EXPERT REACTION: Pfizer announces COVID-19 vaccine is 90% effective

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Not peer-reviewed | Randomised controlled trial | Opinion piece/editorial | People

What do these mean?

Not peer-reviewed: This work has not been scrutinised by independent experts, or the story does not contain research data to review (for example an opinion piece). If you are reporting on research that has yet to go through peer-review (eg. conference abstracts and preprints) be aware that the findings can change during the peer review process.

Randomised controlled trial: Subjects are randomly assigned to a test group, which receives the treatment, or a control group, which commonly receives a placebo. In 'blind' trials, participants do not know which group they are in; in 'double blind' trials, the experimenters do not know either. Blinding trials helps removes bias.

Opinion piece/editorial: This work is based on the opinions of the author(s)/institution.

People: This is a study based on research using people.

US pharmaceutical company Pfizer and its German partner BioNTech announced overnight that their vaccine candidate was more than 90 per cent effective in preventing COVID-19. The results are based on initial data from a large study of 43,538 participants, including 94 confirmed cases of COVID-19. The vaccine is the same one (of two) that featured in an announcement from Prime Minister Scott Morrison last week, with the government securing 50 million more potential vaccine doses through two new agreements, including one with Pfizer. Below Australian experts respond.

Organisation/s: Pfizer

Funder: N/A

Attachments:

Media Release	(https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-announce-vaccine-candidate-against)	Pfizer	Web page

Pfizer's announcement

Expert Reaction

These comments have been collated by the Science Media Centre to provide a variety of expert perspectives on this issue. Feel free to use these quotes in your stories. Views expressed are the personal opinions of the experts named. They do not represent the views of the SMC or any other organisation unless specifically stated.

Dr Diego Silva is from Sydney Health Ethics in the University of Sydney School of Public Health

> "From the viewpoint of research ethics, press releases do not make for good science. These are exciting preliminary results, but it needs to go through peer-review with all the scrutiny that entails.
>
> It is vital to get research results quickly in a pandemic if, and only if, the results are meaningful. Meaningfulness can be ascertained through peer-review and with the ability of the broader scientific community to scrutinize the results, none of which can be achieved through a press release."

Last updated: 10 Nov 2020 3:08pm

Declared conflicts of interest:

None declared.

Associate Professor Linda Selvey is is a public health physician and an infectious diseases epidemiologist at the University of Queensland

> "This announcement is very encouraging, however, it will not, on its own, mean that we will be able to resume 'business as usual' any time soon. Pfizer has announced that they will be able to produce up to 1.3 billion doses by the end of 2021, which would be sufficient to vaccinate 650 million people. This points to the importance of having several vaccines available, in order to ensure that everyone around the world will be protected. An efficacy of 90 percent is encouraging, but, in the situation where there are no restrictions on gatherings or movement, this would mean that around 65 percent of the population would have to be vaccinated in order to stop circulation of the virus (assuming an R0 - reproduction number - of 2.5).
>
> The vaccine is an mRNA vaccine, and has to be stored at -70°C, and can only be stored at 4°C for 24 hours. This will pose challenges for mass vaccination campaigns. It would be important to test the efficacy of the vaccine in more vulnerable populations, such as the elderly or people with compromised immune systems. If it is found to be very effective in these populations, it could be used to protect these people, with other vaccines with greater stability being used to vaccinate the broader population."

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Declared conflicts of interest:

None declared.

Dr Larisa Labzin is an IMB Fellow and NHMRC CJ Martin Fellow at the Institute for Molecular Bioscience at the The University of Queensland. Larisa's research focuses on understanding how the innate immune system recognizes viruses.

"The Pfizer COVID-19 vaccine announcement is very exciting. The 90 percent efficacy they report we presume to mean that of the 94 cases of COVID-19 that were recorded in the trial participants, 84 of those cases were in people who were administered the placebo (so didn't get the vaccine).

There is still a long way to go however to determine how effective this vaccine is across the 43,000 participants who were enrolled, as 94 cases is a small proportion of that. Ongoing monitoring will also help determine how long this vaccine is protective for.

This is still a fantastic outcome for this vaccine, and provides hope for the success of many of the other vaccines too. This mRNA vaccine is designed to elicit immunity against the SARS-CoV-2 spike. Most other vaccines in development are also designed around the spike protein. It's also the first successful use of an mRNA vaccine, meaning this technology could be used for other vaccines against other viruses.

