March 2021

Dear kidney patient,

I am writing to you with regard to the news on vaccinations for Covid-19 and antibodies.

There has been very encouraging news about several new vaccines and the UK's medicines regulator (the MHRA) issued the first approval for a Covid-19 vaccine on 2nd December. This is the vaccine developed by Pfizer. There are now three vaccines approved for use in the UK. The Oxford vaccine was approved for use in the UK on 30th of December, while the Moderna vaccine was approved on the 7th of January.

Vaccinations commenced on 8th December with older people in care homes and health and social care staff receiving the vaccine. This has since been extended to include prioritised vaccination for all patients over 70 and those who are clinically extremely vulnerable (CEV).

We realise that people with kidney disease will have many questions about how well vaccinations will work for them, their safety, and how they will be rolled out.

Key points:

- Patients with significant kidney disease such as those on dialysis programs, those with kidney transplants and those in the advanced kidney care clinic (also called the low clearance clinic) are at high risk of becoming very sick if they contract Covid-19.
- It is your choice whether you have the vaccine but your kidney team would strongly recommend that you do have the vaccine as this will protect the large majority. The risks of becoming very sick with Covid-19 are far higher than an extremely small risk of major side effects from vaccination.
- All of the vaccines being rolled out are suitable for kidney patients over 16 years old (whether transplant, dialysis or other kidney conditions) and should be taken, based on advice from your kidney doctor or GP.

The vaccines will pass stringent safety tests before being approved. There is no evidence that the vaccines themselves could cause infection in patients who are on immunosuppressive drugs for a kidney transplant or some types of kidney disease.

There is no evidence that the vaccine would lead to rejection of a kidney transplant.

- People with kidney disease taking immunosuppressants may have a weaker response to the vaccines, but they are likely to work well enough to make it worthwhile having the vaccine, particularly as people taking immunosuppressants are at higher risk if they get Covid-19
- You will need two doses of the vaccine to achieve optimal early protection against Covid-19. These will be given up to 12 weeks apart.
- Even after you've had your vaccine, you will need to continue to take precautions, wash your hands, wear a mask, make space and keep social distancing.
- If you have any questions or concerns please speak to your kidney doctors, nurses or GP.







How effective are the vaccines?

What have the vaccine clinical trials found?

Clinical trial results published for the three vaccines show between 70-95% effectiveness. Ninety-five per cent efficacy means that, in the clinical trials, there were 95% fewer cases of Covid-19 in people who had the vaccine compared to the people who had the placebo (dummy treatment).

Please note that the vaccines are not licensed for use in those under the age of 16 years old.

Does age affect how well the vaccines work?

It doesn't appear so: older people's immune systems have just as good a response as a younger person to the vaccine.

Was there any difference in outcomes for people from Black, Asian and Minority Ethnic Groups?

No differences in outcomes have been found in Black, Asian and Minority Ethnic groups. There have not yet been any studies of particular subgroups.

How well do the vaccines work for kidney patients and those taking immunosuppressants?

We do not know how many people with kidney disease were included in the vaccine trials because trials generally include the wider population rather than people with specific health conditions.

As the vaccine is new, we will not have all the answers to how different people respond for some time.

It may be that people with kidney disease and people taking immunosuppressants do not respond quite as well. However, it is expected that the vaccines will work well enough make it worthwhile having the vaccine, especially when the high risk to kidney patients from Covid-19 is considered.

Studies are planned to assess the response of kidney patients to vaccination and to identify whether revaccination is required (as with flu vaccination).

Could 'herd immunity' help protect kidney patients?

Possibly. People with kidney disease may not have such a strong response to the vaccine as the general population. However, the key thing with all vaccines is not just an individual's response, but vaccination levels across the population. When large numbers of people in the community become immune through vaccination then the virus cannot spread. This is known as herd immunity and makes it safer for everyone.

What about the trial where people without functioning immune systems are given antibodies instead of a vaccine? Could this be the best thing for people with kidney transplants?

There is an ongoing trial of an antibody treatment for people with severely impaired immune systems who would not respond to the vaccine. These antibodies can be manufactured and given to people directly, although the protection may not last as long as a vaccine. Most people with kidney disease are likely to respond well enough to the vaccine so as not to need the antibody treatment.

Could the virus mutate, meaning that the vaccine no longer works?







As with seasonal flu, the virus may mutate and we might need a slightly different vaccine in future years.

