Executive summary

The Coronavirus Disease 2019 (COVID-19) pandemic caused by the Severe Acute Respiratory Syndrome Coronavirus-type 2 (SARS-CoV-2) continues to raise many uncertainties for transplantation in the UK. This document aims to provide guidance on consent for solid organ and islet transplantation in adults, children and young people (CYP), and on consent for living donors, in the context of the evolving pandemic and the introduction of vaccination programmes against SARS-CoV-2.

The following COVID-19-related issues must be addressed during consent discussions for solid organ and islet transplantation in adults and CYP:

- risk of donor to recipient transmission of SARS-CoV2 via an organ or islet transplant (no documented case to date)
- risk of the recipient getting infected with SARS-CoV2 around the time of transplant from sources not related to the donor
- logistical and organisational issues, e.g. access to operating theatres, critical care beds, ward beds, and outpatient follow-up and re-admission pathways
- risks of not proceeding to transplantation from either a deceased or living donor
- the rationale for, and implications of, social distancing and shielding advice to solid organ and islet transplant recipients and impact of easing of restrictions on their risk of infection with SARS-CoV-2
- the likely impact of vaccination against SARS-CoV-2 on reducing risk of serious illness in solid organ and islet transplant recipients and in people waiting for a transplant

The following COVID-19-related issues must be addressed during consent discussions for living organ donation:

- the stringent infection avoidance precautions required to minimise risk to themselves, to the recipient and to others, particularly in the period prior to admission for donation
- risk of the donor acquiring SARS-CoV-2 during donor assessment and period of admission for donation
- the implications of transplantation for the planned recipient
- the risks of not proceeding to transplantation for the planned recipient

- logistical and organisational issues, e.g. access to operating theatres, critical care beds, ward beds, and outpatient follow-up and re-admission pathways
- the likely impact of vaccination against SARS-CoV-2 on reducing risk of serious illness for the planned recipient and in the living donor

To avoid non-essential hospital visits and the associated risks of SARS-CoV-2 infection, many consent discussions are likely to take place virtually, rather than in person. Transplant units should develop patient-appropriate written information on SARS-CoV-2 and COVID-19 for transplant recipients and living donors in different formats to inform consent discussions, with contingency made for non-English speakers and to overcome barriers to effective communication.

Disclaimer: This Guideline is intended as a 'guide' to best practice which inevitably will change as we develop more knowledge of SARS-CoV-2 and COVID-19. All practitioners need to undertake clinical care on an individual basis and keep themselves up to date with changes associated with COVID-19.

This joint NHS Blood and Transplant (NHSBT) and British Transplantation Society (BTS) Guideline was compiled by the clinical team of NHSBT and BTS representatives and includes the collective opinions of the collaborators. The information presented in the Guideline is subject to change as the knowledge and biology of the disease is further understood.

Every patient must be treated individually. Patients will have different priorities and needs and appropriate communication with each patient is critical. These guidelines should be used in conjunction with current hospital guidance in relation to consent and COVID-19.

Neither NHSBT nor the BTS can attest to the accuracy, completeness or currency of the opinions contained herein and does not accept any responsibility or liability for any loss or damage caused to any practitioner or any third party as a result of any reliance being placed on the Guideline or as a result of any inaccurate or misleading opinion contained in the Guideline.

1. Background

The COVID-19 pandemic is an unprecedented challenge to both the wider NHS and the UK's solid organ transplant communities and raises many uncertainties, including how best to consent patients for solid organ and islet transplantation.

This document aims to provide guidance on consent for solid organ and islet transplantation in adults and CYP during the COVID-19 pandemic. It augments existing guidance.[1] NHS Blood and Transplant (NHSBT) and the British Transplantation Society (BTS) recognise that similar uncertainties relate to the consent of living donors, and this document also considers these issues. It is recommended that it be used alongside current guidance on consent for living kidney donors and for living liver donors.[2,3]

Our understanding of the biology of SARS-CoV-2 and the natural history of COVID-19 is evolving rapidly, including:

- the natural history and impact of SARS-CoV-2 on transplant recipients, in the context of enhanced immunosuppression in the early post-transplant period, and in the longer term
- the viral dynamics, including possible presence in blood and various body compartments at different stages of the infection, as well as the viral acquisition and clearance rate in immunosuppressed patients
- the optimal clinical management of organ transplant recipients with SARS-CoV-2 infection
- the utility of measurement of antibody responses to SARS-CoV-2 and the possible significance to donor and recipient selection
- the impact of vaccination against SARS-CoV-2 in solid organ transplant recipients, people waiting for a transplant, and the general population

