Evidence Summary on *Pfizer-BioNTech COVID-19 Vaccine* for children 5 to 11 years old

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Prepared by	Health Technology Assessment Council Health Technology Assessment Unit
Contact details	hta@doh.gov.ph

Background

On 22 December 2021, the Philippine Food and Drug Administration (FDA) granted Emergency Use Authorization (EUA) for the use of *Pfizer-BioNTech* COVID-19 vaccine *(10µg/dose)* in children ages 5- 11 years old.

The *Pfizer-BioNTech* vaccine *(30µg/dose),* also known as *Tozinameran*, has been previously granted an EUA in the Philippines for the adult (released January 14, 2021) and adolescent population ages 12-17 years old (released November 15, 2021). The HTAC first released its recommendation on the financing of this vaccine, specifically the 30 *µg/dose* for age groups 16 years and older last 02 February 2021, and for 12 years and older last 25 June 2021. The recommendation on 12 to 15 years old was updated last 28 October 2021. As such, *Pfizer-BioNTech* has been part of the vaccines that are currently being implemented in the Philippines for individuals aged 12 and above.

According to the Philippine FDA, *Pfizer-BioNTech* for children ages 5-11 years *(10µg/dose)* differs from the *Pfizer-BioNTech* vaccine for individuals ≥12 years *(30µg/dose)* when it comes to the dosing concentration and the FDA-authorized formulations. *Pfizer-BioNTech for* ≥12 years *(30µg/dose)* is available in two formulations: one requires dilution and uses Phosphate-Buffered Saline as buffer, while the other requires no further dilution and uses tromethamine (Tris) as buffer. Meanwhile, *Pfizer-BioNTech* for children ages 5-11 years *(10µg/dose)* is only available in one formulation that requires dilution, and uses tromethamine (Tris) as the buffer. *Pfizer-BioNTech for* ≥12 years has a concentration of 100*µg/mL* while the vaccine for 5-11 years has a concentration of 50*µg/mL*. As per manufacturer's information, the *30µg/dose* for individuals ≥12 years has a purple cap and the *(10µg/dose)* for children ages 5-11 years has an orange cap.

Pfizer-BioNTech (30µg/dose) was listed by the WHO in its Emergency Use Listing for use among individuals ages 16 and above on 31 December 2020. The recommendation was then updated on 15 June 2021 to extend the recommendation to children ages 12-15 years with comorbidities that put them at high risk of severe COVID-19. As of the latest update of the WHO recommendation for *Pfizer-BioNTech* (21 January 2022), its use for children with comorbidities ages 5-11 years old who are at higher risk for severe COVID-19 has been included in the WHO recommendation. However, given that COVID-19 among healthy children and adolescents is usually mild, the WHO recommended that the use of *Pfizer-BioNTech* (10ug/dose) for this population should be considered only when high vaccine coverage for the primary series and boosters has been achieved for the higher priority-use groups in the recently updated *WHO SAGE Roadmap for Prioritizing Uses of COVID-19 vaccine* (21 January 2022).

As of this writing, *Pfizer-BioNTech (10µg/dose)* has been granted EUA for use in children ages 5 -11 years old in 17 other countries/territories (US, Canada, Australia, the EU, UK, Bahrain, Israel, Saudi Arabia, Chile, Costa Rica, Panama, Uruguay, Honduras, Egypt, Thailand, Malaysia and Singapore). Basic information on *Pfizer-BioNTech* is provided below:

Table 1.1 Characteristics of *Pfizer-BioNTech (10µg/dose)*

Trade name	Tozinameran, COVID-19 mRNA vaccine (nucleoside-modified) [Cominarty]
Other name	*Pfizer-BioNTech* COVID-19 Vaccine
Manufacturer/s	Pfizer Manufacturing Belgium
Vaccine platform	mRNA Vaccine (nucleoside modified)
Dose strength and administration	Two doses of 0.2 mL each (containing 10µg/dose) , 3 weeks apart
Route of administration	Intramuscular (IM)
Drug delivery system	A white to off-white frozen dispersion of 10µg/dose One multidose vial contains 10 doses of 0.2 mL after dilution
Storage condition	Store frozen at -90°C to -60°C° (Shelf life: 6 months) Once thawed, store at 2°C to 8°C (can be used within 10 weeks)
Mechanism of action	*The nucleoside-modified messenger RNA in Comirnaty is formulated in lipid nanoparticles, which enable delivery of the non replicating RNA into host cells to direct transient expression of the SARS-CoV-2 S antigen. The mRNA codes for membrane-anchored, full-length S with two point mutations within the central helix. Mutation of these two amino acids to proline locks S in an antigenically preferred prefusion conformation. The vaccine elicits both neutralizing antibody and cellular immune responses to the spike (S) antigen, which may contribute to protection against COVID-19.*
Contraindications	Hypersensitivity to the active substance or to any of the excipients
PHL EUA status	Released as of December 22, 2021
PHL FDA EUA indication	For active immunization for the prevention of COVID-19 caused by SARS-CoV-2 in individuals 5-11 years of age

The product information/fact sheet for healthcare providers is available here.

Pursuant to the role of the Health Technology Assessment Council (HTAC) which is to develop recommendations in the selection and financing of COVID-19 vaccines for the COVID-19 Vaccine Implementation for 2022, this assessment follows the HTAC evaluation framework to assess COVID-19 vaccines using the following criteria: (1) responsiveness to magnitude and severity; (2) clinical efficacy and safety; (3) affordability, viability and feasibility; (4) household financial impact; (5) social impact; and (6) responsiveness to equity.

Policy Question

The HTAC aims to answer the policy question:

Should the DOH finance ***Pfizer-BioNTech COVID-19 Vaccine (10µg/dose) for the pediatric population ages 5 - 11 years old*** as part of the 2022 COVID-19 Vaccination Program to reduce COVID-19 cases, severe infection, and deaths?

Recommendations *(as of 02 February 2022)*

The HTAC recommends the DOH financing and inclusion of *(10µg/dose)* in the Philippine National Deployment and Vaccination Plan for COVID-19 among the pediatric population ages 5 - 11 years old based on the HTAC criteria of (a) responsiveness to disease magnitude and severity, (b) clinical efficacy and safety, (c) affordability, viability, and feasibility, (d) household financial impact, and, (e) responsiveness to equity; provided the following conditions are met:

- For regions where pediatric vaccination for ages 5-11 will be rolled out, primary series coverage of priority groups (A1 to A3) must be at least 40%;
- The rollout should not prejudice the efforts to complete the primary series vaccination and booster vaccination of A1 to A3 priority groups

The burden of COVID-19 contributed by children in this age group, which comprise 13.87% of the total population in the Philippines, cannot be ascertained due to limited testing capacity, insufficient data, and other possible issues like the different community exposure of children because of reduced mobility. However, there are reported local cases of moderate, severe and critical cases of COVID-19 among children 5-11 years, even in children without comorbidities. In addition, based on US data, the incidence of MIS-C is highest in the 5-11 age group among other age groups. There are also locally reported cases of MIS-C in this age group.

Pfizer-BioNTech (10ug/dose) was found to be efficacious for preventing symptomatic COVID-19 in children ages 5 to 11 years old and will likely protect children ages 5 to 11 years against multisystem inflammatory syndrome in children (MIS-C) resulting from SARS-CoV-2 infection. Cognizant of the lack of long term safety data, HTAC can only make an informed judgment and recommend based on the best available short term data, which showed that Pfizer-BioNTech (10ug/dose) is safe for children ages 5 to 11 years old.

It was also noted that despite having a lower dose, the vaccine for children (5-11 years old) has the same unit cost as the vaccine for 12 years old and above (30µg/dose). Nonetheless, the costing analysis showed that *Pfizer-BioNTech (10ug/dose)* is still considered affordable.

Pediatric vaccination potentially decreases household expenses due to averted costs of isolation and treatment of mild, moderate, and severe COVID-19 in the pediatric population ages 5 to 11 years. Other non-medical costs, productivity loss of the parents of the children, and treatment cost of other family members within the household who had likely contracted COVID-19 further increases the potential of vaccination to reduce household expenses.

Pediatric vaccination poses inherent challenges because of pre-existing inequities in the healthcare system which include inequitable access to information and capacity to diagnose co-morbidities in children (e.g., pediatric specialists), inaccessibility to vaccination sites and inadequate logistical capacity, and the general deficiency in infrastructure, transportation modalities, and health human resources across the different areas in the country.

In addition, as a follow-on to the Expanded Program on Immunization (EPI) implementation for children ages5 years and below, and the National Vaccination Operations Center (NVOC) COVID-19 vaccination for adolescents ages 12 to 17 years old, the HTAC recommends vaccination among the population aged 5-11 years old provided that lessons learned and best practices in the abovementioned programs be carried over the latter program. These include taking into account vaccine hesitancy, difficulties in complying with documentary requirements, maintenance of the cold chain requirement, administration errors, insufficient human resources and ensuring free and prior informed consent.

Further, the HTAC recommends the following in the implementation of the pediatric vaccination for ages 5-11 years:

- To mitigate pre-existing inequities in the healthcare system and achieve equitable coverage:
    - Address structural and organizational challenges within the health system (i.e., focus on improving health education and health promotion activities), specifically:

        - Registering every Filipino a licensed primary care provider to act as the initial and continuing point of contact within the healthcare system
        - Establishing a health service delivery network at provincial and highly urbanized cities with strong public-private partnerships
    - Emphasize the importance of free and prior informed consent
    - Emphasize the need for supporting the autonomy of parents / guardians / pediatric population towards vaccination; and
    - Ensure that information, education, and communication (IEC) materials and other vaccination-related documents are accessible and comprehensible (i.e., translated into the local language of the target population)

- To increase acceptability and mitigate the sources of hesitancy through the following:
    - Secure informed consent or assent forms
    - Add measures such as more careful health screening
    - Hold social preparation and public consultation

- To improve public trust, strengthen rigor and transparency of pharmacovigilance activities

The HTAC considered the following criteria in formulating its recommendation for the vaccine:

Criteria	HTAC Judgment *(as of 02 February 2022)*
What is the magnitude and severity of COVID-19 in children ages 5 to 11 years old? *Is COVID-19 a public health priority?*	In the Philippines, children ages 5 to 11 years old comprise 13.87% of the total population. The burden of COVID-19 contributed by children in this age group cannot be ascertained due to limited testing capacity, insufficient data, and other possible issues like the different community exposure of children because of reduced mobility. Locally, there are reported cases of moderate, severe and critical cases of COVID-19 among children 5-11 years. Of these, 42.19% had no comorbidities, based on the SALVACION registry. Although there are limitations in this registry, this is comparable to those reported in Africa (Nachega et al. 2021). The impact on deaths (CFR) and ICU admissions are likely greater among children in Lower-Middle Income Countries versus High Income Countries (Kitano et al, 2022). In addition, based on US data, the incidence of MIS-C is highest in the 5-11 age group among other age groups. In the Philippine SALVACION Registry, there were 11 MIS-C cases reported, 8 of which were from the 5-11 year age group. Of these 8 cases, 5 had no comorbidities.
Is Pfizer-BioNTech (10µg/dose) safe and efficacious for the pediatric population ages 5 - 11 years old? *Can Pfizer-BioNTech (10µg/dose) significantly reduce the magnitude and severity of COVID-19 in children ages 5 to 11 years old?*	**Yes,** it is efficacious for preventing symptomatic COVID-19 in children ages 5 to 11 years old based on high certainty of evidence. Based on limited evidence, *Pfizer-BioNTech* vaccination will likely protect children ages 5 to 11 years against multisystem inflammatory syndrome in children (MIS-C) resulting from SARS-CoV-2 infection. Currently, there is no data on the efficacy or effectiveness of *Pfizer-BioNTech (10µg/dose)* against variants of concern. One exploratory immunogenicity analysis of a Phase II/III trial which showed minimal to slight decline in neutralization against the Delta variant compared to the reference strain (Walter et al., 2021). **Yes,** the safety profile of *Pfizer- BioNTech (10µg/dose)* for children ages 5 to 11 years old is acceptable based on short-period follow-up of 2.3 months (very low to high certainty of evidence). However, further follow-up data is needed to establish the longer-term safety profile. Real world safety studies and reports also showed an

	acceptable safety profile of *Pfizer- BioNTech (10µg/dose).* *Pfizer-BioNTech (10µg/dose)* passed the benefit-risk profile assessment in children ages 5-11 years based on data on the vaccine efficacy of 90.7% (95% CI: 67.7 to 98.3) against symptomatic COVID-19, effectiveness against MIS-C and household transmission, and acceptable short-term safety. Regardless of the lack of data on the current prevalence of COVID-19 in children ages 5 to 11 years old in the Philippines, studies show that *Pfizer-BioNTech (10µg/dose)* has potential to avert a significant number of infections in the pediatric population (5 to 11 years old), including symptomatic and severe COVID-19, and MIS-C assuming sufficient vaccine coverage; and, may contribute to achieving herd immunity in the general population.
Is Pfizer-BioNTech (10µg/dose) affordable and feasible to use in a national immunization program for the pediatric population ages 5 - 11 years old?	**Yes,** primary vaccination in children ages 5-11 years using *Pfizer-BioNTech (10µg/dose)* is considered affordable. The share of the cost of the *Pfizer-BioNTech (10µg/dose)* to the total vaccine budget is also considered proportionate to the share of the doses to be procured for the different vaccination policies being implemented. The share of the cost to implement vaccination using this vaccine will constitute 7.90% of the total allocated budget for 2021 and 2022 (Php 9.90B of the Php 125.28 B total budget) and will cover 8.96% (27.9 M) of the total number of doses needed to be procured (310.9 M). Furthermore, the health, economic, and social benefits of using *Pfizer-BioNTech (10µg/dose)* in children 5 to 11 years old outweigh the cost of its introduction and implementation. In terms of feasibility, the challenges noted in the COVID-19 vaccine implementation for the pediatric population ages 12-17 years due to difficulties in complying with documentary requirements, maintenance of the cold chain requirement, administration errors, and insufficient human resources can be mitigated and addressed in preparation for the roll out in the 5 to 11 year old population. Several challenges encountered before and during the COVID-19 pandemic in the roll-out of Expanded Programme on Immunization (EPI) vaccines for children ages 5-11 years old have been identified. These include vaccine hesitancy, irregularity of planning, logistical concerns, lack of information, confusion on eligible population and scheduling, and lack of dedicated human resource for EPI vaccines. However, measures for improvement have been initiated by the DOH National Immunization Program (NIP) in order to improve and address the problems identified. These measures can also be adopted in the COVID-19 vaccination for children ages 5-11 years old.
Does Pfizer-BioNTech (10µg/dose) reduce out-of-pocket (OOP) expenses of households due to COVID-19?	**Yes**, *Pfizer-BioNTech* has the potential to reduce out-of-pocket expenses due to averted costs of isolation and treatment of mild, moderate, and severe COVID-19 in the pediatric population ages 5 to 11 years old. Other non-medical costs, productivity loss of the parents/ caregiver of these children, and treatment cost of other family members within the household who had likely contracted COVID-19 further increases the potential of the vaccine to reduce out-of-pocket expenses of households due to COVID-19.
Does Pfizer-BioNTech (10µg/dose) possess the characteristics that are desired by key stakeholders?	Given that there are no local studies to determine acceptability of vaccination among children 5 to 11 years old, HTAC can only recognize the social impact of vaccination in this age group in terms of supporting the attainment of occupations of children which include social learning achieved through peer interaction. This could

	also contribute to the improvement of the quality of life within the households when caregivers of children are relieved of the anxiety of dealing with the consequences of COVID-19 infection and sequelae.
Does Pfizer-BioNTech (10µg/dose) reduce or not further add to existing inequities in the health system?	Pediatric vaccination poses inherent challenges because of pre-existing inequities in the healthcare system which include inequitable access to information and capacity to diagnose co-morbidities in children (e.g., pediatric specialists) inaccessibility to vaccination sites and inadequate logistical capacity, and the general deficiency in infrastructure, transportation modalities, and health human resources across the different areas in the country. These challenges can be translated to opportunities to improve the vaccination coverage of priority groups (e.g., encouraging unvaccinated parents and/or guardians accompanying pediatric vaccinees to get vaccinated as well, improvement of information, education, and communication (IEC) campaigns, among others). To ensure the success of the implementation of COVID-19 vaccination for children ages 5 to 11 years old, we must emphasize the importance of free and prior informed consent, support the autonomy of parents, guardians, and the pediatric population towards vaccination, and ensure that IEC materials are accessible and comprehensible (i.e., translated into the local language of the target population). As for the use of *Pfizer-BioNTech (10ug/dose)* among children ages 5 to 11 years, the less stringent logistic requirements (i.e., 2-8°C for 10 weeks and -90 °C to -60°C for longer periods of time) will not aggravate health inequities related to inoculation of recipients residing in isolated and disadvantaged locations. However, the intricate vaccine handling and preparation of Pfizer-BioNTech may make administration in rural areas without the appropriate capacity more challenging.

