SARS-CoV-2 Deceased Organ Donor Screening

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N.B. This SOP is to be followed by a qualified, trained SN. In the event of a SN who is in training, this SOP is to be used under supervision.

Summary of changes

SOP6405 Donor Characterisation has been added as related document.

The reduction in process steps have resulted in the following sections to be merged and following section numbers altered accordingly:

- Useful Information **& Glossary**
- **1.** Referral **and Assessment** of a potential Deceased Organ Donor

Section 1 has been rearranged to provide more logical flow and consistent approach of guidance in referral and assessment of a potential donor and removed reliance on obsolete POL304.

Section 2 has been revised to remove reliance on obsolete POL304 and changed requirements for completion of **FRM6439** for all potential donors. **FRM6439** and necessary additional steps are now for SARS-CoV-2 positive / indeterminate potential donor donors only.

Sections relating to 'Recording Results on DonorPath' and 'Useful Information' have been removed as their content now sits in Section 1 and 2

Useful Information

Severe Acute Respiratory Syndrome Coronavirus 2 also known as SARS-CoV-2 causes Coronavirus Disease 2019 (COVID-19). The transmission of COVID-19 is thought to occur through respiratory droplets generated by coughing and sneezing, and through contact with contaminated surfaces (WHO 2020).

Glossary

Roles

- **Donor Testing Virologist** – Virologist undertaking deceased donor testing either within regional laboratory or on occasion within donor hospital.
- **PID** – Patient Identifiable Data
- **SN** - Specialist Nurse Organ Donation. For the purposes of this document the term
- 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

Terminology

- **SARS-CoV-2** - Severe Acute Respiratory Syndrome Coronavirus-type 2
- **COVID-19** - Coronavirus disease
- **SARS-CoV-2 Ribonucleic Acid (RNA)** - the test used to detect SARS-CoV-2 infection.
- **NTS** – Nose and Throat Swab
- **ETA** – Endotracheal Aspirate
- **DonorPath** - the secure electronic record that is utilised by SNs to upload clinical information about a patient.
- **TransplantPath** - the secure electronic record that is utilised by Receiving Centres to review clinical information about a patient.
- **NRC** – National Referral Centre

Related Documents/References

- **DAT4077** – Virology Laboratory Email Address List
- **FRM6439** – SARS-CoV-2 Assessment and Screening (in deceased organ donors)
- **FRM6445** – COVID-19 Swab and Endotracheal Aspirate Request Form
- **FRM6634** – Result Table
- **INF1549** – Business Continuity Deceased Donation Assessment Tool
- **POL188** – Clinical Contraindications to Approaching Families for Possible Organ & Tissue Donation
- **SOP3649** – Voice Recording of Organ Donor Clinical Conversations
- **SOP4938 –** Sharing Clinical Information
- **SOP6405** – Characterisation Manual

1. Referral and Assessment of a Potential Deceased Organ Donor

1.1. The SN must ascertain as part of the referral of the potential organ and tissue donor if there are any infection concerns and may include suspected or confirmed SARS-CoV-2 infection.

1.2. All potential deceased organ donors in the UK require nose and throat swabs and endotracheal aspirates tested for SARS-CoV-2 RNA.

1.3. In cases where **COVID-19 is not considered to have contributed to the cause of death,** a positive SARS-CoV-2 RNA result is **not a contraindication for full assessment and donation of non-lung organs**, even if the result suggests current infection. The SN must observe absolute contraindications to donation, as set out in **POL188.**

1.4. When assessing a potential donor with confirmed SARS-CoV-2 infection, the SN must adhere to hospital policies on the use of Personal Protective Equipment (PPE) when caring for patients with positive or indeterminate SARS-CoV-2 infection.

1.5. If samples have already been taken to test for SARS-CoV-2 by the donor hospital, the SN must ensure the outstanding results are followed up in any planned assessment and characterisation of the potential donor and principles of management as specified in **SOP6405**.

