FREQUENTLY ASKED QUESTIONS & ANSWERS

VACCINATION AGAINST COVID-19

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

UPDATED INFORMATION WITH REGARDS TO INTIAL COVID - 19 VACCINATION DOSES AND BOOSTER COVID – 19 VACCINATIONS

SECT	SECTION 1: SAFETY AND EFFICACY OF VACCINES	
1.1	How many doses of the COVID - 19 vaccine will I need?	
	Vaccines currently approved for use in the UK are:	
	 Moderna vaccine Oxford/ Astra Zeneca vaccine Pfizer/ BioNTech vaccine 	
	 Janssen vaccine (not currently available) Novavax vaccine (not currently available) 	
	All of the available vaccines currently approved for use in the UK are suitable for people on the waiting – list for an organ or islet transplant or recipients.	
	Some people will only be offered certain vaccines https://www.nhs.uk/conditions/coronavirus-covid-19/coronavirus-vaccine/	
	The vaccines are the best way to protect people.	
	3 primary vaccination doses	
	The primary vaccinations are given as 3 doses for people on the waiting- list for an organ or islet transplant or recipients. 3 doses are given as opposed to 2 for the general population because preliminary results from UK studies of real world vaccine effectiveness (VE) in people who are immunosuppressed suggest only modest benefit in VE against symptomatic COVID – 19 after 2 doses (see link below). A third primary dose may help provide better protection.	
	Whitaker HJ, Tsang RSM, Byford R et al. Pfizer-BioNTech and Oxford AstraZeneca COVID- 19 vaccine effectiveness and immune response among individuals in clinical risk groups.	
	https://www.nhs.uk/conditions/coronavirus-covid-19/coronavirus-vaccination/coronavirus- vaccine-people-with-severely-weakened-immune-system/	
	https://www.who.int/news-room/feature-stories/detail/vaccine-efficacy-effectiveness-and- protection#:~:text=A%20vaccine's%20efficacy%20is%20measured,vaccine)%20developed% 20the%20same%20outcome.	

	Booster vaccination programme – Autumn/ Winter 2021
	A booster vaccination programme, aimed at maintaining protection against COVID – 19 through winter 2021/22 and further into 2022 was introduced in September 2021, setting the priority of booster vaccination for those in clinical risk groups including people on the waiting-list for an organ or islet transplant or recipients. Booster vaccination was timed at 6 months after completion of the 3rd dose of vaccines.
	Booster programme – Spring 2022
	Immunity derived from vaccinations declines over time and people in clinical risk groups including people on the waiting – list for an organ or islet transplant or recipients are likely to have received their most recent vaccine dose in September or October 2021.
	As people on the waiting – list for an organ or islet transplant or recipients are at much higher risk of severe COVID – 19 an extra dose is advised around 6 months after the last vaccine dose for individuals aged 12 years and over. This is a precautionary strategy to maintain high levels of immunity and is in line with other immunosuppressed groups
	Evidence suggests that primary vaccinations (2 or 3 doses) plus booster doses (when offered) are likely to offer better protection for everybody, including people who are at increased risk from COVID-19 because of underlying health issues and/or taking immunosuppression (e.g., anti-rejection medication).
1.2	If I received the first dose of the COVID – 19 vaccine and I am waiting for the second or third to be administered, will I be able to have an organ or islet transplant if there is a suitable offer for me ?
	Yes. Whilst in most circumstances the organ or islet transplant will not be delayed purely to complete vaccinations latest evidence suggests that a stronger, longer lasting response is expected after completion of a full course of vaccinations. So, if at all possible, you should aim to complete your vaccinations course before your transplant. If the course of vaccinations cannot be completed before the transplant, vaccinations will be resumed once you are more likely to respond better to the vaccines usually a few months after the transplant and varies from patient to patient (see section 1.5). You can discuss this with your doctor in more detail so that you understand the benefits for you.
1.3	I am on the transplant waiting list. Will I need to be suspended from the transplant list for a period of time after receiving a COVID - 19 vaccine?
	No, you will not need to be suspended from the waiting list.
1.4	If I have the COVID – 19 vaccines, will I need to have COVID-19 screening undertaken if I am admitted to hospital for a transplant?
	Yes. The vaccines are given primarily to prevent severe COVID-19, so infection could still occur, even without symptoms. If the COVID - 19 screening test is positive, your team will assess the situation carefully and discuss the options with you. It may or not be possible to proceed to transplant.

