

NHSBT / BTS guidance for clinicians on consent for solid organ transplantation in adults and living organ donation in the context of the COVID-19 pandemic

Executive summary

The Coronavirus Disease 2019 (COVID-19) pandemic caused by the Severe Acute Respiratory Syndrome Coronavirus-type 2 pathogen (SARS-CoV-2) raises many uncertainties for UK solid organ transplantation. This document aims to provide guidance on consent for solid organ transplantation in adults, and on consent for living donors, during the COVID-19 pandemic.

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

- risk of transmission of SARS-CoV-2 from the donor to the recipient
- risk of the recipient developing COVID-19 post-transplant from sources not related to the donor
- logistical and organisational issues, e.g. future access to operating theatres, critical care beds, ward beds, and outpatient follow-up and re-admission pathways
- risks of not proceeding to transplantation
- the rationale for, and implications of, social 'shielding' advice to solid organ transplant recipients

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

- risk of the donor acquiring SARS-CoV-2 during the donation period
- implications of transplantation for the planned recipient
- risks of not proceeding to transplantation for the planned recipient
- logistical and organisational issues, e.g. future access to operating theatres, critical care beds, ward beds, and outpatient follow-up and re-admission pathways

In order to avoid unnecessary hospital visits and the risks of SARS-CoV-2 infection associated with these, it is appropriate that many consent discussions will take place virtually, where possible.

Transplant units need to develop patient-appropriate written information on SARS-CoV-2 and COVID-19 in both print and electronic formats to inform these consent discussions. Contingency will need to be made for non-English speakers or communication barriers due to disability or other reasons.

Background

The Coronavirus Disease 2019 (COVID-19) pandemic is an unprecedented challenge to both the wider NHS and the UK's solid organ transplant communities. This challenge is raising many uncertainties, including how best to consent patients for solid organ transplantation.

This document aims to provide guidance on consent for solid organ transplantation in adults during the COVID-19 pandemic, and augments existing guidance (https://bts.org.uk/wp-content/uploads/2016/09/12_BTS_NHS_Consent_April_2013-1.pdf). NHS Blood and Transplant (NHSBT) and the British Transplantation Society (BTS) recognise that similar uncertainties relate to the consent of living donors, and therefore this document also considers these issues. It is recommended that it be used alongside current guidance on consent for living kidney donors (BTS/RA) (https://bts.org.uk/wp-content/uploads/2018/07/FINAL_LDKT-guidelines_June-2018.pdf) and living liver donors (BTS/BASL) (https://bts.org.uk/wp-content/uploads/2016/09/03_BTS_LivingDonorLiver-1.pdf).

Our understanding of the biology of the novel Severe Acute Respiratory Syndrome Coronavirus-type 2 pathogen (SARS-CoV-2) and the natural history of COVID-19 (the disease caused by SARS-CoV-2) is evolving rapidly. We are continuously learning about many fundamental issues of direct relevance to our patients, including:

- The natural history and impact of COVID-19 on adult organ transplant recipients, especially in the early post-transplant period and other periods of enhanced immunosuppression
- The viral dynamics, including presence in blood and various body compartments at different stages of the infection, as well as the viral acquisition rate in immunosuppressed patients
- Optimum specimen types and diagnostic tools during the different stages of disease
- The optimal clinical management of organ transplant recipients with COVID-19
- The utility of anticipated tests for an antibody response to SARS-CoV-2 exposure and their possible significance to donor and recipient selection

These uncertainties make informed consent challenging. To minimise uncertainties, clinicians need to keep themselves up to date with emerging evidence relevant to the patients they care for. UK patients listed for a transplant or under post-transplant follow-up with suspected or confirmed COVID-19 must be reported to NHSBT (<https://www.odt.nhs.uk/deceased-donation/covid-19-advice-for-clinicians/>).

In order to avoid unnecessary hospital visits and the risks of SARS-CoV-2 infection associated with these, it is appropriate that many consent discussions will take place virtually, rather than in person. Transplant units should consider developing patient-appropriate written information on SARS-CoV-2 and COVID-19 in both print and electronic formats to inform these consent discussions. Contingency will need to be 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 patient information may swiftly become out-of-date. Given these challenges, verbal consent discussions at the time of transplantation are crucial, and must be documented appropriately.