We still need the other vaccines in development, as this vaccine has some limitations: it needs to be stored at -80 degrees Celsius, as the mRNA is quite unstable. This makes giving the vaccine to everyone logistically difficult. We also look forward to the published findings from this vaccine trial, which will hopefully answer many more questions: is it protective in older people and high risk people, how many antibodies or T cells are enough to be protective, and can we use this vaccine technology for other emerging diseases.

We also look forward to seeing how the rest of the vaccines in development compare to this technology, and we hope for equivalent efficacy. This will allow us to compare directly how different vaccine platform technologies work, and to understand better how the virus itself might be manipulating the immune system."

Last updated: 10 Nov 2020 1:07pm

Declared conflicts of interest:

None declared.

Dr Michelle Tate is head of the Viral Immunity and Immunopathology laboratory at the Hudson Institute of Medical Research and a NHMRC Career Development Fellow.

"The results of the Pfizer Phase-3 COVID-19 study are promising, with a reported vaccine efficacy rate of 90 percent. In general, the elderly are the most susceptible to COVID-19 infection and there is significant evidence that they are likely to be poorly vaccinated. What is not currently clear from the study report is how old the participants were in the study and how effective the vaccine was in older adults. The study is certainly a positive step forward, and we eagerly wait for the final results."

Last updated: 10 Nov 2020 1:05pm

Declared conflicts of interest:

None declared.

Professor Raina MacIntyre is Head of the Biosecurity Program at the Kirby Institute at the University of NSW. She is an expert in influenza and emerging infectious diseases.

"The announcement of interim analysis of data from the phase 3 trial of their COVID-19 vaccine is promising, with a reported vaccine efficacy estimate of 90 percent against infection. They do not provide the number of cases in the vaccine arm vs the placebo arm, but we can assume that the majority of the 94 cases (out of the total 43,538 trial participants) that were the basis of the interim analysis occurred in the placebo arm.

They also report that the vaccine trial has not picked up any serious side effects, and that the trial included diverse participants. It is important to have data on different ethnic groups, as the risk of disease does vary by ethnicity, although this is probably more related to socioeconomic factors than race.

The caveat is that this is a press release, and we do need to see the data in a peer reviewed publication to fully evaluate it. We also do not know duration of protection, or how long the protection lasts. The Pfizer vaccine is a mRNA vaccine, which provides the body with the genetic code to manufacture immunogenic proteins from the virus, which will then stimulate protective antibodies. Most trials have shown so far that the immune response to vaccines is more robust than that to natural infection, which is how many vaccines work. Overall, this is very positive news and should give people hope that this and other vaccines will live up to expectations."

Last updated: 10 Nov 2020 1:04pm

Declared conflicts of interest:

None declared.

Hassan Vally is an Associate Professor in Epidemiology at La Trobe University

"Pfizer has released some interim results of their vaccine trial. Although these results are early findings, they provide a welcome bit of good news, especially for those in other places in the world that are seeing a surge in cases right now. In essence, Pfizer report that the initial indication is that their vaccine is looking like it is 90 percent effective. That is, it protects individuals against disease 90 percent of the time. To put this in perspective, we have generally agreed that if we have a vaccine that is 50 percent effective, this will be good enough to proceed with to respond to the pandemic.

So this is indeed a great result, so far. We probably need to be measured in our enthusiasm until the trial has been completed, but we would rather see these sorts of early findings than hear that the vaccine was not working as well as would have hoped."

Last updated: 10 Nov 2020 1:03pm

Declared conflicts of interest:

None declared.

Professor Magdalena Plebanski is Director of the Biomedical and Health Innovation Enabling Capability Platform and Head of the Translational Immunology and Nanotechnology Program at RMIT University. She is a leading expert in vaccine development.

"In an analysis of 94 human trail volunteers (out of >43,000) naturally infected with SARS-COV-2 during the Pfeizer/BioNTech Phase III human trial, volunteers immunised with the BNT162 vaccine were protected from multiple COVID-19 symptoms when compared to placebo. This vaccine targets the spike protein of the SARS-COV-2 virus by presenting it to the body as mRNA, which engages the cells in the body to produce this protein, thereby provoking an immune response.

This is an important milestone for any vaccine developers who are making vaccines based on the spike protein, showing vaccines targeting this viral protein can offer protection. It also means mRNA based vaccines can protect against a viral lung infection, another broadly important finding.

The limitations of this initial analysis, beyond the still small number of individuals being analysed, are that this study does not provide data on the most susceptible populations, such as the immunocompromised or older adults. In fact, initial Phase I and II trials of their vaccine approach showed the induction of virus neutralising antibodies in older adults (65-85 years) was less than half of that of younger adults (18-55 years). It therefore remains to be determined if this vaccine will protect those most vulnerable."

