

Changes in this version

Transplant Clinicians to review FRM6439 when considering an offer of an organ from a potential deceased donor

Table 1 updated. Summary of the general approach to SARS-CoV-2 testing in potential deceased donors in the UK.

Policy

1.0 Introduction

- 1.1 The Coronavirus Disease 2019 (COVID-19) pandemic has had a significant impact on organ donation and transplantation in the UK. Although fundamental questions still remain about the biology of the Severe Acute Respiratory Syndrome Coronavirus-type 2 pathogen (SARS-CoV-2) and the natural history and optimal treatment of COVID-19, knowledge has evolved rapidly since early 2020.
- 1.2 This document provides guidance on the SARS-CoV-2 assessment and screening of potential solid organ donors and transplant recipients in the UK. The policies within this document were originally included within POL296 'Re-opening of Transplant Programmes: Issues for Consideration' and POL301 'COVID-19 – Second Surge Planning', but have been consolidated into a stand-alone policy to facilitate access and to enable easier updating when new evidence and practices emerge. These policies will be reviewed and updated regularly in light of new available evidence and changes in circumstances imposed by the evolving situation. **Users must refer to the www.odt.nhs.uk website for the most recent version of this document and all cross-linked documents.**
- 1.3 Readers must 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'). Similarly, guidance on the consent of potential solid organ transplant recipients and living donors is given elsewhere¹.
- 1.4 **When considering the offer of an organ from a potential deceased donor, transplant clinicians must check FRM6439 'COVID-19 SNOD Checklist' to assess the donor's risk of COVID-19. This is available via ODT Hub Operations.**

2.0 SARS-CoV-2 assessment and screening in potential organ donors

- 2.1 Deceased donors. A summary of the general approach to SARS-CoV-2 testing in potential deceased donors is shown in Table 1.

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- 2.1.1 All potential deceased organ donors in the UK have nose and throat swabs and endotracheal aspirates tested for SARS-CoV-2 ribonucleic acid (RNA). Negative results are required to proceed to organ offering and **a positive screening result precludes organ donation**¹. Unless there is a historic positive result or specific concerns about the case, a single set of negative nose & throat and endotracheal aspirate results for SARS-CoV-2 RNA within 48 hours of organ retrieval is sufficient to complete potential deceased donor characterisation.
- 2.1.2 Negative SARS-CoV-2 RNA testing does not completely exclude evolving SARS-CoV-2 infection. To date, there have been no reported cases of proven donor-derived transmission of SARS-CoV-2 in relation to organs, blood, tissues and cells.
- 2.1.3 On occasion, a potential deceased donor will have no clinical suspicion of COVID-19, negative SARS-CoV-2 RNA tests, but a recent well-documented history of exposure to a proven case of COVID-19 (see **FRM6439 ‘COVID-19 SNOD Checklist’**). The up-to-date definition of exposure to a non-household case is given elsewhere².
- 2.1.3.1 In this scenario, the timing and nature of the exposure will influence the likely suitability for donation to occur. Where exposure took place ≤ 14 days prior to donation, a detailed history and further virological advice is recommended. Negative SARS-CoV-2 RNA screening tests will indicate the suitability for donation in the vast majority of cases.
- 2.1.4 Where a potential deceased donor has recovered from confirmed or suspected COVID-19, and where more than 28 days have passed with no COVID-19-related symptoms, negative respiratory tract SARS-CoV-2 tests enable assessment of suitability for organ donation. This is a precautionary approach which will be reviewed in the light of new evidence as regards to viability of the virus in blood and other compartments outside the respiratory tract. If a shorter period has elapsed since symptom resolution (particularly in proven mild cases), suitability for deceased donation can be assessed on a case-by-case basis. This must be discussed with a consultant in virology or infectious diseases.
- 2.1.5 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 deceased donor initially tests SARS-CoV-2 RNA negative during donor characterisation but is later found to be positive after organs have been transplanted. In such a scenario, NHS Blood and Transplant Organ and Tissue Donation and Transplantation (OTDT) Directorate will contact recipient centres to discuss management options. The event will also be investigated by the OTDT Clinical Governance team.
- 2.1.6 NHSBT does not recommend the routine use of SARS-CoV-2 antibody results for donor characterisation purposes or clinical decision-making on suitability to be an organ donor. It is acknowledged that a complete set of molecular and serological results may be used to assess specific cases.

