SARS-CoV-2 Deceased Organ Donor Screening

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Summary of changes

This is a new SOP however the process has been transferred from DAT3737 COVID 19 Assessment and Screening Flowcharts which will now become obsolete.

Additional guidance in relation to indeterminate SARS-CoV-2 results.

Additional guidance in relation to paediatrics.
Useful Information

Severe Acute Respiratory Syndrome Coronavirus 2 also known as SARS-CoV-2 causes coronavirus disease (COVID-19).

The transmission of COVID-19 is thought to occur mainly through respiratory droplets generated by coughing and sneezing, and through contact with contaminated surfaces (WHO 2020).

The 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 and the natural history and optimal treatment of COVID-19, knowledge has evolved rapidly since early 2020.

This document provides guidance on the SARS-CoV-2 assessment and screening of potential solid organ donors.

Key to COVID-19 Testing:
- Collect sample in correct specimen transport container
- Check labelling
- Contact laboratory before sending samples
- Request laboratory confirm arrival of samples
- Agree and note ETA of results
- COMMUNICATE

Which samples should be taken?

SCREENING OF POTENTIAL ORGAN DONOR FOR COVID-19

1. Upper respiratory tract sample options:
   - individual nose and throat swabs in separate collection tubes OR
   - combined nose and throat swab in one collection tube containing universal transport medium OR
   - single swab used for throat then nose

2. Lower respiratory tract sample in universal container

Plus EDTA sample
Glossary

Roles
SNOD - Specialist Nurse Organ Donation. For the purposes of this document the term ‘SNOD or SN’ will apply to a Specialist Nurse with the relevant knowledge, skills, and training in organ donation, working within NHSBT Organ Donation Services Teams (ODST), including SNOD-Specialist Requester, SNOD-Family Care.

SNOD Trainee – A SNOD in training working alongside and under supervision of a competent and trained SNOD.

TM - Team Manager. To support a SNOD in the implementation of this SOP.

RM - Regional Manager. To support a TM or SNOD in the implementation of this SOP.

CLOD - Clinical Lead for Organ Donation.

ICU Consultant – Intensive Care Unit Consultant.

HO - Hub Operations.

PID – Patient Identifiable Data.

Consultant Virologist – oversee the diagnosis, prevention, and management of infection.

ODST – Organ Donation Services Team.

Terminology
SARS-CoV-2 - Severe Acute Respiratory Syndrome Coronavirus 2.

COVID-19 - Coronavirus disease.

SARS-CoV-2 ribonucleic acid (RNA) - the test used to detect SARS-CoV-2 infection.

DonorPath - the secure electronic record that is utilised to upload clinical information about a patient.

Restrictions
This SOP is to be followed by a qualified, trained SNOD. In the event of a SNOD who is in training, this SOP is to be utilised under supervision.

Related Documents/References
FRM5025 - Additional Testing Request Form
FRM5814 - BBV Screen/Malaria/WNV/T.Cruzi Request Form
FRM6445 - COVID-19 Swab and Endotracheal Aspirate Request Form
FRM6439 - COVID-19 SNOD Checklist
FRM6634 - SARS-CoV-2 Indeterminate Results
POL304 - SARS-CoV-2 Assessment and Screening in Organ Donors and Recipients.
1. **Excluding Confirmed or Possible COVID-19**

   **Referral of a potential Deceased Organ Donor** (N.B. explanatory footnotes below)

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### Information

<table>
<thead>
<tr>
<th>Known Confirmed COVID-19</th>
<th>Suspected COVID-19 tests negative but suspicion due to clinical condition</th>
<th>Suspected COVID-19</th>
<th>NO clinical suspicion, neg SARS-CoV-2 RNA but recent history of exposure to proven case of COVID-19</th>
<th>NOT suspected but routine hospital SARS-CoV-2 (RNA) test results outstanding</th>
<th>Recovered</th>
<th>Hospital SARS-CoV-2 (RNA) test negative</th>
</tr>
</thead>
</table>

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### Action

- **Exclude from Donation**
- SNOID check progress of samples sent by ICU including specimen type and determine when results due back. Await result.
- Establish clear timeline of exposure.
- Check progress of samples sent by ICU including specimen type and determine when results due back. Await result.
- Assess for donation referring to POL304 SARS-CoV-2 Assessment and Screening in Organ Donors and Recipients.
- Assess ICU capacity, see flowchart 2.