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

- An individualised risk-benefit discussion with the patient
- The need to seek out and address patient concerns
- The involvement of families, carers and other close supporters of the patient, provided the patient gives consent to this
- Respect for confidentiality of other patients (e.g. the deceased donor, other patients in a deceased donor's ITU, other patients at the transplant unit, or the intended recipient in the case of living donation)
- Giving appropriate time for the patient to reflect before reaching a decision, considering the time pressures inherent to the process of donation and transplantation
- Clear documentation of the consent discussion in the patient's medical records

Consent for solid organ transplantation in adults

In order to reduce the risk that the potential recipient has COVID-19 at the time of organ transplantation, all potential solid organ transplant recipients must be carefully questioned about symptoms consistent with COVID-19 and contact with persons suspected of COVID-19. These discussions should take place prior to admission for transplantation, if possible. Advice must be sought from local infectious diseases specialists if COVID-19 is suspected. Molecular tests for SARS-CoV-2 may be indicated.

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

- 1) Risk of transmission of SARS-CoV-2 from the donor to the recipient.

- a. Deceased donors. Patients with known or suspected COVID-19 are excluded from donation. NHSBT has commenced molecular-based SARS-CoV-2 screening of all potential deceased donors. These patients will not have had identifiable signs or symptoms of COVID-19 during donor characterisation, and the rationale is to detect virus shedding in someone with unsuspected SARS-CoV2 infection, rendering organ donation safer. These tests appear to be highly specific (>95%), and their true sensitivity will be established once the prevalence of this infection and rate of asymptomatic to symptomatic infection is clarified. Sensitivity in asymptomatic infection is unknown, but detection of viral RNA is the most sensitive methodology available (personal communication, Dr Ines Ushiro-Lumb, NHSBT microbiologist, 24 March 2020). The COVID-19 SNOD checklist (FRM6439) must be checked prior to transplantation (<https://nhsbt.dbe.blob.core.windows.net/umbraco-assets-corp/17992/frm6439-covid-19-snod-checklist.pdf>).
 - b. Living donors. The risk of transmitting SARS-CoV-2 in an organ from an asymptomatic living donor with no concerning contact history has not yet been quantified but is expected to be low. At present there is no requirement for molecular tests for SARS-CoV-2 to screen potential living donors in the UK (see below).
- 2) Risk of the recipient developing COVID-19 post-transplant from sources not related to the donor, and the implications of this for them.
- a. The potential recipient may be within the incubation period for COVID-19 at the time of transplantation. Current data estimate an average incubation period of 5 days. The point prevalence of SARS-CoV-2 infection in the UK general population and the national transplant list population is not known but is expected to increase significantly in the short-term.
 - i. At present there is not enough evidence to suggest that molecular tests should be used to screen for SARS-CoV-2 in asymptomatic patients on the national transplant list, though other countries (e.g. Spain) have recommended this (<https://nhsbt.dbe.blob.core.windows.net/umbraco-assets-corp/18016/donation-international-reflections-17032020.pdf>). Units need to consider the local availability of SARS-CoV-2 testing and the expected waiting time for results if they are considering introducing a local policy.
 - b. The risk of acquisition of SARS-CoV-2 post-transplant will be dependent on many variables, including national policies for the general population and policies within

NHS environments. Current models suggest that a high proportion of the general population will eventually be infected with SARS-CoV-2

(<https://www.imperial.ac.uk/media/imperial-college/medicine/sph/ide/gida-fellowships/Imperial-College-COVID19-NPI-modelling-16-03-2020.pdf>).

