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WHO R&D BLUEPRINT CONSULTATION MEETING

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科兴控股生物技术有限公司 SINOVAC BIOTECH LTD.



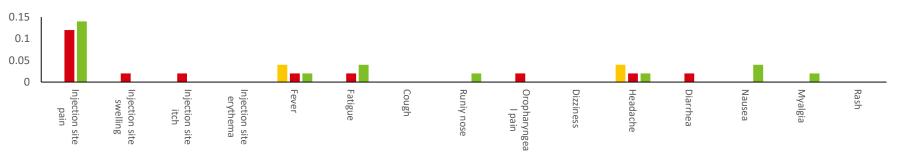


Safety of the 3rd dose of CoronaVac[®]

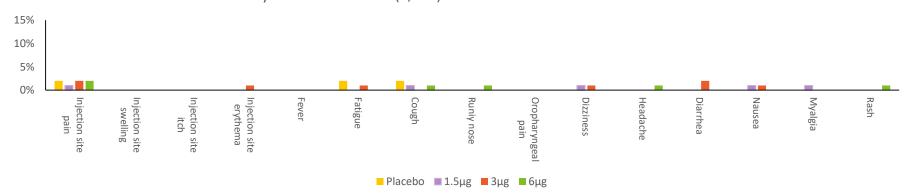
Safety profile within 28 days after the 3rd dose







60 years old and above (0,28d) +3rd dose at 6-8m after the 2nd dose



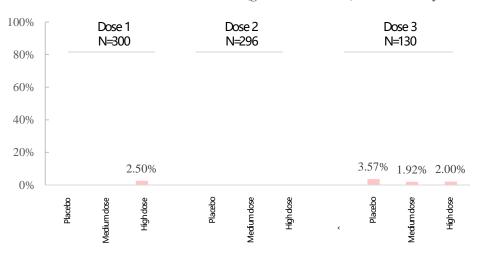
Pan HX, et al. "Immunogenicity and safety of a third dose, and immune persistence of CoronaVac vaccine in healthy adults aged 18-59 years: interim results from a double-blind, randomized, placebo-controlled phase 2 clinical trial" medRxiv (2021) Li M, et al. "A booster dose is immunogenic and will be needed for older adults who have completed two doses vaccination with CoronaVac: a randomized, double-blind, placebo-controlled, phase 1/2 clinical triall" medRxiv (2021)

Safety: 3rd dose of CoronaVac® after 6-8 months of primary immunization performed well in safety;



AEFI did not increased after the 3rd dose

A 3rd dose after 6 months of 2-dose (0,28) vaccination, the incidence of adverse reactions (grade 2 or above) within 28 days

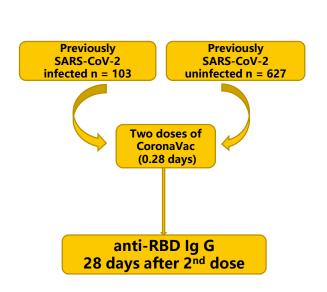


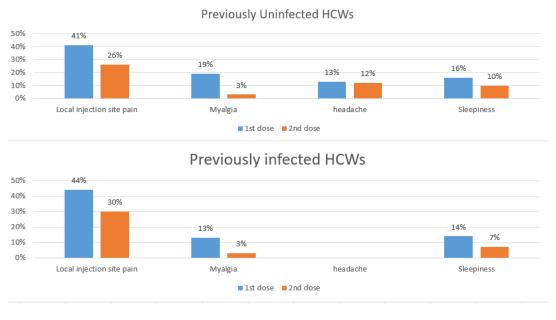
Grade 2 was the highest level of adverse reactions for CoronaVac®
Grade 3 or above was not noticed.

Pan HX, et al. "Immunogenicity and safety of a third dose, and immune persistence of CoronaVac vaccine in healthy adults aged 18-59 years: interim results from a double-blind, randomized, placebo-controlled phase 2 clinical trial "medRxiv (2021) Li M, et al. "A booster dose is immunogenic and will be needed for older adults who have completed two doses vaccination with CoronaVac: a randomized, double-blind, placebo-controlled, phase 1/2 clinical triall "medRxiv (2021)

Two doses of CoronaVac induced higher antibody response among previously Covid-19 infected HCWs







- Median Ig G titer: 1,220 AU/ml (range: 202–10328 AU/mL) in previously infected HCWs vs 913 AU/ml (range: 2.8–15547 AU/mL) in uninfected HCWs
 - Seropositivity rate (≥ 50 AU/ml): 98% in all tested HCWs

