

Changes in this version

This updated guidance includes outcome information data from 2021, including post-vaccination outcomes, guidance on pre-transplant vaccination and latest available treatments for COVID-19.

Policy

1. INTRODUCTION:

For the majority of patients requiring lifesaving and/or life enhancing Solid Organ Transplantation (SOT), receipt of a transplant during the COVID-19 pandemic has an acceptable risk-vs-benefit ratio compared to being on the waiting-list. Evidence from the first wave of infection (Feb-May 2020) in England indicates high mortality in SOT recipients who contract SARS-CoV-2 infection (15-20%)¹ but subsequent waves (Sept 2020 – Aug 2021) indicates a mortality risk of 10% in un-vaccinated patients and mortality risk of 7.7% for double vaccinated patients² – This identifies SOT patients as an extremely vulnerable patient cohort despite vaccination. In light of the available evidence, NHSBT strongly advocates continued offer of a transplant service by units with appropriate risk assessment and informed patient consent.^{3,4}

COVID-19 is a highly contagious disease with clear evidence of person-to-person transmission. It is also clear that infected people may transmit infection during asymptomatic or pre-symptomatic phases of illness. Transmissibility risk is also dependant on SARS-CoV-2 variants e.g. Omicron more transmissible than Delta. These disease kinetics increases the risk of outbreaks in clinical care settings, including SOT transplant units. Two or more, chronologically and geographically aligned new infections in previously negative patients would typically be defined as a nosocomial outbreak.

The following guidance is written as an aide-memoire for transplant Multi-Disciplinary Teams (MDT) to use as part of their service consideration and planning. This guidance:

- Is not intended to replace or conflict with individual Trust/hospital outbreak management policies but to be used in conjunction with such policies.
- Recognises the patient pathway risks unique to SOT recipients and the specialty-specific needs associated with running a safe SOT service.
- Draws from experience of two outbreaks in UK SOT centres during the COVID-19 pandemic and is designed to disseminate the learning from their experience.

The four key principles for units to consider and plan for are: prevention, preparation, escalation and shared learning as part of outbreak management

2. PREVENTION

Transplant units to consider the following factors to prevent or reduce risk of outbreak

- 2.1. Single room (including en-suite facilities) vs multi-occupancy bays: SOT recipients should be cared for in single rooms where available or prioritised for access to single rooms. If single rooms are not available, multi-occupancy bays with SOT recipients should ideally admit only SARS-CoV-2 negative patients, and have an enhanced cleaning regime for shared bathroom facilities and common touch points, e.g. doors, switches. Unless there is an over-riding clinical need, patients should be cared for in the same multi-occupancy bay throughout their in-patient stay, rather than moving between multi-occupancy bays.
- If hospital infra-structure allows, and the required MDT input can be safely and sustainably delivered, SOT should be performed in a 'Green' or 'Cold' (absence of non-elective patient admissions) hospital site, to reduce the risk of co-location of SARS-CoV-2 positive and negative patients. For the majority of transplant units, this is unlikely to be a feasible option due to

essential inter-dependencies with supporting clinical disciplines.

- 2.2. PPE, hand hygiene and social distancing: All professionals likely to have contact with the SOT recipient must have access to and adhere to active guidance on national/local PPE use, hand hygiene and social distancing guidance. Unit leads to enforce a 'zero tolerance' policy to inappropriate adherence to such guidance.
- 2.3. Limiting access: Only care professionals necessary to deliver near-patient care should have access to the transplant ward. Strictly enforce the active version of national/local guidance on visitor policy. If possible, restrict the number of access doors to the transplant ward to the minimum required to ensure regulatory compliance (for ex: fire regulations). Ideally, all access points to be within line of sight to enable ward reception/nursing/medical staff to challenge inappropriate access to the transplant ward
- 2.4. Staff and wait-listed patient screening: It is recommended that local hospital policy on screening of asymptomatic staff should be followed.

