Changes in this version

New

Policy

1.0 Introduction

1.1 The Coronavirus Disease 2019 (COVID-19) pandemic caused by the Severe Acute Respiratory Syndrome Coronavirus-type 2 pathogen (SARS-CoV-2) has led to unprecedented challenges for UK transplantation. Concerns about lack of access to operating theatres, inpatient and critical care beds, and implications for immunosuppressed transplant recipients have resulted in a major reduction in the number of organ transplants undertaken. Some UK transplant units (particularly kidney-only and kidney-pancreas units) have closed completely, while others have significantly restricted their donor and/or recipient criteria.

1.2 Since mid-April 2020, there have been some signs that the peak of the pandemic may be within sight in some regions of the UK[1-8]. However, uncertainties about the future course of the pandemic still remain. The evidence-base on how the pandemic has affected patients on the national transplant list and in the early post-transplant period is still evolving[9].

1.3 NHS Blood and Transplant (NHSBT) is aware that some units may now wish to start considering how best to re-open their transplant services or to expand their current restricted donor and recipient criteria. For those units that wish to explore these possibilities, NHSBT's view is that these considerations are best taken forward at the local level, given pre-existing differences between units and the variation in how the pandemic has affected regions, hospitals, transplant programmes and patient populations (e.g. adults versus children). NHSBT also understands that many units will not wish to (or are unable to) consider expansion or re-opening at this time.

1.4 The challenges faced by units who wish to re-open will vary by organ type, local resource environments, experience of the COVID-19 pandemic thus far, and local donor and recipient groups. However, the principles underlying consideration of re-opening or expansion are expected to be similar across all UK transplant units and will be based primarily on the availability of resources and risk/benefit analyses for patients and staff, taking into account patient views.

1.5 This document has been written as an 'aide memoire' for those units who wish to start considering these processes. It is hoped that this will provide reassurance to transplant clinicians, Trusts/Boards, and patients that a systematic approach has been taken. Units do not need to submit a response to this document to NHSBT in order to re-open, but NHSBT must be informed about decisions to re-open services (section 5.0).

1.6 NHSBT anticipates that re-opening or expansion from current restricted criteria is likely to occur in phases, depending on prioritisation of patient groups according to clinical urgency and emerging availability of resources. NHSBT accepts that decisions to re-open transplant programmes will be reviewed in light of changes to local conditions, an evolving evidence-base, or further peaks of

COVID-19. However, NHSBT has an expectation that units which re-open programmes will accept reasonable organ offers for those patients that are re-activated, and therefore units must be appropriately cautious and realistic in any plans. Units must be confident that they have appropriately addressed all of the issues highlighted in this document.

1.7 NHSBT is also aware that units are seeking additional guidance on SARS-CoV-2 assessment and screening of potential deceased donors, recipients, and living donors. These issues are discussed in sections 2.0, 3.0, and 4.9, respectively. This guidance will be reviewed and updated at least fortnightly in light of new available evidence and changes in circumstances imposed by the evolving pandemic. **Users should check the www.odt.nhs.uk website for the most recent version of this document.**

1.8 Where a unit is unable to re-open a programme due to resource issues alone, consideration must be given to the safe transfer of patients to a neighbouring unit's transplant list following agreement between the units and Trusts/Boards, and accepting that there will be patients and circumstances where this will not be possible.

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

2.1 All potential deceased organ donors in the UK that proceed to organ offering have nose and throat swabs and endotracheal aspirates sent for SARS-CoV-2 polymerase chain reaction (PCR) testing. **A positive screening result precludes organ donation[9]**. Although SARS-CoV-2 ribonucleic acid has been found in sites outside the respiratory tract, testing of additional sites is not justified at present as there is no evidence of active viral replication or risk of transmission.

2.2 Negative SARS-CoV-2 PCR testing does not completely exclude evolving SARS-CoV-2 infection. To date, there have been no reported proven cases of donor-derived transmission of SARS-CoV-2. This takes into account the experiences of countries that have been severely affected by the pandemic and where established transplant programmes are in place (e.g. Italy, Spain, USA, UK).

2.3 Where a potential deceased donor has previously 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 PCR 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.