1.6. If samples are to be taken during SN attendance, the SN must oversee the collection of samples to ensure correct collection, packaging for transport, and correct PID applied.

1.7. Samples must not exceed 48 hours of organ offering and retrieval.

1.8. Examples of correct sampling of a nose and throat swab (NTS) and endotracheal aspirate (ETA) sampling from a closed-circuit ventilated patient can be found here:

Example Video Endotracheal Aspirate
https://www.odt.nhs.uk/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/

1.9. Some patients may not be able to have a nose swab taken (i.e. extensive trauma or bleeding); very rarely, neither nose nor throat swab can be obtained so an oral swab can be taken instead.

ADVICE

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.

2. Results and Interpretation

SARS-CoV-2 RNA ETA and NTS NEGATIVE

2.1. SN must receive the results and input the NTA and ETA results into DonorPath in the 'Investigations' section for donor offering. A completed **FRM6439 IS NOT REQUIRED** to be completed and uploaded to DonorPath for SARS-CoV-2 NEGATIVE donors.

SARS-CoV-2 RNA ETA and NTS INDETERMINATE / POSITIVE

2.2. SN must consult with Donor Testing Laboratory and discuss the collection of any additional samples would be of benefit (analysis of consecutive results can assist interpretation of infection stage) and to send additional for analysis if advised.

2.3. A completed **FRM6439 IS REQUIRED** to be completed and uploaded to DonorPath for SARS-CoV-2 POSITIVE/INDETERMINATE donors.

2.4. SN must collate all SARS-CoV-2 results (even if negative) from the donor hospital or donor screening and input onto **FRM6439** and send a populated **FRM6439** copy to Donor Testing Virologist, by secure email, for the Donor Testing Virologist to input details of result and utilised assays. If unable to send a copy of **FRM6439** to the laboratory for completion, the SN can add the information from telephone discussion on their behalf.

2.5. On occasions where there are multiple results which cannot be safely accommodated within **FRM6439**, **FRM6634** can be used as an additional results table. On occasions where this additional table is used it must also be attached to DonorPath.

2.6. In circumstances where the Donor Testing Virologist can provide interpretation but cannot do so via email the SN must voice record the clinical conversation (as per **SOP3649** and usual clinical practice) with the virologist and add the results information to **FRM6439**.

2.7. In circumstances where the SN seeks the opinion of the Donor Testing Virologist with regards possible interpretation, it is essential that the SN is clear on the ask of the Donor Testing Virologist which is to help provide an interpretation of the results they have generated in the context of the patient history and information provided in **FRM6439**.

2.8. The SN must upload a completed version of **FRM6349** to DonorPath before organ offering to ensure Receiving Centres can review this on TransplantPath for INDETERMINATE / POSITIVE donors.

ADVICE

Where possible, all donor characterisation information is available at the point of donor registration. In circumstances where the SARS-CoV-2 results have not been received and the SN is ready to register the donor with OTDT Hub operations, the SN should contact donor virology testing laboratory to assess timings. Where possible and feasible await the results if imminent.

2.9. On all occasions where new clinical information is obtained post donor registration the SN must follow **SOP4938** as per usual practice. Actions must be documented in sequence of events on DonorPath. It is the SNs responsibility to ensure the most up to date version of **FRM6439** is available to all centres on TransplantPath by uploading onto DonorPath.

Training Plan:

	Trainee new to the process	Trainee trained to the previous revision.
Recommended Training Method	Practical demonstration and read through the document with Regional ODST Quality Lead. Training material for this version will not cover the whole SOP content.	Train out via standardised video from SOP Author to ODST Regional Quality Leads train to TBTR. The same video can be disseminated via QLs and record TBTRs
Assessment	TBTR recording	TBTR recording
Cascade Plan	Practical demonstration and read through the document with Regional ODST Quality Lead. Training material for this version will not cover the whole SOP content.	Train out via standardised video from SOP Author to ODST Regional Quality Leads train to TBTR. The same video can be disseminated via QLs and record TBTRs

Training Score – Training Plan Risk Matrix (Collapsible – Click ▸ icon to open/close)

Use the *Training Plan Risk Matrix* to identify the training method and assessment required.