Therefore, informed consent is challenging. Clinicians need to keep up to date with emerging evidence and relevant guidance relating to the patients they care for.[4-10] UK patients listed for a transplant or under post-transplant follow-up with confirmed COVID-19 must be reported to NHSBT via 'Reporting Incidences of COVID-19' at https://www.odt.nhs.uk/deceased-donation/covid-19-advice-for-clinicians/, and to the UK Renal Registry at https://renal.org/covid-19/data/

In order to avoid unnecessary hospital visits and the associated risks of SARS-CoV-2 infection, it is appropriate for many consent discussions to take place virtually, rather than in person. Transplant units should develop patient-appropriate written information on SARS-CoV-2 and COVID-19 for transplant recipients and living donors in both print and electronic formats to inform these consent discussions, with contingency made for non-English speakers or communication barriers due to disability or other reasons. It is recognised that the rapid development of our understanding of COVID-19, along with the dynamic nature of the logistical and organisational issues that units face, means that written information may swiftly become out-of-date. Given these challenges, verbal consent discussions to update and check previous consent on admission for transplantation (and living donation where applicable) are crucial and must be documented appropriately.

Despite these uncertainties, the principles of consent and the legal frameworks around these remain the same and include:

- an individualised risk-benefit discussion with the patient (or, where appropriate, family members or carers) to confirm that they wish to be active on the waiting list
- the need to seek out and address patient (or, where appropriate, family members or carers) concerns
- respect for confidentiality of other patients (e.g. the deceased donor, other patients in a deceased donor's intensive care unit, other patients at the transplant unit, or the intended recipient in the case of living donation)
- as far as possible, giving appropriate time for the patient to reflect before reaching a decision, considering the inherent time pressures that are associated with some aspects of the deceased donation and transplantation process
- clear documentation of the consent discussion and confirmation of consent in the patient's medical records

2. Recipient consent for solid organ transplantation

In order to reduce the risk that the potential recipient is infected with SARS-CoV-2 at the time of transplantation, all potential transplant recipients must be carefully questioned about symptoms consistent with COVID-19 and contact with persons suspected of COVID-19 as per UK guidance.[8,9,10.] History of previous infection or exposure to SARS-CoV-2 must be detailed,

including dates and nature of contact. These discussions should take place prior to admission for transplantation, as far as possible. Molecular tests for SARS-CoV-2 must be performed pre-transplant as per UK guidance.[8,10] Any other SARS-CoV-2 results available must be utilised and interpreted in the appropriate context of risk/benefit to help inform the consent process.

In the absence of any other contra-indication, vaccination against SARS-CoV-2 with any of the Medicines and Healthcare products Regulatory Agency (MHRA) approved vaccines is recommended for transplant recipients aged 16 years and over and those waiting for a transplant. Children and young people under 16 years of age must be assessed on an individual basis according to the risk of severe COVID-19. [11,12]

Transplant recipients and those waiting for transplant must be informed that the immunological response to the vaccine in immunosuppressed people is currently poorly characterized and they must continue to follow advice from the UK Government and their clinical teams to reduce the risk of infection, even when vaccinated.[12]

Regardless of vaccination status, those about to undergo solid organ or islet transplantation must continue to be screened for COVID-19-related symptoms and asymptomatic carriage of SARS-CoV-2, as per existing guidance.[8] Latest Frequently Asked Questions on COVID-19 Vaccination Information, which address the questions that patients may ask during the consent process, can be found here https://www.odt.nhs.uk/covid-19-advice-for-clinicians/ .

The following COVID-19-related issues must be addressed during consent discussions. Background and supporting information for clinicians is cited alongside.

2.1 Risk of transmission of SARS-CoV-2 from the donor to the recipient

- **Deceased donors.** Patients with known or suspected COVID-19 are excluded from donation. NHSBT performs molecular-based SARS-CoV-2 screening of all potential deceased donors. The COVID-19 SNOD checklist (FRM6439) must be checked prior to transplantation at https://nhsbtdbe.blob.core.windows.net/umbraco-assets-corp/17992/frm6439-covid-19-snod-checklist.pdf. No proven cases of donor-transmitted SARS-CoV-2 have been reported to date, and there have been no

recipient complications from organs transplanted from donors who have recovered from SARS-CoV-2 (report in progress)

