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Covid-19: First UK vaccine safety data are "reassuring," says regulator

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The UK's medicines regulator has described the first safety data related to covid-19 vaccines as "reassuring," with most side effects reported being mild and in line with those seen with other types of vaccine. "The benefits continue to far outweigh the risks," said June Raine, chief executive of the Medicines and Healthcare Products Regulatory Agency (MHRA).

The agency published yellow card data for covid-19 vaccines given between 9 December 2020 and 24 January 2021, which comprise 22 820 reports from 7 164 387 first doses and 474 156 second doses.[1] Most of the reports (16 756) are from people who received the Pfizer-BioNTech vaccine, and these list 49 472 suspected reactions. Administration of the AstraZeneca-Oxford vaccine began later, on 4 January, and 6014 yellow cards were reported up to 24 January, detailing 21 032 suspected reactions. A further 50 yellow card reports did not specify the brand of vaccine.

By 24 January an estimated 5.4 million first doses of the Pfizer-BioNTech vaccine and 1.5 million doses of the AstraZeneca-Oxford vaccine had been administered, and around 0.5 million second doses, mostly of the Pfizer-BioNTech vaccine. Overall, the data show around three yellow card reports per 1000 doses of the vaccine given—a smaller proportion than the 10% of patients reporting them in clinical trials.

"We don't expect everybody who gets a side effect to report on yellow cards," said Munir Pirmohamed, chairman of the expert working group of the Independent Commission on Human Medicines. "The number of yellow card reports we are receiving is very similar to what is seen with, for example, the flu vaccine, so this provides us with a great deal of reassurance."

Most reported side effects were mild; a sore arm was the most common, and others included headache, tiredness, and a mild flu-like illness.

Severe allergic reactions were reported after administration of the first doses of the Pfizer-BioNTech vaccine on 9 December. Subsequently the MHRA advised against its use for people with a history of severe allergic reactions to any ingredients in the vaccine and said that recipients should be monitored for at least 15 minutes.

A total of 101 anaphylaxis or anaphylactoid reactions after the Pfizer-BioNTech vaccination (1-2 cases per 100 000 doses) have been reported to the MHRA up to 24 January, and 13 anaphylaxis reactions after the AstraZeneca-Oxford vaccine.

Bell's palsy is listed as a possible side effect of the Pfizer-BioNTech vaccine, and facial paralysis or paresis after this vaccine was mentioned in 69 yellow card reports; facial paralysis was mentioned in six reports after the AstraZeneca-Oxford vaccine. Philip Bryan, vaccine safety lead at the MHRA, said, "Bell's palsy is something that can also happen naturally, so its association with the vaccine hasn't been established." The MHRA is investigating the association more thoroughly using the Clinical Practice Research Datalink—a database of anonymised GP records covering about 20% of the population.

The MHRA received 107 reports of death after the Pfizer-BioNTech vaccine, 34 after the AstraZeneca-Oxford vaccine, and 2 in which the brand of vaccine was unspecified. Most reports were for older people or people with underlying illness, the MHRA said, and a review of individual reports and patterns of reporting did not indicate that the vaccine played a role in the death. "We know, for instance, based on data from [the Office for National Statistics], that for every 100 000 doses given to people aged 80 or over, around 200 people die of natural causes within a week," Bryan said.

The UK was the first country in the world to approve and start administrating the Pfizer-BioNTech vaccine,[2] but it is certainly not the first in the world to report its adverse reaction data.[3] The MHRA has been criticised for its lack of transparency in not publishing the data or its risk management plan for monitoring the vaccines until almost two months after they began being given.[4 5] Raine said: "We're committed to transparency with the data, we'll be publishing our analysis weekly moving forward." But advice from the Commission on Human Medicines Expert Working Group to ministers regarding the vaccines and Expert Working Group's minutes remain unpublished.

Peter Roderick, principal research associate at the Population Health Sciences Institute at Newcastle University, said: "It's good to see these data coming out, with seemingly positive news for now. I'm pleased as well to hear that there will be weekly reporting." But he added: "MHRA still has some way to go before it can be regarded as a transparent regulator."

1 Medicines and Healthcare Products Regulatory Agency. Coronavirus (covid-19) vaccine adverse reactions. 2021. https://www.gov.uk/government/publications/coronavirus-covid-19-vaccine-adverse-reactions

2 Mahase E. Vaccinating the UK: how the covid vaccine was approved, and other questions answered. *BMJ* 2020;371:m4759. doi: 10.1136/bmj.m4759 pmid: 33298577

3 Torjesen I. Covid-19: Norway investigates 23 deaths in frail elderly patients after vaccination. *BMJ* 2021;372:n149. doi: 10.1136/bmj.n149 pmid: 33451975

4 Roderick P. Transparency in approving covid-19 vaccines. BMJ 2020. https://blogs.bmj.com/bmj/2020/12/17/peter-roderick-transparency-in-approving-covid-19-vaccines/

5 Medicines and Healthcare Products Regulatory Agency. Report of the Commission on Human Medicines Expert Working Group on covid-19 vaccine safety surveillance. 2021. https://www.gov.uk/government/publications/report-of-the-commission-on-human-medicines-expert-working-group-on-covid-19-vaccine-safety-surveillance/report-of-the-commission-on-human-medicines-expert-working-group-on-covid-19-vaccine-safety-surveillance