2.1.7 NHSBT does not recommend the routine use of CT chest for donor characterisation purposes or clinical decision-making on suitability to be an organ donor^{3,4}.

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 guidance⁵. Testing for SARS-CoV-2 infection in asymptomatic potential living donors at the start of assessment and prior to planned surgery will need to be implemented within appropriate timeframes prior to donation to minimise risks of cancellation and/or postponement.

2.2.2 Planned living donors found to be positive for SARS-CoV-2 RNA (in nose & throat swabs) pre-operatively should not proceed to donation.

2.2.3 In the exceptionally rare scenario of very late revision of the previous negative result for the living donor occurring after donation has been completed, the donor should be managed based on clinical need. OTDT Clinical Governance must be informed via the incident reporting site on www.odt.nhs.uk.

2.2.4 If a living donor tests positive for SARS-CoV-2 RNA within two weeks of donation, OTDT Clinical Governance must also be informed on www.odt.nhs.uk. Within this time-frame, it is difficult to distinguish between pre- or post-donation community acquired disease, or nosocomial spread. 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 (NDAD), or through the UK Living Kidney Sharing Scheme (UKLKSS), or to a child or young person).

Table 1. Summary of the general approach to SARS-CoV-2 testing in potential deceased donors in the UK.

Potential donor's COVID-19 status	Acceptability for deceased donation assessment	SARS-CoV-2 screening tests ^d
No clinical suspicion of COVID-19	Can assess suitability	1) Nose and throat swab 2) Endotracheal aspirate 3) Blood in EDTA for retrospective molecular and serological testing
No clinical suspicion of COVID-19 but exposure to a proven case of COVID-19 ≤14 days prior to donation ^a	Assessment of suitability requires additional care, a detailed history and early discussion with virology colleagues. Negative SARS-CoV-2 RNA screening tests will	1) Nose and throat swab 2) Endotracheal aspirate 3) Blood in EDTA for retrospective molecular and serological testing

	indicate the suitability for donation in the vast majority of cases.	
No clinical suspicion of COVID-19 but exposure to a proven case of COVID-19 >14 days prior to donation ^a	Can assess suitability	1) Nose and throat swab 2) Endotracheal aspirate 3) Blood in EDTA for retrospective molecular and serological testing
Previous suspected mild ^b COVID-19 with recovery and no symptoms for >28 days	Can assess suitability	1) Nose and throat swab 2) Endotracheal aspirate 3) Blood in EDTA for retrospective molecular and serological testing
Previous proven mild ^b COVID-19 with recovery and no symptoms for >28 days	Can assess suitability	1) Nose and throat swab 2) Endotracheal aspirate 3) Blood in EDTA for retrospective molecular and serological testing
Previous proven moderate or severe ^c COVID-19 with recovery and no symptoms for >28 days	Assessment of suitability requires additional care, a detailed history and early discussion with virology colleagues; consider the possibility of end-organ damage	1) Nose and throat swab 2) Endotracheal aspirate 3) Blood in EDTA for retrospective molecular and serological testing
Proven COVID-19 without recovery	Not suitable for assessment	No screening tests performed

^aSee FRM6439 and reference². ^bMild – not requiring hospitalisation. ^cModerate or severe – requiring hospitalisation. ^dA positive respiratory SARS-CoV-2 molecular screening test is a contra-indication to deceased donation.