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**NOTES**

- If a patient has previously tested negative but there remains a high suspicion they are positive for SARS-CoV-2 (RNA) due to their clinical condition, then exclude from donation.
- If the patient has been tested as COVID-19 is suspected, the SNOID should establish what tests have been taken and timeline for expected results. The SNOID should not proceed until SARS-CoV-2 has been confirmed as negative. If the results are negative and donation is being explored, unless both throat/nares swab and nasopharyngeal aspirate samples were sent, a full NHU SARS-CoV-2 screen will need to be sent as per flowchart 3.
- Assess suitability. The timing and nature of the exposure will influence the likely suitability for donation to occur. Please refer to POL304 SARS-CoV-2 Assessment and Screening in Organ Donors and Recipients.
- Any concerns regarding the testing or any implications of results to be discussed with TM/RM.
- If SARS-CoV-2 (RNA) samples have already been taken and sent in advance by the ICU, the SNOID must check with the processing lab that the samples have arrived and expected time of results. Progress to flowchart 2.
- If >28 days have elapsed since symptom resolution, particularly in proven mild cases, suitability can be assessed on a case by case basis. All of these cases must be discussed with Dr Usman-Lamb who can be contacted via TM/RM. SNOID to provide detailed timeline.

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(Template Version 03/02/2020)
2. Assessing ICU Capacity

Decisions regarding ICU capacity is at the discretion of the ICU consultant

Information

- Capacity stretched? (in surge?)

<table>
<thead>
<tr>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Discuss with CLOD Explore ways to mitigate Refer to INF1549 - Surge Deceased Donation Assessment Tool</td>
</tr>
<tr>
<td>Capacity overwhelmed</td>
</tr>
<tr>
<td>Stop donation</td>
</tr>
<tr>
<td>SNOD to offer explanation to family and document decision making in DonorPath.</td>
</tr>
<tr>
<td>Suggest local DATIX</td>
</tr>
<tr>
<td>SNOD to complete NHSBT Clinical Governance reporting</td>
</tr>
<tr>
<td>Explore donation (see flowchart 3)</td>
</tr>
</tbody>
</table>

Notes

- If unable to facilitate report via [https://safe.nhsbt.nhs.uk/incident/Submissi on/Pages/Incident/SubmissionForm.aspx](https://safe.nhsbt.nhs.uk/incident/Submissi on/Pages/Incident/SubmissionForm.aspx)

- No conflict of interest in a SNOD nursing a patient who has been declared via NDT. In cases where the patient is a potential DCD, seek agreement from ICU Consultant and escalate to TM/RM. Consider individual SNOD clinical competence and whether they can care for alternative patients on the unit to release staff members to care for potential donor.

- It is essential to be able to review how COVID-19 has impacted patients and the wider NHS both directly and indirectly. [https://safe.nhsbt.nhs.uk/incident/Submission/Pages/Incident/SubmissionForm.aspx](https://safe.nhsbt.nhs.uk/incident/Submission/Pages/Incident/SubmissionForm.aspx)
3. **Organ Donation is being assessed - Instructions for SNODs, Clinicians and Virology Laboratories**

**Deceased Organ Donation is being assessed**

**England, Wales + NI**
- If opted in on ODR send tissue typing, microbiology bloods and SARS-CoV-2 RNA samples, process tissue typing but do not process other samples until family consent. If not opted in on ODR send and process samples after discussion with family.
- Scotland samples cannot be taken without discussion and authorisation from nearest relative after duty to inquire and checking unwillingness or change of mind.

**Continue with donor characterisation**

**Notes**

1. **England, Wales + NI**
   - If opted in on the ODR send tissue typing, microbiology, and SARS-CoV-2 samples, process tissue typing but do not process other samples until family consent.
   - If not opted in on ODR do not send samples until family consent as per SOP3630 Diagnostics - Blood tests. There is no requirement to wait for COVID-19 results before processing tissue typing samples.

2. **Scotland**
   - As per SOP3630 Diagnostics - Blood tests samples cannot be taken without discussion and authorisation from nearest relative after duty to inquire and checking unwillingness or change of mind.

