

Kidney transplantation and patients who decline SARS-CoV-2 vaccination

Pan-London Transplant Collaborative Ethics Group

Refik Gökmen¹, Antonia Cronin^{1,2}, Wendy Brown³, Stephen Cass⁴, Abbas Ghazanfar⁴, Mohammad Ayaz Hossain⁵, Jenny Johnson³, Trish Longdon³, Sue Lyon¹, Adam McLean³, Reza Motallebzadeh⁵, Joyce Popoola⁴, Ayo Samuel³, Raj Thuraisingham⁶, Angela Wood³, Frank Dor^{3,7}

1. Guy's & St Thomas' NHS Foundation Trust; 2. King's College London; 3. Imperial College Healthcare NHS Trust; 4. St George's University Hospitals NHS Trust; 5. Royal Free London NHS Trust; 6. Barts Health NHS Trust; 7. Imperial College London.

1 March 2021

As the SARS-CoV-2 vaccines have started to be rolled out, one of the key ethical questions facing transplant units has been whether listing for transplantation should be contingent on potential transplant recipients having received the vaccine. This document aims to support transplant units in their approach to potential transplant candidates who are hesitant towards or decline vaccination.

Process

The joint NHSBT & BTS guidance on SARS-CoV-2 vaccination in adult solid organ and islet transplant wait-listed patients and adult living donor transplant recipients was published on 22 January 2021.¹ This document includes the following guidance concerning patients who decline vaccination:

Patients who are deemed clinically suitable for solid organ or islet transplantation but decline the offer of SARS-CoV-2 vaccination (full course or second dose) or have contraindications to vaccination should still be considered for transplantation. Clinical multi-disciplinary teams must have detailed discussion of risks versus benefits with the patient, document the discussions and the patient decision before activation or remaining active on the waiting list or proceeding to living donor transplantation.

The Pan London Transplant Collaborative (PLTC) resolved to try to provide more detailed guidance for transplant units for this group of patients, mindful that the issue raises a number of ethical concerns. The PLTC Ethics Group was established (comprised of clinicians (nephrologists, transplant surgeons, specialised nurse from all 5 adult London kidney transplant units with a special interest in clinical ethics, alongside lay members and patients), and met on 8 and 15 February 2021. The work of this group was also informed by separate discussions in meetings of the Guy's & St Thomas' Clinical Ethics Advisory Group on 29 January 2021 and the Imperial College Healthcare NHS Trust Clinical Ethics Committee on 10 February 2021.

1. Arguments for mandating vaccination in kidney patients prior to activation or reactivation on the deceased donor transplant waiting list:

1.1. Duty to protect patients: first do no harm

1.1.1. There is concern that the risks associated with kidney transplantation without prior vaccination against COVID-19 may be excessive. To date, PLTC data has shown that COVID-19 infections were more common in waitlisted patients, but COVID-19 associated mortality is higher in transplant recipients (relative risk HR 3.4); there is

¹ <https://nhsbtdbe.blob.core.windows.net/umbraco-assets-corp/21654/dat3911.pdf>

further concern that SARS-CoV-2 infection in the immediate post-transplant period is likely to bring significant additional risk of mortality. This risk can be compounded by other COVID-associated risk factors, including age, diabetes and obesity²³.

1.1.2. The desire to protect patients against excessive risks has underpinned the decision to defer reactivation on the deceased donor transplant waiting list for many patients during the pandemic in risk stratified groups, and therefore represents a consistency of approach.

1.2. Potential harm to others

1.2.1. It may be argued that admitting unvaccinated patients onto transplant wards may put other patients and staff at risk, and potentially affect the hospital as a whole. While clinicians will need to protect individual patients, they will also need to ensure the safety of others.

1.2.2. The idea that certain freedoms may be accessible only to those who have been vaccinated may become more familiar in coming months, as travel and other aspects of easing lockdown restrictions may become contingent on individuals having received the vaccine. However, many would see a clear difference between restricting access to overseas travel with restricting access to transplantation.

