**COVID-19 Vaccination Question and Answers: Health and Social Care Professionals**

**Q. Why has the dose schedule changed for the COVID-19 vaccines?**

A. The Joint Committee on Vaccination and Immunisation (JCVI), an independent clincial group of experts that provides all Governments in the UK with advice on vaccinations, recommended a maximum interval between the first and second doses of 12 weeks for both the Pfizer BioNTech and AstraZeneca COVID-19 vaccines. This is in recognition of the very high levels of protection offered from the first dose, and that the increased transmission rate of the new strain of coronovirus poses a significant risk of increased case numbers and subsequent deaths. **Simply put, their advice will reduce severe illness and hospitalisations and maximise the lives that can be saved whilst initially working with a limited supply of vaccine**. The JCVI advice is also supported by the four UK Nations’ Chief Medical Officers (CMOs) as explained in their [joint letter](https://www.gov.uk/government/publications/letter-to-the-profession-from-the-uk-chief-medical-officers-on-the-uk-covid-19-vaccination-programmes/letter-to-the-profession-from-the-uk-chief-medical-officers-regarding-the-uk-covid-19-vaccination-programmes). There are further details outlined in a letter from the CMO in Scotland which can be found on the [Scottish Government website](https://www.gov.scot/publications/coronavirus-covid-19---vaccine-letter-from-the-chief-medical-officer-updating-on-the-vaccination-programme---1-january-2021/) which also covers the timing of second doses, and in the [statement from JCVI](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/948338/jcvi-advice-on-priority-groups-for-covid-19-vaccination-30-dec-2020.pdf) on immunisation prioritisation.

**Q. What specifically did the JCVI recommend?**

**A.** In a statement released on the 31 December 2020, the JCVI advisedinitially prioritising delivery of the first vaccine dose as this is highly likely to have a greater public health impact in the short term and reduce the number of preventable deaths from COVID-19*.*  This reflects the need to reach as many people in the shortest possible timeframe, within the available vaccine supplies, against a background of increasing disease activity and high population susceptibility.

**Q. What is the evidence that underpins this recommendation?**

A. The JCVI advised that the short term vaccine efficacy from the first dose of the Pfizer-BioNTech vaccine is calculated at around 90% and the short term vaccine efficacy from the first dose of the AstraZeneca vaccine is calculated at around 70%, **but please note that these efficacy estimates are not directly comparable between the two vaccines because the clinical trials were not standardised** (there weredifferences in trial design and population size), but when looking at research outcomes such as hospitalisation both vaccines demonstrate similar levels of high efficacy and protection. **In other words, both vaccines provide very high levels of protection after the first dose.** Given the level of protection afforded by the first dose and current limited supply of the vaccines, models suggest that initially vaccinating a greater number of people with a single dose will prevent more deaths and hospitalisations than vaccinating a smaller number of people with two doses in the same timeframe. The JCVI also advised that the second dose is still important to provide longer lasting protection and is expected to be as or more effective when delivered at an interval of 12 weeks from the first dose. The JCVI statement can be found [here](https://www.cas.mhra.gov.uk/ViewandAcknowledgment/ViewAttachment.aspx?Attachment_id=103741).

**Q. I have seen a lower efficacy rate quoted for the Pfizer BioNTech vaccine; which should I believe?**

A. In the published phase III efficacy paper for the Pfizer BioNTech vaccine, the vaccine efficacy after dose one and before dose two was given as 52.4%. However, this figure includes COVID-19 infections occurring shortly after the first dose, when the majority of failures occurred, within an interval where the vaccine could not yet be expected to have its intended effect. When vaccine efficacy is measured from a point when vaccine and placebo arms begin to diverge, at a period of 15-21 days, the vaccine efficacy is shown as 89%. Analysis of AstraZeneca vaccine suggests vaccine efficacy after first dose is 73% at day 22, demonstrating similar high levels of vaccine efficacy.

