COVID-19 Vaccination Briefing

Summary

Based on the recommendation from the Medicines and Healthcare products Regulatory Agency, the Government has now approved use of the Moderna and Oxford University/AstraZeneca vaccines in addition to its earlier approval for use of the Pfizer/BioNTech coronavirus vaccine. The Pfizer vaccine was made available across the UK, from 8th December and the Oxford/ AstraZeneca from 4th January. The first doses of the Moderna vaccine were administered in Wales and Scotland on 7th April and in England on 13th April; Northern Ireland is expected to follow suit in the coming weeks.

As of Saturday 17th April, 32.8 million people have received a first dose COVID-19 vaccination and 9.9 million have been given both doses of the vaccine. The progress made to date, aided by the imminent roll-out of the Moderna vaccine, means that the UK remains on course to ensure that everyone aged 50 and over will have been offered a first dose of the vaccine by the end of April and all adults by the end of July.

Estimates of the number of healthcare staff who have received at least one dose of a COVID vaccine vary, but according to NHS England data for March 2021, 93% of frontline NHS staff have been vaccinated, leaving up to 80,000 of staff who had still not taken up the offer. In Wales, 87% of healthcare workers had received a first vaccine dose. Almost 123,000 health and social care staff in Northern Ireland have been vaccinated, while the Scottish government have said that it has exceeded its target for vaccinating NHS staff[1].

As of 16th April, the Joint Committee on Vaccinations and Immunisations (JCVI) is advising that pregnant women should be offered COVID-19 vaccination, in line with their age and clinical risk group, but preferably either the Pfizer or Moderna vaccines.

The RCM has welcomed the updated advice from JCVI as this empowers pregnant women to make their own decisions about whether to receive the vaccine. We, along with the RCOG, are also calling for the national vaccination programme, GPs and maternity services to be supported to develop systems and procedures that support women who wish to have the vaccine to have it as easily as possible. Those providing counselling and information to women about the vaccine in pregnancy must have up to date accurate information and have enough time to talk through questions and concerns with women. In the meantime, our advice to pregnant women is that they should speak to their midwife or obstetrician if they have any questions or concerns.

For more information, please read the latest RCM advice for pregnant women and our professional briefing for midwives to support them in advising pregnant and breastfeeding women.

Following reports of some extremely rare adverse events of blood clots and low platelet counts, following vaccination with the first dose of the AstraZeneca vaccine, the Joint Committee on Vaccinations and Immunisations (JCVI) has updated its advice as follows:

[1] Covid-19: Vaccinated NHS staff numbers vary across England - BBC News

- The benefits of prompt vaccination with the AstraZeneca vaccine far outweigh the risk of adverse events for individuals 30 years of age and over and those who have underlying health conditions which put them at higher risk of severe COVID-19 disease.
- It is preferable for adults aged under 30 years without underlying health conditions to be offered an alternative COVID-19 vaccine, if available.
- People may make an informed choice to receive the AstraZeneca vaccine to receive earlier protection.
- Adults under 30 without underlying health conditions who were prioritised for vaccination during phase 1, because they were at an increased risk of exposure or to reduce the risk of passing the infection on to vulnerable individuals (which will include a significant number of health and care staff), should also be offered an alternative COVID-19 vaccine.
- All those who have received a first dose of the AstraZeneca vaccine should continue to be offered a second dose, irrespective of age. The second dose will be important for longer lasting protection against COVID-19.
- All individuals offered a COVID-19 vaccine should be fully informed about the benefits and risks of vaccination, including clear information on the extremely rare blood clot and low platelet count adverse events, how to monitor for symptoms and what action should be taken by individuals and health professionals in the event of such symptoms arising.

JCVI is finalising its advice on phase 2 of the vaccination programme and will publish further advice, particularly for healthy people under 30 years of age, in due course.