1.3. Inappropriate use of a scarce resource

1.3.1. The increased mortality risk of COVID-19 for transplant patients associated with not being vaccinated may lead us to consider unvaccinated patients not to be suitable recipients for the scarce resource of deceased donor kidneys. One of the central principles of transplantation ethics is to maximise the benefit derived from the scarce resource of donated organs; there is legitimate concern that kidneys may be expected to have better outcomes when transplanted into vaccinated recipients as compared with recipients who have declined vaccination.

1.3.2. In addition, a greater risk of graft loss may be expected if recipients are not able to receive optimal treatment for acute rejection as a consequence of having acquired SARS-CoV-2 infection.

1.3.3. Transplant recipients and other patient representatives are particularly keen to emphasise the responsibility that many recipients feel to ensure the best possible outcomes from organ donation.

1.3.4. Transplant programmes also need to be mindful of the damage which might be done to public perceptions of organ donation and the enterprise of transplantation as a whole due to allocation of organs to patients in whom less than optimal outcome may be expected.

1.4. Possible precedents

1.4.1. It is possible to argue that SARS-CoV-2 vaccination is an inseparable component of transplantation care. Just as patients who declare that they would decline immunosuppression after transplantation would not normally be considered suitable for transplantation, those who decline to protect themselves against SARS-CoV-2 in the

² Willicombe M et al. *Transplantation* 2021 Jan1; 105(1):151-157

³ Mamode N, et al. *Transplantation* 2021 Jan1; 105(1):212-215

context of the current pandemic may be considered as not consenting to standard transplantation care.

1.4.2. There are also precedents for predicating transplantation listing on aspects of patient choice or behaviour, such as mandating abstinence from alcohol for liver transplant listing. In this setting, the main argument relates to inferior transplant outcomes in recipients who continue to consume alcohol, which may have parallels with patients who decline vaccination. Once again, this relates to inappropriate use of the scarce resource of donated organs. As noted above in section 1.3.4 this may cause potential reputational harm to organ donation and transplantation.

2. Arguments against mandating vaccination

2.1. *Autonomy & human rights*

- 2.1.1. Mandating a particular treatment overrides the fundamental principle of autonomy. Healthcare professionals are well-accustomed to respecting patient decisions which may be associated with increased risk, and with which they themselves might disagree.
- 2.1.2. Public Health England and the UK Government have not yet issued specific guidance on consent to SARS-CoV-2 vaccination, and whether there may be any basis for mandated vaccination.
- 2.1.3. There are ways in which a decision not to have the SARS-CoV-2 vaccine may not be analogous to not consenting to post-transplantation immunosuppression or other essential parts of the transplant pathway. Most importantly, the risk of graft loss associated with not being vaccinated is not as high as would be expected if individuals decline immunosuppression.

2.2. *Equity of access*

- 2.2.1. It has become clear that vaccine hesitancy is common in particular patient groups. This includes but is not restricted to BAME populations, who already have reduced access to transplantation, and have been particularly impacted by the COVID-19 pandemic, especially in London. In this context, there is significant concern that mandating vaccination prior to transplant listing would cause more damage to trust in the medical profession, and further exacerbate health inequalities. Irrespective of any theoretical reasons for considering vaccination to be a valid prerequisite for transplant listing, this potentially harmful practical impact on equity of access and trust within disadvantaged communities has emerged as a key objection to any such approach.

2.3. *Practical uncertainties*

There may be number of potential practical difficulties and uncertainties associated with a policy of mandating vaccination, including:

- 2.3.1. Whether, and if so to what extent, can we protect each and every patient with the vaccine? To date the efficacy of the vaccines is still unknown in patients with advanced kidney disease, those on dialysis treatment, or those with functioning transplants.
- 2.3.2. To what extent will vaccination limit infectivity and transmission of the virus? It is likely to remain of the utmost importance to maintain measures to prevent infection, such as physical distancing and use of appropriate PPE.

- 2.3.3. Should those with evidence of natural immunity be exempted from being vaccinated?
- 2.3.4. If, as seems likely, the existing SARS-CoV-2 vaccines have limited efficacy against new virus variants of concern as they emerge, would vaccination still be mandated?
- 2.3.5. As community prevalence falls, would there be a point when vaccination will no longer be mandated?
- 2.3.6. Can those unable to receive the vaccine for medical reasons maintain access to transplantation?
- 2.3.7. If it has been determined that it may be in the best interests of a patient that lacks capacity to be listed for deceased or living donor transplantation, would that imply that vaccination should also be undertaken, in the potential recipient's best interests?