**Q. Can the JCVI recommend something different to the pharmaceutical company’s recommendation?**

A. The JCVI has a world renowned reputation for being one of the best Health Technology Assessment national bodies for vaccination advice and a lot of countries worldwide generally follow the JCVI’s lead. The JCVI provides advice and recommendations on immunisations for the prevention of infections and/or disease following due consideration of the evidence on the burden of disease, on vaccine safety and efficacy and on the impact and cost effectiveness of immunisation strategies. It also considers and identifies factors for the successful and effective implementation of immunisation strategies, as well as identifying important knowledge gaps relating to immunisations or immunisation programmes where further research and/or surveillance should be considered. Over the years, the JCVI has, on more than one occasion, recommended a different approach to vaccination policy out with the manufacturers recommended schedule based on their own intelligence and the epidemiology of the disease. In these situations, vaccine manufacturers never endorse any schedules that are out with their licensing application/emergency authorisation. This would include for legal and litigation reasons as they often do not have any clinical trial data to support any alternative schedule. In this case, the JCVI recommendation for the COVID-19 vaccines seeks to maximise public health benefit, taking into account the epidemiology of the disease and vaccine supply.

**Q. What has the regulator said about these changes?**

A. The Medicines and Healthcare products Regulatory Agency (MHRA) has approved a change to the dosage recommendation following a thorough and independent review of the data, including by its assessors, an Expert Working Group and the Commission on Human Medicines (CHM). After consideration of the data the decision was made to change the recommended interval to a period of “at least 21 days”, allowing for a more extended dosage interval. This has been updated in the Healthcare Professional Information and this can be found [here](https://www.gov.uk/government/publications/regulatory-approval-of-pfizer-biontech-vaccine-for-covid-19/information-for-healthcare-professionals-on-pfizerbiontech-covid-19-vaccine)

**Q. What are the benefits of this change in approach?**

A. The most important practical benefit is that **anyone who has had their first vaccine dose and has just found out that their second vaccine due has been or will be rescheduled, has helped ensure that another health or social care professional or a more vulnerable person gets their first dose of vaccine sooner.** As we roll out the vaccine in Scotland, initially, there is a limited supply available and, as such, it is crucial we make the best use of what we do receive. From the start of December whenever anyone got a first vaccination, their second dose was put aside to give to them a month later. Now those 'second doses' can be used, in the meantime, to vaccinate more people for the first time - more people being vaccinated quickly is a good thing for overall public health protection. Everyone due a second dose is having or will have their appointment rescheduled – **no second doses have been cancelled**. The amendment to the dosing schedule means that we are able to protect a greater number of people more quickly than would otherwise be the case. Taking the approach recommended by the JCVI will therefore allow as many first doses as possible to be provided as quickly as possible, providing substantive levels of individual protection while reaching more of those most at risk. **This will prevent deaths and hospital admissions**.

**Q. How quickly will a first dose of the AstraZeneca vaccine provide me with protection?**

A. The protective effect of the vaccine is noted in people from day 22 after the first dose. Vaccines work by generating an immune response to a foreign antigen, in this case COVID proteins, leading to production of antibodies and memory T cells. The clinical trials for the AstraZeneca vaccine have shown that after the first dose there were detectable antibodies at 28 days – a Geometric Mean Titre (GMT) level of 7,000-8,000 compared to placebo. This is comparable to the figures found in people who have had COVID-19. There was a GMT of more than 20,000, 28 days after the second dose and the response went up the longer the interval between the vaccinations: a GMT of 22k at < 6 week interval; 24k at 6-8 weeks; 34k at 9-11 weeks; and a GMT of 63k when the interval is ≥ 12 weeks. This data is published in the MHRA’s [information for healthcare professionals](https://www.gov.uk/government/publications/regulatory-approval-of-covid-19-vaccine-astrazeneca/information-for-healthcare-professionals-on-covid-19-vaccine-astrazeneca) in a table in section 5. It is worth noting, however, that not everyone may achieve these levels of protection.

**Q. Is this also the case for the Pfizer BioNTech vaccine?**

A. The protective effect of the vaccine is noted in people between 15-21 days after the first dose. The longer dose interval data is only currently available for the AstraZeneca vaccine, and not the Pfizer BioNTech vaccine, but there isn't a good rationale for why the response would be any different. Longer dosing schedules lead to improved responses in other forms of vaccine too. For example, influenza and Ebola vaccinations generate better antibody responses when given at longer intervals, using a variety of vaccination mechanisms.