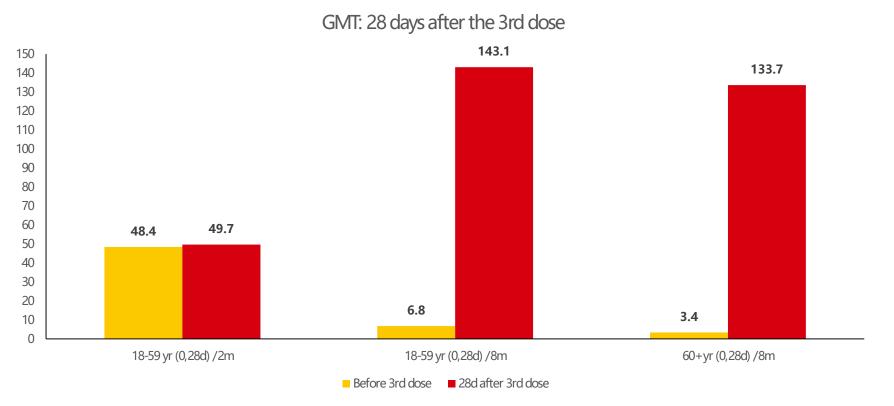
Ahmet Soysal et al. Comparison of immunogenicity and reactogenicity of inactivated SARS-CoV-2 vaccine (CoronaVac) in previously SARS-CoV-2 infected and uninfected health care workers; Human Vaccines & Immunotherapeutics. (2021)



Immunogenicity, timing, and immune persistence of the 3rd dose of CoronaVac[®]

Longer internal between 2nd and 3rd has a better immune response





Pan HX, et al. "Immunogenicity and safety of a third dose, and immune persistence of CoronaVac vaccine in healthy adults aged 18-59 years: interim results from a double-blind, randomized, placebo-controlled phase 2 clinical trial "medRxiv (2021) Li M, et al. "A booster dose is immunogenic and will be needed for older adults who have completed two doses vaccination with CoronaVac: a randomized, double-blind, placebo-controlled, phase 1/2 clinical triall "medRxiv (2021)

6-12 Months interval between 2nd - 3rd dose produce better immune response after 3rd dose

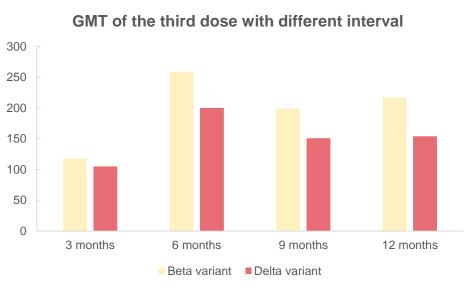


Participents	18-59 years old			
Schedule	Day 0, Day 28, Day 28+Mon 3/6/9/12			
Sample size	Mon-3	Mon-6	Mon-9	Mon-12
	100	100	100	100
	400			



Interval 3/6/9/12 Mo

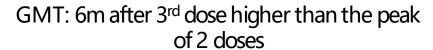




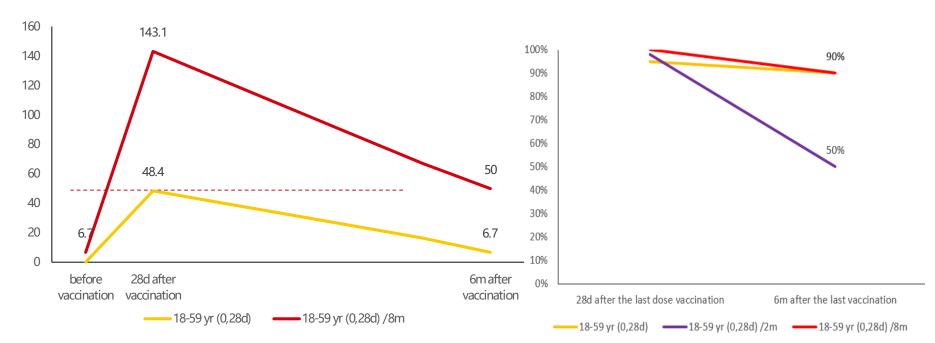
When the interval time is 6/9/12-mon between the second dose and the third dose, the GMT to the variants is higher than that of 3-mon.

Good immune persistence at 6 months after the 3rd dose





Seropositivity remained high 6m after 3rd dose



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Summary



- ▶ Homologous vaccine with a 3rd dose of CoronaVac® is safe
- ➤ Effective in recalling a SARS-CoV-2 specific immune response if given 6-8m after the 2nd dose
- ➤ China is scaling up the 3rd dose inactivated vaccination campaign
- ▶ More data are needed on cell immunity, effectiveness evaluation for the 3rd dose etc.
- Heterologous vaccine is under research



SINOVAC: Supply Vaccines to Eliminate Human Diseases