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

3.1 Potential recipients of deceased donor organ transplants.

3.1.1 Potential transplant recipients must be carefully questioned for symptoms consistent with COVID-19 and for contact with persons with confirmed or suspected COVID-19. A comprehensive social history is required, with details of the patient's social distancing practices and of those within their household, in order to build a picture to inform a risk assessment. Ideally, this would happen before the patient is admitted to hospital. Examination must include a careful chest assessment with measurement of peripheral arterial oxygen saturations. 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.

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- 3.1.2 Undertaking transplant surgery on an **asymptomatic** patient during the incubation period of COVID-19 is thought to carry significant risks of early post-operative mortality⁶. 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.
- 3.1.3 Units must develop protocols for SARS-CoV-2 nose and throat swab testing of potential transplant recipients in conjunction with virology colleagues and should be aware of the following:
- 3.1.3.1 Whilst **highly desirable**, the availability of negative test results (where neither clinical nor epidemiological suspicion of SARS-CoV-2 infection exist) are not absolute prerequisites to proceeding with transplantation. In the context of kidney transplantation, Kidney Advisory Group guidance must be consulted¹. Practices may vary between units depending on turnaround times for results of SARS-CoV-2 swabs, urgency of transplantation, constraints of organ cold ischaemic time, and hospital testing policies. If transplantation proceeds before swab results are available, these must be checked at the expected time of result availability.
- 3.1.3.2 Transplant teams are advised to inform virology colleagues of the pre-transplant timelines for the various organ types so that an appropriate turnaround time target is set. Where appropriate, hospital laboratories should seek to work with regional centres in order to meet required turnaround times. Contingency planning is also needed, given the shortage of supplies and reagents.
- 3.1.3.3 Where swab results are available pre-transplant and are positive, transplantation would not usually proceed. Cases of an emergency nature (e.g. super-urgent liver transplantation) may be an exception. Analysis of a complete set of previous virological results (molecular and serological), together with clinical and epidemiological information, may help in the assessment.
- 3.1.3.4 Consider taking blood in EDTA for retrospective SARS-CoV-2 RNA testing and serology to gather additional information on infection status. It is acknowledged that SARS-CoV-2 RNA has been infrequently detected in the blood of those with COVID-19, but data on the systematic testing of asymptomatic and symptomatic individuals are not available.
- 3.1.4 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 primarily due to concerns about false positive and false negative results³. If units consider using chest CT to screen for COVID-19, clinicians must discuss this with radiology colleagues, and follow the relevant national guidance³.

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- 3.1.5 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. Those with proven COVID-19 should be suspended for an appropriate period according to the clinical context.
- 3.1.5.1 Those who recover and are symptom-free for more than 28 days can be considered for re-activation on the list. In this patient group, the need to test for SARS-CoV-2 before re-activation on the list must be assessed on a case-by-case basis, guided by parameters such as illness severity, time elapsed since recovery, plus discussions with virology or infectious diseases colleagues. Re-activation before 28 days may be appropriate (subject to clinical assessment and full multidisciplinary discussion), given the broad spectrum of COVID-19 disease and depending on the degree of urgency for transplantation.
- 3.1.6 **Surveillance of asymptomatic** potential recipients for SARS-CoV-2 RNA whilst on the waiting list.
- 3.1.6.1 Currently there is no evidence for or against routine surveillance testing for SARS-CoV-2 RNA in asymptomatic patients on the waiting list. Centres are encouraged to enrol patients in research projects that are investigating the utility of screening asymptomatic patients.
- 3.1.7 **Surveillance of asymptomatic** potential recipients for anti-SARS-CoV-2 antibodies whilst on the waiting list.
- 3.1.7.1 Currently there is no evidence for or against routine surveillance testing for anti-SARS-CoV-2 antibody in asymptomatic patients on the waiting list.
- 3.2 Potential recipients of living donor organ transplants.
- 3.2.1 Local policies on SARS-CoV-2 RNA testing must be in line with national guidance⁵. Where swab results are positive pre-transplant, transplantation would not usually proceed.
- 3.3 If an organ transplant recipient tests positive for SARS-CoV-2 RNA within two weeks of donation, 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.
- 3.3.1 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).
- 3.3.2 This must also be reported to the OTDT COVID-19 registry¹.