3. **As per POL304 - SARS-CoV-2 Assessment and Screening in Organ Donors and Recipients**
   - The SARS-CoV-2 RNA samples must be within approx 48 hours of organ retrieval.

4. **The SNOD should oversee the taking of the throat and nose swab and endotracheal aspirate to ensure they are in the correct sample transport container and correctly labelled using 3 PID**
SOP5869/1 – SARS-CoV-2 Deceased Organ Donor Screening

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(Template Version 03/02/2020)
SOP5869/1 – SARS-CoV-2 Deceased Organ Donor Screening

Information
If no result available at time of registering with Hub Operations (HO)

Action
SNOD to advise HO of expected timings for result

Information
SNOD to advise HO of result when available

Action
HO to commence organ offering pending SARS-CoV-2 RNA result

Action
SNOD to advise HO of result when available

Information
Organs placed and result received

Action
NORS team mobilised

Notes
NORS team should not be mobilised until the SARS-CoV-2 RNA negative result is received. Any requirement to mobilise the NORS team in advance of SARS-CoV-2 RNA result being available must be escalated to the RM on call and further agreement sought from the on call NORS team. The retrieval must not commence until the patient is confirmed SARS-CoV-2 RNA negative.

Information
SARS-CoV-2 RNA negative

Action
Continue process

Information
SARS-CoV-2 RNA ETA and N+T Swab positive

Action
Stand Down

Follow Indeterminate Flowchart FRM6634

Information
SARS-CoV-2 RNA Indeterminate Result or 1 pos / 1 neg result

Information
If both nose and throat swab and endotracheal aspirate are positive - stand down. In all other cases follow indeterminate flowchart

Information
Indeterminate results are complex and should be carefully explored. Refer to indeterminate flowchart
SOP5869/1 – SARS-CoV-2 Deceased Organ Donor Screening

Test Indeterminate
(A variety of terms may be applied, but results are not unequivocally positive or negative)

Information

- Get the lab interpretation of result at point of receipt of results. Utilise FRM634
- Take repeat samples (ETA and Nose and Throat swab) and re-submit for immediate testing
- Agree/clarify with the lab on the plan
- Have all results organised using FRM634 for discussion with consultant virologist, including for sending to transplant centres, if relevant.

Action

- Detailing the date and time of test taken, assay used and result along with detailed medical history and clinical picture will provide virologists with further information to support repeat sampling
- Usually the lab will repeat test the new samples in their rapid assay but will also put all 4 samples (initial and repeat) through an alternative test of their choice
- Most labs are able to trigger further testing but if there is any problem, we need to explore alternative places to test the samples; this can be in the donor hospital, one of the transplant centres where the organs have been provisionally accepted, or another lab that is accessible from the donor hospital – depends on the circumstances
- Reason for admission, past history, current history and status all need to be available to support the discussion, as results should never be interpreted in isolation. A combination of FRM6439 and FRM6634 can be used to support these discussions.
4. Other Considerations

**Paediatrics:**

Where a maternal assessment is required, there is no requirement to additionally complete a maternal COVID-19 screen, donor screening is sufficient.

If a paediatric patient does not have an ETT, a nasopharyngeal aspirate may be a more appropriate sample. Nasopharyngeal aspirates are a common occurrence in paediatrics.

Paediatric Unit policy should be followed for ET/nasopharyngeal sampling including volume of saline installation.

In patients <30kg blood sampling may be limited. Please refer to SOP3630 for specific advice.

4.1. On referral to the ODST, the person taking the referral should document in Sequence of Events on DonorPath the status of any other patients on the unit and the level of PPE that is currently in use.

4.2. Prior to registering with Hub Operations, SNODs must have completed FRM6439 COVID-19 SNOD Checklist, email this to Hub Operations and document actions in sequence of events on DonorPath. This form does not routinely need to be emailed to Dr Ushiro-Lumb, only if there has been a discussion regarding a particular case.

4.3. At the time of registering with Hub Operations if results available or once they are available the COVID results must be checked against 3 PID and documented on the results/email. These must then be emailed to Hub Operations.

