

Lung Transplant Service Recovery Plan and Risk Assessment: Continuing services in the COVID-19 Period

The Coronavirus Disease 2019 (COVID-19) pandemic caused by the Severe Acute Respiratory Syndrome Coronavirus-type 2 pathogen (SARS-CoV-2) has led to unprecedented challenges for UK transplantation. Concerns about lack of access to operating theatres, inpatient and critical care beds, and implications for immunosuppressed transplant recipients have resulted in a major reduction in the number of organ transplants undertaken. This is particularly acute in the field of lung transplantation.

NHS Blood and Transplant (NHSBT) is aware that some units may now wish to start considering how best to re-open their transplant services or to expand their current restricted donor and recipient criteria. Their view is that these considerations are best taken forward at the local level, given pre-existing differences between units and the variation in how the pandemic has affected regions, hospitals, transplant programmes and patient populations. NHSBT have set out a number of conditions and suggestions for how transplant units expand current services and where appropriate, these have been included in this document.

At this time we are already performing Super-Urgent and Urgent Lung transplantation. This document would allow us to re-start non-urgent transplantation (for patients stable on the waiting list at home). It should be noted that given the significant decrease in donation during the current pandemic (approximately 80% reduction) that the number of patients coming forward for non-urgent transplantation is likely to be low.

NHSBT have indicated that patients must be informed of decisions to re-open previously suspended aspects of transplant programmes. We will achieve this through telephoning patients, mail/e-mail for written patient information and our RPH Patients' Association. Patients must be informed regarding the risks of developing COVID-19 post-transplantation (including mortality and morbidity) and the feasibility and safety of outpatient follow-up in the pandemic environment.

We will send patients written information on COVID-19-related issues pre- and post-transplant, including advice on social 'shielding' in the early post-transplant period. We will follow NHSBT and British Transplantation Society guidance on consent issues during COVID-19 recognising that information provided is limited by the paucity of available evidence. There should be a low threshold for SARS-CoV-2 PCR swab testing in patients on the transplant list who develop symptoms consistent with COVID-19. Those with proven COVID-19 should be suspended. Those who recover and are symptom-free for more than 28 days can be considered for re-activation on the list. In this patient group, two negative sets of SARS-CoV-2 PCR nose and throat swabs taken at least 24 hours apart provides reassurance that the infection has been cleared (NHSBT POL296/1 28.4.20 – Re-opening of Transplant Programmes: Issues for Consideration). Individual assessment is essential and earlier re-activation may be appropriate given the broad spectrum of COVID-19 disease.

If a donor Lungs becomes available, potential transplant recipients must be carefully questioned by telephone, prior to being brought into RPH, for symptoms consistent with COVID-19 and for contact with persons with confirmed or suspected COVID-19. A comprehensive social history is required, with details of the patient's social distancing practices and of those within their household, in order to build a picture to inform a risk assessment. Ideally, this should happen well before the patient is admitted to hospital by the transplant coordinator but should also be performed when a called in for a potential recipient or on admission. Examination must include a careful chest assessment with measurement of peripheral arterial oxygen saturations. Patients with a significant contact history, or

where clinical suspicion of COVID-19 is present, must be discussed with a consultant microbiologist prior to proceeding with transplantation.

Undertaking transplant surgery on an asymptomatic patient during the incubation period of COVID-19 is thought to carry significant risks of early post-operative mortality (Lei S, Jiang F, Su W, et al. Clinical characteristics and outcomes of patients undergoing surgeries during the incubation period of COVID-19 infection. *EClinicalMedicine*. 2020 Apr 5:100331 [Epub ahead of print]). NHSE/I have indicated that units must test for SARS-CoV-2 on nose and throat swabs in all those admitted to hospital including those admitted for potential transplantation. However, PCR results may not be available prior to transplantation and the availability of negative PCR results should not be absolute prerequisites to proceeding with transplantation. If transplantation proceeds before PCR results are available, these should be checked at the expected time of result availability. The potential recipient must be informed that negative tests are not a guarantee of absence of SARS-CoV-2 infection and that false positives can also occur. Since all potential deceased donors are tested for SARS-CoV-2, it is highly likely that the donation process will be extended significantly. The potential recipient should be brought to RPH early to potentially have sufficient time to receive SARS-CoV-2 test results prior to transplantation. The benefits of this approach must be balanced against the additional risks associated with breaking social distancing practices by early admission of the patient. Where swab results are available pre-transplant and are positive, transplantation would not usually proceed. It should be noted that CT chest scanning for the diagnosis of COVID-19 in asymptomatic patients is unlikely to be helpful in Lung transplant recipients due to the high probability of false positive findings and should not be performed routinely.

Transplant care will be otherwise delivered as usual according to DN625, Operational Procedure for the Transplant Directorate. The burden of immunosuppression may be reduced should an early post-transplant patient develop COVID-19. Changes to follow-up pathways (e.g. virtual clinics, remote blood testing facilities) will be considered wherever feasible but due to the need for surveillance transbronchial biopsies will need to continue face to face for at least the first 3 months post-transplant.

Following transplantation, there must be separation of pre- and early post-transplant patients from those with suspected or confirmed COVID-19 during the inpatient stay and in the outpatient follow-up period. This is particularly important in the ICU setting where a dedicated ICU trained nurse is required to manage the patient in the immediate post-operative phase of care.

Proposal:

1. Re-start non-urgent DBD and DCD transplantation from 8th May 2020. Requirements to be met in order to achieve this:
 - a. Written patient information sent/emailed to patients on 4th May 2020.
 - b. A transplant respiratory consultant will review every patient on the current waiting list to ensure it is appropriate to reactivate. Some patients may require review or repeated investigations prior to reactivation.
 - c. Telephone re-confirmation of consent from patients currently active on the Lung transplant waiting list by 15th May 2020.
 - d. Telephone patients currently suspended for any reason (including due to patient wish in current pandemic) to confirm whether they wish to be reactivated by 23rd May 2020.
 - e. Confirmation of transplant surgeon availability 24/7 to support transplantation.
 - f. Confirmation of transplant coordinator availability to support the transplant process.

