The BMJ

Cite this as: *BMJ* 2020;371:m4714
http://dx.doi.org/10.1136/bmj.m4714
Published: 02 December 2020

Covid-19: UK approves Pfizer and BioNTech vaccine with rollout due to start next week

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The UK's independent Medicines and Healthcare Products Regulatory Agency (MHRA) has approved Pfizer and BioNTech's covid-19 vaccine, with rollout now set to begin as early as next week, the government has announced.

The mRNA vaccine, BNT162b2, was found to be up to 95% effective 28 days after the first dose in a phase III trial.[1] The study evaluated 170 confirmed cases of covid-19, 162 of which were observed in the placebo group. There were 10 severe cases, nine of which were in the placebo group.

The UK has secured a deal for 40 million doses of the vaccine (enough to vaccinate 20 million people), and delivery will be staggered throughout 2020 and 2021. Care home residents and workers will be prioritised to receive the vaccine first, followed by healthcare workers and people over 80.

A spokesperson for the Department of Health and Social Care said, "The vaccine will be made available across the UK from next week. The NHS has decades of experience in delivering large scale vaccination programmes and will begin putting their extensive preparations into action to provide care and support to all those eligible for vaccination.

"To aid the success of the vaccination programme it is vital everyone continues to play their part and abides by the necessary restrictions in their area so we can further suppress the virus and allow the NHS to do its work without being overwhelmed."

The vaccine will be transported in dry ice, as it must be stored at around −70°C. Once delivered it can then be kept in a fridge for five days.

Safety data

The phase III trial began on 27 July and enrolled 43 661 participants. Around 42% of global participants and 30% of US participants had "racially and ethnically diverse backgrounds," and 41% of global participants and 45% of US participants were aged 56 to 85. Pfizer has said that efficacy was consistent across age, sex, race, and ethnicity demographics, with 94% efficacy in people over 65. No results from the trial have yet been published in a peer reviewed journal.

Solicited safety data from a randomised subset of around 8000 participants aged 18 or over, and unsolicited safety data from around 38 000 trial participants who were followed for a median of two months after the second vaccine dose, have also been made available to regulators. The trial's data monitoring committee has not reported any serious safety concerns related to the vaccine.

MHRA's chief executive, June Raine, said, "We are globally recognised for requiring high standards of safety, quality, and effectiveness for any vaccine. Our expert scientists and clinicians worked tirelessly, around the clock, carefully, scientifically, robustly and rigorously poring over hundreds of pages and tables of data, methodically reviewing the data.

"I'm really pleased to say that the UK is now one step closer to providing a safe and effective vaccine to help in the fight against covid-19—a virus that has affected each and every one of us in some way—and in helping to save lives."

Close and continued monitoring

Experts welcomed the news but emphasised that, while it was a "huge step forward," not everyone would be vaccinated straight away, meaning that physical distancing and other measures to control the virus would need to remain in place for some time.

Charlie Weller, head of vaccines at the Wellcome Trust, said, "This decision, independent from government or other external influence, begins to clear the path for this vaccine to be rolled out to a wider population. There are now important considerations and significant logistical hurdles ahead."

She added, "As normal for any vaccine, there will be a need for close and continued monitoring for safety and efficacy as it is delivered. We will also need to continue tracking and improving our understanding on how long the protection lasts.

"We must recognise that not everyone will have a vaccine immediately or even early next year. It is critical that groups most at risk, such as the elderly and frontline healthcare workers, are prioritised to receive the first doses."

Meanwhile, Liam Smeeth, professor of clinical epidemiology and dean of the Faculty of Epidemiology and Population Health at the London School of Hygiene and Tropical Medicine, said that another circuit breaker in January or February was likely to be needed.

"But it is realistic to hope that by March or April the vast majority of older people, care home residents, and those with severe conditions will have been immunised," he said. "We can then work towards wider immunisation—with ideally much of the population covered in time for next winter. Life won't ever be the same as it was before covid-19, but it will feel a whole lot better than now."

1 Mahase E. Covid-19: Pfizer and BioNTech submit vaccine for US authorisation. *BMJ* 2020;371:m4552doi: 10.1136/bmj.m4552.