Section 2. HTAC Recommendation (as of 01 October 2021)

The HTAC maintains its recommendation to use *Pfizer-BioNTech* COVID-19 Vaccine among adolescents aged 16 to 17 years and extends this recommendation for use in children aged 12 to 15 years. The HTAC also recommends extending the use of COVID-19 Vaccine *Moderna* among children aged 12 to 17 years. Moreover, HTAC recommends compliance to standard vaccination program protocols in introducing vaccines for children with only Emergency Use Authorization (EUA).

Furthermore, this recommendation shall be revisited to possibly include children younger than 12 years old once data for this age group becomes available. On the other hand, HTAC does not currently recommend the use of *AstraZeneca, CoronaVac*, and *Janssen* among children and adolescents (12 to 17 years old) due to current limited clinical evidence on their use in the pediatric population.

The criteria considered by HTAC in crafting its recommendations for pediatric vaccination as well as the summary of evidence are shown in the table of the Overview of Evidence Considered below:

Overview of Evidence Considered and HTAC Judgments on Pediatric Vaccination

Pfizer-BioNTech	Moderna	AstraZeneca	Janssen	CoronaVac
mRNA	**mRNA**	**Vector vaccine (chimpanzee adenovirus)**	**Vector vaccine (Ad26 adenovirus)**	**Inactivated virus**
Can the vaccine significantly reduce the magnitude and severity of COVID-19 in the pediatric population?				
Yes, *Pfizer-BioNTech* and *Moderna* have the potential to reduce the disease burden by averting a significant number of infections in the pediatric population (12 to less than 18 years old) including symptomatic and severe COVID-19 assuming sufficient vaccine coverage. The efficacy has not been studied among children < 12 years old.		Potential to reduce the disease burden in the pediatric population cannot be assessed due to limited evidence.		
Is the vaccine safe and efficacious for the pediatric population?				
Efficacy/Effectiveness Yes. Pfizer-BioNTech passed the preferred vaccine efficacy threshold against symptomatic COVID-19 and severe COVID-19 for the pediatric population aged 12-15 years old (Frenck et al., 2021), based on moderate certainty of evidence. Immunogenicity data on adolescents aged 12 to 15 years also demonstrated noninferiority when compared with young adults aged 16 to 25 years old. Current real world studies (Bickel et al.; Seigel et al.; Delahoy et al., Gargano et al.; Public Health England) suggest its potential clinical benefits in terms of symptomatic COVID-19, moderate to severe COVID-19, and hospitalization due to COVID-19. **Efficacy/ effectiveness against Variants**	**Efficacy/Effectiveness** **Yes**. *Moderna* has passed the preferred vaccine efficacy threshold against symptomatic COVID-19 for the pediatric population aged 12 to 17 years old (Ali et al, 2021), based on moderate certainty of evidence. Immunogenicity data on adolescents also demonstrated noninferiority when compared with young adults aged 18 to 25 years old. Real world effectiveness of *Moderna* in the pediatric population cannot be assessed due to lack of data. **Efficacy/ effectiveness against Variants** **Yes.** Real world evidence in individuals aged 16 and	Currently, there is limited evidence on the efficacy, effectiveness, and safety of *AstraZeneca, Janssen* in the pediatric population aged 18 years and below.	**Efficacy/effectiveness** Currently, there is limited evidence on the efficacy of *CoronaVac* in the pediatric population. However, there is currently available evidence limited to one immunogenicity trial (Han et al. 2021). It showed that *CoronaVac* was deemed highly immunogenic in children aged 3 to 17 years old, with geometric mean titers generally higher than adults aged 18 years and older.

