

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 uncertainties for transplantation in the UK. This document provides 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 pandemic **as well as** vaccination against SARS-CoV-2 **and evolving treatment options for people infected with the virus.**

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 **in the UK**)
- 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, **non-pharmaceutical interventions (NPI)** including social distancing **and self-isolation**
- the impact of vaccination against SARS-CoV-2 on reducing risk of serious illness
- **the impact of evolving treatment options to treat people who become infected with SARS-CoV-2**

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

- the stringent **NPI** precautions (**as above**) required to minimise risk **of infection** 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

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

To avoid non-essential hospital visits and the associated risks of SARS-CoV-2 infection, consent discussions **may** take place virtually, rather than in person. Transplant units **are expected to provide up to date** patient-appropriate **and centre-specific** 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 will **continue to 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.

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1. Background

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

This document provides guidance on consent for solid organ and islet transplantation in adults and CYP **in the context of** the COVID-19 pandemic **and** augments existing guidance.¹ The document also considers issues **related to the consent of living donors and** it is recommended that it be used alongside current guidance on consent for living kidney donors and for living liver donors.^{2,3}

Although fundamental questions still remain about the biology of the Severe Acute Respiratory Syndrome Coronavirus-type 2 (SARS-CoV-2), the natural history and optimal treatment of COVID-19, knowledge has evolved rapidly since early 2020 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 **and emerging treatment options**
- 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.⁴⁻⁷

To avoid unnecessary hospital visits and **any** associated risks of SARS-CoV-2 infection, consent discussions **may** take place virtually, rather than in person. Transplant units **are expected to provide up to date** patient-appropriate **and centre-specific** 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 **continue to** 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 **supporting** legal frameworks 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

To reduce the risk that the 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.^{6,7} 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.⁶ 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, **an appropriate course of** vaccination against SARS-CoV-2 with any of the Medicines and Healthcare products Regulatory Agency (MHRA) approved vaccines is recommended for transplant recipients and those waiting for a transplant, **with minimum age criteria in line with Government guidance.** ^{8,9}

Transplant recipients and those waiting for transplant must be informed that the immunological response to **third and fourth doses of** the vaccine in immunosuppressed people is **still being evaluated** and they must continue to follow **latest** advice **about NPI and from** their clinical teams to reduce the risk of infection, even when vaccinated.⁹

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**⁶ 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/> and here <https://bts.org.uk/information-resources/covid-19-information/>

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 symptoms of COVID-19 and a positive SARS-CoV-2 RNA are currently **not** being considered for deceased organ donation**
- **The SARS-CoV-2 Deceased Organ Donor Screen and COVID-19 SNOD checklist (FRM6439)⁴ must be checked prior to transplantation. No proven cases of donor-transmitted SARS-CoV-2 have been reported to date in the UK. Updated NHSBT guidance sets out the circumstances where organ donation from selected donors with positive (or indeterminate) SARS-CoV-2 RNA test results may be reasonable, following virological advice, and where current infection (and therefore the risk of infectivity to recipients) is deemed unlikely.**⁹

Living donors.

- Living donation **can** continue with appropriate safeguards and precautions 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. Molecular tests for SARS-CoV-2 must be performed pre-donation in all living donors as per UK guidance.⁶ **Updated NHSBT guidance on SARS-CoV-2 assessment in potential living donors is available.**⁶
- 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 which **must also take** into account:
 - o risk factors for poor outcomes if the donor were to develop COVID-19 after donation, **particularly in the context of immediate past or asymptomatic infection.**^{6,11}
 - o clinical urgency for the intended recipient to undergo transplantation
 - o the views of the potential living donor.¹²

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 used to inform transplant assessment.
 - b. Molecular tests for SARS-CoV-2 should be performed pre-transplant as per national guidance.⁶ 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, **transplant recipients**, 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.^{13,14} 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.⁷ Possible effects on the patient and graft must be discussed according to the best available data.^{13,14}
- 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 **and significant** change due to COVID-19. Access to operating theatres, critical care beds, ward beds, and outpatient follow-up and re-admission pathways will **vary** depending upon the 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 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 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 **changes within the** UK organ donation environment during the **various phases of 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. The type of alternative organ support **needs to** 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 Non-pharmaceutical interventions (NPI) and self-isolation

- Government advice about **NPI and self-isolation, including for people previously classified as** ‘clinically extremely vulnerable’ changes according to community prevalence of COVID-19 and risk of transmission of SARS-CoV-2.¹⁵ 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.^{16,17} **It is important to be aware of the current advice and guidance on the use of NPIs for immunosuppressed patients to protect against risk of infection from SARS-CoV-2. Consent discussions must include:**
 - a. The rationale and implications for **current** advice and guidance

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- 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 changes over time, which **may have implications for consent discussions**

3. Consent for living organ donation

Living donation has continued where appropriate safeguards and precautions **are** in place to minimise COVID-19-related risks to the donor. Vaccination against SARS-CoV-2 prior to donation **is recommended** and included in their individual risk assessment, taking into account risk factors for poor outcomes if the living donor develops COVID-19 after donation, 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 **UK guidance and local policies on the need for self-isolation** 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.⁶

Seeking consent from potential living donors in the context of COVID-19 is 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 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.¹⁸ 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 asymptotically infected on the day of donation. 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 [decline](#) 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 change depending upon the impact of the pandemic, locally and UK-wide. Possible effects of these changes on the donor must be discussed. Units **could** consider 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 Non-Pharmaceutical interventions 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.¹⁹ 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.^{4,19,20}

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