs should be performed at least twice a week during the post-transplant hospital admission or for a minimum of 10 days post-transplant (whichever is longer). Lateral flow tests for patients discharged home can be utilised.

5.4.6 Although donor-derived transmission of infection from non-lung organs is not expected from these donors, vigilance is essential. 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 recipients of deceased donor organ transplants.

6.1.1 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.

6.1.2 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.

6.1.3 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:

6.1.3.1 Whilst **highly desirable,** the availability of negative RNA test results (where neither clinical nor epidemiological suspicion of SARS-CoV-2 infection exist) are not absolute prerequisites to proceeding with transplantation. If transplantation proceeds before swab results are available, these must be checked at the expected time of result availability. The widespread availability of rapid turnaround RNA tests makes this less likely to be a consideration.

6.1.3.2 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. Transplantation would not usually proceed if the patient has COVID-19 or a swab result indicating a current SARS-CoV-2 infection. Cases of an emergency nature (e.g., super-urgent liver transplantation) may be an exception and should be carefully evaluated. Analysis of a complete set of virological results (molecular and serological), together with clinical and epidemiological information, can help in the assessment.

6.1.4 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[15,16].

6.1.5 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.

6.1.5.1 Those with resolved COVID-19 more than 28 days ago can be considered for re-activation on the list. Reactivation before 28 days may be appropriate in some cases, depending on the urgency of transplantation and after clinical assessment and multidisciplinary discussion. Those with more severe disease may require a longer period to recover, subject to clinical assessment and multidisciplinary discussion.

6.1.5.2 In those with asymptomatic SARS-CoV-2 infection, re-activation on the list may be considered <28 days from the time of first testing positive.

6.1.6 Surveillance of asymptomatic potential recipients for SARS-CoV-2 RNA whilst on the waiting list. Currently there is no evidence for or against routine surveillance testing for SARS-CoV-2 RNA in asymptomatic patients on the waiting list.

6.1.7 Surveillance of asymptomatic potential recipients for anti-SARS-CoV-2 antibodies whilst on the waiting list. Currently there is no evidence for or against routine surveillance testing for anti-SARS-CoV-2 antibody in asymptomatic patients on the

waiting list. Centres may choose to test patients for antibodies, particularly in the context of vaccination but until correlates of protection from infection and disease are better defined, these results must be used with caution.

6.2 Potential recipients of living donor organ transplants.

6.2.1 Local policies on SARS-CoV-2 RNA testing must be in line with national guidance[17]. Where swab results are positive or indeterminate pre-transplant, transplantation would not usually proceed, but prompt review of results with consultant virology or infectious diseases input is recommended (see also 6.1.3.2).

6.3 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. In exceptionally rare circumstances, it is theoretically 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.

6.3.1 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).

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

6.3.3 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 in relation to SARS-CoV-2 status

Potential donor's current status	SARS-CoV-2 RNA results	SARS-CoV-2-related implications for donor assessment
No clinical suspicion of COVID-19 or other SARS-CoV-2-related concerns	Donor hospital NTS negative Donation NTS and ETA negative	Can proceed with donor assessment Can complete donor assessment
No clinical suspicion of COVID-19 but a significant well-documented exposure to SARS-CoV-2 >10 days ago	Donor hospital NTS negative Donation NTS and ETA negative	Can proceed with donor assessment Can complete donor assessment
No clinical suspicion of COVID-19 but a significant well-documented exposure to SARS-CoV-2 within the previous 10 days	Donor hospital NTS negative Donation NTS and ETA negative	Can proceed with donor assessment Can complete donor assessment
No clinical suspicion of COVID-19 but previous asymptomatic SARS-CoV-2 infection	Donor hospital NTS negative Donation NTS and ETA negative	Can proceed with donor assessment Can complete donor assessment. Time from first testing positive will determine which organs may be offered (see Table 2)
No clinical suspicion of COVID-19 but previous resolved COVID-19	Donor hospital NTS negative Donation NTS and ETA negative	Can proceed with donor assessment. Can complete donor assessment. Time from first disease onset will determine which organs may be offered (see Table 2)
No clinical suspicion of COVID-19. Several scenarios fall under this category (see Table 2) but the outcome in terms of donation / organ offering is decided by the same risk assessment process	NTS and/or ETA samples are **positive or indeterminate**	Samples can be repeat tested. Take a new set of samples whenever possible. The history and pattern of results will inform interpretation by the clinical virologist in the testing laboratory; detailed assessment and early escalation are required. **Evidence of current infection which is likely to be resolving or not to be evolving does not necessarily contra-indicate donation**
Ongoing COVID-19	NTS and/or ETA samples are **positive**	**Not** suitable for donor assessment; contra-indication to donation

