UK Kidney Association

Joint Committee for Vaccination and Immunisation (JCVI) announcement on a third COVID-19 vaccine dose for renal patients on immunosuppression

The JCVI has now advised a third COVID-19 vaccine dose (described as a third primary dose) for patients who are significantly immunocompromised and therefore may not have had a full immune response to the standard two vaccine course. They have also stated that the specialist involved should advise on whether the patient fulfils the eligibility criteria and on the timing of any third primary dose.

The rollout of the third primary vaccine dose is likely to begin in the week commencing 13th September.

The UK Kidney Association (UKKA) has reviewed the JCVI guideline and is recommending the use of a third primary COVID-19 vaccine in the following kidney patients:

1. **All kidney patients who have a transplant, including those who have returned to dialysis but still receive or have received immunosuppression in the last 6 months.**
2. **All patients on the transplant waiting list.**
3. **All patients on dialysis.**
4. **Patients who at the time of the original second vaccine programme were receiving significant immunosuppression – these patients are defined further below.**

The UKKA recommends that all kidney patients receiving a third primary vaccine dose should receive an mRNA vaccine as laboratory studies indicate these offer better protection in these kidney patients.

The JCVI has defined the following groups of renal patients as fulfilling criteria for a third COVID-19 vaccine dose:

1. All patients who have a functioning renal transplant.

2. All patients who have had a previous transplant but have returned to dialysis and are continuing to take immunosuppression or have taken immunosuppressive medication within the last 6 months.

3. **The UKKA also interprets this guidance to include those patients who are on the waiting list for renal transplantation and who therefore may subsequently undergo at any time a period of intense immunosuppression during which they would not mount an optimal response to a third vaccine dose. These patients should be prioritised for a third primary vaccine dose immediately**.

4. Patients receiving immunosuppression for autoimmune conditions of their native kidneys who at the time of the initial COVID 19 vaccination programme fulfilled the following criteria
    a. Were receiving or had received within the previous 6 months treatment with rituximab (or other similarly immunosuppressive biologics) or cyclophosphamide (or similarly immunosuppressive chemotherapy).
    b. Had received corticosteroids (> or = 20mg per day prednisolone for more than 10 days in the previous month).

c. Were receiving long-term moderate dose corticosteroids (equivalent to > or = 10 mg prednisolone for more than 4 weeks in the previous 3 months).
d. Had received non-biological immunosuppression (methotrexate >20 mg /week, azathioprine > 3mg /kg /day, mycophenolate mofetil > 1g per day in previous 3 months.
e. At the clinicians' judgement, certain combination therapies at individual doses that are lower than the above including those on >or = to 7.5 mg prednisolone/day in combination with other immunosuppression therapies.
f. Had received high dose steroid equivalent to > or = to 40 mg per day for more than one week in the month prior to vaccination.

5. Patients who have an acquired immune deficiency with a functional lymphocyte disorder, which means those on dialysis. There is significant previous work highlighting that end-stage renal failure patients on dialysis are in a state of functional lymphocyte depletion and are therefore immunocompromised to an equivalent level to those receiving immunosuppressive therapy. **Extensive recent laboratory data** has shown that patients on dialysis mount a suboptimal response to the standard two-dose vaccine course.

   UKKA therefore interprets this guidance and the supporting evidence to include all patients receiving long-term renal replacement therapy by dialysis treatment and therefore recommends that these patients are offered a third COVID-19 vaccine dose as part of their primary vaccination programme.

The scientific basis for the third primary dose has been previously summarised here.

NHSE has stated that if the individual is receiving care within a hospital that operates as a hospital hub and there is an available vaccine supply, they recommend the individual receives the vaccine on-site in line with the consultant's recommendation on timing.

NHSE recommends that if it is not possible to offer the individual a vaccine on site, consultants should write with advice to the individual's GP specifying the optimal timing and any interaction with their current treatment (a template letter can be found below).

UKKA recommends that each renal unit works to support the delivery of a third vaccine dose. The following principles should be considered:

- Although central lists exist for the identification of all functioning solid organ transplant recipients, we advise that renal units write to kidney transplant recipients to ensure that they are aware that a third vaccine dose is advised. This letter should be copied to the general practitioner to ensure prompt identification for those patients who will be vaccinated through their general practice.
- Renal units will need to identify any patients who have previously had a functioning transplant but have returned to dialysis and are continuing to receive immunosuppression and any patients who have returned to dialysis from a failed transplant in the previous six months irrespective of whether or not they are receiving immunosuppression.
- Renal units will need to identify patients who are active or will soon be active on the kidney transplant waiting list.
- Renal units will need to identify any patients who are receiving dialysis.

- Renal units will need to identify patients who are receiving immunosuppression for autoimmune disease who fulfil the listed criteria. Pragmatically, units may feel it sensible to use autoimmune CEV lists generated during the early stages of the pandemic together with updated lists for patients who have started relevant immunosuppression since the beginning of the pandemic (hospital pharmacies usually hold records of all rituximab and cyclophosphamide infusions given and therefore may be useful in rapid identification of these patients).
- The JCVI has recommended the use of an mRNA vaccine (Moderna and Pfizer) whenever possible. In kidney patients, the AstraZeneca vaccine should only be used where there would be a significant delay, or there is a clear medical indication. Patients should be vaccinated with a third primary dose after a gap of at least eight weeks after the second standard COVID-19 vaccine dose.

Timing of forthcoming rituximab and cyclophosphamide doses

For patients who need urgent cyclophosphamide or rituximab as treatment, their treatment should not be delayed whilst the third primary dose is given.

However, for those in whom the timing is more flexible, we recommend patients are given the third primary COVID-19 vaccine dose prior to their next rituximab or cyclophosphamide dose.

e.g. in patients receiving regular rituximab infusions for remission maintenance in AAV – give vaccine approximately 4 weeks prior to next scheduled rituximab infusion (‘at the nadir of immunosuppression’).

e.g. in some lupus patients where escalation to a Eurolupus-type regimen is planned but not urgent – give vaccine immediately and commence treatment after 4 weeks.

Template letters

We have included template letters alongside this document, based on those issued by NHSE for corresponding with the patient, and recommend that you adapt this to your local requirements.