The safety of Covid-19 vaccines

The vaccines will only be approved for use once they have passed stringent safety tests. As is always the case with new vaccines, we will learn more about the long-term safety of the vaccines through long-term clinical studies.

Should I be worried about how quickly the vaccines have been developed?

The speed of development might make people concerned, so it is important to say that corners have not been cut. Before they can be used, the vaccines must pass all the same safety tests and provide the same level of results to the regulator (the MHRA) as for any other vaccine. The <u>BBC</u> has a helpful explanation of the safety checks.

The usual process for vaccine development is relatively slow and it was recognised that things had to be done differently in response to this worldwide emergency. During the development of the Covid-19 vaccines, regulators and researchers have worked in parallel and avoided delays, but are doing all of the same safety checks as with any other vaccine.

Are the vaccines safe for kidney patients?

Are the Covid-19 vaccines live?

None of the Covid-19 vaccines currently in development are traditional "live" vaccines. The Oxford/Astra Zeneca vaccine uses an adenovirus, but its genes have been edited so it cannot replicate and cause infection.

Could the vaccines cause rejection of my transplant?

There is a theoretical concern with all vaccines that because they stimulate the immune system, they might damage transplanted kidneys or cause rejection. This has never been proven to happen with other vaccines, which all work by stimulating the immune system. The benefits of reducing the known risk of Covid-19 for kidney patients outweigh concerns about a theoretical risk and your kidney team recommends that you consider having a vaccination.

Safety and efficacy of the vaccine for people with specific kidney diseases

There is no reason to think there are particular risks for people with these conditions, but you are advised to speak to your doctor if you have any concerns.

Will the vaccines interact with any other medicines?

There is no evidence that the vaccines interact with other medicines. Your doctors will advise you if there is anything that you should be concerned about.







How will the vaccine be rolled out?

Which vaccine will be best for kidney patients?

There is no evidence that one vaccine is better than another for kidney patients or people on immunosuppressants. It would be best to take the first vaccine that is available in your area, to avoid any delays in protecting yourself. If any evidence emerges that suggests that one vaccine is better than another, then you should be offered that vaccine.

Will I be followed up after I have had the vaccine?

As with currently available vaccines, for example the seasonal flu vaccine, there will not be individual follow up. You should alert your doctor if you have any worries about changes in your health, as at any time.

Who will contact us when it is our turn to have the vaccine?

You will be contacted by your kidney team or your GP when it is your turn to have the vaccine.

Will families of kidney patients be able to have the vaccine at the same time?

The Joint Committee on Vaccination and Immunisation (JCVI) have said that there is not enough data yet about how the vaccine can reduce transmission, so the committee cannot recommend that families are vaccinated in order to provide indirect protection. Once enough evidence becomes available, the committee will consider different options for how to protect very vulnerable people by vaccinating their household members. The vaccines are currently not licensed for use in those under the age of 16 years old.

Will we need to take a booster for the Covid-19 vaccine?

The three current vaccines all require two doses (up to 12 weeks apart) initially. We will learn more about how long the vaccine protection lasts as times goes on.

What priority will be given to kidney patients when it comes to getting the vaccines?

The Joint Committee on Vaccination and Immunisation (JCVI) currently advises that people are given the vaccine in the following order:

- 1. Residents in a care home for older adults, and their carers
- 2. Everyone aged 80 and over, and frontline health and social care workers
- 3. Everyone aged 75 and over
- 4. Everyone aged 70 and over, and those who are clinically extremely vulnerable
- 5. Everyone aged 65 and over
- 6. People aged 16 to 64 with underlying health conditions which put them at higher risk of serious disease and death from Covid-19 (who are not in group 4)
- 7. Everyone aged 60 and over
- 8. Everyone aged 55 and over
- 9. Everyone aged 50 and over

What safety measures should I be taking once the vaccination programme is rolled out?

A gradual return to usual activities is probably best. Vaccinated people may still be infectious, so kidney patients should be very careful until they have had their vaccine.







Even after you have had your vaccine, continue to shield until advised it is safe not to.

What will the risk from Covid-19 be once the vaccine is rolled out?

Covid-19 will continue to be present but it will not be something to be scared of because it will not be circulating in communities as it is now, and your chances of picking it up will be very low. It will be another risk to manage by following the same infection control measures as with other diseases, such as washing hands regularly (for example, like the 'flu).

For more information see <u>www.kidneycareuk.org/coronavirus</u>