In the development of this recommendation, the HTA Council has appraised and considered the evidence review of the Philippine COVID-19 Living Clinical Practice Guidelines Group, the International Vaccine Access Center (IVAC) of the Johns Hopkins Bloomberg School of Public Health and World Health Organization review, COVID-NMA living review and review of global and local data pertaining to the epidemiology of 5 to 11 year-old children with COVID-19.

The HTAC also considered that as of 17 January 2022, the Philippine Pediatric Society (PPS) and the Pediatric Infectious Disease Society of the Philippines (PIDSP) recommend the vaccination of the pediatric population (5-11 years old) with priority to the A1 (children of healthcare frontliners) and the A3 (children with comorbidities) populations. They recommended the use of duly-approved vaccines, particularly the 2 dose *Pfizer-BioNTech* (10ug/dose) vaccine with a dosing interval of 3 weeks. Moreover, based on the 19 January 2022 update of the WHO Prioritization Roadmap, WHO recommends to consider using *Pfizer-BioNTech* in children aged 5- 17 years only when high vaccine coverage (primary series and boosters) has been achieved in the higher priority-use groups.

The HTA Council further emphasizes the need to enforce strict conditions for the emergency use of health products to safeguard against eventualities:

- Transparency and accountability in the processes of allowing emergency use of health products, especially for the public health response;

- Continuous collection of safety and effectiveness data in the context of clinical trials and actual use in the real world;
- Close monitoring of recipients and safeguards for expected and unexpected adverse events that may arise from the use of health products under an EUA;
- National coordination of the emergency use under the Philippine FDA and the DOH;
- Cascading of complete information to vaccinees and healthcare providers on potential risks and benefits, and securing of informed consent with regard to receiving the intervention; and

Finally, the HTAC recommends the conduct of research to address the current gaps in evidence with regard to the use of *Pfizer-BioNTech*:

- Real-world effectiveness in the Philippine context particularly focused on the following knowledge gaps:
    - Effectiveness in reducing COVID-19 cases, hospitalizations and deaths, and preventing outbreaks and transmission of disease across the population
    - Effectiveness in reducing asymptomatic infection
    - Duration of protection
    - Impact of the timing and number of doses received
    - Probable need for booster dosing
    - Differences in the effectiveness of the vaccine among special populations (i.e., individuals with comorbidities, immunocompromised patients)
    - Effectiveness of the vaccine against emerging SARS-CoV-2 viral strains
- Continuous safety surveillance and monitoring of all adverse events especially severe allergic reactions, Bell's palsy, serious adverse events such as thrombosis thrombocytopenia syndrome (TTS), myocarditis and other adverse events of special interest (AESI) following vaccination
- Best practices, challenges, and barriers in implementation across different localities
- Monitoring of unexpected or additional costs associated with vaccine implementation.

Current Evidence on *Pfizer-BioNTech COVID-19 Vaccine (10µg/dose)*

The table below summarizes the appraisal of available evidence on *Pfizer Bio-NTech* based on the HTAC evaluation framework.

In addition, the following appendices are provided for further details:

- Appendix 1: Trends in hospitalization in the Philippines, by age group
- Appendix 2: LCPG Report on Clinical Efficacy, Effectiveness and Safety
- Appendix 3: Search Strategy
- Appendix 4: Risk of Bias Assessment by HTAC
- Appendix 5: HTAC GRADE table
- Appendix 6: Odd ratio for transmission per age group (Harris et al., 2021)
- Appendix 7: Vaccine effectiveness against transmission by age group and household number (Hayek et al., 2021)
- Appendix 8: Costing Table

Table 1.2 Key Findings in the Current Evidence Considered for the HTAC Evaluation of *Pfizer-BioNTech (10µg/dose)*

Evaluation Criteria	Question	Current Evidence	HTAC specification
CRITERION 1			
1. Responsiveness to magnitude and severity	*What is the magnitude and severity of COVID-19 in children ages 5 to 11 years old?* *Is COVID-19 a public health priority?*	***Local epidemiologic data on children ages 5 to 11 years old versus older age groups*** In the pediatric population, the DOH Philippines recorded 118,474 COVID-19 cases in children ages 5 -11 years old as of 24 January 2022. The CFR in this age group (0.13%) is comparable to that of adolescents ages 12-17 years old (0.16%) and less than the adult population (19-59 years old: 0.80%; ≥ 60 years old: 7.71%). Cumulative data from the DOH COVID-19 data drop (as of 15 January 2022) recorded a total of 3,164,635 cases of COVID-19. Of these, 3.51% (110,985) were hospitalized, 29.99% (949,355) were not hospitalized and 66.50% (2,105,295) had unknown admission status. ● Of the 110,985 confirmed COVID-19 hospitalized cases, patients ages 5 to 11 years old accounted for only 1.73% of national hospitalization data. Meanwhile, children less than 5 years old accounted for 2.26%, while adolescents 12 to 17 years old represented 2.54% of hospitalized cases. Majority of the confirmed hospitalized cases were adults ages 18 to 59 years old (63.02%) and elderly (30.46%). ● Similarly, plotted hospitalization data from January 2021 to January 2022 disaggregated by age group showed that adults ages 18 to 59 years and the elderly ≥60 years were at higher risk for COVID-19 hospitalization compared to the younger age groups. Trends of hospitalized cases over time, by age group are presented in Appendix 1. ***Evidence on risk of hospitalization, severe disease, MIS-C and death among children ages 5 -11 years old*** In terms of local cases, the SALVACION REGISTRY recorded a total of 510 cases in children aged 5 to 11 years old (as of 31 December 2021). In terms of severity, the majority were mild cases (47.25%), followed by moderate (19.80%) and asymptomatic cases (16.86%); while the remaining were severe (7.45%), critical cases (6.47%) and multisystem inflammatory syndrome in children (MIS-C) (1.57%). Of the 510 cases reported, 172 cases were hospitalized (33.73%) and 31 deaths occured (6.08%). Three cases did not have reported disease severity. - In children who may have been hospitalized (n = 172) (i.e., moderate to critical), 55.81% (96/172) had	The vaccine can potentially reduce the COVID-19 disease burden (health, social and economic impact). Trends in COVID-19 morbidity, mortality and hospitalization rates.

comorbidities while 42.19% (76/172) had no comorbidities. The following are the proportion of hospitalized cases with and without comorbidities, by severity:

Severity	% With comorbidities (n/N)	% Without comorbidities (n/N)
Moderate	48.51% (49/101)	51.49% (52/101)
Severe	71.05% (27/38)	28.95% (11/38)
Critical	60.61% (20/33)	39.39% (13/33)

- In terms of MIS-C, 8 out of the total 11 cases reported were among the 5-11 age group. Among these 8 cases in children ages 5 to 11 years old, 5 cases had no comorbidities while the remaining 3 had comorbidities (i.e., obesity). It is important to note, however, that the reports of MIS-C were most likely underestimated compared to the actual cases.
- Among the 31 deaths recorded:
    - 21 experienced critical disease (63.64% of 33 critical cases)
    - 7 experienced severe disease (18.42% of 38 severe cases)
    - 2 experienced mild disease (0.83% of 241 mild cases), and
    - 1 experienced moderate disease (0.99% of 101 moderate cases).

  It was noted that both mild cases which progressed to death had either neurologic or oncologic comorbidity. Meanwhile, the only moderate case who progressed to death had a neurologic comorbidity. No deaths were observed in asymptomatic cases and cases of MIS-C.

Globally, the WHO noted in their interim statement dated 24 Nov 2021 on vaccination of children and adolescents that overall, there are proportionally fewer symptomatic and severe COVID-19 cases, and deaths in this population compared with older age groups. Global data showed that COVID-19 among children ages 5 to 14 years represented 7% of global cases and 0.1% of global deaths. Further, children and adolescents usually present with mild and fewer symptoms compared to older age groups. However, children are still at risk of experiencing prolonged symptoms (or long COVID-19) and the rare multisystem inflammatory syndrome in children (MIS-C) has been reported to occur and complicate recovery from COVID-19 from this population.

		In a joint position paper, the Israeli Pediatric Association and Israeli Society for Pediatric Infectious disease discussed the disease burden of COVID-19 in Israeli children. As of late October 2021, there were 512,613 reported cases of COVID-19 in children and adolescents. About 43% of these cases (223,850) were in children ages 5-11 years old. They observed that the relatively high incidence rate of the age group was inversely related to the immunization rate of the general population (adults and adolescents) - as the immunization coverage of the older age groups increased and the relative proportion of all new COVID-19 cases in these age groups decreased, cases in the 5-11 age group increased. They also asserted that although COVID-19 morbidity and mortality are significantly lower in children than in adults, the risk of severe COVID-19 is not negligible, even among healthy children without pre-existing comorbidities. Of the 5-11 age group in Israel, 54% of patients with moderate-to-severe COVID-19 and 88% with MIS-C were previously healthy. In addition, they were able to estimate the rate at which severe clinical outcomes of COVID-19 disease occur in children: ● COVID-19 associated hospitalization - 1:200 ● Moderate-to-critical COVID-19 - 1:900 ● COVID-19 associated myocarditis - 1:1600 ● MIS-C - 1:3000 ● MIS-C associated death - 1-2:100 ● Long COVID - ~1:100. Meanwhile, a retrospective cohort review of COVID-19 hospitalization cases of children and adolescents aged 0 to 19 years in six (6) African countries revealed a high morbidity and mortality among this population, with greater likelihood of severe clinical outcomes among children <1 year and children with hypertension, chronic lung disease, and or hematologic disease. Almost half of hospitalized patients (47.5%; 223 of 469 patients) presented with severe or critical COVID-19 disease with only 24.5% of the study population who had at least 1 pre-existing comorbidity. While the most frequently reported symptoms were cough, fever, rhinorrhea, and respiratory distress, 18 of 297 cases (6.1%), were clinically suspected (6 patients) or confirmed (12 patients) to have MIS-C. Among the cohort, 418 patients (89.3%; 95%CI, 86.2% to 92.0%) were eventually discharged while 39 patients died (8.3%; 95% CI, 6.0%-11.2%). Of the 69 patients admitted to the ICU, 22 died. Of the 26 deaths with information on the presence or absence of clinical features of MIS-C, 4 had confirmed or suspected MIS-C. A systematic review for articles and national reports by Kitano et al., 2021 found that the impact on COVID-19 fatality among children ages 0 to 19 years was larger in low and middle income countries (LMICs) compared to high income countries (HICs). Of the 3,788 pediatric COVID-19 deaths gathered from the review, 91.5% were reported from LMICs and 8.5% were reported from HICs. The deaths per 1 million children and case	

		fatality rate were significantly higher in LMICs at 2.77 and 0.24%, respectively compared to HICs at 1.32 and 0.01%, respectively (p<0.001). It was noted; however, that 83.5% of the pediatric population included in the study were from LMICs. Meanwhile, only 28.3% of ICU admissions included in the review were from LMICs. ***Evidence on seroprevalence and transmission among children ages 5 - 11 years old*** Despite the local and global epidemiologic data presented above, the burden of COVID-19 disease among children ages 5 to 11 years may still be largely underestimated. In the US, the CDC conducted a nationwide survey on infection-induced SARS-CoV-2 seroprevalence where every two weeks, about 50,000 serum samples collected by commercial laboratories from routine screening or acute clinical care are tested for SARS-CoV-2 antibodies. As of September 2021, the seroprevalence survey found that 38% (95%CI: 36-40%) of children ages 5-11 years tested positive for SARS-CoV-2 antibodies, indicating previous infection and that the median number of infections per reported case was higher among children and adolescents ages 0-17 years **[median 6.2(Range: 4.7–8.9)]** compared to the number among the general population **[median 6.2 (range: 4.7–8.9)].** Given the low number of cases recorded among children, this data suggests that they are at least as likely as adults to be infected with SARS-CoV-2 but these infections in children are less likely to be reported compared with adults. A limitation of this study, however, is that the seroprevalence estimates may not be representative of the general pediatric population. The WHO also noted that children with SARS-CoV-2 infection present with asymptomatic or mild disease which may mean less tendency to seek healthcare from medical institutions and cases may go unreported. The presentation to the ACIP by Dr. Jefferson Jones (2 November 2021) cited three studies which showed varying results regarding transmission in children and adults. Two studies reported similar rates of transmission from infected children as from adults (Bi et al. 2021; US CDC 2021); while one observed lower transmission rates from infected children compared with those from infected adults (McLean et al. 2021). Jones also stated that secondary transmission from children occurs in both household and school settings. For example, in an outbreak investigation conducted in an elementary school in California, the Marin County Department of Health (MCPH) found a total of 27 laboratory-confirmed COVID-19 cases including the index case of one unvaccinated teacher. The overall attack rate in the affected classroom was 50%; risk correlated with seating proximity to the teacher as 12 of the cases were among the 24 students in the classroom. The remaining 14 cases were either parents or students in another grade who were siblings of the students of the index case. Whole genome sequencing was done in 18 available specimens and were all identified to be the Delta variant. Despite the vaccines being effective against the variant, risk of transmission remains elevated among the unvaccinated and those without strict adherence to prevention strategies.	