3. Living donor recipients

Many of the same arguments as stated above for deceased donor kidney transplantation would also apply to directed living donor transplantation, with the key exception of any consideration given to optimal utilisation of a scarce public resource. If a recipient declines the opportunity to be vaccinated prior to receiving a living donor kidney transplant, both recipient and donor will need to consider the increased risks to recipient and graft survival associated with this. The transplant team may feel that the transplant may proceed if donor and recipient have both given informed consent taking into account these additional risks. This is not uncommon in living donor kidney transplantation in patients with higher risk for poor transplant outcome.

4. Suggested approach

- 4.1. The concerns we have set out above have led many in the transplant community to conclude that a blanket policy of mandating vaccination prior to listing for deceased or living donor kidney transplantation would not be ethically desirable, would be unworkable, and may do more harm than good. It would go against the principle of autonomy and patient choice, and may deprive potential recipients of the benefits of transplantation. However, this must be reconciled with our duty to protect patients from harm and protect the greater good. Therefore in the interests of maximising the utility of donor organs, protecting our patients and hospital staff and maintaining trust in the transplantation programme as a whole, vaccination should be strongly encouraged
- 4.2. We suggest the following approach to vaccine hesitancy among potential kidney transplant recipients:
 - 4.2.1. Explore and understand the reasons behind any individual's vaccine hesitancy and address their concerns. The emphasis should be on encouragement rather than enforcement.
 - 4.2.2. Use peer educators or champions as advocates for the vaccine. There are now also valuable resources for encouraging uptake of vaccination, many of which are signposted on the Kidney Care UK website.⁴ Specific resources for BAME communities

⁴ <https://www.kidneycareuk.org/news-and-campaigns/coronavirus-advice/#vaccine>

include the Kidney Care UK webinar on vaccination in BAME communities, broadcast on 9 February 2021.⁵

- 4.2.3. Assess risks and benefits on an individual basis, moving away from the language of mandated treatments.
- 4.2.4. Discussions with patients who are hesitant about the vaccine should include consideration not only of the risks of not being vaccinated for themselves, but also the potential impact on others (other patients, hospital staff) and the greater good (reputational damage to organ donation and transplantation in case of poor transplant outcomes due to SARS-CoV-2 in non-vaccinated patients)
- 4.2.5. Given the importance of patient risk factors in determining individuals' SARS-CoV-2 - associated risk, it is unlikely that it will be possible to predetermine thresholds of community prevalence or reproduction rate which might prompt changes in vaccination policy applicable to all patients.
- 4.2.6. When making these risk assessments, it is unlikely that unvaccinated patients will be included in the first phase of cautious reopening of transplant programmes, when it will be important to ensure that risk is minimised as far as possible. However, conversations with patients should centre on an overall assessment of risk, and strong encouragement to take up opportunities for vaccination.

5. Summary recommendations

- 5.1. We suggest the following approach with individual transplant candidates who are hesitant about SARS-CoV-2 vaccination:
 - 5.1.1. Consider vaccination status as one component of clinical risk in transplant waitlisting, along with other evidence based clinical risk factors for poor outcomes in SARS-CoV-2 infected transplant patients including age, diabetes, obesity, and surgical and anaesthetic complexity. This will mean that there will be high-risk patients where it is deemed that listing would not be appropriate in the absence of vaccination, until community prevalence and transmission rates fall significantly. It is the duty of individual transplant units to review vaccination status and other clinical risk factors in all patients being considered for kidney transplantation.
 - 5.1.2. Given the rapidly evolving knowledge base regarding SARS-CoV-2 and vaccination efficacy in kidney and transplant patients, we suggest reviewing this guidance frequently and updating recommendations as needed.
 - 5.1.3. Transplant units should collect data on vaccination uptake, transplantation listing and outcomes for all patients who are listed, those that undergo transplantation, and those that remain off the transplant waiting list.

⁵ <https://www.kidneycareuk.org/news-and-campaigns/news/covid-19-and-vaccinations-supporting-the-bame-communities/>