	To comply with hospital infection control requirements, if you are receiving a planned living donor transplant, you may need to self-isolate before your admission to hospital for surgery.
	You are still advised to follow advice at <u>https://www.gov.uk/coronavirus</u> and take all precautions to protect yourself from infection, even after vaccination (see section 1.10).
1.5	If I have recently received my transplant should I have a COVID - 19 vaccine?
	Depending on the anti-rejection treatment you have received, you are advised to wait for a period after the transplant, so that you develop a better response to a vaccine. This may be between one to three months or more, depending on your specific clinical circumstances. None of the currently used vaccines in the UK are contra-indicated for persons on immunosuppression. The transplant team will advise you.
1.6	Could the COVID – 19 vaccines cause rejection of my transplanted organ?
	Many vaccines are routinely given to transplant recipients. There is no evidence to show that organ damage or rejection is associated with use of any of the approved vaccines.
1.7	Do the Covid-19 vaccines contain live coronavirus?
	None of the currently approved vaccines used in the UK contains live virus so they cannot cause infection in the person vaccinated. There is no evidence that the vaccines themselves cause infection in patients following an organ or islet transplant.
1.8	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.
1.9	Should I tell my transplant centre once I receive a COVID - 19 vaccine?
	Yes. Please provide the information on your vaccination card, which will show the name of the vaccine and the date you received it.
1.10	How effective are the COVID – 19 vaccines and how well do they work for people who are organ and islet transplant recipients or people on the transplant waiting list?
	The main aim from vaccinations is to reduce risk of severe infection or death due to COVID- 19. After having any of the vaccines most people with a normal immune system will be protected against serious illness due to COVID-19 disease. Clinical trial results published for the vaccines show between 70-95% effectiveness in healthy volunteers- that is for every 100 vaccinated 'healthy' individuals, 70 to 95 'healthy' individuals were protected from becoming ill

 Research is ongoing to assess the efficacy of vaccinations in clinically vulnerable people, including people on the waiting – list for an organ or islet transplant or recipients. A recent in-depth analysis performed by NHS Blood and Transplant combining data from the UK Health Security Agency (UKHSA), which identifies patients testing positive for COVID-19, the National Immunisation Registry and NHS Blood and Transplant (NHSBT) Transplant Registry has been published. The study compared transplant patients who had received two doses of AstraZeneca or Pfizer vaccine and showed that neither AstraZeneca nor Pfizer vaccine and showed that neither AstraZeneca and Pfizer vaccine and showed that neither AstraZeneca and Prizer vaccine is currently unexplained but studies on the impact of third doses and booster vaccines in transplant recipients who have tested positive for COVID-19, this study indicates that two doses of AstraZeneca vaccine are more effective in reducing the risk of dying from the disease compared to those who are unvaccinated. The difference between AstraZeneca and Prizer vaccine is currently unexplained but studies on the impact of third doses and booster vaccines in transplant patients will be available in 2022 and data collection is already in progress. People waiting for an organ or islet transplant could not be included in this study due to lack of available data. This analysis supports the following recommendations: Vaccination in organ transplant and islet recipients does not provide the same high level of protection against COVID-19 as for the general population In the absence of any other health contraindication, people who are recipients of an organ or islet transplant are strongly encouraged to accept the full course of vaccine in people who are recipients of an organ or islet transplant are strongly encouraged to accept the full course of vaccination (currently three doses of vaccine) and any subsequent		with COVID-19, which is very good when compared with other common vaccines such as influenza.
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		 Encouraging close contacts to be fully vaccinated and take up the offer of further vaccine/ booster doses as they are available. If symptoms suggestive of COVID-19 develop, get tested as soon as possible

	 If testing positive for SARS-CoV-2, making immediate contact with the transplant team for further advice COVID – 19 prevention is the best option but, if you catch the virus it is important to get diagnosed very quickly and to get tested even if you have minor symptoms or have simply been expected to compare who is infected.
	In addition to being vaccinated, new treatments for COVID-19 disease, such as neutralizing monoclonal antibodies and new anti-viral therapies are being made available all the time and they may be suitable for you if you become infected. If so, they work best if given early in the course of infection.
2.1	I am a previous living kidney or lobe of liver donor. Should I have the COVID - 19 vaccine?
	Yes. Everyone who is invited to receive is encouraged to consider it to protect themselves and others. (see appendix and archived FAQs).
2.2	I am a living donor currently under assessment or awaiting a date for surgery. If I'm COVID – 19 vaccinated, how long do I need to wait after I am vaccinated before I can donate?
	You do not need to be vaccinated to be a living organ donor but, vaccination is recommended to protect yourself and others, particularly if you live with someone who is clinically vulnerable (see sections 1.1 and 1.10). If you are vaccinated, your response is expected to be the same as for someone with a normal immune system/healthy volunteer as in the trials (see section 1.10 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 (see section 1.11) to minimise the chances of catching the virus, particularly in the weeks preceding the surgery. You will be screened before coming into hospital as an infection control measure but also for your own protection. Usually, a surgical procedure will not go ahead whilst you have an infection. Postponed or cancelled operations have an impact on you and your recipient. The clinical team will assess your situation and discuss the options with you.