**Q. How can these changes be safe when the clincial trial didn’t test them?**

A. The MHRA and the JCVI looked in detail at all the evidence from the clinical trials undertaken by the pharmaceutical companies, including additional analyses of the data, and concluded that both vaccines offer very high levels of protection from the first dose and although there is slightly more protection offered with the second dose, the wider benefits of offering this to more people persuaded them to recommend this approach. This approach is safe and will protect more people. It it is therefore important, for those who are eligible, to get a vaccine.

**Q. Have vaccines been wasted as a result of this change?**

A. There have been no vaccines wasted as a result of the dosage schedule change. The Pfizer BioNTech vaccine is taken out of ultra-low temperature freezers before a vaccination clinic startsandhas a maximum possible shelf-life of up to 5 days when stored at 2-8 ºC. Given that all Health Boards had prior notice of the changes to the scheduling a few days in advance, they will not have taken vials out of the freezers and no doses will have been wasted. The Oxford vaccine is kept in normal 2-8 ºC fridge temperatures and can be taken out and used when needed.

**Q. When will I be invited for my second vaccination?**

A. Health Boards are responsible for scheduling vaccination appointments. Any appointments for second vaccinations which were scheduled after the 4January 2021 are currently being rescheduled. However, everyone will still receive their second dose, which is expected to be as, or more effective, when delivered at an interval of 12 weeks.

**Q. What happens if I** **miss the second dose?**

A. If a scheduled second vaccination has been missed then please contact the provider where this was scheduled to take place to rearrange as soon as possible. It is important that you return for your second vaccination as this will provide the maximum level of protection possible for a longer duration.

**Q. Will I receive the same vaccine for my second dose as I get for my first dose?**

A. Yes. You should receive the same vaccine for your first and second dose based on current advice from the MHRA and the JCVI. The Chief Medical Officer and Chief Pharmaceutical Officer do not support using different vaccines for first and second doses before research examining this has reported its conclusions.

**Q. Can I get COVID-19 from the vaccine?**

A. No, neither can give the recipient COVID-19. Both of the vaccines simply present SARS-CoV-2 proteins to the immune system. There is no live, replicating virus within either vaccine.

**Q. Will the vaccine protect us against new strains?**

A. The answer to this is, most likely, yes. The protein antigen in the vaccine is large (in terms of proteins, at least) - the mutations are in only small areas of this large protein. The immune system generates antibodies against lots of parts of the protein, not just the bits that have been mutated. The immune system, once primed with the vaccine, should continue to recognise SARS-CoV-2 proteins even after minor mutation.

**Q. When I received my first dose of the Pfizer BioNTech vaccine, I was told I would receive the second dose within 3 weeks/21 days;** **should I be concerned that the schedule has changed?**

A. No, there is no need for concern. The JCVI and four Nation CMO advice provides an explanation of these changes and the MHRA has approved a change to the dosage recommendation. Everyone will receive the full course (two doses) of the vaccine.

**Q. I am administering the vaccinations, am I authorised to follow these changes to the dosing schedule?**

A. Yes, from an NHS perspective, the MHRA, the JCVI and the four Chief Medical Officers have agreed this dosing schedule and as a result vaccinators have the authority to follow it.

**Q. Once I have had the vaccine will things return to normal?**

A. Not yet. You will need to keep doing the same as we have all been doing so well over the last 8 months – wear face coverings, avoid crowded places (particularly indoors), practise good hand hygiene and maintain social distancing. Sticking with these essential measures in the early stages of the vaccination programme is still important. People infected can be infectious before having symptoms, so don't assume you or anyone else doesn't have it. And we don’t yet have evidence that the vaccines prevent transmission of the SARS-CoV2 virus – just that they protect strongly against severe disease. The vaccine roll out has started, and is accelerating, helped by the new dosing schedule, but we have to stay the course until there's enough vaccination done. That will take some months, but it will happen.

**COVID Public Health Directorate**

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