Briefing document on COVID-19 vaccination in the renal community

Purpose:

To provide key messages about vaccination against COVID-19 for people with chronic kidney disease.

To identify the support required from professional and patient organisations to assist in the delivery of vaccinations in this group.

Vaccination against COVID-19 for people with chronic kidney disease, including people receiving dialysis treatment or with kidney transplants is likely to be highly beneficial. Any small risk associated with the vaccination is likely to be significantly outweighed by the potential benefits against COVID-19.

Whilst patients receiving dialysis or with kidney transplants were not included in clinical trials, given experience with other vaccinations, there is no evidence to suggest that any of the available vaccinations for COVID-19 would not be safe and protective in these group of patients.

So far results from approximately 44,000 patients who have participated in clinical trials of the Pfizer vaccine have been reported. 21,720 participants in this trial received the vaccine itself whilst 21,728 participants received the placebo. A two vaccine schedule achieved a 95% efficacy with consistency across age, gender and ethnicity in those aged 16 and over. Side effects over the follow up period were comparable to other well tolerated vaccines.

The New England Journal publication on the trial can be found here: https://www.nejm.org/doi/full/10.1056/NEJMoa2034577.

Data on the vaccine have been extensively reviewed by the Medicine and Health Products Regulatory Agency (MHRA) and the Joint Committee on Immunisation and Vaccination (JCVI) who recommended its use.

The MHRA has provided guidance on the small number of individuals who should not receive this vaccination: https://www.gov.uk/government/news/confirmation-of-guidance-to-vaccination-centres-on-managing-allergic-reactions-following-covid-19-vaccination-with-the-pfizer-biontech-vaccine

Safety and efficacy of vaccination for people with chronic kidney disease

The MHRA has approved the use of the Pfizer vaccine in all groups of patients with chronic kidney disease, including patients receiving dialysis or with kidney transplants, those in CKD stage 5, or those receiving immunosuppression for autoimmune disease. It is anticipated that those who receive a COVID-19 vaccine will develop antibodies against COVID-19 and be protected against COVID-19.

Studies are being rapidly designed to evaluate the immune response (antibody and T cell) to COVID-19 vaccination in people with kidney disease. This will help further guide the immunisation schedule for patients with kidney disease.

For patients with kidney disease receiving immunosuppression

- Patients receiving all types of immunosuppression can receive the vaccine.
- In kidney transplant patients vaccines are safe and are not thought to cause kidney transplant rejection (although this will continue to be monitored closely).
- Although vaccination may be less effective in generating an immune response in patients who are receiving immunosuppression compared to those not receiving immunosuppression, vaccination is still likely to be of benefit in this high risk group.

For further information please see

The Green Book chapter 14 a: key information for professionals on immunisation against COVID-19 https://www.gov.uk/government/publications/covid-19-the-green-book-chapter-14a

The Kidney Care UK Website which contains patient facing information:* https://www.kidneycareuk.org/news-and-campaigns/coronavirus-advice/#research

**This includes links to vaccine information in South Asian languages and other resources for diverse communities.*

The British Renal Society, the British Transplantation Society and the Renal Association together with our charity partners and the NHSE Renal Clinical Reference Group have convened a group to develop standards and operational guidelines to support the delivery of COVID-19 vaccination in renal units.

We will also be working with our scientific community to support efficacy studies and research on the effect of the vaccine in renal patients.

A library of resources generated will be made available which will be accessible through the society websites over the next few weeks.

Prioritisation for vaccination

- Many people living with kidney disease are at a significantly increased risk if they are infected with COVID- 19.
- The current national COVID -19 vaccination policy is largely based on age, with patients over 80 receiving the vaccine first.
- Four groups of kidney patients have been identified who may be especially vulnerable and are included in the government clinically extremely vulnerable (CEV) list. These groups comprise:

1. All patients receiving any form of dialysis; those receiving In-Centre Haemodialysis (ICHD) may be at highest risk

2. All patients who have a kidney transplant

3. All patients in CKD stage 5 non dialysis - GFR < 15 not yet receiving renal replacement therapy

4. All patients receiving strong immunosuppression for autoimmune kidney disease.

- The group that are felt to be most at risk from COVID-19 are patients receiving ICHD patients due to an increased risk of acquiring COVID-19, a higher risk of death from COVID-19 and potential difficulty accessing community vaccination due to dialysis schedules.

- Protecting ICHD patients from COVID -19-related critical illness will reduce the need to provide RRT for these patients in critical care units, sustaining wider critical care capacity during the pandemic.

- There is a strong case for people on the kidney transplant waiting list (which mainly comprise patients receiving dialysis and patients with CKD 5 in the advanced kidney care clinic) to have early vaccination. They have a higher risk from COVID-19 early post transplantation due to the high levels of immunosuppression therapy required.

- In patients with autoimmune disease of their native kidneys, there is also a case for offering vaccination where possible prior to them receiving immunosuppressive such as rituximab.

- On present prioritisation, people with chronic kidney disease/transplant in the CEV group will be vaccinated in group 4, at the same time as those aged 70-74yrs receive their vaccines in the general population.

- The professional societies have made a formal request to the Joint Committee for Vaccines and Immunisations, Chief Medical Officer, and Medical Director of NHSE that patients receiving ICHD are considered as group 1 equivalent for COVID-19 vaccination.

The renal professional societies and charities are working to increase the priority with which kidney patients will be vaccinated.