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

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[3]
No clinical suspicion of COVID-19	Can assess suitability	1) Nose and throat swab PCR 2) Endotracheal aspirate PCR 3) Blood in EDTA for retrospective PCR and serological testing
Previous suspected mild[1] COVID-19 with recovery and no symptoms for >28 days	Can assess suitability	1) Nose and throat swab PCR 2) Endotracheal aspirate PCR 3) Blood in EDTA for retrospective PCR and serological testing
Previous proven mild[1] COVID-19 with recovery and no symptoms for >28 days	Can assess suitability	1) Nose and throat swab PCR 2) Endotracheal aspirate PCR 3) Blood in EDTA for retrospective PCR and serological testing
Previous proven moderate or severe[2] COVID-19 with recovery and no symptoms for >28 days	Can assess suitability; consider the possibility of significant end-organ damage	1) Nose and throat swab PCR 2) Endotracheal aspirate PCR 3) Blood in EDTA for retrospective PCR and serological testing
Proven COVID-19 without recovery	Not suitable for assessment	No screening tests performed

[1]Mild – not requiring hospitalisation. [2]Moderate or severe – requiring hospitalisation. [3]A positive respiratory SARS-CoV-2 PCR screening test is a contra-indication to deceased donation.

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

3.1 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.

3.2 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[10]. It is noted that there is advice from NHS England and NHS Improvement released on 24 April 2020 to say that units must test for SARS-CoV-2 on nose and throat swabs in all those admitted to hospital – clearly that would include those admitted for potential transplantation.

3.3 Units must discuss policies on SARS-CoV-2 PCR tests on nose and throat swabs of asymptomatic potential transplant recipients with virology or infectious diseases colleagues and should be aware of the following:

3.3.1 PCR results may not be available prior to transplantation depending on local turnaround times and transplant logistics. The availability of negative PCR results are not absolute prerequisites to proceeding with transplantation. Policies on the need to wait for test results or not are likely to 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 guidance. If transplantation proceeds before PCR results are available, these should be checked at the expected time of result availability.

3.3.2 The potential recipient must be informed that negative tests are not a guarantee of absence of SARS-CoV-2 infection. Similarly, false positives can also occur.

3.3.3 As all potential deceased donors are tested for SARS-CoV-2, it is highly likely that the donation process will be extended significantly. Clinicians should consider logistics and may wish to admit the patient early to have sufficient time to receive SARS-CoV-2 test results prior to transplantation. The benefits of this approach must be balanced against the additional risks associated with breaking social distancing practices by early admission of the patient.

3.3.4 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.

3.3.5 Consider taking blood in EDTA for retrospective SARS-CoV-2 PCR and serology to gather additional information on infection status. It is acknowledged that SARS-CoV-2 ribonucleic acid has been infrequently detected in blood, even in symptomatic patients with positive SARS-CoV-2 PCR from respiratory samples.

3.4 Some units are also using chest CT to screen potential transplant recipients for **asymptomatic** COVID-19 at admission for transplantation because of the relatively rapid turnaround time of radiology results when compared to nose and throat swab tests. If units consider this approach, clinicians must discuss this with radiology colleagues and be aware of the following:

3.4.1 There is uncertainty regarding the utility of routine CT chest scanning for the diagnosis of COVID-19 in asymptomatic patients[11]. This is especially pertinent to those with known underlying chest diseases where there is a high probability of false

positive results. The risk of missing a transplant opportunity in this situation must be discussed with patients.

3.4.2 A negative CT chest scan does not exclude COVID-19 in asymptomatic patients. This risk must be discussed with patients.

3.4.3 If units institute a policy of routine CT chest scanning for the diagnosis of COVID-19 in asymptomatic patients admitted for transplantation, then they should consider collecting follow-up data on patients with positive chest CT findings and negative SARS-CoV-2 PCR. This will enable a better understanding of the predictive value of CT positivity in PCR negative asymptomatic patients. Units should also have a clear policy as to when and how these patients can be re-activated on the transplant list.

3.5 There should be a low threshold for SARS-CoV-2 PCR swab testing in patients on the transplant list who develop symptoms consistent with COVID-19. Those with proven COVID-19 should be suspended. 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, two negative sets of SARS-CoV-2 PCR nose and throat swabs taken at least 24 hours apart provides reassurance that the infection has been cleared. Individual assessment is essential and earlier re-activation may be appropriate given the broad spectrum of COVID-19 disease.

3.5.1 In selected cases, and depending on the degree of urgency for transplantation, a shorter period between recovery and transplantation could be considered pending discussions with virology or infectious diseases colleagues.

4.0 Issues for transplant units to consider

4.1 Appropriate Trust/Board support and approval. Also consider the following:

4.1.1 Engagement with senior management at an early stage of this process, with their support to re-open transplant services.

4.1.2 Early involvement of Trust/Board leads for anaesthetics, critical care, microbiology and infection control in discussions, with their support to re-open transplant services.

4.1.3 Fulfilment of local clinical governance requirements.

4.2 Access to adequate resources. Also consider the following:

4.2.1 The availability of the appropriate multi-disciplinary team. This includes transplant medical and surgical staff and also other essential staff.