The *Process Criticality Score* is determined by the potential impact on donor/patient safety and/or product quality using the table below for guidance:

	Impact on Donor, Patient safety or product quality
1. Negligible	A process whose failure, in full or in part, **cannot** impact product quality, patient/donor safety or the ability to supply products/services.
2. Minor	A process whose failure, in full or in part, **may**: (i) impact other processes thereby indirectly impacting product quality, patient/donor safety (e.g. harm only results where multiple failures in multiple processes align) (ii) result in the discard of a small number of replaceable products and/or (iii) result in an inconvenient delay to the supply of products/services (e.g. delay of 1-3hrs of non-urgent product/service).
3. Moderate	A process whose failure, in full or in part, **may**: (i) indirectly impact product quality, patient/donor safety (e.g. harm only results where failures in more than 1 process align) (ii) result in the discard of a medium number of replaceable products and/or (iii) result in a temporary delay to the supply of products/services (e.g. delay of 4-12hours of non-urgent products/services).
4. High	A process whose failure, in full or in part, is **likely** to:

	(i) directly impact product quality, patient/donor safety (ii) result in the discard of a large number of replaceable products (iii) result in the discard of an irreplaceable product and/or (iv) result in a delay to patient treatment.
5. Very High	A process whose failure, in full or in part, is **certain** to: (i) directly impact product quality, patient/donor safety (ii) result in the discard of a large number of replaceable products (iii) result in the discard of an irreplaceable product and/or (iv) result in a delay to patient treatment.
Process Criticality Score	2

The *Criticality of Change Score* is determined by assessing the nature of change(s) and complexity of the process using the table below for guidance.

	Change to Trainee(s)
1. Negligible	An existing process to which no material changes are made. E.g. format changes, minor clarifications of existing practice, fixing typos.
2. Minor	An existing process to which new information is added but where changes to existing knowledge and practices are minimal. E.g. clarifications that tighten existing practices
3. Moderate	An existing process of low complexity with material changes requiring different people to take action and/or people to change the tasks they perform. E.g. new roles/responsibilities, changes to the order of existing tasks, new tasks
4. High	A new process of moderate complexity, OR An existing process of moderate complexity with material changes requiring different people to take action and/or changes to the way tasks are performed. E.g. New roles and responsibilities, changes to tasks and/or the order in which tasks are performed, changes in equipment/materials, changes to values, measures or settings.
5. Very High	A new process of high complexity, OR An existing process of high complexity with material changes requiring different people to take action and/or changes to the way tasks are performed. E.g. New roles and responsibilities, changes to tasks and/or the order in which tasks are performed, changes in equipment/materials, changes to values, measures or settings.
Criticality of Change Score	3

Training Plan Risk Matrix:

Process Criticality →

Criticality of Change ↓	1. Negligible	2. Minor	3. Moderate	4. High	5. Very High
1. Low	1	2	3	4	5
2. Moderately Low	2	4	6	8	10
3. Moderate	3	6	9	12	15
4. High	4	8	12	16	20
5. Very High	5	10	15	20	25

	Trainee new to the process	Trainee trained to the previous revision.
Process Criticality Score	2	
Criticality of Change Score	3	3
Training Score	6	6

Recommended Training Method and Assessment:

Training Score	Level of Risk	Examples of Training Methods	Examples of Assessment
1 - 3	Low	Read only	Record on FRM511 only
4 - 8	Manageable	Email, team brief, word brief	Knowledge/Observation Check & FRM511
9 - 14	Medium/Significant	Formal training package	Knowledge/Observation Check & FRM511 or FRM5076
15 - 25	High	Practical	FRM5076 or equivalent