Lobbying to prioritise kidney patients to a higher group than group 4 in the vaccination schedule is taking place centrally through:

- A position statement: https://renal.org/health-professionals/covid-19/ra-resources/covid-19-vaccination-adult-patients-kidney-disease
- A letter to the Chief Medical Officer (CMO) and the JCVI committee
- Lobbying through charities such as Kidney Care UK, who have facilitated an article in the Health Services Journal: https://www.hsj.co.uk/exclusive-huge-covid-death-rate-among-vulnerable-patients-who-have-to-travel-to-hospital/7029118.article and in the Mail on Sunday and have lobbied multiple MPs with this campaign summary.
- The National Kidney Federation has also released a supportive press release statement: https://www.kidney.org.uk/press-release

Information not yet known

The trials did not specifically seek to enrol people with kidney disease, although approximately 250 patients with chronic kidney disease were included in the Pfizer trial cohort.

- We do not know exactly how long after the second vaccine optimum immunity is achieved, though early data suggests benefits may be rapid.

- We do not know how efficacious the vaccine is likely to be in dialysis or transplant patients or the optimum time after a transplant for the vaccines to be given.

- We do not know for how long post vaccination immunity is protected and therefore we do not know when further vaccination will be required.

Actions for renal units in preparation for vaccination of kidney patients

Consider appointing a renal COVID-19 vaccination leadership team e.g.

- A senior doctor
- Senior nurse/nurses
- Nurse educator
- Pharmacist
- A representative from each of the four modalities represented by the renal CEV groups
- Link to non- NHS provider units
- Psychosocial support
- Administrative and data collection support

This team should establish clear links to the main Trust COVID-19 vaccination team and local primary care teams

Trust prioritisation of kidney patients

Please ensure that:

1. Your Trust executive and vaccination operational teams are aware of the increased COVID-19 risk to kidney patients. Some Trusts are finding it difficult to use all opened vaccines and are discarding vaccines at the end of the day – please remind them that evening dialysis shifts may be a good use of 'spare' vaccines.
2. Please share the HSJ article as needed to explain the case for kidney patients.
3. Your Trust has a list of dialysis patients in age stratification and that these patients are included in cohorts of outpatients invited to receive the vaccine via any hospital hubs.

4. Ensure your Trust Clinically Extremely Vulnerable (CEV) lists are up to date so CEV kidney patients can be prioritised. Please add patients who have entered any of the categories since March/April 2020 when they were originally submitted. This should be done through your Trusts' COVID-19 digital lead and will ensure that at very least your CEV patients are all offered vaccination during group 4 roll out.

Staff identification and training

- Please complete the RA/BRS vaccine survey to ensure we have a national picture of ability to offer vaccines to renal patients via renal unit staff https://www.surveymonkey.co.uk/r/VSYQDSR
- Ensure your nurses' vaccination competencies are up to date and that teams are aware this may be a request
- Identify any additional staff who could be trained to administer the vaccine
- Please make your Trust central vaccination team aware if you are not able to provide vaccination programmes within your service

Vaccine allocation and transport

Please start to model the following in anticipation that the kidney patients will be reprioritised:

- Transport of vaccine to all relevant sites, including satellite HD units.
- Storage of vaccines at all relevant sites

Patient and staff communication and patient consent

- Offer **consistent messaging** to ensure all staff are aware of the key vaccination messages.

The Kidney Care UK website contains clear succinct information which is easily available: www.kidneycareuk.org/coronavirus

Direct patients to this resource.

KQuIP have also produced a short key messages document which can be found here: https://renal.org/kquip/covid-19-learning-hub-communications

- **It is very important that staff provide consistent clear messaging across the renal community**
- Give clear information to patients about COVID-19 vaccination, including to those for whom English is not a first language.
- Despite fears about COVID-19, anecdotal evidence suggests many patients remain concerned or reluctant to receive the COVID-19 vaccination
- If renal staff or patients are being vaccinated, please consider asking permission to photograph them to act as messaging models for others.
- Generate a standard letter to ensure that GPs are aware vaccination has taken place where given by the renal unit and are aware that renal specialists support vaccination for kidney patients. The BRS/BTS/RA COVID-19 vaccination working group will produce a template letter for GPs in the next few days.
- Ensure all renal clinic letters confirm that the COVID-19 vaccine is safe in renal patients who are both CEV and those not in the CEV group. This will help ensure that GPs do not hesitate to give the vaccine to renal patients due to lack of knowledge.

Vaccination prescribing and administration

A national Patient Group Direction is available: https://www.england.nhs.uk/coronavirus/publication/patient-group-direction-for-covid-19-mrna-vaccine-bnt162b2-pfizer-biontech/

Ensure you have up to date protocols and that staff have been able to access the national e-learning tools available: https://www.e-lfh.org.uk/programmes/covid-19-vaccination/

Vaccination recording

Please design your system to ensure accurate and timely recording of the vaccine administration.

Data collection

The UK Renal Registry (UKRR) will be developing two systems of data collection:

1. Via the units in real time which is likely to be faster
2. Via NHS digital data linkage search which will capture all patients regardless of the provider of the vaccine but will take longer to set up

The UKRR has already sent a letter to all clinical directors in England to ask for the collection of the following for every vaccinated patient:

- NHS number
- Date of birth
- Date of vaccination
- Type of vaccination
- Date of vaccination decline if the patient declined the vaccination

Patient vaccination information is required for ESKD patients under the substantive care of their renal centre:

- in-centre HD (ICHD)
- home HD (HHD)
- peritoneal dialysis (PD)
- transplant
- CKD 4/5
- dialysed AKI (dialysed in the renal centre)

The UKRR is collecting patient identifiers for the same group of patients as at the end of 2020, so that the denominator is known and vaccination rates can be calculated.

For sharing with your Trust Executive

Please share the HSJ article to ensure your Trusts are aware of the vulnerability of renal patients following infection with COVID-19.

https://www.hsj.co.uk/exclusive-huge-covid-death-rate-among-vulnerable-patients-who-have-to-travel-to-hospital/7029118.article