

Changes in this version

- 1) Updated references to include the letter from the surgical Royal Colleges on prioritisation of transplant services.
- 2) Reference to content of letter from surgical Royal Colleges on 23rd June 2020 and importance of highlighting with senior managers of programmes at an early stage.
- 3) Addition of consideration of regional or networked solutions to enable programmes to re-open.
- 4) In the context of kidney transplantation, noted that Kidney Advisory Group guidance should be highlighted with senior managers of programmes at an early stage.

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 There are signs that the peak of the pandemic has passed in some regions of the UK¹⁻⁶. 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 evolving⁷.
- 1.3 NHS Blood and Transplant (NHSBT) is aware that units are considering how best to re-open their transplant services or to expand their current restricted donor and recipient criteria. 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 some units will be unable to consider expansion or re-opening at this time.
- 1.4 The challenges faced by units that wish to re-open will vary by organ type, local resource environments, experience of the COVID-19 pandemic, and local donor and recipient groups. However, the principles underlying consideration of re-opening or expansion for both living and deceased donor transplantation 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 NHSBT notes the letter from the surgical Royal Colleges on 23rd June, highlighting the backlog of patients requiring assessment for transplantation and the need to re-open deceased and living

donor transplant programmes¹⁸. The letter also strongly supports the restoration of solid organ transplant services with appropriate priority. NHSBT endorses these recommendations, which align with existing commissioning guidance and with this document.

- 1.6 This document is written as an 'aide memoire' for those units who wish to start 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).
- 1.7 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 realistic in any plans. Units must be confident that they have appropriately addressed all of the issues highlighted in this document.
- 1.8 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 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.**
- 1.9 Where a unit is unable to re-open a programme, 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. **Regional or networked solutions may need to be applied.** During this transition period, whilst all centres are working towards becoming fully operational, the option to transfer living donors and/or recipients for surgery to other centres could facilitate living donor transplants, including kidney exchanges, which may otherwise be declined in a single centre.

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

- 2.1 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 donation⁷.**
- 2.2 Negative SARS-CoV-2 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.

2.3 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.

2.4 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 ^c
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 ^a 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 ^a 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 ^b 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 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

^aMild – not requiring hospitalisation. ^bModerate or severe – requiring hospitalisation. ^cA positive respiratory SARS-CoV-2 polymerase chain reaction (PCR) screening test is a contra-indication to deceased donation.

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

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- 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 mortality⁸. 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.
- 3.3 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:
- 3.3.1 Whilst **highly desirable**, the availability of negative test results are not absolute prerequisites to proceeding with transplantation. In the context of kidney transplantation, Kidney Advisory Group guidance must be consulted⁷. 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.
 - 3.3.2 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.
 - 3.3.3 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.
 - 3.3.4 As all potential deceased donors are tested for SARS-CoV-2, the donation process may be extended. Clinicians must give consideration to 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 (minimal) additional risks associated with breaking social distancing practices by early admission of the patient.

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- 3.3.5 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.
- 3.3.6 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.
- 3.4 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 results⁹. If units consider using chest CT to screen for COVID-19, clinicians must discuss this with radiology colleagues, and follow the relevant national guidance¹⁰.
- 3.5 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.
- 3.5.1 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.

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. *Their attention must be drawn to the letter from the surgical Royal Colleges of 23rd June regarding prioritisation of transplant services¹⁸. In the context of kidney transplantation, Kidney Advisory Group guidance must also be consulted⁷.*
- 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:

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- 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 must 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.
 - 4.2.4 Access to quorate multi-disciplinary team meetings, which may include meetings by teleconferencing.
 - 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 are advised to undergo enhanced social distancing ('shielding') to reduce the risk of SARS-CoV-2 infection, where this is possible, and in line with national guidance¹¹⁻¹³.
 - 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. Pre- and early post-transplant patients must 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.
 - 4.3.4 Local guidance on staff testing must be followed¹⁴.
 - 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

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- 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 ideally 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.
 - 4.4.3 Transport times for organs from donor hospitals at long distances from implanting centres are likely to be compromised by the relative lack of scheduled flights. Organ ischaemic times need to be considered accordingly.
 - 4.4.4 Refer to Advisory Group guidance, where available.
- 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 distancing and/or shielding in the early post-transplant period.
 - 4.6.2 NHSBT and British Transplantation Society guidance on consent issues during COVID-19⁷. 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. 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.

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- 4.7.2 Management of immunosuppression in an early post-transplant patient that develops COVID-19¹⁵.
- 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. Refer to Kidney Advisory Group guidance⁷ for kidney-specific details and 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). Consideration must be given donor/recipient suitability to proceed, prioritisation of theatre lists for suitable pairs and access to appropriate in-patient and out-patient facilities (see 4.9.7).
- 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 and exposure to 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 The duration of enhanced social distancing pre- and post-donation. This must be in line with national guidance¹⁶.
- 4.9.5 NHSBT and British Transplantation Society guidance on consent for living donors⁷. 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 donors pre- and early post-donation, from those with suspected or confirmed COVID-19 during an inpatient stay, and in the outpatient follow-up period. Where possible, donors pre- and early post-donation 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 and adhere to Human Tissue Authority licencing requirements¹⁷. Detailed analyses of patient flow may be useful.

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- 4.9.8 Capturing data for the NHSBT living donor registry on the donation episode, immediate post-operative recovery and life-long follow-up 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 Whether there is a 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. If outpatient follow-up post-transplant (or post-donation) is with the referring unit, confirm availability of adequate capacity.
 - 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 when deceased donor or living donor transplant programmes are re-started. The Clinical Governance team will then inform the ODT Hub management team, the relevant Advisory Group Chair, and the ODT Medical Director.

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- 5.1.1 Units are able to change their donor criteria (e.g. donor age, DBD/DCD donor type) on a monthly basis. 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 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 is appropriate to keep patients on their transplant list (and previously planned living donors) informed of unit decisions.

6.0 References

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