4.2.1.1 Units should be aware of the challenges of performing transplant surgery while wearing appropriate personal protective equipment. For example, there may be a need for back-up senior surgical and/or anaesthetic and support staff in prolonged or more complex cases.

4.2.2 Access to ward beds, operating theatres, critical care beds, and anaesthetic cover with appropriate staffing levels and skills mix.

4.2.3 Access to the necessary equipment and materials including personal protective equipment, blood products, specialised equipment (e.g. organ perfusion machines), organ support services (e.g. inpatient haemodialysis provision, haemofiltration consumables), organ preservation fluids, and anaesthetic agents[12].

4.2.4 Access to quorate multi-disciplinary team meetings.

4.2.5 Assessment and monitoring (potentially remotely) of patients on the active and suspended transplant lists.

4.2.5.1 Access to standard unit diagnostic work-up and monitoring investigations.

4.3 Microbiology and infection control policies meeting national and Trust/Board standards. Also consider the following:

4.3.1 The local incidence and prevalence of COVID-19 and how these might impact on potential donors and recipients.

4.3.2 Whether or not patients on the active transplant list should be advised to undergo enhanced social distancing to reduce the risk of SARS-CoV-2 infection, where this is possible.

4.3.3 The separation of pre- and early post-transplant patients from those with suspected or confirmed COVID-19 during an inpatient stay, and in the outpatient follow-up period. Where possible, pre- and early post-transplant patients should be cared for in single rooms or COVID-19-free areas of the ward (or COVID-19-free wards if available) to minimise risk of SARS-CoV-2 transmission. If care is provided in a ward or hospital not normally used to caring for acute transplant recipients, adequate mitigations must be ensured. Detailed analyses of patient flow may be useful.

4.4 Deceased donor selection criteria, e.g. age, donor type (DBD/DCD), body mass index, co-morbidities, possible exposure to SARS-CoV-2, expected organ cold ischaemic time, etc. Also consider the following:

4.4.1 Decisions on the selection of donors and recipients for transplantation are expected to be more challenging. Consider also the availability of advice from consultant colleagues to support collective decision-making out-of-hours, including advice from a consultant in virology or infectious diseases.

4.4.2 Deceased donor organ retrieval will increasingly be a night-time activity in order to further minimise the impact on theatre activity in donor hospitals. This, and the need to wait for results of SARS-CoV-2 swabs from potential donors, will likely lead to prolonged times between donor referral and organ retrieval.

4.5 Recipient selection. Consider any restriction to recipient criteria, e.g. clinical priority, waiting time, underlying disease, co-morbidities, HLA sensitisation, match points, surgical complexity, modality of organ support, recovery from COVID-19, etc. Also consider the following:

4.5.1 Patients must be informed when they are suspended or re-activated on the transplant list, and must be given information regarding the risks of developing COVID-19 post-transplantation. Patients must be given the opportunity to raise queries or concerns.

4.5.2 The patient's ability to give informed consent given the complexity of the discussions in 4.5.1, and the feasibility and safety of outpatient follow-up in the pandemic environment.

4.5.3 The expected patient mortality, morbidity, and quality-of-life on the transplant list and post-transplant as well as expected mortality and morbidity if COVID-19 occurs post-transplant.

4.5.4 The capacity of critical care units and their ability to facilitate deceased donation is difficult to predict. Therefore, waiting times for patients active on national transplant lists are expected to be more uncertain.

4.6 Patient information and consent. Consider the following:

4.6.1 The availability of written information to patients on COVID-19-related issues pre- and post-transplant, including advice on social 'shielding' in the early post-transplant period.

4.6.2 NHSBT and British Transplantation Society guidance on consent issues during COVID-19[13]. It is important to acknowledge that the information that can be provided to patients is limited by the paucity of available evidence.

4.7 Immunosuppression and other medications. NHSBT is aware that units that have maintained transplantation through the pandemic have examined their induction immunosuppression protocols. Consider the following:

4.7.1 The burden of immunosuppression required in the early post-transplant period and how this might affect potential recipient selection during the COVID-19 pandemic.

4.7.2 Management of immunosuppression in an early post-transplant patient that develops COVID-19[14].

4.8 Post-transplant outpatient management. Consider the following:

4.8.1 Changes to follow-up pathways (e.g. virtual clinics, remote blood testing facilities) and the patient's likely ability to adhere to these pathways.

4.8.2 Access to inpatient beds if re-admission is required.

4.9 Living donors. The safety of living donors is paramount and the risks of COVID-19 to the donor need to be carefully considered. Also consider the following:

4.9.1 A phased approach to re-introduction of living donor programmes is recommended given the ability to plan donor-recipient pairs. The initial phase is expected to include pre-existing identified or cancelled pairs (both directed and via the UK Living Kidney Sharing Scheme).

