

## **From the Dutch Federation of Nephrology and the Dutch Society of Kidney Patients**

**Based on current understanding, the Dutch Societies of nephrologists and kidney transplant physicians in consultation with the Dutch National Institute for Public Health and the Environment, think the benefits of vaccination with the current Pfizer and Moderna vaccines are much greater than the possible risk of adverse effects. Therefore, our advice to patients with kidney disease is:**

**Get the COVID-19 vaccination, but continue to follow the government rules to protect yourself as much as possible from infection with the coronavirus.**

**For patients with kidney disease, additional general advice on COVID-19 vaccination is:**

- **There are a only few rare exceptions to the general rule, when it may be wise to postpone vaccination in consultation with your attending physician. For example, patients who have recently received extensive treatment with immunosuppressive drugs.**
- **Get the vaccination also if you are pregnant AND you use immunosuppressive drugs, have received a kidney transplant, have end-stage renal failure or are on dialysis.**
- **Get the vaccination also if you have completely recovered from coronavirus infection.**
- **Do not come to the vaccination site if you are in quarantine for possible coronavirus infection or if you had a confirmed coronavirus infection less than 4 weeks ago.**
- **Report to your attending physician when your vaccination is scheduled and which vaccine will be used. If necessary, extra measures can be taken and/or extra check-ups can be planned. In doubt, always consult your attending physician.**
- **Never change your immunosuppressive medication by yourself without consulting your physician.**

### **Explanatory notes:**

- **Patients with a kidney disease for which they need to use immunosuppressive drugs, kidney transplant recipients, dialysis patients and patients with end-stage renal failure, are at higher risk of a serious course of a coronavirus infection (COVID-19) and should be protected as well as possible in this day and age with high risk of infection.**
- **As mRNA vaccines have proven high effectiveness in studied groups including elderly volunteers, the Dutch National Institute for Public Health and the Environment recommends to vaccinate patients with immunosuppressive drugs twice with an mRNA vaccine, according to the standard schedule. In the future, other vaccine types can be used, if they also turn out to be effective and safe.**
- **As there are insufficient data on the level of protection against the coronavirus after vaccination in patients using immunosuppressive drugs, it is imperative to keep the risk of infection as small as possible, even after vaccination.**
- **As recovery from a coronavirus infection during use of immunosuppressive drugs often takes more time, patients should be vaccinated only 4 weeks after a coronavirus infection.**

- Pregnant women are generally advised not to take the vaccination, but that opinion does not apply for women with health problems resulting in a higher risk of a serious course of COVID-19 (<https://www.nvog.nl/actueel/standpunt-vaccinatie-tegen-covid-19-random-zwangerschap-en-kraambed/>). The abovementioned group of pregnant women is therefore recommended to be vaccinated.
- In patients who recently received extensive immunosuppressive treatment because of their kidney transplantation or kidney disease, it could be wise to postpone vaccination to increase the chance of successful vaccination. This theoretical chance of a better efficacy of vaccination should be weighed against the risk of coronavirus infection with all the consequences that entails. The attending physician of patients who received such a treatment will usually have already informed them of this. In doubt, always consult your attending physician.
- Apart from general advice there can be other considerations of importance in individual patients, so in doubt, the attending physician should always be consulted to possibly deviate from this general advice.

**As new information becomes available, these recommendations will be updated as soon as possible and we will inform you via the website.**

**Questions about these recommendations can be sent to us via the website and will be addressed by experts as soon as possible.**

## **FAQs about Vaccination**

**Vaccination has started. Good news, of course. But it also raises many questions. These questions about the vaccines come in at hospitals, the website “nieren.nl”, the kidney patient society and the nephrology society.**

Here you will find some frequently asked questions with corresponding answers. This is general information. Please keep in mind that there is not much knowledge about corona vaccines at this moment. Also, some things in your personal situation may be slightly different. So ask your physician's advice, as well.

### **Is the vaccine safe for patients with kidney disease?**

If competent authorities have approved the vaccines, we already have a lot of information about the vaccines. We know the biological mechanism, safety data from animal research and the safety data from clinical studies with tens of thousands people. This shows that the vaccines currently on the market, are very safe. Adverse reactions such as fever, joint pain and local pain at the injection site have been reported, but all of these side effects disappeared spontaneously within a few days and they mean that your immune system has been put to work to build immunity. Furthermore, allergic reactions are rarely seen: in less than 1 in 100.000 persons.

To ensure safety even further, possible side effects will be continuously monitored in studies, also after administration of the vaccines, so we will be quickly informed about a possible side effect. Up to now, this has not happened.