- **Living donors.** Living donation has continued where the local environment has enabled appropriate safeguards and precautions to be put in place to minimise COVID-19-related risks to the donor and recipient. The risk of transmitting SARS-CoV-2 in an organ from an asymptomatic living donor with no relevant contact history is expected to be very low as there are no reports of donor-derived transmission from any organ transplant to date. Molecular tests for SARS-CoV-2 must be performed pre-donation in all living donors as per UK guidance.[8] The need for vaccination against SARS-CoV-2 prior to donation may be considered as part of the individual risk assessment for the living donor, taking into account:
  - risk factors for poor outcomes if the donor were to develop COVID-19 after donation
  - prioritisation of population groups to receive the vaccine
  - clinical urgency for the intended recipient to undergo transplantation
  - the views of the potential living donor

2.2 Risk of the recipient being diagnosed with SARS-CoV-2 infection post-transplant from sources not related to the donor, and the implications of this

- The potential recipient may be within the incubation period for SARS-CoV-2 at the time of transplantation; screening will be negative in the early stages post-infection. Current data suggest an average (range) incubation period of 5 (1 to 14) days.
  a. Units need to follow local policies, and where testing is being done results should be used to inform transplant assessment.
  b. Molecular tests for SARS-CoV-2 should be performed pre-transplant as per national guidance.[8,10] False negatives can occur and the risk of this must be discussed with the patient. Positive results must also be discussed with specialists in the issuing laboratory, to ensure meaningful interpretation in the correct patient context.
- The risk of acquisition of SARS-CoV-2 immediately before or after the transplant will be dependent on many variables, including:

- compliance with national policies for the general population and policies within NHS environments
- the uptake of vaccination against SARS-CoV-2 in the general population, clinically extremely vulnerable people, and NHS staff

- Clinicians must also consider the local COVID-19 situation within their region and unit at the time of transplantation. This is especially relevant to patients who are likely to require prolonged stays in hospital or the critical care environment post-transplant or those at risk of re-operation post-transplant.
- The mortality risks of COVID-19 in a solid organ transplant recipient in the early post-transplant period continue to be monitored but are significant in adults and appear less so in CYP.[13] In adults, modification of immunosuppression according to latest guidance will form an important part of the management approach for patients who develop COVID-19, but this is cautioned in CYP due to excellent patient and transplant outcomes.[9] Possible effects on the patient and graft must be discussed according to the best available data.[13]
- If any changes have been made to transplant unit immunosuppression policies in the context of COVID-19, these must be discussed with the potential recipient (or, where appropriate, family members or carers).

2.3 Logistical and organisational issues

- Potential recipients must be made aware that the NHS care environment has undergone rapid change due to COVID-19. Access to operating theatres, critical care beds, ward beds, and outpatient follow-up and re-admission pathways will change depending upon the relative impact of the pandemic, both nationally and locally. Possible effects of these changes on the patient and their transplant must be discussed, including access to COVID-minimal recipient pathways. Units should consider if transfer of the patient and organ/islets to another (less affected) unit is feasible and advisable.
- Units need to provide clear guidance for patients on follow-up pathways if they are significantly different from pre-COVID-19 pathways. Individual risk assessments will be needed in order to balance the risk of SARS-CoV-2 exposure with the need for unit follow-up.

2.4 Risks of not proceeding to transplantation

- The likelihood of the potential recipient receiving another organ offer of the same quality or better if this offer is declined (e.g. patient age, size / weight, blood group, HLA sensitisation, waiting time, HLA type, etc.). In living donation, consider the likelihood of the planned recipient receiving another organ if living donor transplantation does not proceed.
- The UK organ donation environment during the COVID-19 pandemic including the availability of organs for transplant from both living and deceased donors (i.e. opportunity for a transplant) and the impact of local considerations on waiting times.
- The risk of developing COVID-19 while remaining on the transplant list and the likely mortality if this occurs. Consideration needs to be given to the risk versus benefit of waiting for vaccination against SARS-CoV-2 prior to transplantation, given the lack of data about immunological response pre- or post-transplantation, and existing prioritisation of population groups. The type of alternative organ support should also be considered (e.g. ventricular assist devices, home haemodialysis versus unit haemodialysis versus peritoneal dialysis) and how this might affect risks of SARS-CoV-2 infection and survival on the list. Similar considerations are relevant to the recipient if living donor organ transplantation does not proceed to plan.