- g. Confirmation of ICU capacity to deliver non-urgent transplantation including availability of ICU trained nursing staff to support post-operative care (including facility to deliver VA-ECMO if necessary).
- 2. Phased reintroduction of less urgent aspects of the Lung transplant programme. We are continuing to review patients in the outpatient setting who are within the first year after transplant to complete investigations. We are continuing to reduce the face to face appointments wherever possible and utilise telephone consultation for many patients under follow-up. A 'drive through' blood test service has been introduced to avoid unnecessary exposure for shielded patients. The following aspects of the programme are considered to be moderate urgency and warrant ramping up in the coming weeks to establish a 'new normal' during the ongoing pandemic. The recovery plan will be monitored on a weekly basis. Additional out-patient clinic sessions may be required due to decreased clinic capacity and a backlog of patients from the telephone clinics currently run.
 - a. Restart weekly assessments for potential transplant recipients with advanced Lung failure. This requires access to investigation including; Routine blood tests, lung function testing, 6 minute walk distance, echocardiography and right and left heart catheterisation, CXR, CT scanning, MRI and Nuclear Medicine. The proposal would be to initially see 1 patient per week (w/c 11th May 2020), increasing 2 patients when capacity allows (ideally by 1st June 2020). Directorate management will need to ensure investigation capacity and transplant assessment coordinator availability prior to inviting the first patient to come for assessment. Consideration will need to be given to obtaining negative SARS-CoV-2 PCR on nose and throat swabs prior to the assessment, infection control issues during the series of investigations and the balance of risk for the advanced Lung failure patient coming to RPH in the current pandemic. Patients currently listed for primary and secondary transplant assessment as an outpatient will be reviewed by a transplant consultant to assess the need to move to a more urgent status.
 - b. Restart Primary assessment clinics for patients referred for Lung transplantation. This would commence in a highly selected fashion for patients who are clinically urgent. We would envisage only seeing 2-3 patients per clinic for the first month. This would commence from 18th May 2020
 - c. Restart face to face out-patient review of patients active on the Lung transplant waiting list. This would commence from 22nd May 2020.
 - d. Consider restarting routine out-patient review of Lung transplant patients (depending on shielding status) w/c 15th June 2020. This date is 12 weeks from the start of shielding in the UK. This would require national direction and return to business as usual in the availability of all out-patient investigation modalities. There may be an ongoing requirement for transplant consultants to contribute to the ICU COVID-19 emergency rota which would limit the ability to deliver business as usual. Consideration could be given to the possibility of outpatient review in non-COVID-19 clinical environment away from RPH provided appropriate investigation is available. Due to the limitation of outpatient rooms during the COVID-19 pandemic we will most likely need to continue with telephone assessment of selected patients (for example, those more than 5 years post Lung transplant who remain asymptomatic with satisfactory allograft function). A process to ensure that routine blood test can be performed needs to be established.

3. Risk Assessment for Lung Transplant Service

- a. Current risks of restarting service: Patients attending will be identified as being high risk for COVID-19 and would attend an identified COVID-free area in outpatients. Those with active symptoms identified by telephone pre-screening will have their appointment deferred until at least 2 weeks after recovery. Other risks include:
 - i. Medical and nursing workforce availability due to self-isolation/leave/ICU redeployment.
 - ii. Patient confidence to come to hospital environment (increase in DNA rates).
 - iii. Second COVID-19 wave and need to suspend services.
 - iv. Limitation of availability of investigations and catheter laboratory space.
 - v. Limitation of out-patient rooms due to isolation of shielding patients.
- b. Current risks of not restarting service:
 - i. Advanced Lung failure carries significant risk of mortality with transplantation giving the potential to increased length of life. If left untreated these patients will continue to be at high risk of mortality. Our own data shows there is a 20-30% waiting list mortality. Highlighting the pressing need to examine all options.
 - ii. Current patients awaiting transplant assessment are likely to breach RTT with an increasing backlog.
- c. What are the alternative treatments available to patients?
 - i. There are no real alternative treatments available for patients referred for consideration of Lung transplantation.
 - ii. The expertise to deliver care to advanced Lung failure patients and post-transplant follow-up is limited and we are one of the largest UK centre for Lung transplantation with a large cohort of patients under follow-up.
 - iii. Alternative COVID-free facilities could be formally explored.
- d. Actions identified to reduce risk to patients:
 - i. All appropriate procedures and safeguards will be followed, as for other shielding patient groups coming to outpatients.
 - ii. A COVID-free clinic area will be identified.
 - iii. Patients will be pre-screened by telephone for COVID-19 symptoms prior to attendance and their appointment deferred if needed.
 - iv. There will be appropriate distancing. Patient numbers will be kept low and appointments well-spaced, with the aim being for patients to go straight to consultation rooms, minimising waiting area usage according to Infection Control direction.
 - v. A letter detailing risks and benefits of attending out-patients will be sent to patients with the option to defer attendance.
- e. Which services/individuals have been consulted with in producing this information?

Clinical Decision Cell meeting, Transplant Clinical Lead, Lung Transplant consultant group, Surgery and Transplant Operations Manager (Amanda Miles), Ambulatory care leads (Carrie Symington, Angie Jackson).

- f. Conclusion: Based on an appraisal of the risks vs benefits using information currently available we feel it is appropriate to restart services as outlined above.

Signed

5th May 2020