APPENDIX: ARCHIVED SECTIONS/QUESTIONS

SECTION 1: PRIORITISATION AND EXCEPTIONS FOR VACCINATION (archived)		
1.1a	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. People who are eligible to receive vaccination include:	
	 All adults over 18 years of age Young people between 12 to 17 years of age Children and young people between 12-15 years of age if they are more vulnerable to infection and/or live with someone who is more vulnerable to infection (e.g., transplant recipients or people who are immunosuppressed) 	
	JCVI advises that for the 2021 booster vaccine programme individuals who received vaccination in Phase 1 of the vaccination programme (priority groups 1 to 9) should be offered a third dose booster vaccine. This includes:	
	 those living in residential care homes for older adults all adults aged 50 years or over frontline health and social care workers all those aged 16 to 49 years with underlying health conditions that put them at higher risk of severe COVID-19 (as set out in the green book), and adult carers adult household contacts (aged 16 or over) of immunosuppressed individuals 	
	Latest guidance can be found at this link: https://www.nhs.uk/conditions/coronavirus-covid-19/coronavirus-vaccination/	
1.2a	I am an adult on the transplant waiting list will I be prioritised to receive a vaccine?	
	The criteria for vaccination are referenced in section 1.1a above. Your medical condition initially put you ahead of other groups because you are classified as clinically extremely vulnerable, but other criteria were used as well, such as age.	
	The JCVI 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. This is strongly recommended for all transplant recipients and patients waiting for a transplant. (see sections 1.1 and 1.10 in main document for further details)	
	Separate advice is given for children under the age of 16 years and pregnant and breast- feeding women (see also sections 1.3a & 1.5a)	



1.3a	Should children and young people on the transplant waiting list receive the vaccine?
	Vaccination before transplantation is recommended for children and young people of 12 years and above provided that transplantation is not delayed if the vaccination cannot be given before.
	In addition, Individual assessment is advised in children under 16 years of age according to their risk of exposure and serious outcome from COVID-19.
1.4a	I live in a household with someone who is on the transplant waiting list or who is a transplant recipient. Should I be vaccinated too?
	The JCVI recommends household contacts of severely immunosuppressed patients (like organ transplant recipients) are offered vaccination (see section 1.1a).
	It is still important that everyone continues to take precautions to prevent transmission of the virus to vulnerable individuals, even when vaccinated.
1.5a	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 vaccine any components of the 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 current 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.
	Special considerations apply to the following groups of people, whether they are on the transplant waiting list or a transplant recipient or in the general population:
	1. Pregnant and breast-feeding women,

	According to their most recent advice, the JCVI recommends that you can have a vaccine if
	 Pregnant or think you might be
	Breastfeeding
	Trying for a baby
	Women in the later stages of pregnancy can become seriously ill due to COVID-19 but the vaccine cannot give you or your baby COVID-19. Pregnant women should be offered vaccines at the same time as people of the same age or risk group.
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	2. If you have participated in a 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.
	For further information
	Government advice:
	<u>https://www.gov.uk/coronavirus</u>
	nttps://www.gov.uk/government/publications/covid-19-vaccination-women-of- childbearing-age-currently-pregnant-planning-a-pregnancy-or-breastfeeding/covid- 19-vaccination-a-guide-for-women-of-childbearing-age-pregnant-planning-a- pregnancy-or-breastfeeding
	JCVI advice: Http://www.uk/www
	https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attach ment_data/file/1007737/Greenbook_chapter_14a_30.lulv2021.pdf
	 MHRA advice: https://www.gov.uk/government/collections/mhra-guidance-on-
	coronavirus-covid-19#vaccines-and-vaccine-safety
SECTION	ON 2: SAFETY AND EFFICACY OF THE VACCINES (archived)
2.1a	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 vaccine that is MHRA 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 vaccines have been administered since the start of the rollout in the UK. Reports of serious side effects, such as allergic reactions, are very rare.
	As with any new medicine in the UK, vaccines are closely monitored to allow quick identification of new safety concerns.
	A condition known as vaccine induced immune thrombocytopenia and thrombosis (VITT) has been described in a small number of people after they received a first dose of the Astra Zeneca vaccine. It is rare but can cause serious complications. In the UK, 405 cases of