		As for the role of children in transmission of SARS-CoV-2 in Israel, during the Delta surge, one-third of all infected persons (both children and adults) were found to have contracted COVID-19 from children ages 5-11 while almost half (49%) of infections were from children ≤17 years. The role of children in SARS-CoV-2 transmission increased as more adults received their COVID-19 vaccination. Meanwhile, the role of children in household transmission is still uncertain. ***Evidence on variants of concern*** In the COVID-19 Omicron Global Update presented in the SAGE Extraordinary Meeting (19 January 2022), the WHO COVID-19 analytics team estimated that as of 11 January 2022, the Omicron variant causes a 186% (95% CI: 148 to 222) increase in transmission compared to the Delta variant in countries in the Western Pacific Region (WPRO) which includes the Philippines. Data from the DOH Epidemiology Bureau (EB) showed that from December 2021 to January 2022 (period of Omicron surge), there was a decrease in cases for ages 20 to 59 years old while an increasing trend is observed for the 19 and younger population and 60 and older population. However, EB noted that it is not enough to conclude whether the younger and older population are now the drivers of transmission. Cumulatively, as of 24 January 2022, 15,950 samples taken by convenience and purposive sampling tested positive for VoCs across all ages (total number of samples tested was not available). Of these, 53.99% (8,612 samples) was Delta, 22.76% (3,630 samples) was Beta, and 19.87% (3,170 samples) was Alpha. Only 3.53% (535 samples) of the samples was Omicron. There was no disaggregation of cases caused by VoC by age group. ***Social and Economic Impact of COVID-19 in children*** COVID-19 has led to significant disruptions not only in the delivery of other priority health services (e.g., immunization, maternal and child health, non-communicable diseases) but also in the social and economic life of the nation by arresting the growth of the economy, displacing migrant and local workers, loss of jobs, increase in the fraction of workers who are currently employed but are absent from work (due to being an active case of COVID-19 or as a caregiver of a COVID-19 patient in the family e.g. children) and food insecurity (NEDA, 2020; PSA 2020; International Labor Organization, 2020;TESDA, 2020). Further, disruption in education of children (i.e. loss of learning due to school closures also leads to both social and economic losses). Social safety nets for the poorest and other vulnerable sectors have not been enough to compensate	

		for these losses (TESDA, 2020). The lockdowns and community quarantines have also been shown to have an impact on the mental health of Filipinos and have affected how common Filipino households adjust under the new normal, unable to visit and freely enjoy quality time with members of their families, as captured in some focus group discussions conducted by the HTAC and the HTA Unit. Locally-contextualized modelling studies are needed for more accurate projections of the potential impact of vaccination along with other interventions, under different scenarios. These can better inform decision-making. **HTAC Judgment**: In the Philippines, children ages 5 to 11 years old comprise 13.87% of the total population. The burden of COVID-19 contributed by children in this age group cannot be ascertained due to limited testing capacity, insufficient data, and other possible issues like the different community exposure of children because of reduced mobility. Locally, there are reported cases of moderate, severe and critical cases of COVID-19 among children 5-11 years. Of these, 42.19% had no comorbidities, based on the SALVACION registry. Although there are limitations in this registry, this is comparable to those reported in Africa (Nachega et al. 2021). The impact on deaths (CFR) and ICU admissions are likely greater among children in Lower-Middle Income Countries versus High Income Countries (Kitano et al, 2022). In addition, based on US data, the incidence of MIS-C is highest in the 5-11 age group among other age groups. In the Philippine SALVACION Registry, there were 11 MIS-C cases reported, 8 of which were from the 5-11 year age group. Of these 8 cases, 5 had no comorbidities.	
CRITERION 2			
2. Clinical efficacy, effectiveness, and safety	*What is the **efficacy and effectiveness** of Pfizer-BioNTech (10µg/dose) in terms of: reducing*	For the evidence on efficacy, the following reviews were considered: Philippine Living Clinical Practice Guidelines Group (LCPG Group) review (updated as of 04 January 2022) 2), International Vaccine Access Center (IVAC) of the Johns Hopkins Bloomberg School of Public Health and World Health Organization review as of 13 January 2021; and COVID-NMA living review as of 21 January 2022. To supplement these reviews, a systematic search of the literature databases PubMed, medRxiv, bioRxiv, and Cochrane Library was also	The vaccine achieves the following efficacy parameters:

	the incidence of symptomatic and severe COVID-19, hospitalization due to COVID-19, and death due to COVID-19 in children ages 5 to 11 years old?	conducted with the last search on 21 January 2022. You may refer to Appendix 3 for the search strategy utilized. Overall, there was 1 publication detected, reporting a Phase I and Phase II/III RCT that evaluated the efficacy, safety and immunogenicity of *Pfizer-BioNTech (10µg/dose)* in children ages 5 to 11 years old. Results of these trials were also reported in the US FDA Briefing Document (26 October 2021) and ACIP Interim Recommendations (12 November 2021). There was also one real world study (Zambrano et al., 2021) on the effectiveness of *Pfizer-BioNTech (30µg/dose)* against multisystem inflammatory syndrome in children (MIS-C) in adolescents added as supplemental evidence for the younger pediatric population. Lastly, three real world evidence on the impact of Pfizer-BioNTech *(30µg/dose)* adult vaccination on SARS-CoV-2 transmission to children were also included. **Evidence from trials** ***Efficacy outcomes*** ***Description of evidence*** Overall, the reference reviews detected one Phase II/III RCT (Walter et al., 2022) that reported efficacy outcomes for *Pfizer-BioNTech (10µg/dose)* in children ages 5 to 11 years old (median follow up period: 2.3 months). The US FDA Briefing Document (26 October 2021) and ACIP Interim Recommendations (12 November 2021) also reported the results of this trial, with the ACIP Recommendations document reporting a longer follow-up period (3.3 months) compared to the published manuscript (2.3 months).The Phase II/III trial had two cohorts - Cohort 1 (n=2,268, started on 24 Mar 2021) which was used to evaluate efficacy, immunogenicity and safety and Cohort 2 (n=2,394, started on 15 Aug 2021) which was used to evaluate safety only. Walter et al. only reported outcomes for Cohort 1 while the FDA briefing document reported outcomes for both cohorts. Details of the trial are presented in Table 1.2.1 below. Table 1.2.1. Study characteristics of the Phase II/III RCT on *Pfizer-BioNTech (10µg/dose)* **Author Year Country Study Design** | **Study Setting** | **Population** | **Intervention** | **Control** | **Outcomes**	**Preferred VE: ≥70% reduction** in the risk of symptomatic infection with vaccination versus no vaccination **Minimum acceptable VE (point estimate): at least 60% reduction** of symptomatic COVID-19; **at least 80% reduction** of severe COVID-19, hospitalization due to COVID-19; **at least 80% reduction** of death due to COVID-19.

Walter et al., 2022 United States, Spain, Finland, Poland Phase II/III RCT	June to September 2021 (Cohort 1) Dominant variant: US (Delta), Spain (Alpha, Delta), Finland (Alpha, Delta), Poland (Alpha, Delta)	Healthy participants, ages 5-11 years N=2,268	2 doses 10μg *Pfizer-BioNTech,* 21 days apart (n=1,528)	2 doses saline placebo, 21 days apart (n=757)	VE against symptomatic COVID-19, ≥7 days after dose 2 in participants without previous evidence of infection Median follow up period: 2.3 months VE against symptomatic COVID-19, ≥7 days after dose 2 in participants with or without previous evidence of infection Follow-up: 2.3 months (Walter et al. 2022); 3.3 months (ACIP, 2021)	

Key findings

Risk of bias

The HTAC rated the *RoB* of Walter et al. (2022) as *low* for the outcome symptomatic COVID-19 in participants without previous evidence of infection and symptomatic COVID-19 in participants with or without previous evidence of infection.

Results of the trial on clinical efficacy

The results of Walter et al., 2022 on the vaccine efficacy of *Pfizer-BioNTech (10μg/dose)* in children ages 5 to 11 years old against symptomatic COVID-19, ≥7 days after dose 2 are presented below. There were no reported cases of severe COVID-19. Meanwhile, the trial identified asymptomatic COVID-19 as one of its outcomes of interest, based on the protocol. However, vaccine efficacy for this outcome was not reported in Walter et al., 2022. Certainty of evidence was assessed using the GRADE approach by the HTAC. Details on the GRADE assessment are presented in Appendix 5.

For critical outcomes:

Using *Pfizer-BioNTech (10μg/dose)* in children ages 5 to 11 years old (at least 7 days after the

second dose), compared to placebo, reduces the risk for:

- Symptomatic COVID-19 in participants without evidence of previous infection
  - by 90.7% (95% CI: 67.7 to 98.3), based on high certainty of evidence
- Symptomatic COVID-19 in participants with or without evidence of previous infection
  - by 90.9% (95% CI: 68.3 to 98.3), based on high certainty of evidence

Note that the vaccine efficacy against symptomatic COVID-19 in participants with or without previous evidence of infection had a longer follow up period of 3.3 months as reported in the ACIP Interim Recommendations (2022). Hence, this is the VE value for this outcome that was reflected in this ES. Meanwhile, for the outcome *symptomatic COVID-19 in participants without previous evidence of infection*, the ACIP did not report vaccine efficacy, thus the vaccine efficacy for this outcome was taken from Walter et al., 2022 which had a shorter follow up period (i.e., 2.3 months). Nevertheless, the VE values from the ACIP [VE: 90.5% (95%CI: 98.3)] and Walter et al., 2022 [VE: 90.7% (95% CI: 67.4 to 98.3)] are not significantly different.

There were no cases of severe COVID-19 or multisystem inflammatory syndrome in children (MIS-C), and deaths reported among the 1,510 participants in the vaccine arm and 746 participants in the placebo arm (Walter et al., 2022).

For important outcomes:
The trial did not report important efficacy outcomes such as symptomatic COVID-19 in children ages 5 to 11 years old with comorbidities and asymptomatic COVID-19.

Immunogenicity outcomes

Description of evidence

Overall, there were two studies - one Phase I and one Phase II/III RCT - published in a single article (Walter et al., 2022**)** which evaluated the immunogenicity of *Pfizer-BioNTech (10µg/dose).*
Details of the trials are presented in Table 1.2.2 below.

Table 1.2.2. Study characteristics of the Phase I open label, dose-finding study and Phase II/III RCT on *Pfizer-BioNTech (10µg/dose)*

Author Year Country Study Design	Study Setting	Population	Intervention	Control	Outcomes

Walter et al., 2022 United States Phase I RCT	March 24 through July 16, 2021 Dominant variant: US (Alpha)	Healthy participants, ages 5-11 years N= 49	2 doses Pfizer-BioNTech, 21 days apart Dosing: 2 doses 10 µg/dose (n=16) 2 doses 20 µg/dose (n=16)		- SARS-CoV-2 neutralization titers (GMT) 7 days after the second dose		
Walter et al., 2022 United States, Spain, Finland, Poland Phase II/III RCT	June to September 2021 (Cohort 1) Dominant variant: US (Delta), Spain (Alpha, Delta), Finland (Alpha, Delta), Poland (Alpha, Delta)	Healthy participants, ages 5-11 years N=2,268	2 doses 10µg *Pfizer-BioNTech,* 21 days apart (n=1,528)	2 doses saline placebo, 21 days apart and in 16-25 years old using 30µg dose vaccine (n=757)	- Geometric mean neutralization titers (GMT) 1 month 7 days after the second dose - Geometric mean ratio of neutralizing GMT 1 month after the second dose (compared to 16-25 year old) - Geometric mean fold rise (GMFR) from before vaccination to 1 month after dose 2 - Seroresponse rate 1 month after second dose		

Key findings

Results of the immunogenicity trials

The Phase II/III RCT (Walter et al., 2022) reported an increase in geometric mean neutralization titers in children vaccinated with *Pfizer-BioNTech (10µg/dose)* 1 month after the second dose [GMT: 197.6 (95% CI:1106.1 to 1296.6)] compared to placebo [GMT: 11 (95% CI: 9.7 to 11.8)]. When compared to GMT before vaccination, a geometric mean fold rise (GMFR) in neutralization titers of 118.2 (95% CI: 109.2 to 127.9) was observed. Further, when compared to the GMT observed in the older population (16 to 25 years old) who received 30µg/dose of the vaccine, the GMT ratio was 1.04 (95% CI: 0.93 to 1.18). This GMT ratio met the immunobridging criteria of a lower boundary of the two-sided 95% confidence interval greater than 0.67, the predefined point estimate of a geometric mean ratio of 0.8 or greater, and the FDA-requested point estimate criterion of a geometric mean ratio of 1.0 or greater. Details on the immunogenicity outcomes reported in the trial are presented in Table 1.2.3 below.

Table 1.2.3. Geometric mean neutralization titers (GMT) seroresponse rate in children ages 5 to 11 years old and adults ages 16-25 years old

Outcome	*Pfizer-BioNTech*		Placebo	
	5-11 years old (10µg)	16-25 years old (30µg)	5-11 years old	16-25 years old
Serum neutralization titers (GMT) before vaccination (95% CI)	10 (9.9 to 10.3)	10 (9.8 to 10.8)	10 (10.0 to 10.0)	10 (10.0 to 10.0)
Serum neutralization titers (GMT) 1 month after dose 2 (95% CI)	1197.6 (1106.1 to 1296.6)	1146.5 (1045.5 to 1257.2)	11 (9.7 to 11.8)	10 (10.0 to 10.0)
Seroresponse 1 month after dose 2	99.2%	99.2%	*Not reported*	*Not reported*

Meanwhile, the Phase I RCT (Walter et al., 2022) reported a GMT of 4,163 (95% CI: 2,584.7 to 6,704.0) in the 10µg/dose group and 4,583 (95% CI: 2,802.9 to 7,494.8) for the 20µg/dose group. The study did not report immunogenicity outcomes for the other arms i.e. 30/30µg group and 30/10µg group.

Evidence from real world studies

Description of evidence

There were no real world studies detected by the reference reviews and systematic search for the clinical effectiveness (VE against symptomatic and severe COVID-19, hospitalization due to COVID-19, and death due to COVID-19) and immunogenicity of *Pfizer-BioNTech (10µg/dose)* for the pediatric population ages 5 to 11 years old. This shall be updated once new real- world evidence has been reviewed.

Meanwhile, there was one (1) test-negative case-control study detected (Zambrano et al., 2022) which evaluated the effectiveness of *Pfizer-BioNTech (30ug/dose)* against Multisystem Inflammatory Syndrome in children (MIS-C) in adolescents ages 12 to 18 years old. Despite the study not matching the population of interest, it was mentioned in the review that this analysis provides supportive evidence that vaccination of children and adolescents is highly protective against MIS-C and COVID-19. There is currently no local data examining this outcome. The characteristics of the Zambrano et al., 2022 study is presented in Table 1.2.4 below.

Table 1.2.4 Study characteristics of Zambrano et al., 2022 study on VE against MIS-C

Author Year Country Study Design	Study Setting	Population	Case patients	Control	Outcomes
Zambrano et al. (2022) [US CDC] (Published) United States CDC Test Negative Case Control	July 1 to December 9 2021 Delta variant dominance	In-patient children 12-18 years old, N=283	Hospitalized children with MIS-C (n=102) ● Fully vaccinated with *Pfizer BioNTech (30ug/dose)*: 5 ● Unvaccinated: 97 *All MIS-C case patients were required to have laboratory evidence of current or recent infection:* ● *RT-PCR or*	In-patients without evidence of current SARS-CoV-2 infection, (n=181) ● Fully Vaccinated with *Pfizer BioNTech (30ug/dose):* 65 ● Unvaccinated: 116 *There were two sets of hospitalized controls:* *1) with COVID-19-like*	Vaccine effectiveness (VE) against MIS-C (2 doses, given ≥28 days before hospitalization) Percentage of patients requiring life support

			antigen-positive; antibody not performed: 11 (10.8%) • *RT-PCR or antigen-positive; antibody-positive: 12 (11.8%)* • *Antibody-positive only: 76 (74.5%)* • *Pre-admission results only: 3* (2.9%)	*symptoms, but tested negative for SARS-CoV-2 infection by RT-PCR or antigen-testing 2) without COVID-19-like symptoms (18/91 syndrome-negative controls had no record of SARS-CoV-2 testing)*	

Apart from the direct protection conferred by vaccination against the clinical outcomes such as symptomatic COVID-19, severe COVID-19, hospitalization and death due to COVID-19, the HTAC explored the potential of COVID-19 vaccination of reducing transmission of SARS-CoV-2 infection and providing indirect protection to individuals who cannot be vaccinated but live in vaccinated households. There are three studies included in this review - two in Israel and one in the UK - that reported the impact of vaccination on household transmission. Characteristics of the included studies are detailed in Table 1.2.5.

