NHS
Blood and Transplant
Copy No:

Effective date: 14/01/2021

#### FREQUENTLY ASKED QUESTIONS & ANSWERS

#### **VACCINATION AGAINST COVID-19**

ORGAN AND ISLET TRANSPLANT RECIPIENTS,
PATIENTS ON THE TRANSPLANT WAITING LIST AND
LIVING DONORS

### SECTION 1: PRIORITISATION AND EXCEPTIONS FOR VACCINATION Who is being offered a vaccine and when? The order of priority for vaccination is defined by the government, based upon criteria related to the risk of severe disease from COVID-19. The Joint Committee on Vaccination and Immunisation (JCVI) currently advises on the order in which people are vaccinated, as follows: 1. residents in a care home for older adults and their carers 2. all those 80 years of age and over and frontline health and social care workers 3. all those 75 years of age and over 4. all those 70 years of age and over and clinically extremely vulnerable 5. all those 65 years of age and over 6. all individuals aged 16 years to 64 years with underlying health conditions which put them at higher risk of serious disease and mortality 7. all those 60 years of age and over 8. all those 55 years of age and over 9. all those 50 years of age and over Latest guidance can be found under the 'vaccination' section at this link: https://www.gov.uk/coronavirus 1.2 I am an adult on the transplant waiting list or a transplant recipient, will I be prioritised to receive a vaccine? The criteria that determines order of vaccination is referenced in the question 1 above. Your medical condition puts you ahead of other groups, but there are other criteria used as well, such as age. JCVI advises that persons aged less than 70 years who are clinically extremely vulnerable should be offered vaccine alongside those aged 70 to 74 years of age. Separate advice is given for children under the age of 16 years and pregnant women (see also sections 1.3 & 1.5)

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## 1.3 Should children and young people on the transplant waiting list receive the vaccine?

Vaccine trials have only just begun in children and there is, therefore, very limited data on safety and immunogenicity in the under 16 age group.

Recommendations on vaccinating children with underlying conditions will be reviewed after the initial roll-out phase, as additional data on use of the vaccines in adults should allow a better assessment of risks and benefits. Individual assessment is advised in children under 16 years of age according to their risk of exposure and serious outcome.

Vaccination may be considered for children with serious neuro-disabilities who spend regular time in specialised residential care setting due to risk of severe COVID -19.

# 1.4 I live in a household with someone who is on the transplant waiting list or who is a transplant recipient. Will I be prioritised to receive the vaccine?

There is not enough data yet about whether the vaccine can reduce transmission of the virus, so the JCVI cannot recommend that families are vaccinated in order to provide indirect protection. In the meantime, it is important that everybody continues to take precautions to prevent transmission of the virus to vulnerable individuals.

#### 1.5 Are there any groups of people that should not receive the vaccines?

Contraindications to receive the Pfizer BioNTech, the Oxford University/ AstraZeneca or the Moderna vaccines are very limited. Close monitoring of vaccine safety is in place to identify any new issues.

The vaccine should not be given to

#### 1. Those who have had confirmed serious allergic reaction to

- a previous dose of the same COVID-19 vaccine
- any components of the COVID-19 vaccine

There is no evidence of any safety concerns from vaccinating individuals with a history of previous unexplained allergic reaction or severe allergic reaction to any other drug, vaccine or food item. This advice will be kept under review.

#### 2. Those who currently have proven COVID-19

If you have any symptoms of COVID-19, please do not attend for vaccination and discuss with your doctors when to reschedule your vaccination. It is usual practice, with any vaccine, to wait for recovery from an acute infection or illness. A minimum of 28 days is recommended.

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There is no evidence of any safety concerns from vaccinating individuals with a history of COVID-19 or with detectable antibodies.

#### 3. Pregnant women

There is insufficient evidence to recommend routine COVID-19 vaccination during pregnancy, but individual risk versus benefit assessment for vaccination is recommended for any pregnant woman designated as clinically extremely vulnerable.