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Declared conflicts of interest:

None declared.

Nikolai Petrovsky is a Professor in the College of Medicine and Public Health at Flinders University. He is also Research Director, Vaxine Pty Ltd

"It is great to see this first human effectiveness announcement from Pfizer, albeit without much data to allow better understanding of what this headline result at the interim analysis might ultimately mean. This outcome should answer the doubters who previously claimed that a human coronavirus vaccine might not even be possible – the clear answer from this data is yes it is possible.

Key still unanswered questions will be the durability of protection, does the vaccine completely prevent infection (sterilising immunity) or just make symptomatic infection asymptomatic, what are the immune correlates of protection, what is the efficacy against serious disease in the elderly and those with chronic disease or immune-suppression etc. So while this is a key step forward there are still many hurdles to be mounted before the world can breathe a sigh of relief.

The weakness, if any, of MRNA remains lack of long term human safety and efficacy data and the need for -80°C freezers for the vaccine storage and distribution, so currently this vaccine will not be a solution for people in most of the developing world – but nevertheless this announcement is a great start and should provide renewed energy to all the other COVID vaccine developers to similarly get Phase 3 outcome data.

All vaccine developers now have an actual efficacy benchmark to shoot for and this will make it much easier in future to determine which will be the ultimate winners in this race. Given the premature nature of this data and the fact we don't have any long term outcome data beyond a few months, this does not guarantee that mRNA vaccines will prove to be the best candidates long-term and there is definitely still room for all the other vaccine technologies, including adjuvanted recombinant proteins, inactivated whole virus, and viral vectors, to demonstrate their relative merits.

The world still needs 7.5 billion doses of vaccine, 15 billion if as with Pfizer's vaccine everyone needs two doses. Hence, there will be room for many more vaccine candidates from other producers to help meet this insatiable demand. Just as the world ended up with many different car types despite the initial success of Henry Ford in gaining early dominance, so too the world is likely to end up with many different COVID vaccines.

The team here at Vaxine take heart from this preliminary Pfizer announcement, look forward to seeing the actual trial data in due course, and will press on with our Covax-19 recombinant protein vaccine candidate that has already shown promising protection data in animal models, with renewed vigour."

Last updated: 10 Nov 2020 12:53pm

Declared conflicts of interest:

Nikolai is Research Director of Vaxine Pty Ltd, which is currently undertaking clinical trials of a COVID-19 vaccine.

Dr Roger Lord is a lecturer (Medical Sciences) with the Faculty of Health Sciences at The Australian Catholic University and Research Fellow with The Prince Charles Hospital (Brisbane).

"Pfizer-BioNTech have announced their vaccine candidate is 90 percent effective in preventing SARS-CoV-2 (COVID-19) infection in trial participants. This is an exciting development but one which will require independent scrutiny of trial data to confirm this efficacy.

The phase 3 trial involved 43,538 participants with no reported safety concerns. Interim analysis of 94 participants (half vaccinated, half placebo) demonstrated a 90 percent efficacy rate in those vaccinated 7 days after receiving the second dose.

While very encouraging, this is only a small sample of the total number of participants in the trial. The efficacy rate may be lower than reported once clinical data is analysed for all participants in the trial.

This is a novel RNA-based vaccine platform and secondary endpoint analysis to determine levels of seroconversion (ability to produce a protective immune response) have not yet been performed and made available. Once analysis of all the participants involved in the clinical trial have been completed we will have a clear indication of the efficacy of the vaccine.

If the efficacy remains significant, formidable distribution challenges will be the next hurdle as 2 doses are required, and the vaccine must be kept at -80 degrees Celsius."

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Declared conflicts of interest:

None declared.

Paul Griffin is Director of Infectious Diseases at Mater Health Services, Associate Professor of Medicine at the University of Queensland, and Medical Director and Principal Investigator at Q-Pharm, Nucleus Network

"The announcement overnight that the Pfizer/BioNTecch mRNA vaccine has been demonstrated to be more than 90 percent effective in preventing COVID-19 is truly exciting, not only for this particular vaccine, but for vaccines for COVID-19 in general. The information released overnight is from an interim analysis of the data from their large phase 3 study that has enrolled nearly 44,000 participants and has evaluated 94 confirmed cases of COVID-19 in trial participants. It was also reported that no serious safety concerns have been observed, and safety and additional efficacy data continue to be collected.

Based on these results it seems a submission for Emergency Use Authorization (EUA) to the U.S. Food and Drug Administration (FDA) is imminent. It will be important to see the full data set and the results formally presented in a peer reviewed publication however the interim data certainly seems to support the use of this vaccine.