Table 1.2.5. Characteristics of studies on the impact of vaccination on transmission - Harris et al. (2021), Hayek et al. (2022), and Prunas et al. (2022)

	Harris, et al., 2021 **[Published]** England	**Hayek, et al., 2022** **[Published]** Israel	**Prunas et al., 2022** **[Published]** Israel
Study design	Matched case-control and stratified cohort	Retrospective cohort study	Chain binomial modelling using data from Maccabi Healthcare services
Study period	Data extraction: March 23, 2021	Early period: January 17, 2021 to March 28, 2021 (Alpha variant)	Data extraction: June 1, 2020 to July 28, 2021

	Dominant variant: Alpha	Late period: July 11, 2021 to September 30, 2021 (Delta variant)	Before and After Delta variant dominance/emergence	
Population	Unvaccinated household contacts (0 to 60+ years old) of index cases (≥16 years old) Infected between January 4, 2021 to February 28, 2021 and has a specimen collected within 2 to 14 days after the specimen date of the index case N= 1,018,842	Unvaccinated children and adolescents without prior COVID-19 infection N, early period = 400,733 N, late period = 181,307	Vaccinated and unvaccinated individuals and households N, individuals= 2,472,502 from N, households = 1,327,647 N, fully vaccinated=758,228 N, partially vaccinated=105,305 N, unvaccinated=1,608,969	
Intervention	Contacts of vaccinated (*Pfizer or AZ*) index cases ≥21 days before infection: N= 9,363 (n=2,969 are 0 to 15 years old)	Unvaccinated children and adolescents in households with parents vaccinated with *Pfizer-BioNTech (30µg/dose)* (two doses of the primary series with or without booster dose)	Contacts of index cases who are fully vaccinated with *Pfizer-BioNTech (30µg/dose)* ● *≥10d dose 2 and <90d dose 2* N, pre Delta = 861 N, post Delta = 57 ● *≥90d dose 2* N, pre Delta = 72 N, post Delta = 3,377	
Comparator	Contacts of unvaccinated index cases: N=960,765 (n=263,190 are 0 to 15 years old) Contacts of vaccinated index cases (*Pfizer-BioNTech [30µg/dose] or AZ*) at < 21 days	Unvaccinated children and adolescents in households with unvaccinated parents	Contacts of unvaccinated index cases N, pre Delta = 184,191 N, post Delta = 5,586 Contacts of index cases partially vaccinated with *Pfizer-BioNTech (30µg/dose)*	

	before infection: N = 47,950 (n=13,429 are 0 to 15 years old)		*(≥10d dose 1 and <10d dose 2)* N, pre Delta = 6,131 N, post Delta = 257
Outcomes	Odds ratio on confirmed COVID-19 infection in household contacts of ● index cases vaccinated ≥21 days vs. < 21 days before infection ● index cases vaccinated ≥21 days before infection vs. unvaccinated	- Change in the risk of SARS-CoV-2 infection among susceptible children in the household - Decrease in risk that a vaccinated parent would be infected - Decrease in risk that a vaccinated infected parent would infect a susceptible child	- VE against susceptibility to infection - VE against infectiousness given infection - VE against transmission based on secondary attack rates (i.e. RT-PCR confirmed contacts within 14 days of the index case of the index case) with: ● unvaccinated index cases ● partially vaccinated index cases ● fully vaccinated index cases

Key findings

Results of Zambrano et al. (2022):

The study concluded that vaccination with *Pfizer-BioNTech (30µg/dose)* in children ages 12 to 18 years old (at least 28 days before hospitalization) reduces the risk for MIS-C as compared to no vaccination:

- by 91% (95% CI : 78% to 97%) in the entire study population
- by 90% (95% CI: 75%to 96%) in patients with serologic evidence of previous infection only

Further, none (0%) of the fully-vaccinated MIS-C patients required life support as compared to 39% in the unvaccinated MIS-C patients.

Zambrano et al. further discussed that this analysis lends supportive evidence that vaccination of children and adolescents is highly protective against MIS-C and COVID-19 and underscores the importance of vaccination of all eligible children.

		Results of studies on the impact of vaccination on transmission The study of Harris, et al., 2021 showed a significantly lower odds of becoming a secondary case of confirmed COVID-19 infection in household contacts of index cases who are fully vaccinated with *Pfizer-BioNTech (30µg/dose)* ≥21 days after dose 2 as compared to contacts of index cases who are fully vaccinated <21 days from dose 2 [Odds ratio [OR]: **0.49 (0.44 to 0.56)**], and unvaccinated index case [OR = **0.51 (95% CI 0.42, 0.62)**]. In terms of transmission to household contacts 0 to 19 years old, there were also significantly lower odds of secondary attack for contacts of index cases who are fully vaccinated with *Pfizer-BioNTech (30µg/dose) at age* 16-39 years old [OR = **0.69 (95% CI: 0.53 to 0.90)**] and 40-59 years old [OR = **0.53 (95% CI: 0.41 to 0.69)**] as compared to unvaccinated. However, the data of transmission from index cases 60 years and older for this age group of household contact was inconclusive due to a relatively wide confidence interval. Furthermore, the study did not evaluate transmission wherein index cases were children below 16 years old which might be due to their ineligibility for vaccination at the time of study. The retrospective cohort study in Israel (Hayek et al., 2022) explored the two mechanisms of indirect protection of vaccination on unvaccinated children who live with vaccinated parents. First, as a direct effect, full vaccination reduces the risk of a parent becoming infected by **94.4% (95%CI: 93.2%, 95.4%)** during the early period and by **86.3% (95% CI: 83.4%, 88.6%)** during the late period. This reduces the likelihood of an infected parent from becoming a household contact of an unvaccinated child. Second, vaccination reduces the infectiousness of an infected parent by **72.1% (95%CI: 36.6%, 89.3%)** after full vaccination and by **79.6% (95%CI: 55.9%, 91.8%)** after booster vaccination. This reduces the risk of transmission of an infected parent to the unvaccinated child. Additionally, the study compared the risk of SARS-CoV-2 infection among unvaccinated children in vaccinated households vs unvaccinated households. Regardless of the study period, (whether during the Alpha or Delta surge), age of unvaccinated child, or household size, the decrease in risk of infection was higher in households with two vaccinated parents compared to a single vaccinated parent (Appendix 7 and Table 1.2.6). Similar to the two mechanisms explored by Hayek et al. (2022), Prunas et al. (2022) used chain binomial modeling for household transmission to estimate the vaccine effectiveness against susceptibility to infection and vaccine effectiveness against infectiousness given infection. These two outcomes (risk of infection and risk of infectiousness given infection) were combined to calculate the total vaccine effectiveness, which was estimated to be **91.8% (95% CI: 88.1%, 94.3%)** within 10 to 90 days, and **61.1%**	

(95% CI: 5.2%, 84.1%) more than 90 days after the second dose during the pre-Delta phase and **65.6% (95% CI: 4.9%, 87.6%)** within 10 to 90 days and **24.2% (95% CI: 9.0%, 36.9%)** more than 90 days after the second dose, during the Delta phase. The study also analyzed the risk for children less than 12 years of age of acquiring SARS-CoV-2 infection from a vaccinated vs an unvaccinated infectious household member; however, the results were inconclusive (Table 1.2.6).

Table 1.2.6. Point estimates reported from detected studies on the impact of vaccination on transmission

Harris, et al., 2021 **[Published]** **England**	**Hayek, et al., 2022** **[Published]** **Israel**	**Prunas et al., 2022** **[Published]** **Israel**
Results for Pfizer-BioNTech *(30µg/dose)* only Index cases vaccinated >21 days vs. < 21 days before infection Odds ratio: 0.49 (95% CI: 0.44 to 0.56) Index cases vaccinated >21 days vs. unvaccinated Unadjusted odds ratio: 0.57 (95% CI 0.49, 0.65) Matched case-control odds ratio: 0.51 (95% CI 0.42, 0.62) Odds ratio in household contacts aged 0 to 19 years old (yo): ● *index case ages 16-39 yo:* 0.69 (95% CI: 0.53 to 0.90) ● *index case ages 40-59 yo:* 0.53 (95% CI: 0.41, 0.69) ● *index ages 60+ yo:* 0.45 (95% CI: 0.14, 1.44)	*Risk of SARS-CoV-2 infection among susceptible children in the household* ***Early period (Alpha variant dominance)*** - Decrease in risk from one vaccinated parent: **26.0% (95% CI: 14.0%, 36.2%)** - Decrease in risk from two vaccinated parents: **71.7% (95%CI: 68.6%, 74.6%)** ***Late period (Delta variant dominance)*** - Decrease in risk from one boosted parent: **20.8% (95%CI: 11.4%, 29.1%)** - Decrease in risk from two boosted parents: **58.1% (95% CI: 53.1%, 62.6%)** *Risk that a fully vaccinated parent would be infected*	*VE against susceptibility to infection* ***Pre-Delta*** - 10 to 90 days after Dose 2: **89.4% (95% CI: 88.7%, 90.0%)** - >90 days after Dose 2: **58.3% (95% CI: 45.8%, 67.9%)** ***Delta*** - 10 to 90 days after Dose 2: **72.0% (95% CI: 65.9%, 77.0%)** - >90 days after Dose 2: **40.2% (95% CI: 37.6%, 42.6%)** *VE against infectiousness given infection* ***Pre-Delta*** - 10 to 90 days after Dose 2: **23.0% (95%CI: -11.3%, 46.7%)** - >90 days after Dose 2: **6.9% (95%CI: -124.8%, 61.4%)** ***Delta***

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<td>Note: Index cases included in the study were aged 16 and above.

Odds ratio per age of household contact and index case (See Appendix 6)</td>
<td><u>Early period</u>
- Decrease in risk from infection: 94.4% (95%CI: 93.2%, 95.4%)

<u>Late period</u>
- Decrease in risk from infection: 86.3% (95% CI: 83.4%, 88.6%)

<u>Risk that a vaccinated infected parent would infect a susceptible child</u>

<u>Early period</u>
- Decrease in risk from infection from a fully vaccinated infected parent: 72.1% (95%CI: 36.6%, 89.3%)

<u>Late period</u>
- Decrease in risk from infection from a boosted infected parent: 79.6% (95%CI: 55.9%, 91.8%)</td>
<td>- 10 to 90 days after Dose 2: -27.9% (95%CI: -248.9%, 53.1%)
- >90 days after Dose 2: -27.9% (95%CI: -53.7%, -6.5%)

<u>VE against infectiousness given infection, restricted to children <12 years</u>

<u>Pre-Delta</u>
- 10 to 90 days after Dose 2: 41.0% (95%CI: -13.7%, 69.4%)
- >90 days after Dose 2: 6.9% 15.1% (95%CI: -17671.7%, 99.6%)

<u>Delta</u>
- 10 to 90 days after Dose 2: -91.2% (95%CI: -706.6%, 54.7%
- >90 days after Dose 2: -7.1% (95%CI: -40.3%, 18.3%)</td>
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HTAC Judgment: Pfizer-BioNTech (10µg/dose) passed the HTAC-specified preferred vaccine efficacy threshold against symptomatic COVID-19 for the pediatric population ages 5 to 11 years old (<u>Walter et al., 2022</u>). Based on limited evidence among adolescents aged 12-17 years old, Pfizer-BioNTech vaccination will likely protect children against MIS-C resulting from SARS-CoV-2 infection (Zambrano et al., 2021).
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<td>What is the efficacy and effectiveness of Pfizer-BioNTech (10µg/dose) in terms of: reducing</td>
<td>For the evidence on efficacy, the following reviews were considered: <u>Philippine Living Clinical Practice Guidelines Group</u> (LCPG Group) review (updated as of 04 January 2022) 2) International Vaccine Access Center (<u>IVAC</u>) of the Johns Hopkins Bloomberg School of Public Health and World Health Organization review as of 13 January 2021; and <u>COVID-NMA</u> living review as of 21 January 2022.To supplement these reviews, a systematic search of the literature databases PubMed, medRxiv, bioRxiv, and Cochrane Library was also</td>
<td>Preferred VE: ≥70% reduction in the risk of symptomatic infection with vaccination versus no vaccination</td>
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	incidence of symptomatic and severe COVID-19, hospitalization due to COVID-19 and death due to COVID-19 ***caused by variants of concern*** *in children ages 5 to 11 years old?*	conducted with the last search on 21 January 2022. You may refer to Appendix 3 for the search strategy utilized. Overall, there was 1 publication detected, the US FDA Briefing Document (26 October 2021) which reported exploratory immunogenicity analysis against the Delta variant from the results of a Phase II/III trial (Walter et al., 2022). The Phase II/III trial had two cohorts - Cohort 1 (n=2,268, started on 24 Mar 2021) which was used to evaluate efficacy, immunogenicity and safety and Cohort 2 (n=2,394, started on 15 Aug 2021) which was used to evaluate safety only. Walter et al. only reported outcomes for Cohort 1 while the FDA briefing document reported outcomes for both cohorts. **Evidence from trials** ***Efficacy outcomes*** The reference reviews and systematic search did not detect any clinical trial evidence examining the efficacy of *Pfizer-BioNTech (10µg/dose)* in children ages 5 to 11 years old against COVID-19 caused by VOCs. This shall be updated once new clinical evidence has been reviewed. ***Immunogenicity outcomes*** ***Description of Evidence*** Overall, the reference reviews detected the US FDA Briefing Document (26 October 2021) which reported the immunogenicity of *Pfizer-BioNTech (10µg/dose)* against COVID-19 caused by the Delta variant in children ages 5 to 11 years old. The report presented data from exploratory descriptive analysis of a randomly selected subset of participants of the Walter et al., 2022 / Study C4591007 which is the same trial mentioned in the efficacy section of this Evidence Summary. Details of the analysis are presented in Table 1.2.5 below. Table 1.2.7. Study characteristics of Walter et al. (2022) exploratory immunogenicity analysis	**Minimum acceptable VE (point estimate): at least 60% reduction** of symptomatic COVID-19; **at least 80% reduction** of severe COVID-19, hospitalization due to COVID-19; **at least 80% reduction** of death due to COVID-19

Author Year Country Study Design	Study Setting	Population	Intervention	Comparator	Outcome
Walter et al., 2022 / Study C4591007 United States	June to September 2021 (Cohort 1) Dominant variant: US (Delta), Spain (Alpha, Delta), Finland (Alpha,	*Evaluable Immunogenicity Population* Randomly selected participants ages 5-11 yo	2 doses Pfizer-BioNTech *10µg*, 21 days apart N=34	Saline placebo N=4	Neutralizing GMT against Delta vs reference strain USA-WA1/2020 1 month after the second dose

	Delta), Poland (Alpha, Delta)				

Key Findings

Immunogenicity results

The exploratory analysis of immunogenicity, showed minimal to slight decrease in neutralization titers against Delta variant compared to the reference strain (1.24-fold reduction), based on HTAU computation.GMT values against the reference strain and Delta variant are presented in Table 1.2.6 below

Table 1.2.8. Geometric mean neutralization titers (GMT) of reference strain (USA-WA1/2020) and Delta variant at pre-dose 1 and 1 month post-dose 2 in children ages 5 to 11 years old

Assay Target	Time Point	Pfizer-BioNTech GMT (95% CI)	Placebo GMT (95% CI)
Reference strain USA-WA1/2020	Pre-Dose 1	10.0 (10.0, 10.0)	10.0 (10.0, 10.0)
	1 month post-Dose 2	365.3 (279.0, 478.0)	10.0 (10.0, 10.0)
Delta variant	Pre-Dose 1	10.0 (10.0, 10.0)	10.0 (10.0, 10.0)
	1 month post-Dose 2	294.0 (214.6, 405.3)	10.0 (10.0, 10.0)

Evidence from Real World Studies

There were no real world studies detected by the reference reviews and systematic search for the clinical effectiveness and immunogenicity of *Pfizer-BioNTech (10µg/dose)* against VOCs in the pediatric population ages 5 to 11 years old.