	2021. The condition presents 5 to 28 days' post vaccination with low platelets, blood clotting in unusual places - including the brain, and unusual antibody formation.
	The JCVI has recommended adults aged 18-39 years without underlying health conditions, who are yet to receive their first dose, should be offered either the Pfizer or Moderna vaccines as an alternative to the AstraZeneca vaccine, provided this does not delay their vaccination.
	For specific questions about the AstraZeneca vaccine, please refer to sections 2.11a-2.18a Further information at: <u>https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_da</u> <u>ta/file/992072/PHE_COVID-19_AZ_vaccine_and_blood_clots_factsheet_8June21.pdf</u>
2.2a	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 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 vaccines.
2.3a	Do the COVID -19 vaccines contain live coronavirus?
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2.3a 2.4a	Do the COVID -19 vaccines contain live coronavirus? None of the approved vaccines contains 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 and Janssen vaccines use an adenovirus vector (carrier), but this cannot cause infection in the person vaccinated. What are the side effects of the vaccines?



2.5a	Will I be able to choose what vaccine I receive?
	There are several vaccines being produced. Specific considerations related to the AstraZeneca vaccine are detailed below (see sections 2.11a-2.18a). 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. Studies into how effective different vaccines are in transplant recipients and immunosuppressed patients by vaccine type are on-going.
2.6a	If I don't have a high level of antibodies against COVID-19 (SARS-CoV 2) after vaccination, does it mean I'm not protected?
	Measuring antibody levels can vary considerably depending on how they are measured and, on its own may not adequately reflect the amount of protection you have from the vaccine. Even though recent UK and international evidence has confirmed that immunosuppressed patients may not have levels of antibody that are as high as we expect to see in non-immunosuppressed patients, there are other forms of immunity after vaccination, such as T cells, and research is on-going to fully understand the relevance of lower antibody levels. As outlined in 2.16, recent analysis suggests that vaccination still offers the best protection from severe disease or death due to COVID-19 for transplant recipients and patients waiting for a transplant.
	The JCVI still recommend being vaccinated and observing social distancing and face coverings even after receiving the full course of the vaccine (see section 1.10 and 1.11)
2.7a	Will the vaccine still be effective if the virus mutates?
	Similar to seasonal flu, the coronavirus changes (mutates) naturally, 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 these changes in the virus may have on the efficacy of the vaccines and the response to them in different groups of people, including those who are immunosuppressed/with weakened immune systems. If needed, vaccines can be changed to improve responses to new variants and protection for those who are more vulnerable to infection.
2.8a	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



2.9a	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 on vaccine efficacy, 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 <u>https://www.kidneycareuk.org/search/?query=vaccination</u> National Kidney Federation <u>https://www.kidney.org/coronavirus/vaccines-kidney-disease</u> British Liver Trust <u>https://britishlivertrust.org.uk/update-for-people-with-liver-disease-on-the- covid-19-vaccine/</u> Renal Association <u>https://renal.org/health-professionals/covid-19/covid-19-</u>
	vaccination/vaccine-information British Transplantation Society <u>https://bts.org.uk/information-resources/covid-19-information/</u> Public Health England <u>https://coronavirusresources.phe.gov.uk/</u>
2.10a	Could 'herd immunity' help protect organ and islet transplant recipients or people waiting for a transplant?
	It is not clear if herd immunity is achievable and the JCVI is monitoring the situation. Due to the timeframes involved and the lack of 'longitudinal studies', it remains uncertain whether or not 'herd immunity' to SARS CoV2 infection can be achieved.
2.11a	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.
	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.
2.12a	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.



2.13a	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
2.14a	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 <u>following from around 4 days to four weeks after vaccination you should seek</u> <u>medical advice urgently</u> 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)
2.15a	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.
2.16a	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.
2.17a	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 advises that it is safe to receive a first or second dose of AstraZeneca vaccine in this situation unless you are aged under 40 years and due your first vaccine dose. For anyone aged under 40 years, irrespective of previous history or clotting disorders, the recommendation is to offer Pfizer or Moderna vaccines



2.18a	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.