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	
1.1	**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) 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. At the outset, JCVI advised that persons aged less than 70 years who are clinically extremely vulnerable were offered vaccine alongside those aged 70 to 74 years of age. They also recommend that adult patients who are about to receive planned immunosuppressive therapy (i.e. waiting for a transplant) should, where possible, be considered for vaccination prior to starting such treatment.

	Separate advice is given for children under the age of 16 years and pregnant and breast-feeding women (see also sections 1.3 & 1.5)
1.3	**Should children and young people on the transplant waiting list receive the vaccine?**
	Young people aged 16 and over will be invited for vaccination as noted above. Some will receive an invitation prior to their 16th birthday to help with the booking process. Vaccine trials in children and young people under the age of 16 have begun but there is very limited data on safety and efficacy 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?**
	On 31st March 2021, the JCVI recommended adult household contacts of severely immunosuppressed patients (like organ transplant recipients) should be offered COVID-19 vaccination alongside priority group 6. If you are in this category, your GP is likely to contact you to make arrangements for vaccination. It is still 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 <u>not</u> 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 and emerging evidence will be incorporated into this Q&A) 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. There is no evidence of any safety concerns from vaccinating individuals with a history of COVID-19 or with detectable antibodies.

Groups where the vaccine is not contra indicated but additional risk vs benefit discussion is recommended before proceeding to vaccination:

Pregnant and breast-feeding 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 https://www.gov.uk/government/collections/mhra-guidance-on-coronavirus-covid-19#vaccines-and-vaccine-safety
- Section 2 of this guidance

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.

	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. As with any new medicine in the UK, COVID-19 vaccines are closely monitored to allow quick identification of new safety concerns. The MHRA has recently announced that they are investigating a possible link between the Astra Zeneca vaccination and blood clots. Pending such investigation, the JCVI has recommended adults aged 18-30 years without underlying health conditions, who are yet to receive their first dose, should be offered either the Pfizer or Moderna vaccines. Adults in this age group can make an informed choice to receive the AstraZeneca vaccine to enable earlier protection. The likelihood of serious (potentially life-threatening) blood clots occurring is very rare (incidence currently believed to be in the order of 1 in 250,000 or 4 in one million). So far, this condition seems to be associated with low platelets, blood clotting in unusual places - including the brain, and unusual antibody formation. For specific questions about the AstraZeneca vaccine, please refer to sections 2.24-2.32
2.2	**Should I be worried about how quickly the vaccines have been developed?**
	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 resolve within 24 to 48 hours from vaccination: • 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. Specific considerations related to the AstraZeneca vaccine are detailed below (see sections 2.24-2.33). Of the other approved vaccines, there is currently no evidence that any one vaccine is better than another and it is recommended that suitable recipients receive any of these vaccines when one is offered to them.
2.6	**How many doses of the vaccine will I need?**
	Currently approved vaccines are routinely given as 2 doses, 3 to 12 weeks apart. For patients on the transplant waiting list, it is recommended that two doses of vaccine are given 21-28 days apart (depending upon vaccine type), before starting immunosuppression therapy. Where this is not possible, your clinical team will advise you on the best plan for you according to your individual circumstances. It is very important that you follow up to date advice on the dosing, in order to 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 has been adjusted in response to the rapid spread of the infection and more changes/adaptations may be needed as new scientific evidence becomes available.
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. To comply with hospital infection control requirements, if you are receiving a planned living donor transplant, you will need to self-isolate for two weeks after your last dose of vaccine before your admission to hospital for surgery.
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. You are still advised to follow government advice at https://www.gov.uk/coronavirus 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 not been proven to be scientifically associated 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?**
	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 start working. It works even better after the second dose. There is some chance you might still get coronavirus infection and infect others even if you have the vaccine. This means it is important to continue to protect yourself and others in line with government guidance: - face covering - physical distancing - handwashing 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.

	There is limited data available on the efficacy of vaccination in transplant recipients and people who are taking immunosuppressant medications. Research is on-going to assess this and there may be opportunities for transplant recipients to be involved in some of the larger trials. Some data suggest a weaker antibody response in transplanted individuals but, the vaccine works in many ways and plays an important role in preventing severe disease. Updates will be provided as data becomes available.
2.18	**Will the vaccine still be effective if the virus mutates?**
	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 does not 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. Everyone who is offered vaccination is encouraged to accept it to protect themselves and others. We recognise that some people may be hesitant about vaccination and they need to trust that it is the right decision for them. NHS organisations, patient organisations and professional societies work together to produce information for patients about vaccination that is factual, accurate and up to date. Some examples can be found at the following links: Kidney Care UK https://www.kidneycareuk.org/search/?query=vaccination National Kidney Federation https://www.kidney.org/coronavirus/vaccines-kidney-disease British Liver Trust https://britishlivertrust.org.uk/update-for-people-with-liver-disease-on-the-covid-19-vaccine/

	Renal Association https://renal.org/health-professionals/covid-19/covid-19-vaccination/vaccine-information British Transplantation Society https://bts.org.uk/information-resources/covid-19-information/ Public Health England https://coronavirusresources.phe.gov.uk/
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. Experience with vaccines that have been used for a long time show that, even with a weaker response, they still offer protection. (see section 2.17) 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. (see section 2.17) Vaccination before starting immunosuppressive therapy is recommended to offer the best chance of a good response to the vaccine. There is no evidence that the vaccines themselves cause infection in patients following an organ or islet transplant.
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?**
	Interim outcomes of trials (RECOVERY and REMAP-CAP) to assess the impact of antibody treatment for people with COVID-19 infection have shown no overall benefit for people in hospital care. Both trials are still analysing whether plasma could benefit some groups of patients, such as people with low natural antibody levels or for people with severely impaired immune systems who would not respond to the vaccine. Most transplant recipients and people waiting for a transplant are likely to respond well enough to the vaccine so as not to need this type of antibody treatment.