		HTAC Judgment: Currently, there is no available evidence on the efficacy of *Pfizer-BioNTech (10µg/dose)* against VOCs in the pediatric population ages 5 to 11 years old. One exploratory immunogenicity analysis of a Phase II/III trial showed minimal to slight decline in neutralization against the Delta variant compared to the reference strain.	
	What is the duration of protection of the Pfizer-BioNTech (10µg/dose) in terms of reducing the incidence of symptomatic and severe COVID-19, hospitalization due to COVID-19 and death due to COVID-19 in children ages 5 to 11 years old?	The current interim evidence shows that *Pfizer-BioNTech (10µg/dose)* provides protection against laboratory-confirmed symptomatic COVID-19 for children ages 5-11 years based on a median follow up period of 2.3 to 3.3 months after receiving two doses. Data on the duration of protection of *Pfizer-BioNTech* among children ages 5-11 years will be assessed as more evidence becomes available. **HTAC Judgment:** Cannot be assessed based on current data	Minimum acceptable duration of protection: confers at least 6 months protective immunity Preferred: ≥1-year protective immunity
	What is the safety of Pfizer-BioNTech (10µg/dose) in children ages 5 to 11 years old in terms of: serious adverse events, all-cause mortality systemic reactogenicity local reactogenicity special adverse events of interest	For the evidence on safety of *Pfizer-BioNTech (10µg/dose)* among children ages 5-11 years, the following reviews were considered: 1) Philippine Living Clinical Practice Guidelines Group (LCPG Group) review (updated as of 04 January 2022); 2) International Vaccine Access Center (IVAC) of the Johns Hopkins Bloomberg School of Public Health and World Health Organization review as of 13 January 2022; and 3) COVID-NMA living review as of 21 January 2022. To supplement these reviews, a systematic search of the literature databases PubMed, medRxiv, bioRxiv, and Cochrane Library was also conducted with the last search on 21 January 2022. You may refer to Appendix 3 for the search strategy utilized. Overall, there was 1 journal article detected, reporting a Phase I and Phase II/II RCT, and 5 reports on real world evidence that evaluated the safety of *Pfizer-BioNTech (10µg/dose)* among children ages 5-11 years. Results of the trials were also reported in the US FDA Briefing Document (26 October 2021) and ACIP Interim Recommendations (12 November 2021). ***Safety data from clinical trials***	Local and systemic reactions are tolerable, self-limiting and do not require hospitalization. No serious adverse events were caused by the vaccine. **Short term outcomes** (e.g., reactogenicity and allergic reactions, AESI): at least 2 months

	(i.e. Bell's palsy, Myocarditis/Pericarditis, Thrombosis with Thrombocytopenia Syndrome, Capillary *Leak Syndrome, Immune Thrombocytopenia, Multisystem Inflammatory Syndrome in Children [MIS-C] Post Vaccination)*	***Description of Evidence*** The reference reviews detected one publication (Walter et al., 2022) which reported the safety outcomes of *Pfizer-BioNTech (10 µg/dose)* among children ages 5-11 years from one Phase II/III randomized clinical trial and one Phase I, open label, dose-finding study. This trial is the same trial mentioned in the efficacy section of this Evidence Summary. The Phase II/III trial had two cohorts - Cohort 1 (n=2,268, started on 24 Mar 2021) which was used to evaluate efficacy, immunogenicity and safety and Cohort 2 (n=2,394, started on 15 Aug 2021) which was used to evaluate safety only. Walter et al. only reported outcomes for Cohort 1 while the FDA briefing document reported outcomes for both cohorts. Details of the two trials are presented in Table 1.2.7 below.	**Long term outcomes** (e.g., serious AEs, all-cause mortality, AESI, Vaccine-associated enhanced disease): at least 1 year

Table 1.2.9. Study characteristics of the Phase II/III RCT and Phase I study on *Pfizer-BioNTech (10 µg/dose)* (Walter et al., 2022)

Author, Year Country Study Design	Study Setting	Population	Intervention	Comparator	Outcomes
Walter et al., 2022 US, Spain, Finland, Poland Phase II/III RCT (US FDA Briefing Document, 26 October 2021)	June to September 2021 (Cohort 1) | June to October 2021 (Cohort 2) Dominant variant: US (Delta), Spain (Alpha, Delta), Finland (Alpha, Delta), Poland (Alpha, Delta)	Healthy participants, ages 5-11 years (Cohort 1 N = 2,268; Cohort 2 N = 2,394)	Pfizer-BioNTech, 10µg/dose, 2 doses, 21 days apart (Cohort 1 n=1,528; Cohort 2 n = 1,598)	Saline placebo, 2 doses, 21 days apart (Cohort 1 n=757; Cohort 2 n = 796)	Reactogenicity events, 7 days after each dose Unsolicited adverse events from Dose 1 through 1 month after Dose 2 Serious adverse events Dose 1 through 6 months after Dose 2 Follow-up period: Cohort 1: 2.3 months after

					dose 2 Cohort 2: 2.4 weeks after dose 2
Walter et al., 2022 US Phase I open-label, dose-finding study	March 24 through July 16, 2021 Dominant variant: US (Alpha)	Healthy participants, ages 5-11 years (N=49)	Pfizer-BioNTech, 2 doses, 21 days apart Dosing: 2 doses 10 µg/dose (n=16) 2 doses 20 µg/dose (n=16) 2 doses 30 µg/dose (n=4) 2 doses, 30µg first dose, 10µg second dose (n=12)		Reactogenicity events, 7 days after each dose Unsolicited adverse events from Dose 1 through 1 month after Dose 2

Key findings

Risk of bias

The HTAC rated the *RoB* of Walter et al. (2022) as *low* for the outcome of local adverse reaction, systemic adverse reaction, and any adverse event, which are short term outcomes, as the median follow up period of the trial is 2.3 months which is acceptable for short term outcomes based on HTAC specifications. For the outcome serious adverse events, a long term outcome was rated *high/unclear* due to incomplete outcome data since the median follow up period is not sufficient for long term outcomes.

Results of clinical safety

Short-term safety outcomes:

Based on the computed risk ratio (RR) from the Phase II/III RCT, *Pfizer-BioNTech (10µg/dose)* for children ages 5-11 years compared to placebo increases risk for:

- systemic adverse reactions by:
  - **1.40 times (95% CI: 1.26 to 1.56)** within 7 days after dose 2, based on high certainty of evidence
- local adverse reactions (injection site pain only) by:

		- **2.24 times (95% CI: 2.02 to 2.49)** within 7 days after dose 1, based on high certainty of evidence - **2.28 times (95% CI: 2.05 to 2.55)** within 7 days after dose 2, based on high certainty of evidence Meanwhile, *Pfizer-BioNTech (10µg/dose),* shows inconclusive safety data on the risk for: ● **any adverse events [RR: 1.19 (95%CI: 0.91 to 1.55)]** from dose 1 through 1 month after dose 2, based on moderate certainty of evidence. ● **systemic adverse reaction [RR: 1.06 (95% CI: 0.96 to 1.17)]** within 7 days after dose 1, based on moderate certainty of evidence. Meanwhile, the Phase I trial reported that most local reactions were mild to moderate, and were transient. Fever was more common among the highest dosing group and all four participants that received two doses of 30µg developed mild to moderate fever within 7 days after dose 2. <u>Long-term outcomes:</u> Based on the computed risk ratio (RR) from the Phase II/III RCT, *Pfizer-BioNTech (10µg/dose)* for children ages 5-11 years showed inconclusive risk for the serious adverse events from dose 1 through cut off (Cohort 1: September 13, 2021; Cohort 2: October 8, 2021) when compared to placebo **[RR: 1.98 (0.22 to 17.69)],** based on very low certainty of evidence. There were no deaths reported in the study among 3,109 vaccine recipients and 1,538 placebo recipients until the cut-off period (*cohort 1: September 13, 2021; cohort 2: October 8, 2021*). <u>Adverse events of special interest:</u> The Phase II/III RCT reported the following AESIs: ● Ten participants in the vaccine arm (0.9%) and 1 in the placebo arm (0.1%) reported lymphadenopathy. ● There were no cases of myocarditis, pericarditis, hypersensitivity, or anaphylaxis reported among vaccine recipients. ● Four rashes observed on the arm, torso, face, or body, with no consistent pattern were reported among vaccine recipients and were considered to be related to vaccination. The rashes were mild and self-limiting, and had an onset of 7 days or more after vaccination. ***<u>Safety data from real world evidence</u>***	

There were five safety surveillance studies detected via a targeted search that reported on the safety of *Pfizer-BioNTech* for the pediatric population 5 to 11 years old: 3 from the US Center for Disease Control (CDC), 1 from the Government of Canada, and one from EudraVigilance of the European Medicines Agency.

Description of Evidence

Five safety surveillance studies on *Pfizer-BioNTech* for the pediatric population (5-11 years old) were included: three were from the US Center for Disease Control (CDC) namely, Hause et al., 2021, Su et al., 2022, and Klein et al., 2022; one was from the Government of Canada, and one from the EudraVigilance website. The characteristics of these surveillance reports are indicated in Table 1.2.8 below:

Table 1.2.10. Characteristics of safety surveillance reports from countries implementing pediatric vaccination.

Agency/Author/Presenter, Year [Period of Observation]	Reporting system	Population (N)	Intervention	Limitations
US CDC Hause et al., 2021 *(published December 31, 2021)* [November 3 - December 19, 2021]	Vaccine Adverse event Reporting System (VAERS)	N=4,249 reports out of 8,674,378 doses as of December 16, 2021 Data covers age group: 5-11 years old	*Pfizer-BioNTech* 10µg/dose, 2 doses, 21 days apart	● Passive surveillance reporting is subject to reporting bias ● Data on race/ethnicity were not provided in >40% of VAERS reports. ● Short surveillance period and might change as safety monitoring continues and more doses are administered
	V-Safe	N=42,504 at least one dose N=29,899 fully vaccinated		● V-safe is a voluntary program and might not be representative of the vaccinated population. ● Short surveillance period and might change as safety monitoring continues and more doses are administered

		Data covers age group: 5-11 years old		
US CDC Su et al., 2022 *(presented January 5, 2022)* [November 3 - December 19, 2021]	VAERS	*Same VAERS data set reported in Hause, et al. but with more updated results* Data covers age group: 5-11 years old	*Pfizer-BioNTech* 10µg/dose, 2 doses, 21 days apart	*Same VAERS data set reported in Hause, et al.*
US CDC Klein et al., 2022 *(presented January 5, 2022)* [December 2020 - December 11 2021]	Vaccine Safety Data Link (VSD)	N=257,840 at least one dose N=173,645 fully vaccinated Data covers age group: 5-11 years old	*Pfizer-BioNTech* 10µg/dose, 2 doses, 21 days apart	● Limited to VSD participating health centers only
Government of Canada (as of December 31, 2021) [November 19 to December 31, 2021]	Public Health Agency of Canada's Canadian Adverse Events Following Immunization	N = 58,326 fully vaccinated Data covers age group: 5-11 years old	*Pfizer-BioNTech* 10µg/dose, 2 doses, 8 weeks apart (optional: 21 days apart) OR *Pfizer-BioNTech* 30µg/dose, 8 weeks apart (optional: 21	● The data might be affected by underreporting, missing information, and differing adverse event reporting practices across jurisdictions in Canada ● This includes reports of 11-year-olds who received the *Pfizer-BioNtech* 30*µg/dose* formulation prior to authorization of the pediatric dose are included in the 5 to 11 age group.

	Surveillance System (CAEFISS) and Health Canada's Canada Vigilance program		days apart)	
European Medicines Agency (as of January 11, 2022) [December 2020 to January 11, 2022]	EudraVigilance	As of 11 Jan 2022, 14.3 M full vaccinations have been given to <18 years. However, there was no data disaggregated for the 5 to 11 years age group. Data covers age group: 3-11 years old	*Pfizer-BioNTech* (dose strength not mentioned)	• The information relates to suspected side effects, i.e. medical events that have been observed following the administration of the COVID-19 vaccines, but which are not necessarily related to or caused by the vaccine. • The number of cases in the website, including those reported with fatal outcomes, which may have a variety of different causes, should be put in the context of the different vaccines' exposure (numbers of given doses may vary significantly from one vaccine to another). • No mention of which dose of vaccine [10µg or 30µg] was received

Key Findings

Safety results

The results from the safety surveillance studies among vaccinated pediatric population with ages ranging from 3 years old to 17 years old are reported in Table 1.2.9 below:

Table. 1.2.11. Results of safety surveillance reports from countries implementing pediatric vaccination.

	VAERS US *(Su et al., 2022)*	**V-safe** US *(Hause et al., 2021)*	**VSD** US *(Klein et al., 2022)*	**CAEFISS and CVP** Canada *(Government of Canada 2022)*	**EudraVigilance** EU *(EMA, 2022)*

Adverse events	Not reported	Not reported	Not reported	103 reports	432 reports (includes 3-11 years old)
Serious Adverse Events (SAE)	2.4% of AE reports	No serious adverse events reported	Not reported	15 of 103 AE reports	Not reported
Non-serious AEs	97.6% of AE reports	Not reported	Not reported	88 of 103 AE reports	Not reported
Local adverse reactions	Not reported	after dose 1: 54.8% of participants after dose 2: 57.5% of participants	Not reported	Not reported	Not reported
Systemic adverse reactions	Not reported	after dose 1: 34.7% of participants after dose 2: 40.9% of participants	Not reported	Not reported	Not reported
Adverse Event of Special Interest (AESI):					
Myocarditis	12 verified reports *Reporting rate:* ● 2 per million doses administered in females after dose 2 ● 4.3 per million doses	Not reported	2 cases	991 reports (includes 5 years and above, no disaggregation of data) *Note: As of 14 Jan, 72.93 M doses have been administered in*	Not reported

				administered in males after dose 2			*Canada for ages 5 and above*	
			Cardiac disorders	Not reported	Not reported	Not reported	Not reported	27 reports (includes 3-11 years old)
			Seizure	10 verified reports	Not reported	2 cases	Not reported	Not reported
			Appendicitis	Not reported	Not reported	9 cases	Not reported	Not reported

HTAC Judgment: Short-term safety of *Pfizer-BioNTech (10µg/dose)* in children ages 5-11 years is acceptable. No case of myocarditis was reported in the clinical trials. It has occurred rarely following receipt of mRNA vaccines in adolescents and older age groups, but the risk of vaccine-associated myocarditis is lower than that associated with SARS-CoV-2 infection in adolescents and adults. Further follow-up data is needed to establish longer-term safety.