#### For further information

- Government and JCVI advice https://www.gov.uk/coronavirus
- MHRA advice <a href="https://www.gov.uk/government/collections/mhra-quidance-on-coronavirus-covid-19#vaccines-and-vaccine-safety">https://www.gov.uk/government/collections/mhra-quidance-on-coronavirus-covid-19#vaccines-and-vaccine-safety</a>

If you have participated in a COVID-19 vaccine trial and you are called to receive a vaccine, you should seek advice from the trial coordinator. You will be provided with advice on whether you should be vaccinated through the routine programme.

#### **SECTION 2: SAFETY AND EFFICACY OF THE VACCINES**

#### 2.1 How safe are the vaccines?

All vaccines approved for use meet strict standards of safety, quality and effectiveness set out by the independent Medicines and Healthcare products Regulatory Agency (MHRA).

Any COVID-19 vaccine that is approved must go through the same clinical trials and safety checks that all other licensed medicines go through. The MHRA follows international standards of safety and any MHRA-approved vaccine is safe for use in organ and islet transplant recipients, people on the waiting list and living donors provided there is no other contra-indication.

Other vaccines that are being developed will only be available on the NHS once they have been thoroughly tested to make sure they are safe and effective. Millions of COVID-19 vaccines have been given since the start of the roll-out in the UK. Reports of serious side effects, such as allergic reactions, are very rare. The vaccines approved or currently being considered for approval cannot themselves cause infection as they do not contain live coronavirus.

As with any new medicine in the UK, COVID-19 vaccines will be closely monitored to allow quick identification of new safety concerns.

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

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No. The speed of development might make some people concerned, so it is important to say that no corners have been cut. Before they can be used, the vaccines must meet all the same very stringent criteria set by the regulator (the MHRA) as for all other medicines.

The usual process for vaccine development is very long 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 to avoid delays. Newer technologies, already being developed for other diseases, have enabled the more rapid development of COVID-19 vaccines.

#### 2.3 Do the Covid-19 vaccines contain live coronavirus?

None of the Pfizer/BioNTech, Oxford University/Astra Zeneca or Moderna vaccine contain live coronavirus so they cannot cause infection in the person vaccinated.

These vaccines are considered safe for organ transplant recipients and people on the transplant waiting list.

The AstraZeneca vaccine uses adenovirus, but this virus cannot cause infection in the person vaccinated.

#### 2.4 What are the side effects of the vaccines?

Most side effects of the COVID-19 vaccines are mild and should not last longer than a week, such as

- a sore arm where the needle went in
- · feeling tired
- a headache
- feeling achy
- low grade fever

#### 2.5 Will I be able to choose what vaccine I receive?

There are several COVID-19 vaccines being produced. However, there is currently no evidence that any one vaccine is better than another for anyone.

It is recommended that suitable recipients receive any of the approved vaccines when one is offered to them.

#### 2.6 How many doses of the vaccine will I need?

Currently approved vaccines are given as 2 doses, 3 to 12 weeks apart. It is very important that you follow up to date advice on the dosing, in order to

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	achieve the best response to the vaccines. New scientific evidence or new vaccines may become available, which may differ from what we are doing at the moment.
2.7	Why should I take 2 doses of the vaccine?
	Response to the vaccine can be seen from around 14 days after the first dose. The second dose will further improve this and make the response last longer.
2.8	Why are we being asked to wait longer for the second dose?
	This will allow as many people at higher risk of severe COVID-19 to benefit from the protection provided by the first dose of the vaccine, as quickly as possible.
	The vaccine roll-out is being changed in response to the fast spread of the infection, based on the available scientific evidence.
2.9	If I received the first dose of the vaccine and am waiting for the second to be administered, will I be able to have a transplant if it is offered to me?
	Yes. Response to the vaccine starts around two weeks after the first dose and a stronger, longer lasting response is expected after the second dose.
2.10	I am on the transplant waiting list. Will I need to be suspended from the transplant list for a period of time after receiving the vaccine?
	No, you will not need to be suspended from the waiting list. Response to the vaccine starts around 2 weeks after the first dose and improves significantly after the second dose.
2.11	If I receive the vaccine and then my transplant soon afterwards, will I need the vaccine again?
	We do not have enough evidence to answer this question at present. Your transplant team will look at your individual case.
2.12	If I have the vaccine, will I need to have COVID-19 screening undertaken if I am admitted to hospital for a transplant?
	Yes. The vaccine is primarily given to prevent severe COVID-19, so infection could still occur and result in no symptoms or very mild symptoms.