Yes. Real world evidence in individuals aged 16 and older across 4 studies [Lopez Bernal et al. (UK); Nasreen et al. (Canada); Dagan et al. (Israel); Barlow et al. (US)] showed that Pfizer-BioNTech passed the vaccine effectiveness in preventing symptomatic COVID-19 caused by Delta, Alpha, Beta, and Gamma variants. However, an Israel MOH report showed that it did not pass the minimum VE (14 days after 2nd dose) for symptomatic COVID-19 caused by the Delta variant. In another US study (Griffin et al.), although it did not report vaccine effectiveness, showed a decrease in rates of infection caused by the Delta variant in fully vaccinated individuals compared to partially vaccinated and unvaccinated individuals. Israel MOH report showed that Pfizer-BioNTech passed the VE against severe COVID-19 caused by the Delta variant. Meanwhile, one real world study in Canada (Nasreen et al. 2021), showed that the vaccine also passed the minimum VE against severe COVID-19 caused by Alpha variant but failed against severe COVID-19 caused by the Delta variant. We noted that these studies evaluating effectiveness against variants of concern included both children (16 year old and older) and adults. **Safety** Yes. Based on the current evidence from the phase III clinical trial with high certainty of evidence (Frenck et al.) and real world safety reports (Hause et al., Bickel et al.), short-term safety of Pfizer-BioNTech for the pediatric population (12 to 15 years old) is acceptable. However, further follow-up data is needed to establish longer-term safety. Despite the rare cases of myocarditis and pericarditis that have been reported following vaccination of young adults with the *Pfizer-BioNTech* (Pepe et al., Lane et al.), the benefits still outweigh the risks for vaccination in this population.	older in one study [Nasreen et al. (Canada)] showed that *Moderna* passed vaccine effectiveness against symptomatic COVID-19 caused by Alpha and Delta variants. One real world study in Canada (Nasreen et al.) showed that the vaccine also passed the minimum VE against severe COVID-19 caused by Alpha and Delta variants. We noted that these studies evaluating effectiveness against variants of concern included both children and adults. **Safety** **Yes.** Based on the current evidence from the phase III clinical trial with high certainty of evidence (Ali et al), short-term safety of *Moderna* for the pediatric population (12 to 17 years old) is acceptable. However, further follow-up data is needed to establish longer-term safety. Despite the rare cases of myocarditis and pericarditis that have been reported following vaccination of young adults with the *Moderna* (Pepe et al, Lane et al.), the benefits still outweigh the risks for vaccination in this population.		Further studies are anticipated to strongly conclude its evidence for efficacy and effectiveness for the pediatric population aged 18 years and below. **Efficacy/ effectiveness against Variants** While there are countries using this vaccine for the pediatric population (e.g., Chile, China, Indonesia), there are no available reports on efficacy and effectiveness against variants of concern detected from these countries. Moreover, the trial of *CoronaVac* on the pediatric population did not evaluate its efficacy against variants of concern. **Safety** Currently, there is limited evidence on the safety of *CoronaVac* for the pediatric population. Current available evidence from the Phase I/II trial shows that short term safety in children and adolescents aged 3 to 17 years old were found to be similar to the adult population. Further studies are anticipated to strongly conclude on its safety for this age group.
Is the vaccine affordable and feasible to use in a national immunization program (viability) for the pediatric population?			
Affordability Yes, vaccinating children and adolescents aged 12 to 17 years using *Pfizer-BioNTech* and *Moderna* is affordable. According to the DOF, the supply of Pfizer-BioNTech procured in 2021 are sufficient to vaccinate the pediatric population aged 12 to 17, thus, its implementation will not incur additional cost from the 2022 budget. **Feasibility** Yes, vaccinating children and adolescents aged 12 to 17 years using *Pfizer-BioNTech* and *Moderna* is feasible. Although the implementation was generally challenging due to the intricacies in the storage, handling, and preparation of these vaccines, the NVOC implemented measures and ensured proper training and preparation prior to the rollout to mitigate these challenges.		Affordability and feasibility were not assessed due to limited clinical evidence in the pediatric population. Further, *AstraZeneca, Janssen,* and *CoronaVac* currently do not have EUA for the pediatric population.	

Does the vaccine reduce out-of-pocket (OOP) expenses of households due to COVID-19?	
Yes. Based on current evidence, *Pfizer-BioNTech* and *Moderna* have the potential to reduce out-of-pocket expenses of Filipino households due to averted costs of isolation and treatment of mild, moderate, and severe COVID-19	Out of pocket expenses were not assessed for *AstraZeneca, Janssen, CoronaVac* due to limited clinical evidence in the pediatric population. Further, this vaccine currently does not have EUA for the pediatric population.
Does the vaccine possess the characteristics that are desired by key stakeholders?	
Yes. *Pfizer-BioNTech* and *Moderna have been* issued an EUA by the FDA Philippines for the pediatric population. Results of a survey conducted by the DOH-HPB on the acceptability of the pediatric population showed that COVID-19 vaccination is acceptable to adolescents (12 to 17 years old). Another survey administered by a US-based University suggests that vaccinating children against COVID-19 is acceptable to parents of children and adolescents below 18 years old. However, as it is an online survey, the study had limitations in terms of representativeness of the study population, i.e. lack of representation of the population without internet access. Meanwhile, we noted that the program implementers foresee additional challenges and complexity to the current COVID-19 vaccination implementation by expanding it to the pediatric population, i.e. the need to get both parental consent and assent from the adolescent in the implementation, the need for additional human and logistical resources to accommodate the pediatric population. The assurance of meeting all public health measures to students, teachers, and other school personnel is an important consideration in the reopening of schools	*AstraZeneca, Janssen, and Coronavac* have not yet received an EUA from the Philippine FDA for the pediatric population. As such, public acceptability for its use was not assessed.
Does the vaccine reduce or not further add to existing inequities in the health system?	
Yes, pediatric vaccination will reduce inequities in the health system, assuming that the decision to vaccinate children is made in consultation with stakeholders, and pediatric vaccination shall be rolled out following the country's prioritization criteria, cognizant of the following: Burden of COVID-19 to the pediatric population, especially those with comorbidities; Sufficient supply to cover the pediatric population per DOF.	Not assessed for this domain due to limited clinical evidence in the pediatric population. Further, *AstraZeneca, Janssen, and CoronaVac* currently does not have EUA for the pediatric population.