

Plain Language Summary of the PICOB00 Study

Early Results of a 2nd Booster in 18-49 and 50-69 Year Olds Primed with Pfizer

Overview of the PICOB00 Study

The **P**latform Trial **I**n **C**oVID-19 Priming and **B**oosting (**PICOB00**) is a clinical trial that explores different COVID-19 vaccination strategies. This trial is being run across 3 locations in Australia: Perth, Adelaide and Launceston.

Summary of Results

This summary shares early results from the study involving people aged 18-49 and 50-69. These groups received two Pfizer vaccines initially, and then a 1st booster outside of the study. When joining this study, they were randomly given one of three possible COVID-19 vaccines as a 2nd booster. We looked at the effects of this 2nd booster over 84 days.

We looked at the impacts of the booster vaccines on the immune system and looked for any side effects or safety issues. The three booster shots tested were the original Pfizer (BNT162b2), Moderna (mRNA-1273), and Novavax (NVX-CoV2373) vaccines.

Who Took Part

- **Total Participants:** 743 people joined the study (between March 2022 and August 2023)
- **18-49 Group:** 120 people. 91 females (76%) and 27 males (22%)
- **50-69 Group:** 103 people. 85 females (83%) and 18 males (17%)
- **COVID-19 History:** 74 participants (62%) in the 18-49 year old group and 27 participants (26%) in the 50-69 year old group had prior COVID-19 infections before they joined the study.

What We Found

Building the Body's Defence (Immune Response)

- The vaccines teach your body to recognise and fight the COVID-19 virus by making special defenders called antibodies. These are proteins the body uses to fight infections.
- We measured antibody levels in each person to see how well the vaccines worked over time.
- People who received Pfizer or Moderna had higher antibody levels after 28 days than those who received Novavax. However, by day 84, antibody levels decreased in all groups.
- It's not clear how important the higher antibody levels are from the Pfizer and Moderna vaccines.

Difference Between Age Groups

- **18-49 Group:** Had higher antibody levels after 28 days until day 84 compared to the 50-69 year old group.
- **50-69 Group:** Had lower antibody levels throughout the study and a more significant drop by day 84.

Fighting New Virus Types (Immune Response)

- We tested how well the antibodies could stop new variants of the virus.
- We tested the antibodies from people's blood to see if they could stop new versions of the virus from infecting cells in lab experiments.
- All vaccines were better at stopping the original virus strain than against newer variants like Omicron BA.5 and XBB.1.5.
- This shows the importance of updating vaccines to better combat these new variants. The vaccines currently recommended for use in Australia do target newer circulating variants.

Side Effects and Safety

- Most side effects were mild, such as sore arms, headaches, and feeling tired.
- Severe reactions occurred slightly more in the 50-69 group (less than 11%) compared to the 18-49 group (less than 10%)
- This shows the vaccines were safe for most people in these groups.

Getting COVID-19 After the Vaccine

- Some people caught COVID-19 after their booster, but none required hospitalisation.
- This evidence supports our understanding that the vaccines are effective in preventing severe illness.

Key Takeaways

- **Effective Boosters:** Pfizer and Moderna vaccines provided a higher antibody response against COVID-19, compared to Novavax.
- **Safe with Mild Side Effects:** Most side effects were mild and temporary.
- **Need for Updated Vaccines:** As the virus evolves, it's important to keep updating the vaccines to fight off new strains better
- **Public Health Impact:** Booster shots are important for continued protection against COVID-19 and highlight the importance of updating vaccines to combat new COVID-19 strains. This is why older vaccines have been discontinued and replaced with new versions that better target the latest strains like the XBB.1.5 vaccines, which are currently in use.

Acknowledgements

Thank you to the team of researchers and the people who took part. This study was funded by the Medical Research Future Fund (2014690) and Snow Foundation.

Authorship and Reference

Summary authored by George Salama. Original full report: McLeod C et al. (2024). *The Platform Trial In COVID-19 Priming and BOOsting (PICOB00): the immunogenicity, reactogenicity, and safety of different COVID-19 vaccinations administered as a second booster (fourth dose) in BNT162b2 primed individuals aged 18-<50 and 50-<70 years old.*