	Does Pfizer-BioNTech (10µg/dose) provide a highly favorable benefit/risk profile in the context of observed vaccine effectiveness and safety? *Can*	Trial evidence in children ages 5 to 11 years supports the clinical benefits of *Pfizer-BioNTech (10µg/dose)* in terms of decreased occurrence of symptomatic COVID-19 in this age group. No cases of MIS-C, severe COVID-19 or deaths were recorded in the study. Immunogenicity data from the same trial demonstrated only minimal to slight decrease in neutralization titers from *Pfizer-BioNTech* against the Delta variant compared to the reference strain (Walter et al., 2022). One real world study (Zambrano et al., 2022) among adolescents aged 12-17 show that *Pfizer-BioNTech* vaccination will likely provide additional clinical benefits in terms of protection against MIS-C resulting from SARS-CoV-2 infection even in younger children. Although epidemiological data show that most children present with asymptomatic infection or mild to moderate COVID-19 disease, real world studies on transmission show that vaccination may provide some	Favorable benefit/risk profile

	Pfizer-BioNTech (10µg/dose) significantly reduce the magnitude and severity of COVID-19 in children ages 5 to 11 years old?	benefit in terms of reducing transmission of SARS-CoV-2 infection and indirect protection of individuals who cannot be vaccinated but live in vaccinated households. Based on the 2021 World Population Data of the United Nations Population Fund, the population ages 0 to 14 years comprise 29.5% of the Philippine demography which is relatively higher than the share of this age group to the world population which is at 25.30%. The indirect benefits from achieving higher vaccination coverage by including children ages 5 to 11 may also be considered. Apart from clinical benefits provided by vaccination, other benefits of vaccinating children ages 5 to 11 years include the potential to allow reopening of schools and minimize disruption of the education of school-age children and the social benefits on the psychosocial well-being of children who have had limited mobility since the start of the pandemic. On the other hand, trial evidence showed that children ages 5 to 11 years are at risk of systemic and local reactogenicity following vaccination, although adverse reactions were mostly mild to moderate and transient. However, the risk of long-term safety outcomes such as serious adverse events, deaths are still inconclusive due to the short follow-up period. No cases of myocarditis, pericarditis, hypersensitivity, or anaphylaxis were reported in the trial while 0.9% of vaccine recipients and 0.1% of placebo recipients experienced lymphadenopathy. Similarly, most adverse events reported in real world safety data were non-serious. Reports of myocarditis and cardiac events among vaccinated children ages 5 to 11 years were received by surveillance mechanisms of the United States, Canada, and the European Union. **HTAC Judgment:** *Pfizer-BioNTech (10µg/dose)* passed the benefit-risk profile assessment in children ages 5-11 years based on data on the vaccine efficacy of 90.7% (95% CI: 67.7 to 98.3) against symptomatic COVID-19, effectiveness against MIS-C and household transmission, and acceptable short-term safety. Regardless of the lack of data on the current prevalence of COVID-19 in children ages 5 to 11 years old in the Philippines, studies show that *Pfizer-BioNTech (10µg/dose)* has potential to avert a significant number of infections in the pediatric population (5 to 11 years old), including symptomatic and severe COVID-19, and MIS-C assuming sufficient vaccine coverage; and, may contribute to achieving herd immunity in the general population.	

CRITERION 3			
3. Affordability, viability and feasibility	*What are the current implementation experiences, challenges and strengths related to the use of COVID-19 Vaccines in the pediatric population (12-17 years old), which can be applicable to the implementation in children ages 5 to 11 years old, specifically on the following?* - *delays in supply delivery with implications on capacities of manufacturers* - *incidents of errors in preparation and administration using specific vaccine brands* - *implementation advantage or benefit in using*	Based on a consultation with the National Vaccine Operations Center (NVOC) and DOH regional offices, the following are positive observations and best practices noted during the implementation of COVID-19 Vaccination Program among the pediatric population ages 12-17 years which will be carried on when the pediatric COVID-19 vaccination is expanded to children ages 5-11 years old: ● ***Timely delivery of vaccines:*** The NVOC noted that there were no delays in the delivery of vaccines from the manufacturer to the central warehouse. ● ***Stringent documentary requirements:*** Documentation from the accompanying parent/guardian was required to provide proof of affiliation to the pediatric vaccinee. Obtaining informed consent from the parent/guardian and assent from the child were strictly implemented prior to vaccination. ● ***Stringent screening process:*** The rollout for the pediatric population was tailored to ensure that vaccinees with comorbidities, including those with a history of conditions that were considered AESIs associated with vaccination (e.g. myocarditis and pericarditis) are identified and educated properly. ● ***Available and accessible vaccination sites:*** While the rollout of COVID-19 vaccination for the pediatric A3 (with comorbidities) population was initially aimed to be conducted at hospitals, the LGUs eventually conducted the vaccination activities at the mega-sites to accommodate the vaccinees and their guardians, and to ensure that standard public health measures are maintained as the number of cases during the Delta surge was only starting to decrease during the start of the rollout. ● ***Strategies to increase access to vaccination:*** Apart from conducting the vaccination program at large venues, strategies such as setting up of temporary posts, mobile buses, and house visits were implemented to be able to cover most of the pediatric population ages 12-17 years. These strategies also allowed parents and children to be vaccinated together at one site. ● ***Preference for vaccines from the US:*** The availability of promotional materials for US-made vaccines (e.g., *Moderna* and *Pfizer-BioNTech*) and the culture of dependence in US-made products advocated for COVID-19 vaccination among the pediatric population. ● ***Presence of medical specialists at the vaccination site:*** Aside from the usual AEFI teams present in vaccination sites, the on-site supervision of pediatricians and allergologists during vaccination of the pediatric population facilitated the timely and appropriate management of AEFIs (vs the on-call visit of the specialists for the adult vaccination). Meanwhile, the following are the common challenges encountered in the implementation of the COVID-19 Vaccination Program among the pediatric population ages 12-17 years:	There are no significant barriers and if there are, the plans to address the barriers are clearly reflected in the vaccine roadmap and other relevant documents.

	specific vaccine brands - *variations in implementing the COVID-19 vaccination program in LGUs* - *handling serious AEFIs and challenges in the management of serious AEFIs* - *any other implementation barriers*	• ***Compliance to stringent documentary requirements in certain situations:*** Compliance was difficult with regard to the documentary requirements (e.g. proof of affiliation to the child) and the presence of the parent/guardian. This was especially true for children of OFWs. • ***Cold chain requirement:*** Cold chain facilities experienced difficulties due to the unstable electric supply brought upon by the typhoons. • ***Inadvertent vaccination using vaccines with no EUA for pediatric use:*** The NVOC received a few reports of inadvertent vaccination using vaccines that do not have an EUA for pediatric use (e.g., *AstraZeneca* and *Sinovac*). This administration error was common during the National Vaccination Days (NVDs) where there were no special lanes for the pediatric age group. • ***Insufficient human resource:*** Vaccination teams were limited which caused HCWs to become more fatigued leading to more errors toward the end of the day. This was observed especially during the NVDs where the turnout was twice or thrice the crowd when the rollout started. Apart from the aforementioned general implementation challenges above, the key informants also noted the following challenges specific to the implementation of *Pfizer-BioNTech* for the pediatric population ages 12-17 years: • ***Cold chain requirement:*** Most LGUs, particularly in Region VI, still do not have the capacity to store *Pfizer-BioNTech* at ultra-low temperatures. The central storage of this vaccine is still at the Provincial Health Offices (PHO) or municipalities that have ultra-low temperature freezers (ULTFs). This causes delays and complications in the delivery of *Pfizer-BioNTech* to the LGUs and vaccination sites. • ***Distribution/freight capacity:*** The quantity of vaccines that can be directly delivered to provinces is limited to the capacity of the aircraft. Further, some aircrafts do not have the capacity to transport dry ice, which is required to maintain the cold chain requirements of *Pfizer-BioNTech.* Hence, the vaccine cannot reach certain areas in the country (e.g. Bicol region). • ***Consent withdrawal due to near-expiry vaccines:*** Despite the extension of the shelf-life of near-expiry *Pfizer-BioNTech* by the FDA Philippines in late 2021, some parents/guardians withdrew their consent since the product labelling still bears the original, unextended expiration date which is before the intended vaccination date (i.e., vaccination was conducted in December 2021 but the original expiry date as indicated on the label was November 2021). There was an instance noted by the NVOC where a written complaint was received from a parent, demanding an explanation from the DOH, WHO, and Pfizer Inc. on the use of vaccines beyond the labeled expiration date. Further details on the said written complaint were not provided. • ***Errors due to the intricate preparation of Pfizer-BioNTech:*** The NVOC received a few reports of inadvertent administration of thawed, undiluted vaccines in adults.	

		Meanwhile, the following were the challenges specific to the current implementation of *Moderna* for the pediatric population ages 12-17 years: ● ***Coordination with third-party logistics partner:*** The third party logistics partner which handles the hauling and storage of this vaccine brand was supposed to deliver up to the LGU level (i.e., end-to-end logistics). However, they did not have previous connections with the DOH regional offices which posed problems in coordinating and communicating supply delivery leading to delays in distribution. There were noted failures in delivering to far flung areas. ● **AEFIs following *Moderna:*** Anecdotal reports on the higher severity of adverse events following *Moderna* compared to *Pfizer-BioNTech* were shared within families and communities. Hence, *Moderna* was less preferred for its use among the pediatric population. The key informants have noted the following observed measures to address these challenges: ● Requirements prior to vaccination were tweaked during the rollout to facilitate compliance. As an alternative to proof of affiliation, certification from the barangay captain was also accepted. A different guardian (e.g. neighbor, grandparent) was allowed to take the child to the vaccination site provided that they present an informed consent form and authorization note signed by the parent. ● To be able to include *Pfizer-BioNTech* in the vaccine portfolio of LGUs that only had the capacity for storage at 2-8°C, supplies of *Pfizer-BioNTech* were temporarily stored in PHOs and municipalities that had access to ULTFs. However, this still posed challenges in the delivery to the LGU and vaccination sites, as mentioned above. ● To prevent errors in the preparation and administration of *Pfizer-BioNTech,* additional pharmacists were hired to ensure dedicated roles wherein the pharmacist is in charge of dilution and preparation of the vaccine while the vaccinator is solely in charge of administration. **HTAC Judgment:** The challenges noted in the COVID-19 vaccine implementation for the pediatric population ages 12-17 years due to difficulties in complying with documentary requirements, maintenance of the cold chain requirement, administration errors, and insufficient human resources can be mitigated and addressed in preparation for the roll out in the 5 to 11 year old population.	

	From the roll out of Expanded Programme on Immunization (EPI) vaccines for children ages 5-11 years old (before and during the COVID-19 pandemic), what are the current implementation experiences - best practices, challenges and lessons learned - that can be applicable to the implementation of COVID-19 vaccination in children ages 5 to 11 years old?	***Best practices in the DOH NIP rollout of EPI vaccines for children ages 5-11 years old*** ● *Before the COVID-19 pandemic:* ○ ***Active involvement of the the LGUS, RHUs, schools, and Parent-Teacher Association*** in the vaccination program ○ **Collaboration with the Department of Education (DepEd)** for the smooth implementation of the vaccination of school-age children. - Schools as catchment for the target population. - Preparation of vaccinee masterlist and collection of waivers accomplished by DepEd personnels. Consent forms for vaccination were already integrated in the student handbook or being handed out in the school to be signed in. - Teachers served as health educators. - Vaccination, data recording and AEFI monitoring performed by DOH personnels. ○ **Accessible and efficient data recording and sharing** as midwives were tasked to share data to both DepEd and DOH. ● *During the COVID-19 pandemic:* ○ **Scheduling of simultaneous implementation** of COVID vaccination and Community-based Immunization (CBI) implementation. CBI and catch-up campaigns were also intensified. ○ **Partnership with private sectors** through media engagement and provision of PPEs. ○ **Development of community-based immunization cards** to be used by all regions. ***Challenges in the DOH NIP rollout of EPI vaccines for children ages 5-11 years old*** ● *Before the COVID-19 pandemic:* ○ **Microplanning** was not done regularly. ○ **Varying data recording and management systems** such as *iClinicSys, ODK, Vacctrack* were used. ○ **Vaccine cards developed in some regions lacked immunization cards for school-based immunization**. ○ **Vaccine hesitancy especially among parents and guardians** due to the previous Dengvaxia scare. ● *During the COVID-19 pandemic:* ○ Vaccine hesitancy due to COVID-19 and immunization misconceptions. ○ Implementation of community-based vaccination and house-to-house campaigns are more resource and labor intensive than school-based immunization ○ Conflict between children's class schedules and vaccine roll-out	Best practices and lessons learned will be incorporated in future rollouts. Measures to address challenges encountered and foreseen are developed for planning considerations on vaccine implementation, particularly for the COVID-19 vaccination roll-out for children ages 5 to 11 years old.

		○ No updated target vaccinee list and masterlists of learners were not readily available. ○ Confusion on criteria for eligible population ○ Unavailability of parents and guardians to give consent and accompany their children for vaccination ○ Confusion on immunization schedule of regular immunization and COVID-19 vaccination. No established period of interval for regular immunization doses and COVID-19 vaccine doses. ○ Delayed and incomplete collection of data since multiple types of immunization are implemented in the community. ○ Diverted human resources and other resources both utilized by NIP and COVID-19 Vaccination. ***Measures for the improvement of the implementation of the EPI for children ages 5-11:*** ○ Establish a standardized data recording system for COVID and NIP Vaccines ○ Conduct intensive and appropriate advocacy and health education to alleviate vaccine hesitancy brought by previous Dengvaxia issue. ○ Implement immunization service delivery through a whole-of-society approach. ○ Perform intensive microplanning using bottom-to-top approach, and establish coordination/operations teams at the national and regional levels. ○ Develop plans to reach the target population in private institutions and out-of-school youth in the community. ○ Place more focus on identified priority areas during the start of the campaign to gain momentum ○ Engage closely with local chief executives (LCEs) ○ Strategize the schedule of delivery of commodities and ancillaries with campaign implementation ○ Constantly monitor supplies to avoid stock-outs. Ensure the availability of antigens, commodities and supplies prior implementation. **HTAC Judgment:** Several challenges encountered before and during the COVID-19 pandemic in the roll-out of EPI vaccines for children ages 5-11 years old have been identified. These include vaccine hesitancy, irregularity of planning, logistical concerns, lack of information, confusion on eligible population and scheduling, and lack of dedicated human resource for EPI vaccines. However, measures for improvement have been initiated by the DOH NIP in order to improve and address the problems identified. These measures can also be adopted in the COVID-19 vaccination for children ages 5-11 years old.	

