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

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, children and young people (CYP) and on consent for living donors, in the context of COVID-19.

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

- 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. 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 transplant recipients and subsequent easing of restrictions

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 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

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 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 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 transplantation.

This document aims to provide guidance on consent for solid organ transplantation in adults and CYP during the COVID-19 pandemic and as transplant centres re-open or expand their programmes. 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 the SARS-CoV-2 and the natural history of COVID-19 is evolving rapidly. We are continuously learning about many fundamental issues of direct relevance to patients, including:

- The natural history and impact of COVID-19 on organ transplant recipients, in the early post-transplant period, in the context of enhanced immunosuppression and in the longer term
- 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
- 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. Clinicians need to keep up to date with emerging evidence and relevant guidance relating to the patients they care for.[4-8] UK patients listed for a transplant or under post-transplant follow-up with suspected or 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 ITU, 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 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 as per UK guidance.[4,7,8] 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.[4,8]
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

2.1.1 **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 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 at https://nhsbtdbe.blob.core.windows.net/umbraco-assets-corp/17992/frm6439-covid-19-snod-checklist.pdf. No proven cases of donor-transmitted COVID-19 have been reported to date.

2.1.2 **Living donors.** Experience of living donation in the context of the COVID-19 environment is limited. 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 low. Molecular tests for SARS-CoV-2 must be performed pre-donation as per UK guidance.[4,8]

2.2 Risk of the recipient developing COVID-19 post-transplant from sources not related to the donor, and the implications of this

2.2.1 The potential recipient may be within the incubation period for COVID-19 at the time of transplantation. Current data suggest an average incubation period of 5 days.

a. At present there is insufficient 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.[9] Units need to follow local policies.

b. Molecular tests for SARS-CoV-2 should be performed pre-transplant as per national guidance.[4,8] False negatives can occur and the risk of this must be discussed with the patient.

2.2.2 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.

2.2.3 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.

2.2.4 The mortality risks of COVID-19 in a solid organ transplant recipient in the early post-transplant period have not been fully quantified but are significant in adults and appear less so in CYP. In adults, modification of immunosuppression 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.[10]

2.2.5 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

2.3.1 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 may undergo further changes. Possible effects of these changes on the patient and their transplanted organ must be discussed, including access to COVID-minimal patient pathways. Units should consider if transfer of the patient and organ to another (less affected) unit is feasible and advisable.

2.3.2 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

2.4.1 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.

2.4.2 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.

2.4.3 The risk of developing COVID-19 while remaining on the 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. Similar considerations are relevant to the recipient if living donor organ transplantation does not proceed to plan.

2.5 Shielding

2.5.1 Since 22nd March 2020, Public Health England and the Chief Medical Officer of Scotland define solid organ transplant recipients as 'extremely vulnerable' to COVID-19 and have strongly advised social 'shielding' to prevent SARS-CoV-2 infection.[11,12] On 28th May 2020, the British Association of Paediatric Nephrologists issued revised guidance downgrading paediatric kidney transplant recipients (other than those within three months of transplant or those receiving anti-T-cell therapies within six weeks), to 'vulnerable' from 'extremely vulnerable'.[13]

2.5.2 The rationale for this advice, and the implications of it, must be discussed, to include:

a. It may be necessary to shield whilst waiting for an organ transplant, according to local guidance.

b. 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. 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.[4,8]

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.[14] Background and supporting information for clinicians is cited alongside.

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

3.1.1 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 low (see section 2.1).

3.1.2 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

3.2.1 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.

3.2.2 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.

3.2.3 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.

3.3 Logistical and organisational issues

3.3.1 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 may undergo further 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 to facilitate donation.

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

3.4 Self-isolation

3.4.1 Potential living donors must be made aware of the need for self-isolation, along with members of their household, for 14 days before the planned date of donation.[15]

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