Therefore, we advise you to participate in such studies and give the Municipal Health Administration permission to share your vaccination data with the Dutch National Institute for Public Health and the Environment. This way, we can increase safety even more. You attending physicians are continuously working together with the National Institute for Public Health and the Environment to monitor safety, specifically in patients with kidney disease.

### **Which vaccine is the most suitable?**

For patients with chronic kidney failure and patients on dialysis, there is no preference yet. Additional research data are needed. Therefore, it is recommended to accept the call to vaccination and to report to your attending physician in the hospital or on the dialysis ward when you were vaccinated and with which vaccine. In the RECOVAC study, we will analyse whether there are differences in efficacy between vaccines in kidney disease patients.

For kidney transplant recipients and other kidney disease patients who use immunosuppressive drugs, it is uncertain whether these drugs hamper the development of immunity (antibodies). The vaccines might be less effective in these patients. For these reasons we recommend you be vaccinated with the currently approved RNA vaccines (from Pfizer and Moderna). These have good efficacy in the studies, also in elderly who usually respond less, so the Dutch National Institute for Public Health and the Environment in consultation with the attending physicians recommends to vaccinate this group with an RNA vaccine, whilst awaiting studies on the other vaccines. As efficacy in kidney disease and kidney transplant patients is not yet known, the RECOVAC consortium will investigate this. From the results of this research we will also learn how to protect patients as much as possible on the long term.

### **Are the different vaccines tested in sufficient kidney disease patients to know how safe they are for this group of patients?**

In the clinical studies with tens of thousands of patients, there were few kidney disease patients. Based on current data and opinions, we think that the available vaccines are very safe for kidney disease patients because the side effects (e.g. local pain or an allergic reaction) will not be substantially different than in people included in the clinical studies. However, the vaccines might be less effective in kidney disease patients and might not provide protection quite as good or as long as in other people, because due to renal failure or use of immunosuppressive drugs the development of an immune response can be inhibited. As kidney disease and kidney transplant patients have not yet been studied, it is important that many kidney disease and kidney transplant patients participate in studies, so we can continuously monitor efficacy and safety.

### **What about living donors: would they be better vaccinated before or after donation? And could they possibly be given priority?**

Living kidney donors are not kidney disease patients, themselves. Kidney donors are healthy, otherwise they would not be allowed to donate their kidney. Therefore, they are not given special priority. However, they may be given priority because of their age (>60 years), profession (e.g. nursing home personnel), or other factors that apply for all Dutch citizens. It is recommended that living donors be vaccinated at the first opportunity. After vaccination, there is no need to wait for donation to be performed. A donor cannot donate when they have COVID-19 disease themselves. In that case you should wait for the donor to be cured.

## **Will the vaccine be sufficiently effective in kidney disease patients?**

See before mentioned

## **I heard that the vaccine may not protect that well in transplant patients. Should they not just get a third vaccination?**

At this moment, we know that the healthy volunteers who have participated in the pharmaceutical study were well protected against COVID-19 after 2 vaccinations. We do not know yet how long the protection lasts. Nothing is known yet about level and duration of protection in transplant patients. In the first place, it had to be investigated whether protection is quite as good and second, whether protection will last as long. When this has been investigated, adjustments could be proposed. It might be that a third vaccination is needed. However, then there will be the question whether the third vaccination should be after a month or half a year or a year. We hope to get an answer to that in the RECOVAC study by measuring antibodies and cellular immune response. At this moment the Dutch National Institute for Public Health and the Environment recommends also for kidney disease patients to follow the usual schedule of 2 vaccinations and not a third vaccination or higher dose. People who have participated in the pharmaceutical study will be followed for a long time to test long-term protection.

## **Are you immediately immune after vaccination or does it take a few days?**

With the current vaccines people need to be vaccinated twice. Thereafter, it takes approximately 2 weeks until someone is completely protected. This depends on the immune system of the vaccinated person. The healthy volunteers who participated in the pharmaceutical study are considered "protected" from 7 days after the second vaccination. However, regarding the data, it appears there already is some measure of protection from 10 days after the first vaccination. As it is still uncertain how well protected kidney disease patients and kidney transplant patients will be after vaccination, for the time being, it is necessary for these patients to continue to follow the advice of the government even after vaccination, to minimize corona virus infection risk as much as possible.

## **I have kidney failure and I am pregnant. Should I be vaccinated?**

Yes, pregnant women who have chronic kidney damage and/or are on dialysis are advised to be vaccinated. In general, pregnant women are advised not to be vaccinated because there is still limited experience with vaccination in pregnant women. However, that advice does not apply to women with health problems who thus are at increased risk to become severely ill from corona, in which case the unborn child could be in danger as well. Based on mechanism of action and experience with other vaccinations in pregnancy, experts expect that the corona vaccination will not pose a risk to the unborn child.