	Is Pfizer-BioNTech (10µg/dose) affordable?	According to the Department of Finance (DOF), the price of *Pfizer-BioNTech (10µg/dose)* offered to the Philippine government is comparable to the price range for which it is available in various markets globally. The UNICEF vaccine market dashboard did not provide a specific price per dose of *Pfizer-BioNTech (10µg/dose)* for children ages 5 to 11 years old. However, the price per dose of *Pfizer-BioNTech (10µg/dose)* offered to the Philippine government is slightly below the UNICEF price range for which *Pfizer-BioNTech* (dose not specified) is available among low to middle-income countries (LMICs). Based on the number of doses of *Pfizer-BioNTech (10µg/dose)* included in the National Government procurement portfolio as disclosed by the Diseases Prevention and Control Bureau (DPCB), a costing analysis was conducted for the implementation of *Pfizer-BioNTech (10µg/dose)* (details of the costing assumptions and scenarios are provided in Appendix 8). The unit cost of the vaccine used in the analysis was based on the price offered to the government as disclosed in confidence by the DOH- Bureau of International Health Cooperation (BIHC). The additional cost of consumables and logistics were sourced from the DOH National Immunization Program (NIP) and the DOH Supply Chain Management Services (SCMS). Meanwhile, operations (i.e. human resource mobilization and training cost) will not incur additional cost to the DOH since COVID-19 vaccinations are now incorporated in the routine vaccination programs of the LGUs. Based on the calculations, the total cost of the primary vaccination roll-out with *Pfizer-BioNTech (10µg/dose)* for 13.93 million vaccinees ages 5 to 11 years old is at around **Php 9.90 B**. The total 2021 and 2022 budget for the different COVID-19 vaccination policies (i.e. primary vaccination for all ages, booster for 5 years and above) is estimated at **Php 125.8 B** as disclosed by the DOF. Based on the total number of procured and donated COVID-19 vaccines as of 28 January 2022, an estimated **Php 52.25 B** of the Php 125.8 B is still available in order to cover the cost of other upcoming procurements. Excluding the vaccinated population (data as of 23 January 2022) and the currently available unused vaccines that are yet to be administered (data as of 23 January 2022), the remaining demand to cover for the target 2021 and 2022 vaccination policies and priority groups is estimated at 82.24 million vaccine doses. Assuming a median vaccination cost per individual per dose across brands (Php 440.43), these 83.24M doses which includes the *Pfizer-BioNTech (10µg/dose)* for children ages 5 to 11 years old, will incur a total of Php 37 billion which is within the calculated remaining budget (Php 52.25 B). Thus, vaccination of children ages 5 to 11 years old using *Pfizer-BioNTech (10µg/dose)* is considered affordable. **HTAC Judgment:** Based on the costing analysis, *Pfizer-BioNTech (10µg/dose)* is considered affordable.	Affordability will be measured using the sufficiency of the allocated amount to achieve vaccination targets. **The vaccine unit cost is comparable with those in other ASEAN countries.* **The vaccine implementation cost is a reasonable and acceptable allocation of resources.*

	What are the budget implications of using Pfizer-BioNTech (10µg/dose) in children ages 5 to 11 years old?	The potential budget impact to the national government of the use of *Pfizer-BioNTech (10µg/dose)* as primary homologous vaccination for the pediatric population 5-11 years old was calculated at **Php 9.90 B**. It is estimated to consume **7.90%** of the total government budget for vaccines from 2021 to 2022 (Php 9.90 B of the Php 125.28B total budget) to procure **8.96%** of the needed doses (27.9M doses of 310.9M doses) to implement the following target policy scenarios aimed to be completed by 2022, some of which were initiated in 2021: • primary vaccination of 12 years and older • booster doses for 12 years and older • primary vaccination for 5-11 years old • booster vaccination for 5 to 11 years old • primary vaccination for 0 to 4 years old With this, the share of the cost of implementing *Pfizer-BioNTech (10µg/dose)* for the 13.93M children ages 5 to 11 years old is proportionate to the share of the doses needed to be procured for the different vaccination policies being implemented. **HTAC Judgment:** The share of the cost of the *Pfizer-BioNTech (10µg/dose)* to the total vaccine budget is considered proportionate to the share of the doses to be procured for the different vaccination policies being implemented.	Proportionality of the size of the population to be vaccinated versus the cost. The share of the cost to implement the COVID-19 vaccine within the total vaccination budget is not too disproportionate to the share of the population to be vaccinated using the said vaccine in the total population to be vaccinated.
	Does Pfizer-BioNTech (10µg/dose) represent good value for money in terms of preventing COVID-19 morbidity and mortality?	*Pfizer-BioNTech (10µg/dose)* in a primary homologous series for children ages 5 to 11 years old represents good value for money in terms of reducing the incidence of symptomatic COVID-19. Rough estimates of the vaccination cost per case averted are high. However, HTAC has bases to conclude that these will be offset by averted healthcare costs (i.e., total COVID-19-related PhilHealth claims, out of pocket expenditures), economic gains (i.e., in terms of recovery in GDP), and social gains. **HTAC Judgment:** The HTAC deems that the health, economic, and social benefits of using *Pfizer-BioNTech (10µg/dose)* in children 5 to 11 years old outweigh the cost of its introduction and implementation.	The HTAC deems that the health, economic, and social benefits of the vaccination program outweigh the costs. The vaccine is a cost-effective/ efficient allocation of resources.

CRITERION 4

4. Household Financial Impact

Will Pfizer-BioNTech (10µg/dose) reduce or not add further to the out-of-pocket expenses of Filipino households?

As mandated by Philhealth Circular 2021-0014, Philhealth Circular 2020-0012, and Philhealth Circular 2020-0009, the following benefit packages with corresponding case rates related to COVID-19 are available for the general population. Note that these also cover the pediatric population as there are no separate benefit packages for this subgroup

1. Home Isolation Package for asymptomatic and mild cases (C19HI) = Php 5,917.00
2. Community Isolation Package for symptomatic and confirmed cases (C19CI): Case rate= Php 22,499.00
3. Mild COVID-19 pneumonia for elderly and with comorbidities (C19IP1): Case rate= Php 43,997.00
4. Moderate COVID-19 pneumonia (C19IP2): Case rate= Php 143, 267.00
5. Severe COVID-19 pneumonia (C19IP3): Case rate= Php 333,519.00
6. Critical COVID-19 pneumonia (C19IP4): Case rate= Php 786,384.00

Based on Philhealth data, there were a total of 117 hospitalization claims from April 2020 to September 2021 for the pediatric population ages 5 to 11 years old. Table 1.2.10 below summarizes the cost of COVID-19 illness (inferred from total hospital bill) and out-of-pocket expenses incurred by patients belonging to the pediatric population 5 to 11 years old at different levels of severity. The mean financial coverage for hospitalization ranged from 70.65% to 90.05%. Financial coverage was seen to increase with severity of the COVID-19 disease.

Table 1.4. Philhealth data on COVID-19 Hospitalization Costs and Claims in the Pediatric Population 5-11 years old

Severity *[Benefit package]*	**Case Rate**	**Total Number of Paid Claims**	**Total Isolation / Hospital Cost**		**Out-of-Pocket Payment**		**Average % of Financial Coverage** *[proportion of financial coverage out of the total bill]*
			Range of Hospitalization Cost *[PHP]*	**Median Hospitalization Cost** *[PHP]*	**Range of Out-of-Pocket Payment** *[PHP]*	**Median Out-of-Pocket Payment** *[PHP]*	
Mild COVID-19 *[C19IP1]*	₱ 43,997.00	52	₱3,764.50 to ₱386,039.35	₱57,283.15	₱0.00 to ₱342,042.35	₱13,286.15	70.65%
Moderate	₱143,267.00	52	₱35,640.50 to	₱140,364.6	₱0.00 to	₱0.00	85.65%

The adoption of the vaccine can reduce out-of-pocket spending of individuals and families due to averted COVID-19 disease and/or hospitalization.

COVID-19 *[C19IP2]*			₱391,217.61	8	₱247,950.61		
Severe COVID-19 *[C19IP3]*	₱ 333,519.00	8	₱102,775.70 to ₱845,450.65	₱288,010.62	₱0.00 to ₱511,931.65	₱0.00	87.13%
Critical COVID-19 *[C19IP4]*	₱ 786,384.00	5	₱346,460.30 to ₱1,564,458.38	₱500,457.36	₱0.00 to ₱778,074.38	₱0.00	90.05%

Meanwhile, there were a total of 388 community isolation claims recorded by PhilHealth from 2020 to September 2021 for asymptomatic and mild cases for pediatric patients 5 to 11 years old. The median cost of community isolation based on bills recorded was Php 18,703.50, while the median claims cost was also at Php 22,449.00. Therefore, the median out-of-pocket expenses for community isolation is at Php 0.00 (Php 0.00 to Php 34,091.86). The median financial coverage is at 97.56%.

The out-of-pocket expenses reflected above only represents medical costs shouldered by patients and their families. Other non-medical costs such as transportation, food, and productivity loss of the parents of these children were not incorporated due to lack of data. In addition, the above costing of household costs did not include the treatment/ management cost of other family members within the household who had likely contracted COVID-19.
Considering these other incurred costs shouldered by households further increases the potential of the vaccine to reduce out-of-pocket expenses of households due to COVID-19.

HTAC Judgment: Based on current evidence, *Pfizer-BioNTech* has the potential to reduce out-of-pocket expenses due to averted costs of isolation and treatment of mild, moderate, and severe COVID-19 in the pediatric population ages 5 to 11 years old.

CRITERION 5

5. Social Impact	*Does Pfizer-BioNTech (10µg/dose) possess the characteristics desired by key stakeholders (i.e., policy- and decision-makers, health workers, program managers and/or implementers, patient groups, CSOs, communities, general public)?* • *Safety* • *Efficacy* • *Transparency in the regulatory/approval process and information on the vaccines* • *Availability* • *Potential for high and equitable coverage* • *Ease in logistical and implementation requirements* • *Cost-efficiency to the government*	Based on the results of the focus group discussions conducted in the context of vaccinating the adult population by the HTAC among *healthcare workers, patient groups, civil society organizations and community leaders* from low- and high-prevalence areas, the results from the deliberations in congressional inquiries on the COVID-19 vaccination roadmap, public hearings, and consultations with government decision-makers and implementers, the following are the important and desirable attributes of COVID-19 vaccines and the corresponding evidence for the *Pfizer-BioNTech (10µg/dose)* specifically in children ages 5 to 11 years old. 1) **Safe and efficacious** - Evidence: *Pfizer-BioNTech (10µg/dose)* is effective in preventing symptomatic COVID-19 in children ages 5-11 years, based on one published Phase II/III trial (Walter et al., 2022). Additionally, based on an exploratory analysis of a selected subset from the same trial, *Pfizer-BioNTech (10µg/dose)* showed only minimal to slight decrease in neutralization titers against the Delta variant compared to the reference strain. Based on trial and real world evidence, short-term safety of *Pfizer-BioNTech (10µg/dose)* among children ages 5-11 years is acceptable. Further follow-up data are needed to establish longer-term safety. Further evidence is needed to establish the vaccine's effectiveness in preventing COVID-19 in children ages 5-11 years old in the real world setting, especially against the Omicron variant. 2) Underwent a **transparent regulatory process** of being evaluated and approved by health authorities - Evidence: *Pfizer-BioNTech (10µg/dose)* underwent the usual regulatory process of the FDA Philippines. The Philippine FDA issued an EUA for the vaccine on 22 December 2021 for its use among children 5 to 11 years old. 3) **Potential for high and equitable coverage across the population** - Evidence: *Pfizer-BioNTech (10µg/dose)* once thawed can be stored at temperatures of 2-8°C for 10 weeks which can be catered by most RHUs. However, storage for a longer period of time (up to 6 months) requires more stringent logistical requirements such as ultra-cold freezers which are only available in tertiary hospitals. - The Philippine Pediatric Society (PPS) and Pediatric Infectious Disease Society of the Philippines (PIDSP) released a joint position statement (published 17 January 2022) recommending the vaccination of children ages 5 to 11 years old against COVID-19. With the rapid circulation of the Omicron variant, the PPS-PIDSP reiterated their recommendation for the vaccination of the age-appropriate groups, with the addition of children ages 5-11 years old against COVID-19 using	The vaccine possesses all or most of the characteristics desired by key stakeholders Qualitative responses will contextualize the Filipino experience and may impact on implementation strategy

	• *Public acceptability* • *Availability of mechanisms to compensate vaccine recipients for any untoward event following vaccination* • *Appropriateness of the vaccine to special at-risk groups and patients with comorbidities*	duly-approved vaccines. Prioritization of children in the age group who have comorbidities and children of healthcare frontliners was also recommended. 4) **Ease in logistics and administration** - Evidence: *Pfizer-BioNTech (10µg/dose)* must be stored in ultra-cold freezers with a storage requirement of -60 to -90°C for up to 6 months. Once thawed, it may be stored at 2-8°C for 10 weeks only. Intensive training on the special storage, handling, and administration of the *Pfizer-BioNTech (10µg/dose)* is required to ensure product integrity across an uninterrupted cold chain. Meanwhile, based on current experience, the implementation of *Pfizer-BioNTech (30µg)* for the population ages 12 years and older in the Philippine COVID-19 Vaccination Program was generally challenging due to the intricate vaccine preparation which is prone to error. - Based on a consultation with the NVOC and selected regional offices invited by the NVOC, plans are already in place for the upcoming implementation of COVID-19 vaccination for children ages 5-11 years old. A phased implementation will be done to ensure that new protocols will be followed as vaccines for this age group have a different dose and different preparation (i.e. vaccine for 5-11 years old needs to be diluted while vaccine for ages 12 and older may or may not need dilution). The vaccination in children ages 5-11 years old will also follow campaign style such as those utilized for measles and rubella vaccination. This style is expected to speed up implementation and increase coverage. Further, to prevent preparation errors and inadvertent administration of doses , the NVOC plans to follow scheduling for the different vaccinations (i.e., dedicated day/s for the 5-11 vaccination as well as for other vaccinations such as the primary vaccination for other age groups and booster vaccination); and, to dedicate site/s and a vaccination team for the 5-11 vaccination. The NVOC has also started engaging private pharmacies as possible vaccination sites to be integrated in the LGU vaccination implementation activities. Per usual standard operating procedures, the DOH regional offices will also be involved in the implementation to provide solutions to issues which might be encountered. In terms of foreseen implementation barriers, aside from possible errors in preparation and administration, the NVOC has cited demand generation as a possible challenge in the implementation due to anti-vaccination groups promoting against the vaccine for children. Despite this, the NVOC noted that US-made vaccines, such as *Pfizer-BioNTech, are highly* acceptable to the public. Further, the representatives from DOH regional offices expressed concern regarding the currently implemented “no vaccination, no ride/entry” policy in NCR which may hinder access of some children and their guardians to vaccination sites should this policy be implemented nationwide. Possible solutions that	

		were raised in the consultation were the conduct of house to house vaccinations, and the setting of temporary vaccination posts at the barangay level which have been implemented in some regions during the roll-out for adolescents which also captured adults. The NVOC and regional offices also provided the following best practices observed during the roll-out in adolescents ages 12 to 17 years old which they are planning to adapt during the roll-out in children ages 5 to 11 years old: - requiring proof of affiliation of the parent/guardian to the vaccinee and strict implementation obtainment consent from parent/guardian and assent from the vaccinee - tailored screening process to ensure that vaccinees with comorbidities and those with history of conditions considered as AEFI (e.g. myocarditis and pericarditis) are identified and educated properly - conduct of vaccination at mega-sites to accommodate the vaccinees and their guardians, and to ensure standard public health measures are maintained despite the expected increase in size of crowds. - setting up of temporary posts, mobile buses, and house visits to cover as much target population as possible - on-site supervision of medical specialists such as pediatricians and allergologists to facilitate timely and appropriate AEFI management - hiring of pharmacists in charge of dilution of the vaccine to allow vaccinators to focus on administration - The NVOC has also provided the status of their readiness to implement vaccination in children ages 5 to 11 years old. According to them, the following are already prepared: ○ detailed roll-out plan of the vaccination program ○ strong contingency plans in case of natural calamities and other unexpected situations ○ identified locations for the initial roll out which has been deemed appropriate and accessible for the implementation ○ assessment plans i.e. initial visits and dry runs to assess how to contextualize the implementation per setting and final inspections by DOH regional offices to ensure preparedness for the first rollout - Existing mechanisms of the current COVID-19 vaccination roll-outs will be applied for the following areas of implementation for the 5-11 vaccination : ○ vaccine and ancillary supplies distribution mechanism	

