From the Chief Medical Officer
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FOR ACTION

Chief Executives HSC Trusts (*for onward cascade to Medical Directors)*
Chief Executives, Public Health Agency/Health and Social Care Board.
GP Medical Advisers, Health & Social Care Board
All General Practitioners and GP Locums *(for onward distribution to practice staff)*

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Dear Colleague

SUSPENSION OF THE 15 MINUTE WITH MRNA VACCINE FOR COVID 19

1. The four Chief Medical Officers of the UK and lead DCMOs for vaccines have considered whether, in the light of the very considerable need to speed up vaccination and boosting in the light of the omicron variant the 15 minute wait for some mRNA Covid-19 vaccines should be temporally suspended. **https://www.gov.uk/government/publications/suspension-of-the-15-minute-wait-for-vaccination-with-mrna-vaccine-for-covid-19-uk-cmos-opinion/suspension-of-the-15-minute-wait-for-vaccination-with-mrna-vaccine-for-covid-19-uk-cmos-opinion**

2. Their view, having considered the views of the COVID-19 Vaccine Benefit-Risk Expert Working Group (EWG), NHS planners and others is that with the low rates of anaphylaxis, in the context of the considerable need for people to be boosted or vaccinated, the 15 minute wait after a vaccination with mRNA vaccine will cause more harm than it can avert because it will significantly reduce the number of people who can be vaccinated over a short period of time. This position is also supported by the Medical and Healthcare Regulatory Agency (MHRA) and the Commission for Human Medicines (CHM)

3. The 15 minute wait should therefore be suspended for first, second and homologous or heterologous boost vaccinations with mRNA vaccine given the current situation. Similar positions have been adopted elsewhere in the UK in line with the needs in each of other nations. This change should take effect from 16th December. All individuals receiving their vaccine from this date should be provided with a leaflet advising them of allergic symptoms and what to do should

they experience these symptoms. Due to the speed of this change a printed leaflet is not yet available therefore vaccination sites should print the appropriate number of leaflets using the following link, until hard copies become available - https://www.publichealth.hscni.net/publications/waiting-after-your-covid-19-vaccination

4. The long term decisions on the 15 minute wait, when the current need for extreme speed of vaccination and boosting is over, will rest with the Commission on Human Medicines (CHM), the Medicines and Healthcare products Regulatory Agency (MHRA) and the Joint Committee on Vaccination and Immunisation (JCVI). This should be a temporary measure on the grounds of public health need to protect as many citizens as possible over a short period of time.

5. The 4 UK CMOs recognise that this will lead to a marginal increase in risk for a very small number of people, but substantially fewer than would be harmed by a slower vaccine rollout in the current public health emergency leading to some citizens not getting boosted or vaccinated prior to exposure to omicron. This includes a consideration that any prior vaccination and particularly boosting is likely to lessen the likelihood of severe disease arising from omicron variant infection.

6. In making this recommendation, the 4 UK CMOs would like to stress that very small number of people with a strong history of dangerous or unexplained allergic reactions (eg anaphylaxis) **should still have the 15 minute wait as at present**, and people should be told to come back or seek medical attention if they become unwell in the hours following vaccination. In addition, all children aged 12 to 17 years of age should also wait for 15 minutes post vaccination.

7. The background to this decision is set out in Annex A for information.

8. We would therefore urge all GPs, Community Pharmacies and Trust vaccination clinics to implement this decision with effect from 16 December.

Yours sincerely

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Chief Medical Officer

Linda Kelly
Acting Chief Nursing Officer

Mrs Cathy Harrison
Chief Pharmaceutical Officer

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This letter is available on the Department of Health website at https://www.health-ni.gov.uk/topics/professional-medical-and-environmental-health-advice/hssmd-letters-and-urgent-communications

ANNEX A

BACKGROUND TO THE DECISION TO SUSPEND THE 15 MINUTE WAIT FOR VACCINATION WITH MRNA VACCINE FOR COVID 19

The current threat and response.

1. Omicron is spreading extremely rapidly, with a doubling time of 2-3 days. If this is maintained it will spread extremely rapidly through the population. Even if less severe than delta, with the very high numbers involved modelling from several groups show this will cause substantial mortality, severe illness and pressure on the NHS. This constitutes a national health emergency.