This is a timely announcement given the agreement that was publicised last week in this country to secure 10 million doses of this vaccine. There will be some inherent logistical challenges given the requirement for it be stored at minus 80 degrees Celsius but this challenge has been overcome successfully it seems in the large international clinical trials that are underway. It will also be important to see how the vaccine has performed in terms of the many other endpoints being analysed in the clinical trials.

While very exciting for this particular vaccine, I think its reasonable to extrapolate some of this optimism to the other vaccines in clinical trials given it has now been shown that it is possible to generate an immune response from a COVID-19 vaccine that provides high levels of protection. We still don't know if this level of protection will be seen in all populations, age groups and in people with various comorbidities for example, so it remains likely we will need multiple vaccines and the ongoing development of other promising candidates should definitely continue."

Last updated: 10 Nov 2020 12:51pm

Declared conflicts of interest:

Paul is running a number of COVID-19 vaccine studies (Novavax and UQ).

Professor Bruce Thompson is Dean of the School of Health Sciences at Swinburne University

"The recent announcement from major pharmaceutical company Pfizer is a very positive step in the development of a vaccine for the SARS-COV-2 virus. Although the results released are preliminary, and as yet to go through the rigour of scientific peer review, they do provide significant hope that a efficacious vaccine will be available short to medium term. This is a spectacular achievement by the scientific community to have a vaccine developed, and entered into phase 3 clinical trials, on a virus that was little known 11 months ago."

Last updated: 10 Nov 2020 12:50pm

Declared conflicts of interest:

None declared.

Professor Sarah Palmer is the Co-Director of the Centre for Virus Research at The Westmead Institute for Medical Research and Professor in the Faculty of Medicine at the University of Sydney

"This is very encouraging news. But we will need to learn more about the long-term immunity generated by this vaccine. In addition, it is unclear at the moment whether this vaccine will be effective for groups with weaker immune systems such as the elderly or persons with other complicating health factors. Also, while this is good news, we should be aware that it is likely we will require regular immunisations – just as we do to combat the flu – to maintain our immunity against new and emerging strains of SARS-CoV-2."

Last updated: 10 Nov 2020 12:45pm

Declared conflicts of interest:

None declared.

Dr Adam Taylor is an Early Career Research Leader in the Emerging Viruses, Inflammation and Therapeutics Group at the Menzies Health Institute Queensland at Griffith University

"The release of this preliminary data by Pfizer of their Phase 3 clinical trial is an exciting glimpse at the effectiveness of their COVID-19 vaccine. This candidate has already proven to be safe in earlier clinical trials. Although more data from this trial is required before we can say 'here's a vaccine that can begin to be distributed', it's clear we have good reason to be optimistic. We also need to realise that these preliminary results are not an excuse for us to drop our guard or ignore existing measures aimed at preventing the spread of the virus."

Last updated: 10 Nov 2020 12:42pm

Declared conflicts of interest:

None declared.

Professor Marc Pellegrini is an Infectious disease physician at the Walter and Eliza Hall Institute of Medical Research (WEHI)

"This interim analysis is incredibly promising but we do need to see the published results so we can scrutinise them in more detail. At this stage we don't know whether it is effective in preventing only the most severe cases of the disease or whether it also prevents mild cases of the disease as well. If it was effective in preventing people from transmitting the virus, it would be incredibly valuable. If it is 90 per cent effective, it will be on par with the hepatitis B vaccine, which is incredibly effective in preventing people from getting that particular virus and has been a game-changer in halting transmission of hepatitis B.

The fact that they have not had any safety concerns in the trial is a good sign. We don't know how long the vaccine would last for – it might be like the flu vaccine where you need to get vaccinated every year. With this particular vaccine, you get two shots, but even with those two injections we don't know how long that immunity will last, it could be six months, a year, or it might be 10 years. The Food and Drug Administration (FDA) in the US would also need to scrutinise the final results of this study and the Therapeutic Goods Administration (TGA) in Australia, if we were to roll it out here.

This vaccine is relatively easy to manufacture, so once it's approved it could be rolled out relatively quickly, maybe even as early as March next year. If this vaccine does prove to be safe and effective, we could start rolling it out to our most vulnerable people first, such as our frontline healthcare workers and those in aged care settings."

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Declared conflicts of interest:

None declared.

