



## **PPS-PIDSP Statement on COVID-19 Vaccines for Children**

**6 September 2021**

The Food and Drug Administration (FDA) of the Philippines has approved the use of the Moderna COVID-19 vaccine for adolescents, amending its Emergency Use Authorization (EUA) allowing it to be administered to those ages 12 and up. This is in addition to the BNT162b2 vaccine from Pfizer-BioNTech already approved for use in adolescents.

Results of the Phase 3 trials for the Moderna vaccine showed an acceptable safety and efficacy profile among adolescents 12 to 17 years old. The study enrolled 3732 participants randomized to receive mRNA-1273 (2489 participants) or placebo (1243 participants). No cases of COVID-19 with an onset of 14 days after the second injection were reported in the vaccine group, and four cases occurred in the placebo group. No serious adverse events were noted. The geometric mean titer ratio of pseudovirus neutralizing antibody titers in adolescents relative to young adults (18 to 25 years of age) was 1.08 (95% confidence interval [CI], 0.94 to 1.24), and the absolute difference in serologic response was 0.2 percentage points (95% CI, -1.8 to 2.4), which met the non-inferiority criterion of the immune response in adolescents as compared with that in young adults.

Concerns regarding the safety of the mRNA vaccines have been raised, however, benefits outweigh the potential risks. In an interim analysis of surveillance data of mRNA COVID-19 vaccines, incidence of selected serious outcomes was not significantly higher 1 to 21 days post-vaccination compared with 22 to 42 days post-vaccination. The analysis included a total of 11 845 128 doses of mRNA vaccines (57% BNT162b2; 6 175 813 first doses and 5 669 315 second doses) administered to 6.2 million individuals (mean age, 49 years; 54% female individuals). No vaccine-outcome association met the pre-specified

requirement for a safety signal. Reports of myocarditis following vaccination of the mRNA vaccines have been noted, the United States Centers for Disease Control and Prevention (CDC) states that as of August 25, 2021, its Vaccine Adverse Event Reporting System (VAERS) has received 1,377 reports of myocarditis or pericarditis among people ages 30 and younger who received COVID-19 vaccine and have confirmed 798 cases. Most cases have been reported after mRNA COVID-19 vaccination (Pfizer-BioNTech or Moderna), particularly in male adolescents and young adults. The CDC continues to recommend COVID-19 vaccination for everyone 12 years of age and older, given the risk of COVID-19 illness and related, possibly severe complications.

A systematic review of 42 studies which included 9,353 children evaluated the risk of severe COVID-19 infection in children with pre-existing conditions and reported that children with pre-existing conditions are 1.8 times more likely to have severe infection and/or require intensive care, with children with pre-existing conditions 2.8 times more likely to die compared to children without pre-existing conditions. Among the 9,353 children, the review stated that 64 children were obese, 58 had chronic respiratory disease, 45 had cardiovascular disease, 33 had neurologic disorders, 26 had immune disorders, 19 had metabolic disease, 12 had hematologic disorders and 11 had cancer, additionally 5 children had renal disease, 2 had GI co-morbidities and 71 children had other conditions. Childhood obesity was found to be likely associated with a worsened prognosis. These above-mentioned conditions are similar to the A3 category of the Department of Health.

Vaccine coverage for the Philippines has already reached almost 20% of the target population being fully vaccinated, with areas in the National Capital Region reporting the highest percentages. There are some regions of the country, however, who are still to vaccinate a significant portion of their population. For the pediatric population,

considerations for the roll-out includes the availability of the vaccines and targeting the group most at-risk for severe disease.

*With all these considerations, the Philippine Pediatric Society (PPS) and the Pediatric Infectious Disease Society of the Philippines (PIDSP) recommend that the older and more vulnerable age groups should still be prioritized in the vaccination roll-out, with an equitable distribution among different regions of the country. Once the whole country has a sufficient percentage vaccinated in the priority adult groups, children 12 years-old and above may be considered for vaccination; the vaccine roll-out can be initiated in high-transmission areas and should prioritize the adolescents that are qualified in the A3 (children with co-morbidities) and A1 (children of healthcare frontliners) category.*

#### REFERENCES:

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