2. Whilst some protection by any level of vaccination against severe disease is likely, data to date show that 2 doses of any available vaccine is not sufficient to prevent symptomatic disease.

3. There is therefore a need to boost as much of the population as possible before the peak of the Omicron wave, or provide first vaccination to those with no prior protection. It is likely that this will reduce significantly the number of people becoming ill, hospitalised and dying. Given the speed of the current wave this will need to be undertaken very rapidly.

4. The mRNA vaccines have shown better ability to boost and are therefore the basis for the current booster campaign. In the CovBoost study antibody reponses to mRNA vaccine boost were also much quicker than for other vaccine modalities (typically 7-10 days).

Basis of the 15 minute wait.

5. All currently deployed vaccines have proven safe with low rates of severe side effects. As with all vaccines occasional cases of anaphylaxis have been reported, and the rates are slightly higher (but still very low) in the case of nRNA vaccines from Pfizer/Biontech and Moderna but still overall very rare. For mRNA vaccines there have been 2 fatal Yellow Card reposts of anaphylaxis linked to primary course vaccination and no deaths from anaphylaxis linked to booster vaccination reported in the UK to date.

6. The extract is some of the key points from the COVID-19 Vaccine Risk Benefit Expert Working Group (EWG):

    a) Anaphylaxis following mRNA COVID-19 vaccination is a very rare but a potentially life-threatening event.

    b) The EWG has previously stated that occurrence of anaphylaxis, where the first two doses of the same vaccine have been previously administered with no allergic reaction, would be extremely unlikely and agreed that the 15 minute observation time can be waived for homologous boosters (where the booster is the same vaccine as the first two doses) where no allergic reaction occurred on the first two doses.

c) The overall reporting rate of anaphylaxis with booster doses (0.26 per 100,000) was below that of reporting for the first two doses, with Moderna (1.47 per 100,000) and Pfizer (1.23 per 100,000). There had been 28 reports of anaphylaxis events with Pfizer booster doses (12 on a homologous i.e. Pfizer boosters, after Pfizer first/second dose; and 16 on heterologous schedule (i.e. Pfizer booster after AZ or Moderna or where primary dose was unspecified first and second doses).

d) Five of the 28 anaphylaxis Pfizer reports met the case definition criteria for anaphylaxis; of which four were heterologous, the fifth case was homologous, but the patient had received concurrent flu vaccine which is a potential co-suspect in the case. There were 9 reports of anaphylaxis events with Moderna booster doses, all reports on a heterologous schedule.

e) Within the 15-minute waiting time **17 events** were reported and outside the 15-minute waiting time, **14 events** were reported, but within the same day. The exact timings were not always specified, for instance– several said'<1 day' or 'after a few minutes' or 'outside the vaccination centre'. **Six reports** indicated an onset time of 5 minutes or less from vaccination.

f) There were no fatal reports, however **18 of the reports** stated adrenaline was administered and **8 were hospitalised**. It was noted that several had pre-existing allergies to a variety of allergens.

g) The CMOs take these data as read. They demonstrate a real, but very rare, absolute risk 2 reports of fatalities. It is not clear whether the 15 minute wait contributed to the non-fatal outcomes. The 15 minute wait was observed in the reports with fatal outcomes.

The risks of the 15 minute wait in the current situation.

7. Initial analysis from NHSE for England, which is likely to be similar to other nations, implies that under the conditions of a system working at full capacity (as is needed now) the 15 minute wait reduces throughput by 23%. This leads to over 500,000 people not getting a vaccine in the initial period who would otherwise have done so.

8. Even allowing for the relatively crude initial calculations here, the absolute number of people put at risk because they cannot get vaccinated due to the 15 minute wait (in the high tens of thousands or higher) is much greater than the more precisely calculated number who get anaphylaxis.

9. Since the mortality rate for Covid-19 is non-trivial (although not yet calculated for Omicron) the probability of harm through delay is, in the view of the CMOs substantially in excess of the probability of benefit from maintaining 15 minute waits under the current situation.

10. The CHM has also agreed that the 15 minute observation period for primary course, third doses and booster doses of mRNA vaccines could be waived on a temporary basis during the emergency response to the Omicron variant. They will keep this under close review.