Professor Elizabeth Hartland is Director and CEO of the Hudson Institute of Medical Research

"The SARS-CoV-2 vaccine candidate produced by the Pfizer-BioNTech partnership is based on a new technology, where mRNA is introduced into the body that leads to the production of virus components recognised by the immune system. This is a completely new approach to vaccine development and has some advantages over classical vaccine manufacture in terms of how quickly the product can be made and distributed.

Early results from a large trial of nearly 40,000 people receiving two doses have suggested the vaccine produces effective immune protection in 90% of people. This is very encouraging in the fight against the SARS-CoV-2 pandemic and also for future vaccine development."

Last updated: 10 Nov 2020 12:39pm

Declared conflicts of interest:

None declared.

Associate Professor Sanjaya Senanayake is a specialist in Infectious Diseases and Associate Professor of Medicine at The Australian National University

"This announcement should be a cause for optimism tempered with caution. On the plus side, a vaccine efficacy of 90 percent is very high, and a lot higher than many were expecting. In terms of being cautious with this news, it is only preliminary data related to 94 people who developed COVID-19 during this Phase 3 trial of over 43,000 people in about six countries: the final analysis is to be released, I believe, when 164 participants develop COVID-19. And like the US election, the initial results may not be indicative of the final ones. Also, these data aren't coming from a journal article, so it is difficult to analyse the details of the findings.

This is a mRNA vaccine, and there has never been a commercially available mRNA vaccine before; therefore, sorting out the logistics of production etc will be important. In addition, this kind of vaccine needs to be kept at very low temperatures (-70 degrees C) which will also be a challenge regarding distribution and storage. However, all that being said, this is good news, especially as the Australian government has a contract with Pfizer to supply 10 million doses of this vaccine to us. And of course, just because the Pfizer vaccine might be very effective doesn't mean that the other candidate vaccines won't be. Irrespective of the ultimate outcomes, the cooperation, coordination and speed with which so many vaccines are being developed for COVID-19 continues to be extraordinary."

Last updated: 10 Nov 2020 12:38pm

Declared conflicts of interest:

None declared.

Associate Professor Nicholas Wood is a vaccine expert and paediatrician at the University of Sydney

"News of the vaccine effectiveness from the Pfizer BioNtech trial is very good. This is based on data from the 94 COVID cases that occurred in trial participants.

However, more detail on effectiveness in specific age groups and their comorbid conditions will be needed. As is safety data on the total trial cohort to at least two-months-post the second dose of the vaccine - but nevertheless exciting data."

Last updated: 10 Nov 2020 12:37pm

Declared conflicts of interest:

None declared.

Professor Angus Dawson is a Professor of Bioethics and Director Sydney Health Ethics in the School of Public Health at the University of Sydney

"The announcement of these results is good news but we should still be cautious. We need to see the full data published in a good peer-reviewed journal and much further work needs to be done.

The trials have involved small numbers of people in quite select groups. These results are from a very small group of initial participants, they are not, as I understand it, the full provisional results. Careful monitoring for any safety concerns needs to be in place before the vaccine is rolled out.

Even if everything goes well, we can expect limited vaccine availability in the next few months, and it will be crucial to decide how to prioritise who should receive the vaccine. Most countries' plans give first priority to frontline health care workers as they are at increased risk and help to protect us all.

The elderly may also be a priority group because they are most at risk from severe COVID-19, but do we have safety and efficacy data from trials involving the over 65s? This is good news but we need to take care to do everything we can to preserve trust in SARS-CoV-2 vaccines and vaccination in general."

(mailto:?subject=SciMex.org%20ERT%20REACTION:%20Pfizer%20announces%20vaccine%20is%20COVID-19%20vaccine%20is%2090%25%20effective&body=https://www.scimex.org/newsfeed/expert-reaction-pfizer-announces-covid-19-vaccine-is-90-effective)

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None declared.

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Professor Robert Booy is a researcher in child and adolescent health from the Sydney Medical School, University of Sydney and The Children's Hospital at Westmead

Media contact details for this story are only visible to registered journalists.

"The information on the Pfizer study is truly exciting. Not only is the vaccine appearing to be 90 percent efficacious, but the confidence limits around that are likely to be quite narrow, meaning that there is confidence in the estimate of protection.

The vaccine they have developed (mRNA) has never been implemented into routine approaches before, so we need further evidence of its safety.

An mRNA vaccine is a new concept and we know with previous new vaccines there can sometimes be unusual and unexpected side effects.

Currently, we have information relating to 40,000 people which is impressive, but once the vaccine is introduced widely there will be millions who get protected by vaccination and we need to continue close surveillance of how well the vaccine is tolerated."

Last updated: 10 Nov 2020 12:33pm

Declared conflicts of interest:

None declared.