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	You are still advised to follow government advice at <a href="https://www.gov.uk/coronavirus">https://www.gov.uk/coronavirus</a> even after vaccination.
2.13	If I have recently received my transplant should I have the vaccine?
	Depending on the anti-rejection treatment you have received, you may be advised to wait for a period after the transplant, so that you develop a better response to the vaccine. This may be three months or more in some individuals. The transplant team will advise you.
2.14	Could the vaccines cause rejection of my transplanted organ?
	Many vaccines are routinely given to transplant recipients. Organ damage or rejection has never been proven to happen with use of any of the approved vaccines.
2.15	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. If concerned, always ask.
2.16	Should I tell my transplant centre once I receive the vaccine?
2.10	Should I tell my transplant centre once i receive the vaccine?
	Yes, please. Please provide the information on your vaccination card, which will show the name of the vaccine and the date you received it.
2.17	How effective are the vaccines?
	After having any of the vaccines most people will be protected against serious illness due to COVID-19 disease.
	It takes a few weeks after the first dose for the vaccine to work. It works even better after the second dose.
	There is some chance you might still get coronavirus infection even if you have the vaccine. There is not enough evidence now to show that the vaccine prevents you from infecting others if you have the virus. This means it is important to continue to protect yourself and others in line with government guidance:
	- face covering - physical distancing - handwashing

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These precautions must continue to be adhered to even after you are vaccinated. We need to allow time for as many people as possible to be vaccinated, for the number of infected people to decrease significantly, and details about level of protection in transplant recipients to become known. Clinical trial results published for the vaccines show between 70-95% effectiveness, that is for every 100 vaccinated individuals, 70 to 95 individuals were protected from becoming ill with COVID-19, which is very good when compared with other common vaccines such as influenza. Will the vaccine still be effective if the virus mutates? 2.18 Similar to seasonal flu, the coronavirus may mutate and we might need slightly different vaccines. This is monitored very carefully by public health authorities. Work is continuously being done to understand the impact that the changes that happen all the time in the virus may have on the efficacy of the vaccines. This is being tested and, if needed, vaccines can also be changed to improve responses to new variants. 2.19 Does age affect how well the vaccines work? It doesn't appear so. Older people have been shown to be equally protected from disease through vaccination when compared with younger people 2.20 Is there any difference in vaccine efficacy in people from Black, Asian, Mixed Race and Minority Ethnic Groups? No differences in outcomes have been found in Black, Asian, Mixed Race and Minority Ethnic groups but, there is currently limited evidence available from clinical trials, as the numbers enrolled were smaller. 2.21 How well do the vaccines work for organ and islet transplant recipients or people on the transplant waiting list? As the vaccines are new, we will not have all the answers to how people with different health conditions respond for some time. We do not know how organ or islet transplant recipients or those waiting for a transplant will respond to the vaccines but it is expected that vaccination will offer protection. There is no evidence that the vaccines themselves cause infection in patients following an organ or islet transplant.

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2.22	Could 'herd immunity' help protect organ and islet transplant recipients or people waiting for a transplant?
	Possibly. Organ and islet transplant recipients or people waiting for a transplant 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.
2.23	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 organ and islet 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. The protection only lasts for a few weeks and it is not yet known if there is protection. Most transplant recipients and people waiting for a transplant are likely to respond well enough to the vaccine so as not to need the antibody treatment.
	SECTION 3: LIVING DONORS
3.1	I am a previous living kidney or lobe of liver donor. Should I have the vaccine?
	Yes. Everyone who is invited to receive vaccination is encouraged to consider it.
3.2	I am a living donor currently under assessment or awaiting a date for surgery. If I'm vaccinated, how long do I need to wait before I can donate?
	Current advice is that you do not need to be vaccinated in order to be an organ donor. If you are vaccinated, the available vaccines do not carry a risk to the recipient, as they do not contain live coronavirus. It is important you continue to apply strict precautions as per government advice, to minimise the chances of catching the virus.