ETA – endotracheal aspirate; NTS – nose and throat swab. Colour code denotes appropriateness to progress to detailed donor characterisation and not necessarily suitability for donation and transplantation. This can only be ascertained once characterisation and assessment are completed (see Table 2).

Table 2: Clinical scenarios where deceased donor organ offering may be appropriate, with respect to donor SARS-CoV-2 status

Resolved SARS-CoV-2 infection with negative RNA in NTS and ETA at the time of donor characterisation			
Infection or disease status	**Time from disease onset***	**Implications for organ offering**	**Notes**
Asymptomatic	Less than 10 days	Assess suitability of organs **other than lungs**	
Asymptomatic	10 days or more	Assess suitability of **all** organs	
Resolved COVID-19	Less than 10 days	Assess suitability of organs **other than lungs**	Unlikely scenario. Unlikely to be RNA negative in resolved severe COVID-19
Resolved COVID-19	10 days or more	Assess suitability of **all** organs	
Resolved or resolving SARS-CoV-2 infection with positive or indeterminate* RNA in NTS and/or ETA at the time of donor characterisation			
Infection or disease status	**Time from disease onset****	**Implications for organ offering**	**Notes**
Asymptomatic	Less than 10 days	SNODs to seek interpretation from clinical virologist in the testing laboratory; **non-lung** offering is possible, particularly if >7 days and vaccinated*	Early resolution, particularly in vaccinees and re-infected individuals, may allow **non-lung** offering.
Asymptomatic	10 days or more***	SNODs to seek interpretation from clinical virologist in the testing laboratory; **non-lung** offering is possible*	If residual detection of non-viable virus or a resolving infection is likely, then assess suitability of organs **other than lungs.** If results indicate **current re-infection*** ** which is likely to be resolving or not to be evolving, **non-lung** offering is possible
Resolved COVID-19	10 days or more***	SNODs to seek interpretation from clinical virologist in the testing laboratory; **non-lung** offering is possible*	If residual detection of non-viable virus is likely, then assess suitability of organs **other than lungs.** If results indicate **current re-infection*** ** which is likely to be resolving or not to be evolving, **non-lung** offering is possible
New positive or indeterminate SARS-CoV-2 RNA in NTS and/or ETA with no suspicion of COVID-19 (i.e., incidental finding on screening)			
Infection or disease status	**Time from disease onset**	**Implications for organ offering**	**Notes**
Asymptomatic positive RNA known at the time of potential donor referral **or** identified during potential donor characterisation	Not applicable	SNODs to seek interpretation from clinical virologist in the testing laboratory; **non-lung** offering is possible*	If residual detection of non-viable virus or a resolving infection is likely, then assess suitability of organs **other than lungs.** If results indicate **current infection which is likely to be resolving or not to be evolving**, **non-lung** offering is possible

ETA – endotracheal aspirate; NTS – nose and throat swab. *Low levels of SARS-CoV-2 RNA can be intermittently detected beyond the end of the infectious period. **In asymptomatic infection, time from testing positive applies. ***Epidemiologically, re-infection is defined as positive tests at least 90 days apart. Colour code corresponds to Table 1 and indicates the possibility of viable virus in the respiratory tract.