There is a lack of evidence to recommend for or against routine screening of asymptomatic patients on the waiting list for a transplant. It is recommended that local hospital policy on screening of asymptomatic patients should be followed. For SARS-CoV-2 testing guidance immediately prior to transplantation please see **POL304** found at <https://www.odt.nhs.uk/covid-19-advice-for-clinicians/>

- 2.5. Pre-admission screening for SARS-CoV-2 status: Admission policies to the transplant ward, especially if receiving inter-hospital transfers, must be reviewed to reduce the risk of inadvertent admission of a SARS-CoV-2 infected patient. It is advisable to have check lists that mandate confirmation of SARS-CoV-2 negative status prior to accepting the patient for transfer.
- 2.6. SARS-CoV-2 vaccination of wait-listed patients: Patients wait-listed for SOT should be strongly encouraged to complete the full vaccination course. As of January 2022, a full course for most patients on the waiting list is a three-dose primary vaccine course followed by a booster. Pre-transplant vaccination is likely to provide the best protection against severe outcomes in the event of post-transplant COVID-19. Live donor transplant recipients should be strongly encouraged to complete their vaccination course prior to elective transplantation.

3. PREPARATION

It is imperative **that** the transplant service pro-actively prepares to respond to a potential SARS-CoV-2 infection outbreak. Pro-active planning will help to improve response times in the event of an outbreak and enable deployment of an agreed and standardised response plan taking into account the individualised needs of the transplant ward/service.

- 3.1. Familiarisation with local outbreak policy: An outbreak could be declared on any day including weekends. Therefore, all on-call consultant physicians and surgeons involved in care delivery must familiarise themselves with the local hospital outbreak policy. This will enable responsive early management of the outbreak at any time (24/7)
- 3.2. Risk assessment of the local transplant pathway: It is advisable for transplant leads in conjunction with local Infection Prevention & Control (IPC) teams to undertake a risk assessment of the transplant ward and their specific patient pathway to identify and mitigate any avoidable risks. Working jointly with local IPC teams, if relevant, a specialty-specific version of the hospital outbreak policy could be developed and signed off.

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- 3.3. Protocol for dealing with an outbreak: Transplant leads, working with the wider MDT and local IPC team should consider documenting an outbreak management standard operating protocol (SOP) for their unit and include:
- Information on early warning triggers
 - Agreed trigger for activating the outbreak policy responses, (e.g. continuation or suspension of the transplant programme)
 - Role clarity and responsibilities for key personnel in outbreak management
 - An exit plan to step down outbreak management escalation which includes pre-defined triggers (e.g. minimum number of days during which there are no new confirmed nosocomial infections) and resulting policy responses (e.g. re-opening the ward for admissions).
- The protocol document must be easily accessible (24/7), to enable optimal, timely and consistent response times.
- 3.4. Defining process for decision-making by the MDT in the event of an outbreak: It is advised that the transplant MDT discuss and agree triggers and associated responses in the event of an outbreak. The responses could include agreement on conditions that need to be met to safely continue or suspend the transplant program and the mitigations that are needed to re-start the programme in the event of suspension. A minimum quoracy of the transplant MDT should be defined and 'stood up' to make decisions on continuing or suspending transplantation. It is also advisable for the transplant MDT to define the process and frequency for reviewing the continuation/suspension decision.

4. ESCALATION

Given the characteristics of the pandemic fluctuating community incidence and prevalence of infection, the virus kinetics and the number of likely entry points for the infection, transplant units are likely to experience an outbreak despite maximal preparation and vigilance. In the event of a transplant ward outbreak declaration, a locally agreed escalation plan would enable continued safe care delivery.

- 4.1. Immediate outbreak actions as per hospital policy: In line with local hospital policies, an outbreak response team led by unit clinical and nursing leads should be established. Hospital outbreak management policy actions with involvement of IPC must be followed. The hospital outbreak policy may stipulate escalation to and involvement of external agencies such as [UK Health Security Agency](#) (Health Protection Units and Consultant in Communicable diseases) or equivalent organisations in the devolved nations.
- 4.2. Immediate outbreak action as per SOP: Unit outbreak management SOP (as per 3.3 above) actions should be followed by identified role leads.
- 4.3. Early MDT decision making: The agreed quorate transplant MDT meeting to be stood up within 12 hours of outbreak declaration to review the available information. The MDT should specifically consider and make a recommendation on continuation or suspension of the transplant program and document the reasons for the agreed outcome.
- 4.4. Asymptomatic staff/patient screening as part of outbreak management: Screening of asymptomatic patients and staff as part of outbreak management to follow local hospital policy
- 4.5. Patient movement as part of outbreak management: Local outbreak policy to be followed on:
- Moving or cohorting SARS-CoV-2 positive patients (which may be dependent on local availability of single rooms).
 - Visitor access to the ward
 - Movement of patients from the outbreak ward to departments such as Radiology as relevant to individual patient needs