In other respects, the advice from the JCVI remains what it was prior to last week's statement on the AstraZeneca vaccine:

- Except for the advice for individuals under 30 without underlying health conditions to be offered an alternative to the AstraZeneca vaccine for their first dose (see above), JCVI has not expressed a preference between the vaccines in any specific population. Because there is as yet no evidence on the interchangeability of the COVID-19 vaccines, the advice remains that the second dose of the vaccine should be from the same manufacturer as the first dose.
- All the COVID-19 vaccines should be administered in two doses, a minimum of either 21 days (Pfizer) or 28 days (AstraZeneca, Moderna) apart. JCVI recommends that operationally, the second dose of all vaccines should be routinely scheduled between four and 12 weeks after the first dose on the grounds that "this will allow more people to benefit from the protection provided from the first dose during the roll out phase. Longer term protection will then be provided by the second dose". If an interval longer than the recommended interval is left between doses, the second dose should still be given.
- Frontline health and care workers remain a high priority for vaccination, and those workers who are at high risk of acquiring the infection, at high individual risk of developing serious disease or at risk of transmitting infection to multiple vulnerable persons or other staff in a healthcare environment, are considered of higher priority for vaccination than those at lower risk. JCVI recommend that this prioritisation should be taken into account during vaccine deployment.

The latest guidance for the roll-out of the vaccines is available from the following links:

- England - https://www.england.nhs.uk/coronavirus/publication/operational-guidance-vaccination-of-frontline-health-and-social-care-workers/
- Northern Ireland - Letters and urgent communications 2021 | Department of Health (health-ni.gov.uk)

- Scotland - https://www.nhsinform.scot/coronavirus
- Wales - Coronavirus (COVID-19) | Topic | GOV.WALES

RCM Advice

We strongly encourage all members to receive the COVID-19 vaccine, although members who are pregnant or planning to become pregnant soon may wish to seek advice before deciding to get vaccinated (see section below on pregnancy and breastfeeding).

Receiving the coronavirus vaccine is the most effective method of protecting you, your family and friends and the women and families that you care for. Frontline healthcare workers, particularly older staff, and those with underlying health conditions, are at higher risk of infection and of suffering serious, and sometimes long term, complications.

Accordingly, we absolutely condemn the propagation of misinformation and scare stories by anti-vaccination campaigners. Should you come across online anti-vaccination propaganda, we would recommend that you report this to the relevant social media platform and ask that it be taken down.

However, while we support the immunisation of midwives and MSWs, we recognise that some members may be reluctant to be vaccinated. The administration of the vaccine is not mandatory, and we therefore caution employers against applying undue pressure, coercion or formal measures on staff who refuse the vaccine.

If you have recently been given the flu vaccine, please note that the JCVI recommend a gap of seven days between receiving a flu vaccine and receiving the coronavirus vaccine.

Shielding in England and Wales ended on 1st April and in Northern Ireland on 11th April; in Scotland, shielding advice remains in place. If you are extremely clinically vulnerable, you are advised to only return to work when it is safe to do so, following the results of individual and workplace risk assessments. Please also refer to the latest RCM advice on health and safety and COVID-19.

In the meantime, if you have any concerns about receiving the vaccine that are related to your health, particularly if you have underlying conditions, then you should discuss these with your GP or your Occupational Health department. If you have any concerns about your safety at work, then please raise these with your RCM representative and/or your manager. You may also wish to refer to this information booklet from Public Health England, which is specifically aimed at healthcare workers.

Background and context[2]

In trials, the ***Pfizer/BioNTech*** COVID-19 vaccine demonstrated a two-dose efficacy of 95%, consistently across age, gender and ethnicity. The vaccine must be stored at -70˚C +/- 10˚ and has a shelf life of six months. Once thawed the vaccine may be stored for five days at 2-8˚C. The ***Oxford/AstraZeneca*** vaccine demonstrated overall efficacy of 70%. The vaccine should be stored at between +2 ˚C to +8 ˚C and has a shelf life of six months. The ***Moderna*** vaccine demonstrated overall efficacy of 94%; against severe COVID-19 efficacy was 100%. Vaccine vials should be stored frozen between -25 ˚C to -15 ˚C, with a shelf life of seven months at these temperatures. Once thawed, the

[2] The information in this and subsequent sections of this briefing have been derived from the latest guidance from PHE to support frontline workers in delivering the coronavirus vaccine - COVID-19 Greenbook chapter 14a (publishing.service.gov.uk)

vaccine may be stored refrigerated at 2 ˚C to 8 ˚C, protected from light, for up to 30 days if not punctured. The unopened vial is stable for 12 hours at 8 ˚C to 25 ˚C.