So: get vaccinated if you are pregnant and use immunosuppressive drugs, have a kidney transplant, have a severely compromised kidney function or are on dialysis.

## **When is it my turn to be vaccinated?**

Patients with chronic kidney damage, dialysis patients and kidney transplant patients 18-60 years of age will be vaccinated by the general practitioners, according to the Dutch National Institute for Public Health and the Environment schedule by February. Home residents older than 75 years and home residents with impaired mobility of 60-75 years old are scheduled for vaccination at the general practitioner's office, possibly at home, by March. Nursing home residents

and mentally challenged people living in an institution will be vaccinated by the institution's physician by January/February.

**Who is part of the group with a medical indication?**

Everyone who has a medical indication for influenza vaccination at the general practitioner's, will automatically qualify for corona vaccination. In any case, these are patients with chronic kidney damage, dialysis patients and patients living with a kidney transplant.

**Why does the group with a medical indication have an age limit of 60 years?**

The Ministry of Health, Welfare and Sport explains that people over 60 years of age already have a higher risk in case of corona infection, regardless of whether there is underlying disease. Therefore, it was chosen to let go of this distinction in this group and to vaccinate all people over 60 years of age.

**Where do I have to be vaccinated? At the general practitioner's, the nephrologist or the Municipal Health Administration?**

Patients with chronic kidney damage, dialysis patients and kidney transplant patients of 18-60 years at the general practitioner's. Home residents over 75 years of age and home residents with impaired mobility of 60-75 years old at the general practitioner's office, possibly at home. Nursing home residents and mentally challenged people living in an institution will be vaccinated by the institution's physician.

**I want another corona vaccine. What should I do? Can I refuse my call?**

At the moment we cannot advise on which vaccine is the best and whether there are differences in efficacy at all. Of course you can refuse your call. However, you should realize two things: 1) the other vaccine will possibly be available at a (much) later time, 2) in the mean time you are at increased risk of COVID-19 infection. Therefore, it is wise always to consult your nephrologist before you refuse the vaccination.

**Can my physician indirectly oblige me to be vaccinated?**

No, you cannot be obliged to be vaccinated. Everyone should make the decision themselves, but nephrology societies and transplant nephrologists urgently advise all patients to be vaccinated and an inquiry among internal medicine physicians shows that 97% of physicians want to be vaccinated themselves, which indicates that in the medical world there is great confidence in the corona vaccines.

**I have already had corona, is vaccination necessary?**

Yes, do get vaccinated even if you are completely cured of a coronavirus infection. There are people who had only minimal exposure to the real virus of who did not build a solid immune response (e.e. due to underlying disease) and so acquired only little immunity. They benefit from it in any case. In addition, to vaccines, as to all learning processes applies: repetition is better. It is important not to come to the vaccination site if you are in quarantine due to possible coronavirus infection or have had a confirmed coronavirus infection less than 4 weeks ago.

**I heard you can have fever as a vaccine side effect. Should I get tested for corona if I develop a fever shortly after vaccination?**

In the first few days after vaccination with an RNA vaccine, 10-20% of people develop fever and/or joint symptoms and if there are no other corona related symptoms (such as respiratory symptoms and loss of smell/taste) it is not necessary to get tested for corona. If more than 5 days after vaccination a fever develops or if there are other symptoms indicating COVID-19, then it is necessary to remain at home and to get tested for corona. After the first vaccination only a part of the people will be safe from corona infection and even after the second vaccination unfortunately not everyone will be safe.

**What should I do if I develop side effects?**

If you develop side effects, you can report this to the Pharmacovigilance Center. The center can thus monitor safety of drugs and vaccines. It is prudent to report side effects to your attending physician as well, at a regular outpatient clinic visit or dialysis session.

**What do the Dutch renal patients association and the Dutch kidney foundation do for patients?**

In close coordination with each other, the kidney foundation, the renal patients association and the professional community have urged priority in vaccination of kidney disease patients. For that purpose, letters were sent to the Ministry of Health, Welfare and Sport, the Dutch National Institute for Public Health and the Environment and the National Health Board.

Additionally, together with the professional community and the Dutch National Institute for Public Health and the Environment they try to answer questions of renal patients, such as which vaccine is most suitable for which patient and when and how will these be available.

Researchers of the RECOVAC consortium are preparing two studies in which vaccine efficacy and side effects, especially in kidney disease patients, will be documented, so we will be able to give more specific advice in the future.