2.5 Shielding

- The UK Government advice about social shielding for 'clinically extremely vulnerable' people changes according to community prevalence of COVID-19 and risk of transmission of SARS-CoV-2.[14] The professional societies have produced resources and risk stratification advice to facilitate individualised risk assessments for both adults and CYP transplant recipients and those waiting for a transplant. [15,16]
- Discussion about current advice and guidance, to include:
  a. The rationale and implications for the advice and guidance.
  b. The need for individual risk assessment for those waiting for a transplant and those who are post-transplant, together with adherence to local guidance.
  c. Information that the advice may change over time, which needs to be taken into consideration in consent discussions.

3. Consent for living organ donation

Experience of living donation in the COVID-19 environment is limited but has continued where the local environment has enabled appropriate safeguards and precautions to be put in place to minimise COVID-19-related risks to the donor. Vaccination against SARS-CoV-2 prior to donation may be considered and included in their individual risk assessment, taking into account risk factors for poor outcomes if the living donor develops COVID-19 after donation, prioritisation of population groups to receive the vaccine, clinical urgency for the intended recipient to undergo transplantation and the views of the potential living donor.

Prior to donation, living donors must be carefully questioned for symptoms consistent with COVID-19, and contact with persons suspected of COVID-19. Molecular tests for SARS-CoV-2 must be performed pre-donation as per UK guidance. The importance of adherence to social distancing and self-isolation policies prior to admission to hospital must be emphasised to minimise risk to the donor, their recipient and others with whom they will come in contact during their in-patient stay.[8,10]

Seeking consent from potential living donors in the context of COVID-19 is especially challenging and raises some unique clinical and ethical considerations. In any case of living donation, the lack of direct physical health benefit to the living donor is always balanced with the benefit to the recipient from receiving a transplant and the interests of the donor in wishing to donate. COVID-19 adds an additional dimension and the following COVID-19-related issues must be addressed during consent discussions. Confirmation of consent discussions with potential living donors in the context of COVID-19 is required for Human Tissue Authority (HTA) approval and must be documented in referral letters to Independent Assessors according to HTA guidance.[15] Background and supporting information for clinicians is cited alongside.

3.1 Risk of transmission of SARS-CoV-2 from the donor to the recipient

- The risk of transmitting SARS-CoV-2 in an organ from an asymptomatic living donor with no relevant contact history has not been quantified but is expected to be very low (see section 2.1).

- Potential living donors must be made aware of the implications of transplantation for the planned recipient (also see 2.2) and the risks of not proceeding to transplantation for the planned recipient (also see 2.4).

3.2 Risk of the donor acquiring SARS-CoV-2 during the period of admission for donation and the implications of this to them

- The potential donor may be within the incubation period for COVID-19 or be asymptomatically infected on the day of donation. Current data estimate an average incubation period of five days. Molecular tests for SARS-CoV-2 must be performed pre-donation as per UK guidance but false negatives can occur, and this possibility must be discussed.
- Living donors might acquire SARS-CoV-2 within the hospital environment that they might not have acquired if they had not donated. This risk depends on the rate of SARS-CoV-2 infection in the general population, adherence to infection control and prevention policies, and the uptake of vaccination against SARS-CoV-2 in NHS staff. It is therefore difficult to quantify definitively.
- Organ function is temporarily reduced after living donation and glomerular filtration rate is approximately halved post-donor nephrectomy, with up to 75% of function recovered by one-year post-donation. It is not known if COVID-19 in those with transiently reduced organ function carries an additional morbidity and mortality risk.
- Living donors may accept an invitation to be vaccinated against SARS-CoV-2 prior to donation. The implications of this must be considered in the context of their individual risk assessment and the risk to their planned recipient and others (e.g. in the UK Living Kidney Sharing Scheme) if transplantation is delayed.

3.3 Logistical and organisational issues

- Potential donors must be made aware that the NHS care environment has undergone change due to COVID-19. Access to operating theatres, critical care and in-patient beds, outpatient services for assessment and follow-up and re-admission pathways are subject to rapid and unpredictable change depending upon the impact of the pandemic, locally and UK-wide. Possible effects of these changes on the

donor must be discussed. Units should consider if transfer of the donor to another unit is feasible and reasonable to facilitate donation.

- Units need to provide clear guidance for donors on follow-up pathways if they are significantly different from pre-COVID-19 pathways.

3.4 Social distancing and self-isolation

- Potential living donors must be made aware of the need for social distancing and self-isolation, along with members of their household, according to local and national guidance.[18] Individual risk assessments are advised to determine the optimal length of the self-isolation period and minimise the risk of acquiring SARS-CoV-2 prior to admission and late cancellation of planned living donor transplants.[10,17,18]

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