- 4.6. Initiating COVID treatments: Early consultant-led assessment on commencement of COVID-19 specific treatments (for ex: Sotrovimab, Dexamethasone) is advised for new SARS-CoV-2 positive SOT recipients on the ward. Enrolment in appropriate clinical trials should be considered. Resources such as RA/BTS guidance (<https://bts.org.uk/information-resources/covid-19-information/>) can help inform shared decision making with patients.
- 4.7. Immunosuppression changes: Early, consultant-led decision-making on changes to immunosuppression of SARS-CoV-2 positive SOT recipients should be considered. Resources such as RA/BTS guidance⁵ (<https://bts.org.uk/information-resources/covid-19-information/>) can help inform shared decision making with patients.
- 4.8. Discharge of patients following outbreak declaration: Asymptomatic patient contacts (currently SARS-CoV-2-negative) or asymptomatic SARS-CoV-2-positive patients may be discharged from the transplant ward following outbreak declaration.
- 4.9. Out-patient follow up for patients discharged during the outbreak: Asymptomatic patient contacts (currently SARS-CoV-2 -negative) or asymptomatic SARS-CoV-2-positive patients may be discharged from the transplant ward following outbreak declaration and need out-patient follow up before expiry of their mandatory self-isolation period. Measures must be taken to minimise the risk of transmission of SARS-CoV-2 including:
 - Virtual clinics
 - Face-to-face appointments at the end of clinic lists (with decontamination of the clinic space after review)
 - Telephone review for symptoms prior to clinic attendance
 - Review of travel arrangements if reliant on public transport/taxi or dependant on another vulnerable adult to drive the patient.
 - [Continued screening for SARS-CoV-2 infection status](#)
- 4.10. Standing down outbreak response plan: In line with local hospital outbreak policy, the transplant ward escalation stand down triggers and responses should be defined.

5. SHARED LEARNING

Management of a SARS-CoV-2 outbreak on a transplant ward is likely to be stressful and unit leads should consider mechanisms to embed any shared learning, both within the unit as well as [the wider transplant community](#)

- 5.1. De-brief following the outbreak: After the step down from outbreak escalation, a de-brief meeting is recommended involving the wider transplant MDT, led by the unit medical/surgical and nursing leadership. The meeting could be a forum to support staff affected and
 - Agree changes, if any, that would be necessary to reduce future risk of outbreaks
 - Update the transplant ward outbreak SOP with relevant changes
 - Agree communication strategy with affected patient groups
 - Agree a mechanism to share leaning internally.
- 5.2. Notification to other agencies: Other than mandated notifications ([e.g. UKHSA](#)) as part of the local hospital outbreak management policies, unit leads need to inform relevant NHSBT advisory group chair/s of the outbreak and any lessons learnt. Sharing the learning with other transplant units in the UK to pro-actively mitigate similar risks in their units will improve patient safety.

References:

¹ SARS-CoV-2 infection and early mortality of waitlisted and solid organ transplant recipients in England: A national cohort study. Am J of Transplant, 2020; 20: 3008-3018

² Real-world Effectiveness of the Pfizer-BioNTech BNT162b2 and Oxford-AstraZeneca ChAdOx1-S Vaccines Against SARS-CoV-2 in Solid Organ and Islet Transplant Recipients
Chris J Callaghan 1, Lisa Mumford, Rebecca M K Curtis et al; Transplantation (Online ahead of print)
DOI: 10.1097/TP.0000000000004059

³ 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
<https://bts.org.uk/information-resources/covid-19-information/>

⁴ NICE COVID-19 Rapid Guideline: Renal Transplantation, August 2020
<https://www.nice.org.uk/guidance/NG178>

⁵ Guidance on the management of transplant recipients diagnosed with or suspected of having COVID-19
<https://bts.org.uk/information-resources/covid-19-information/>