4.9.2 Living donor criteria, e.g. age, underlying organ function, co-morbidities, surgical complexity.

4.9.3 Screening of potential living donors for SARS-CoV-2 infection and the need to check for symptoms of COVID-19. 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.

4.9.4 Whether or not patients waiting to donate should be advised to undergo enhanced social distancing to reduce the risk of SARS-CoV-2 infection, and if this should continue post-operatively (and for how long).

4.9.5 NHSBT and British Transplantation Society guidance on consent for living donors[13]. It is important to acknowledge that the information that can be provided to potential living donors is limited by the paucity of available evidence.

4.9.6 Living donor follow-up pathways (e.g. virtual clinics, remote blood testing facilities), patient information on how to access outpatient services, and plans if re-admission is required.

4.9.7 The separation of pre- and early post-donation patients from those with suspected or confirmed COVID-19 during an inpatient stay, and in the outpatient follow-up period. Where possible, pre- and early post-donation patients should be cared for in single rooms or COVID-19-free areas of the ward (or COVID-19-free wards if available) to minimise risk of SARS-CoV-2 transmission. If care is provided in a ward or hospital not normally used to caring for living donors, adequate mitigations must be ensured. Detailed analyses of patient flow may be useful.

4.9.8 Capturing data for the NHSBT living donor registry on the donation episode and immediate post-operative recovery to ensure outcomes are accurately recorded.

4.10 Data gathering mechanisms to identify any adverse post-transplant outcomes after unit re-opening or expansion. Also consider the following:

4.10.1 Regular multi-disciplinary team meetings to assess unit performance and outcomes.

4.10.2 Gathering outcome data from patients discharged to the care of other Trusts/Boards.

4.10.3 Units should also consider the need for pre-defined triggers to pause a programme, halt expansion, or continue to the next phase of expansion.

4.10.4 NHSBT outcome monitoring through cumulative sum control charts and Advisory Group mechanisms will continue during the COVID-19 pandemic and any adverse outcome triggers will be dealt with via pre-existing pathways. In the event that post-transplant COVID-19-related mortality occurs, this will be taken into account appropriately.

4.11 Discussion with, and involvement of, referring units regarding the above issues.

4.12 Consider the need for discussion of plans to re-open transplant programmes with local patients' associations.

4.13 Management of transplant lists. Of the units that closed, many did not suspend patients on their lists at the time of closure. Those units that now plan to re-open in a phased way to selected recipients may need to suspend large numbers of patients on their lists to prevent unnecessary organ offers being made and subsequent delays in organ offering pathways. There are two ways to achieve this:

4.13.1 Units can suspend individual patients themselves, via their routine systems (NTN or ODT Online), leaving selected patients active.

4.13.2 NHSBT can suspend the entire list of a unit, leaving units to activate selected patients as needed via their routine systems. This will take up to a week to be actioned, so units taking this approach must plan appropriately. Please email Mike Gumn (michael.gumn@nhsbt.nhs.uk) and Julie Whitney (julie.whitney@nhsbt.nhs.uk).

5.0 Notification of re-opening or expansion of currently restricted programmes

5.1 NHSBT must be informed via clinicalgovernance.odt@nhsbt.nhs.uk. The Clinical Governance team will then inform the ODT Hub management team, the relevant Advisory Group Chair, and the ODT Medical Director.

5.1.1 ODT Hub are unable to record new unit-specific donor criteria at this time. Work is ongoing to introduce an update to enable units to change their specific donor criteria (e.g. donor age, DBD/DCD donor type) on a monthly basis. ODT Hub will write to all units with details of this work in the coming week. Please email Mike Gumn and Julie Whitney if there are any queries regarding this process (see 4.13.2 for addresses).

5.1.2 ODT Hub are unable to record specific donor criteria for individual patients on the transplant list at this time.

5.1.3 Units must inform the ODT Hub if they wish to remain within organ fast-track schemes (including virology fast-track schemes) or not.

5.2 NHS Commissioners must be informed.

5.3 Trust/Board Chief Executive or Medical Director, and communications departments must be informed.

5.4 Clinicians at referring units must be informed of decisions to re-open transplant programmes.

5.5 Patients must be informed of decisions to re-open transplant programmes. Consider how this will be achieved (e.g. via mail, e-mail, text messaging services, Trust/Board website, patients' associations, etc.). For those units who decide not to re-open services at this time, it would be appropriate to keep patients on their transplant list informed of unit decisions.

6.0 References

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