3.3.3 Clinical management of the recipient will be as per clinical need, and in line with local and national guidance⁷. On occasion, transplant and virology teams may wish to consider interventions such as remdesivir or experimental treatments such as convalescent plasma⁸⁻¹¹.

4.0 References

- 1) NHS Blood and Transplant. COVID-19: Clinical Advice. <https://www.odt.nhs.uk/deceased-donation/covid-19-advice-for-clinicians/>. Accessed 12 October 2020.
- 2) UK Government. Guidance for contacts of people with confirmed coronavirus (COVID-19) infection who do not live with the person. <https://www.gov.uk/government/publications/guidance-for-contacts-of-people-with-possible-or-confirmed-coronavirus-covid-19-infection-who-do-not-live-with-the-person/guidance-for-contacts-of-people-with-possible-or-confirmed-coronavirus-covid-19-infection-who-do-not-live-with-the-person#:~:text=You%20are%20at%20risk%20of,not%20go%20into%20isolation>. Accessed 29 October 2020.
- 3) Kim H, Hong H, Yoon SH. Diagnostic Performance of CT and Reverse Transcriptase-Polymerase Chain Reaction for Coronavirus Disease 2019: A Meta-Analysis. *Radiology*. 2020 Apr 17:201343 [Epub ahead of print].
- 4) The Royal College of Radiologists. Statement on the use of CT chest to screen for COVID-19 in pre-operative patients. <https://www.rcr.ac.uk/college/coronavirus-covid-19-what-rcr-doing/clinical-information/role-ct-chest/role-ct-screening-0>. Accessed 12 October 2020.
- 5) NICE. Arranging planned care in hospitals and diagnostic services – NG179. <https://www.nice.org.uk/covid-19>. Accessed 12 October 2020.
- 6) COVIDSurg Collaborative. Mortality and pulmonary complications in patients undergoing surgery with perioperative SARS-CoV-2 infection: an international cohort study. *Lancet*. 2020 Jul 4;396(10243):27-38.
- 7) British Transplantation Society. Guidance on the management of transplant recipients diagnosed with or suspected of having COVID-19. <https://bts.org.uk/information-resources/covid-19-information/>. Accessed 12 October 2020.
- 8) NHS England. Interim Clinical Commissioning Policy: Remdesivir for patients hospitalised with COVID-19 (adults and children 12 years and older). <https://www.england.nhs.uk/coronavirus/publication/interim-clinical-commissioning-policy-remdesivir-for-patients-hospitalised-with-covid-19-adults-and-children-12-years-and-older/>. Accessed 12 October 2020.
- 9) Department of Health. HSS (MD) 65/2020 – COVID-19 – Therapeutic alert update: Remdesivir for patients hospitalised with Covid-19 (Adults and children aged 12 years and older). <https://www.health-ni.gov.uk/publications/letters-and-urgent-communications-2020>. Accessed 12 October 2020.

- 10) Scottish Government. Interim Clinical Commissioning Policy: Remdesivir for patients hospitalised with COVID-19 (adults and children 12 years and older). <https://www.gov.scot/publications/coronavirus-covid-19-therapeutic-alert-for-remdesivir/>. Accessed 12 October 2020.
- 11) All Wales Therapeutics and Toxicology Centre. Publication of an interim clinical commissioning policy: Remdesivir for patients hospitalised with COVID-19 (adults and children 12 years and older). <https://www.awttc.org/coronavirus-covid-19-therapeutic-advice/covid-19-therapies-alerts-and-advice>. Accessed 12 October 2020.