- i. Clinicians must also consider the local COVID-19 situation within their transplant unit at the time of transplantation, e.g. if there are patients with COVID-19 in the transplant ward or critical care units. 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 returning to theatre post-transplant.
 - c. The mortality risks of COVID-19 in a solid organ transplant recipient in the early post-transplant period have not been quantified but are likely to be significant. Immunosuppression reduction will form an important part of the management approach. Possible effects on the patient and graft should be discussed.
 - i. If any changes have been made to transplant unit induction immunosuppression policies due to the COVID-19 pandemic, these must be discussed with the potential recipient.
- 3) Logistical and organisational issues.
 - a. Potential recipients must be made aware that the NHS care environment is undergoing rapid change due to COVID-19. Access to operating theatres, critical care beds, ward beds, and outpatient follow-up and re-admission pathways are likely to undergo significant (and unpredictable) changes. Possible effects of these changes on the patient and their transplanted organ must be discussed. Units should consider if transfer of the patient and organ to another (less affected) unit is feasible and reasonable.
 - b. Units need to provide clear guidance for patients on follow-up pathways if they are significantly different than 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.
- 4) Risks of not proceeding to transplantation.
 - a. 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.
 - b. The UK organ donation environment during the COVID-19 pandemic and how the availability of donated organs might change.

- c. The risks of COVID-19 while remaining on the national transplant list and the likely mortality if this occurs. 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.
- 5) As of 22 March 2020, Public Health England has defined solid organ transplant recipients as being extremely vulnerable to COVID-19 and has strongly advised social 'shielding' to prevent SARS-CoV-2 infection. The rationale for this advice, and the implications of it, must be discussed.

Consent for living organ donation

Prior to donation, living donors must be carefully questioned for symptoms consistent with COVID-19, and contact with persons suspected of COVID-19. The risk of transmitting SARS-CoV-2 in an organ from an asymptomatic living donor with no concerning contact history has not yet been quantified but is expected to be low. At present there is no requirement for molecular tests for SARS-CoV-2 in potential living donors in the UK. Units will need to consider the local availability of SARS-CoV-2 testing if they wish to introduce a local policy.

Seeking consent from potential living donors during the COVID-19 pandemic is especially challenging. 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. COVID-19 adds an additional dimension and the following COVID-19-related issues must be addressed during consent discussions. Background and supporting information for clinicians is given alongside.

- 1) Risk of the donor acquiring SARS-CoV-2 during the donation period and the implications of this to them.
 - a. The potential donor may be within the incubation period for COVID-19 or be asymptotically infected on the day of donation. Current data estimate an average incubation period of five days. The point prevalence of SARS-CoV-2 infection in the UK general population is not known but is expected to increase significantly in the short-term.
 - b. Living donors might acquire SARS-CoV-2 within the hospital environment that they might not have acquired if they had not donated. This risk cannot be quantified at present.

- c. Organ function is temporarily reduced after living donation. For a living kidney donor, GFR is approximately halved after donation, 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.
- 2) Implications of transplantation for the planned recipient.
- a. Risks of transmission from the donor to the recipient. The risk of transmitting SARS-CoV-2 in an organ from an asymptomatic living donor with no concerning contact history has not yet been quantified but is expected to be low.
 - b. Risk of the recipient developing COVID-19 post-transplant from sources not related to the donor.
 - c. The implications of COVID-19 in a solid organ transplant recipient in the early post-transplant period have not been quantified but are likely to be significant. Possible effects on the patient and graft must be discussed.
- 3) Risks of not proceeding to transplantation for the planned recipient.
- a. The risks of morbidity and mortality to the planned recipient if the living donor organ transplant does not proceed.
 - b. Consider the likelihood of the planned recipient receiving another organ if living donor organ transplantation does not proceed. Clinicians must also consider the UK organ donation environment during the COVID-19 pandemic and how the availability of donated organs might change.
 - c. The risks of COVID-19 while remaining on the national transplant list and the likely mortality if this occurs. The type of organ support should also be considered (e.g. home haemodialysis versus unit haemodialysis versus peritoneal dialysis) and how this might affect risks of SARS-CoV-2 infection and survival on the list.
- 4) Logistical and organisational issues.
- a. Potential donors must be made aware that the NHS care environment is undergoing rapid change due to COVID-19. Access to operating theatres, critical care beds, ward beds, and outpatient follow-up and re-admission pathways are likely to undergo significant (and unpredictable) changes. 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.
 - b. Units need to provide clear guidance for donors on follow-up pathways if they are significantly different than pre-COVID-19 pathways.