4.4. Once the donation process is complete, the SNOD is to complete FRM5499 SN to DRD handover form and complete the section on SARS-CoV-2 RNA. The SNOD is to indicate if the SARS-CoV-2 RNA has been sent or has been stood down.
5. Frequently Asked Questions

Below are a range of frequently asked questions. Please be aware that no-one size fits all. Always best to gather all relevant information and discuss with TM/RM/ Dr Ines Ushiro-Lumb or Dr Dale Gardiner if there are any uncertainties – never assume.

Q1 If other patients on the unit have had COVID but are now testing negative, do they pose any infection risk if still symptomatic?

Would require a good history and review. This case would be an example of one that requires further escalation / discussion with Dr Ines Ushiro-Lumb in the context of the case. Residual symptoms during a prolonged recovery phase does not mean there is still a risk of transmitting the virus but the fact that the symptoms are significant enough for the patient to still be in ICU would warrant further discussion.

Q2 Is there any guidance on the risk of one patient transmitting COVID to another patient on an open unit?

Explore case by case, a good history is essential. If good infection control procedures are being applied risks will be mitigated. Consideration of any aerosol generating procedure. Detailed history is essential for assessment. Consider spread by contact (i.e. whether staff are cohorted).

With the increased number of ICU admissions due to COVID19, we are once again getting referrals of patients who may be in physical proximity to SARS-CoV-2 positive patients. For example, inside rooms but with open doors and free access as all staff are in full PPE, which will protect them. Cross infection can only happen if the virus is carried from one patient's secretions to another and this should not happen with changes of gloves and aprons. If aerosol generating procedures are being undertaken, there will be a risk of virus present in the ambient air, but the patients should have no (or minimal) exposure to this, as they are in close circuit ventilation.

This in itself should not be the single reason not to accept the referral, just assess the situation as a whole.

By and large, in the absence of other issues, proceed. If transplant centres are in doubt, they should discuss with their own Virologists.

Q3 Where units have already undertaken a full COVID screen including ETA sample and there is no change in donor clinical condition or the environment they are cared for in (i.e. no new COVID cases in vicinity etc.) is there a requirement to repeat the tests if a certain timeframe has elapsed?

There needs to be a comprehensive history about the patient and the surroundings. Consideration of where we are in the deceased donation pathway. If you envisage any delay in the pathway, consider taking another sample.

If original results are not yet back, it is helpful to be cautious because of potential problems with getting original result. As a minimum the SNOD/SR should engage with the laboratory and confirm the samples were received and an expected time for results.

In circumstances where the samples have already been taken consideration needs to be given to the timeline of the pathway between the time of sample collection and expected retrieval.
Consideration should be given to the patient’s environment, no change to the patient’s clinical status (fever, WCC, radiology) or any new clinical symptoms during that time.

In regard to patient possible nosocomial infection the most important consideration is completion of FRM6439 taking into consideration a full history and any risks. Consider taking a new set of samples if you expect a prolonged deceased donation pathway.
6. Useful documents and links

SOPs
SOP3630 - Diagnostics-Blood Tests

FRMs
FRM5025 - Discretionary Testing Request Form
FRM5814 - BBV Screen/Malaria/WNV/T.Cruzi Request Form
FRM6445 - COVID-19 Swab and Endotracheal Aspirate Request Form
FRM6439 - COVID-19 SNOD Checklist
FRM6534 - SARS-CoV-2 Indeterminate Results
FRM5499 - SN to DRD handover form

INFs
INF1549 - COVID-19 Surge Deceased Donation Criteria Assessment Tool

POLs
POL304 - SARS-CoV-2 Assessment and Screening in Organ Donors and Recipients

DATs
DAT3906 – COVID-19 Guidance for OTDT Specialist Nurse Colleagues

Hub Operations email address: odthub.operations@nhsbt.nhs.uk

Clinical Governance reporting form
https://safe.nhsbt.nhs.uk/incidentSubmission/Pages/Incident/SubmissionForm.aspx

Example Video Endotracheal Aspirate
https://www.odt.nhs.uk/deceased-donation/covid-19-advice-for-clinicians/example-of-eta-sampling/

Example Video Throat and Nose Swab
https://www.odt.nhs.uk/covid-19-advice-for-clinicians/nose-and-throat-sampling/

Ethical Framework www.moralbalance.org

WHO
https://www.who.int/health-topics/coronavirus#tab=tab_1