If the course is interrupted or delayed, it should be resumed using the same vaccine, but the first dose should not be repeated. Every effort should be made to determine which vaccine the individual received and to complete with the same vaccine. For individuals who started the schedule and who attend for vaccination at a site where the same vaccine is not available, or if the first product received is unknown, it is reasonable to offer a single dose of the locally available product. In these circumstances, as both the vaccines are based on the spike protein, it is likely that the second dose will help to boost the response to the first dose.

Booster doses of COVID-19 vaccine are not yet recommended because the need for, and timing of, boosters has not yet been determined.

It should not be routine to offer appointments to give the COVID-19 vaccine at the same time as other vaccines. Based on current information, scheduling should ideally be separated by an interval of at least seven days to avoid incorrect attribution of potential adverse events.

The JCVI recommendations on the immunisation programme are based on evidence from the UK that the risk of poorer outcomes from COVID-19 infection increases dramatically with age, both for healthy adults and those with underlying health conditions. Those over the age of 65 have by far the highest risk, and the risk increases with age. Residents in care homes for older adults have been disproportionately affected by the virus.

People who are defined as extremely clinically vulnerable are at high risk of severe illness from COVID-19. Pregnant women and children who are extremely clinically vulnerable should seek advice from their GP or specialist doctor about vaccination.

There is no evidence of safety concerns from vaccinating individuals with a history of COVID-19 infection, or with detectable COVID-19 antibody. However, vaccination should be deferred in those with confirmed infection, until confirmed recovery and at least four weeks after onset of symptoms or four weeks from the first PCR positive specimen in those who are asymptomatic.

There are very few individuals who cannot receive the vaccine, other than anyone who has had a confirmed anaphylactic reaction to a previous dose of a COVD-19 vaccine or to any components of the vaccine. Individuals with a history of anaphylaxis to food, an identified drug or vaccine, or an insect sting can receive any COVID-19 vaccine, if they are not known to be allergic to any component of the vaccine. The British Society for Allergy and Clinical Immunology has advised that individuals with a history of immediate onset-anaphylaxis to multiple classes of drugs or an unexplained anaphylaxis should not be vaccinated with the Pfizer/BioNTech vaccine. The Oxford/AstraZeneca vaccine can be used as an alternative.

Vaccinated individuals should be advised that the COVID-19 vaccine may cause a mild fever which usually resolves within 48 hours. This is a common, expected reaction and isolation is not required unless COVID-19 infection is suspected.

All adverse reaction occurring after vaccination should be reported to the Medicines and Healthcare products Regulatory Authority, via the Yellow Card Scheme, and documented in accordance with local procedures.

Pregnancy and breastfeeding

Although clinical trials on the use of COVID-19 vaccines during pregnancy are not advanced, the available data do not indicate any harm to pregnancy. Accordingly, JCVI now advise that women who are pregnant should be offered vaccination at the same time as non-pregnant women, based on their age and clinical risk group. JCVI also advise that Pfizer and Moderna are the preferred vaccines to offer to pregnant women, based on extensive post-marketing experience of these vaccines in the USA, with no safety signals so far.

Routine questioning about last menstrual period and/or pregnancy testing is not required before offering the vaccine. Women who are planning pregnancy or in the immediate postpartum can be vaccinated with a suitable product for their age and clinical risk group.

If a woman finds out she is pregnant after she has started a course of vaccine, she may complete vaccination during pregnancy using the same vaccine product (unless contra-indicated). Alternatively, vaccine should be offered as soon as possible after pregnancy. Women who are inadvertently vaccinated in early pregnancy should be offered the second dose of the same product.

As there is no known risk associated with being given a non-live vaccine whilst breastfeeding, JCVI advise that breastfeeding women may be offered any suitable COVID-19 vaccine.