2.24	**My first dose of vaccine was AstraZeneca and I'm due my second dose soon. Should I receive it?**
	The JCVI guidance is clear that adults who have not experienced any trouble with blood clots following their first dose of AstraZeneca vaccine can safely receive the second dose of the same vaccine. To date, all reported cases of serious blood clots happened after receiving the first dose of vaccine. Thus far there have been no reports of adults being well after the first dose but experiencing blood clots after the second dose of vaccine. Therefore, you should receive your second dose of AstraZeneca vaccine on your scheduled date. The risk of death from COVID-19 is much higher than the risk of blood clots related to the AstraZeneca vaccine, particularly for kidney dialysis patients and recipients of organ and islet transplants.
2.25	**Have there been any clotting complications in the recipients of organ or islet transplants who have received the AstraZeneca vaccine?**
	Not to our knowledge but we are closely monitoring the situation.
2.26	**Can I have the Pfizer vaccine as my preferred first or second dose?**
	For first doses, the vaccine you are offered is in line with JCVI advice and will relate to your age. For people aged 30 years or over, any vaccine type is deemed safe for both first and second doses. For adults under 30 years of age, who are invited to receive their first dose of vaccine, the recommendation is to offer an alternative vaccine approved for use in the UK. For the first dose of vaccine, you will receive an invitation from your GP, who will offer you the vaccine that is right for you based on latest JCVI advice. It will not be possible to choose the vaccine type when you attend for your vaccination itself. For second doses of vaccine, the JCVI advice is that anyone, irrespective of age, who had a first dose of AstraZeneca vaccine and had no problems related to blood clots afterwards, can safely receive a second dose of AstraZeneca vaccine. Adults who experienced blood clots after the first dose of AstraZeneca vaccine should not have a second dose of the same vaccine type. They should receive an alternative vaccine type for the second dose. Your GP will ensure that you receive a second dose of vaccine that is right for you when the time comes for your scheduled appointment.

2.27	**I am a woman, aged between 20 to 50 years. Should I receive my second dose of AstraZeneca vaccine?**
	Always follow the latest Government guidance and advice from your GP (see 2.24 and 2.26)
2.28	**I have received one or two doses of AstraZeneca vaccine. Do I need to be tested for blood clots?**

	No. If your health is unchanged post vaccination, no tests are needed. If you experience any of the **following from around 4 days to four weeks after vaccination you should seek medical advice urgently** from your GP or nearest hospital
	• a new, severe headache which is not helped by usual painkillers or is getting worse
	• an unusual headache, which is worse when lying down or bending over and accompanied by
	  • blurred vision, nausea, and vomiting
	  • difficulty with your speech
	  • weakness, drowsiness, or seizures
	• shortness of breath, chest pain, leg swelling or persistent abdominal pain
	• new, unexplained pinprick bruising or bleeding (other than at the injection site)

2.29	**I received a dose of AstraZeneca vaccine a few weeks ago and developed headaches or bruising or bleeding (e.g. bleeding gums/nose bleeds/blood in urine or stools). What should I do?**
	If you are experiencing new symptoms (as above) after you have received a dose of vaccine, please contact your GP or nearest hospital or transplant team (if appropriate). They may arrange for you to have some specific blood tests to check that your blood clotting is normal.
2.30	**I developed blood clot (e.g. in my leg/arm/dialysis fistula) AFTER my first dose of AstraZeneca vaccine. Should I have my second dose?**
	The JCVI advises against a second dose of AstraZeneca vaccine in this situation. Your GP can arrange for you to receive the Pfizer or Moderna vaccine instead for your second dose (see 2.26). It is a good idea to discuss this with your GP when you are offered your second dose so that the right vaccine type is available for you when you attend for your vaccination.

2.31	**I have PREVIOUSLY suffered from blood clots in my leg/arm/elsewhere in my body? Should I receive my first dose of AstraZeneca vaccine?**
	The JCVI advices that it is safe to receive a first or second dose of AstraZeneca vaccine in this situation unless you are aged under 30 years and due your first vaccine dose. For adults aged under 30 years, irrespective of previous history or clotting disorders, the recommendation is to offer Pfizer or Moderna vaccines (see 2.26).
2.32	**I am currently taking blood thinning medication for another health reason. Should I receive the AstraZeneca vaccination?**
	In the absence of any other contra-indication (as above) it is safe for you to receive the AstraZeneca vaccination if you are taking blood thinning medications.
2.33	**My child is awaiting a transplant or is a transplant recipient. If offered vaccination, should they avoid the AstraZeneca vaccine?**
	Children & Young People under 16 years of age are only considered for vaccination in exceptional cases (see 1.3). Currently in the UK, the AstraZeneca vaccine is not licensed to be used in children and young people and clinical trials are in progress.
	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 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.