		○ logistics system for transportation of vaccination staff, and supplies ○ waste management system ○ monitoring and response systems for AEFIs ○ nationwide monitoring system for vaccine coverage ○ monitoring and evaluation process for LGU or regional vaccination - Planning efforts are ongoing for the following: ○ national policy and guidelines development for the vaccination of children ages 5-11 years old ○ dissemination of plans (e.g. tools and templates) to vaccination sites ○ negotiations to ensure sufficient vaccine doses for children ages 5-11 years old ○ procurement of ancillary supplies and consumables ○ communication, advocacy and social mobilization plans ○ training of vaccination teams ○ town hall meetings for stakeholder engagement ○ preparation of consent waivers and forms - Lastly, concerns regarding strain in human resources have been raised as the vaccination teams to be dedicated for the vaccination of children ages 5 to 11 years old will come from the existing pool vaccination teams for adult and adolescent vaccination which is currently insufficient. In addition to the increased target population without additional human resources, the surge of cases due to the Omicron variant has also strained the current pool of vaccination staff. 5) **Cost-effective** - Evidence: The health, economic, and social benefits of implementing the vaccination program with *Pfizer-BioNTech (10µg/dose)* in the pediatric vaccination outweigh the negative impact of COVID-19 such as deaths due to COVID-19, medical costs, social disruption, and unprecedented challenges in the health system. Its cost is within the range of current new vaccines that are also part of the National Immunization Program (NIP). 6) **Public acceptability** Evidence: **General Public's Acceptability of Administration of COVID-19 Vaccination for the Pediatric Population**	

Global and Regional View of Vaccine Acceptance and Related Behaviors (Johns Hopkins Center for Communication Programs, WHO GOARN)

A living global survey being conducted by Johns Hopkins Center for Communication Programs and the World Health Organization's (WHO) Global Outbreak Alert and Response Network (GOARN) on the acceptability of pediatric vaccination across different countries was found. The survey asks parents of children under 18 years old if they will choose to vaccinate their oldest child under age 18 when eligible.

Table. 1.5.1 Responses from Filipino parents surveyed over time showed the following rates of willingness:

Time Period	% Willingness to definitely or probably allow their children to get vaccinated once they are eligible for COVID-19 vaccine
May 20-30, 2021	81.93%
December 1-15, 2021	90.87%
December 16-31, 2021	77%
January 1-15, 2022	81%

According to Johns Hopkins Center for Communication Programs, this drop in willingness can be a data artifact due to the revision of the question to add the component "oldest child under age 18" in consideration of the start of implementation of adolescent vaccination. The increase from 77% to 81% in the January 1-15 survey may indicate this as well. Survey results should be observed over time to see whether acceptability will increase again after the revision of the question. Johns Hopkins also noted that this observation was also seen in similar settings such as Indonesia and Vietnam.

The age range of the children of the respondent parents were not specified and no disaggregated data for the response of parents of children ages 5-11 years old.

The COVID-19 pandemic in children and young people during 2020-2021: A complex discussion on vaccination (Rudan et al. 2021)

An editorial paper by Rudan et al. published on 25 December 2021, presented the complex debate on the COVID-19 vaccination of children and young people.

As cited in Rudan et al. (2021) the European Center for Disease Prevention and Control suggested that decisions on pediatric vaccination should consider the vaccine uptake in older age groups, the incidence of COVID-19 in the general population, and practical issues concerning availability and access to vaccines globally.

Meanwhile, Rudan stated that proponents of mass vaccination in children suggest that vaccinating children will improve children and adolescent's well-being and mental health allowing them to resume education and social interactions which are important to their development. They suggested that this will also prevent the pediatric population from becoming a pocket of the population wherein COVID-19 would continue to circulate freely leading to mutation of the virus into new variants.

Rudan et al.'s paper also highlighted that ethical concerns would need to be carefully documented and addressed. Notable concerns include specific situations and needs of children with developmental disorders and chronic conditions, health inequities and vaccine hesitancy. Vaccination willingness and hesitancy should first be assessed before attempting vaccination. The following surveys were conducted among caregivers of minors to assess caregiver's willingness to vaccinate their minor children.

Table 1.5.2 Surveys on Willingness to Vaccinate Children Cited in Rudan et al. 2021

Author (Year)	Study Period	Country	Survey participants	Vaccination willingness and hesitancy
Goldman et al. (2020)	26 to 31 March 2020	US, Canada, Israel, Japan, Spain , and Switzerland *COVID-19 Parental Attitude Study (COVIPAS)*	1,541 caregivers Median age of children: 7.5 years old	● Willing to vaccinate their children once vaccine is available: 65% ○ Most common reason for willingness: Protection of their child (62%) ○ Most common reason for hesitancy: Vaccine's novelty (52%)

			Teasdale et al. (2021)	9 March, 2021 to 2 April 2021	US *(nationwide)*	2,074 parents/ caregivers of children ≤12 years	● Willing to vaccinate their children once vaccine is available: 49% ○ Primary reasons for hesitancy: Safety and lack of need for vaccines ● Lower income and less education were associated with greater parental vaccine hesitancy.
			Ruggiero et al. (2021)	November 2020 to January 2021	US *(nationwide)*	427 parents of children (aged 1–18 years; 34.1% have children ages 4 to 8 yo; 25.1% have children ages 8 to 12 yo)	● Willing to vaccinate their children: 49.45%
			Szilagyi et al (2021)	February to March 2021	US *(nationwide)*	1,745 parents of children (<5 years: 24%, 5 to 10 years: 36%, 11 to 18 years: 40%)	● Likelihood of child COVID-19 vaccination: ○ Very likely : 28% ■ High among parents of older children ■ High among parents with bachelor's degree or higher education ■ Among those had already received or were likely to receive a COVID-19 vaccine ■ Had Democratic affiliation ○ Somewhat likely : 18% ○ Somewhat unlikely: 9% ○ Very Unlikely: 33% ○ Unsure 12% ● Concerns were centered around vaccine safety and side effects

			Teasdale et al. (2021)	9 March to 11 April 2021	US *(New York City)*	1,119 primary caregivers of a child ≤ 12 years of age	● Plans to vaccinate their children (≤12 years): 61.9% ● Unsure: 23.3% ● No plans to vaccinate their children:14.8% ○ Most common reason for hesitancy: Vaccine safety and effectiveness (81.2%) ● Vaccinated parents and parents intended to get themselves vaccinated: 67.3% ○ Pediatric vaccine hesitancy is strongly tied to parental vaccine hesitancy.
			Zhang et al (2020)	1 to 7 September 2020	China	2,053 factory workers, guardians of children <18 years old	● Willing to vaccinate their children: 72.6%
			Yang et al (2021)	7 to 19 February 2020	China	12,872 questionnaires guardians of children aged 0–6 years old	● Willing to vaccinate their children: 70.87%
			Wan et al (2021)	December 2020 to February 2021	China	468 parents of 3–6 year old children	● Willing to vaccinate their children: 86.75% ○ Most common reason for willingness: Worried about their children being infected in the future (78.57%) ● Hesitant to vaccinate their children: 13.25% ○ Most common reason for hesitancy: Did not believe in the safety of vaccines (67.74%)

			Feng et al (2021)	30 November, 2020 to 31 January 2021	China	3,703 guardians of children <18 years old	● Willing to vaccinate their children: 84.0%
			Wang et al (2021)	September 2020 to April 2021	China	914 guardians of children with special disease (congenital heart disease, preterm birth, others) Mean age of children: 1.4 years old *Face-to-face questionnaire interview*	● Willing to vaccinate their children with special diseases: 49.9%
			Brandstetter et al (2021)	5 to 28 May 2020	Europe *(Data used is from KUNO-Kids health study which is a multipurpose birth cohort study situated in Germany)*	612 parents with children ages 1.5 - 5 years old	● Intended to vaccinate their children: 51% ● Parents intended to get themselves vaccinated: 58%
			Montalti et al (2021)	December 2020 to January 2021	Italy	5054 parents/ guardians of children aged <18 years old	● Willing to vaccinate their children: 60.4% ● Considering: 29.6% ● Hesitant to vaccinate their children: 9.9%

Choi et al (2021)	25 May to 3 June 2021	South Korea	226 parents of children ≤18 years old and 117 children 10 -18 years old	● Children willing to get vaccinated: 49.6% ● Parents willing to have their children be vaccinated: 64.2% ○ Factors associated intention to vaccinate: ■ High confidence in the safety of the vaccines ■ Willingness to vaccinate themselves ■ Awareness of the need to vaccinate children against COVID-19	

Social impact of the COVID-19 pandemic and pandemic response on children and adolescents

According to the WHO Interim Statement on COVID-19 vaccination for children and adolescents (24 November 2021), vaccinating children may help minimize school disruptions. Prolonged school closure can result in education loss and exacerbation of pre-existing inequalities and marginalization of learning. This also leads to loss of access to a wide range of school-provided services which include school meals, health, nutrition, water, sanitation and hygiene.

Further, social isolation places children at risk of :

- potential for predatory behavior from adults related to spending more time online
- cyberbullying from other children
- disruption in physical activities and routines
- increased emotional distress
- mental health problems

7) Availability of mechanisms to manage any untoward serious adverse reactions following vaccination

- Evidence: Evidence: Republic Act 11525 or the COVID-19 Vaccination Program Act of 2021 establishes the COVID-19 National Vaccine Indemnity Fund to provide funds and authorize PhilHealth to pay compensation to any person inoculated through the vaccination program, in the case of death and permanent disability. In response to RA 11525, PhilHealth released PhilHealth Circular No. 2021-0007

		last 17 June 2021. The circular, otherwise known as the "Implementing Guidelines on the Coverage of COVID-19 Vaccine Injury due to Serious Adverse Effects (SAEs) following immunization resulting in hospitalization, permanent disability or death under the COVID-19 National Vaccine Indemnity Fund (The COVID-19 Vaccine Injury Compensation Package), aims to provide coverage for cases of hospital confinement, permanent disability, or death due to SAEs from the use of COVID-19 vaccines administered through the COVID-19 vaccination program. **8) Appropriateness of the vaccine in special at-risk groups and patients with comorbidities** - Evidence: The interim results from the Phase II/III clinical trial (Walter et al., 2022) enrolled children ages 6 months to 11 years of age. However, to date, only the interim results for the 5-11 year age group have been published. The reported VE against symptomatic COVID-19, without evidence of previous infection **[VE: 90.7% (95% CI: 67.7 to 98.3)]** and safety data allow it to be used for this special population. - The updated WHO interim recommendations (22 January 2022) on the use of the *Pfizer-BioNTech* stated that children ages 5 to 17 years with comorbidities that put them at higher risk of serious COVID-19 should be offered vaccination. - Meanwhile, healthy children and adolescents usually experience mild disease. The WHO noted that multisystem inflammatory syndrome in children (MIS-C) can occur even after mild or asymptomatic infection; however, this is considered rare. With this, the WHO recommends the use of *Pfizer-BioNTech* for children ages 5 to 17 years old only when high vaccine coverage both for primary series and booster vaccination has been achieved in higher priority-use groups. This has also been emphasized in the recently updated WHO SAGE Roadmap for prioritizing uses of COVID-19 vaccines. - The WHO also recommended for countries to consider the individual and population benefits of vaccinating this age group based on country-specific epidemiologic and social context. **HTAC Judgment:** Given that there are no local studies to determine acceptability of vaccination among children 5 to 11 years old, HTAC can only recognize the social impact of vaccination in this age group in terms of supporting the attainment of occupations of children which include social learning achieved through peer interaction. This could also contribute to the improvement of the quality of life within the households when caregivers of children are relieved of the anxiety of dealing with the consequences of COVID-19 infection and sequelae.	

CRITERION 6

6. Responsiveness to equity

How will Pfizer-BioNTech 10µg/dose and its use impact pre-COVID-19 and COVID-generated health and socioeconomic inequities?

Which groups might be unfairly disadvantaged, in relation to the COVID-19 disease burden and delivery of Pfizer-BioNTech 10µg/dose?

Pfizer-BioNTech 10µg/dose requires the use of ultra-low temperatures freezers with storage temperature at -90 °C to -60 °C for up to 6 months. Once thawed, it can be stored for 10 weeks in refrigerators at 2–8 °C which are commonly available in hospitals. With this, vaccination sites must ensure efficient roll out within the shelf-life of the vaccines to avoid wastage.

As of this writing, there are two brands currently being rolled out for the pediatric population 12-17 years old - *Pfizer-BioNTech* and *Moderna;* and only *Pfizer-BioNTech* is indicated by the Philippine FDA for children ages 5-11 years old.

As of January 23, 2022, 201,635 individuals (15.85%) out of the 1,272,207 individuals currently eligible in the Pediatric A3 priority group (12-17 year olds with comorbidity) have already received a full regimen of COVID-19 Vaccines. This is lower than the full vaccination coverage for the rest of the pediatric population (ROPP) where 7,044,795 individuals or 61.53% are already fully vaccinated out of the 11,449,863 target. These vaccination coverages pertain to appropriately vaccinated adolescents ages 12 to 17 years, and excludes vaccinees who were inadvertently administered with vaccines which do not have EUA for the pediatric population. Vaccination coverage by brand of are as follows:

Priority Group	**Vaccination Coverage (fully vaccinated / target vaccinees)**	
	Pfizer-BioNTech	***Moderna***
Pediatric A3	*14.32% (182,169 /* 1,272,207*)*	*1.41% (17,897 /* 1,272,207*)*
ROPP	*53.21% (6,092,630 /* 11,449,863*)*	*8.18% (936,175 /* 11,449,863*)*

Ideally, health interventions can be fairly adopted and distributed/ implemented for eligible populations without aggravating existing health inequities especially for vulnerable sectors of our society.

The higher percent coverage for Pfizer may also be affected by the availability of the brand. Further, the NVOC mentioned that *Pfizer-BioNTech* is the preferred brand for this age group compared to *Moderna* based on anecdotal opinion from vaccinees due to perceived higher severity of adverse events in *Moderna*.

The overall vaccination coverage in the Philippines for the primary series and booster dose, by priority group as of 23 January 2022, is as follows:

WHO Prioritization groups	DOH Prioritization groups	Philippine COVID-19 Vaccination Coverage	
		Primary Series	Booster Dose
Highest Priority Use	A1	92.27%	36.03%
	A2	65.88%	13.34%
	A3	90.68%	14.52%
High Priority Use	A3	90.68%	14.52%
	EA3	13.40%	1.12%
	A4	62.37%	6.33%
	A5	61.43%	3.33%
Medium Priority Use	ROAP	79.01%	5.15%
	A3 Pedia	15.83%	0.00% (Not yet eligible)
Lowest Priority Use	ROPP	61.44%	0.00% (Not yet eligible)

		In terms of regional coverage, there is an observed disparity in the vaccination coverage, for primary series. As of 23 January 2022, NCR reported the highest vaccination coverage of the primary series at 109.28% (10,800,266 out of the 9,883,071). The higher number of vaccinated individuals versus the targets is likely due to individuals who are residents of nearby provinces who were vaccinated in NCR. Meanwhile, the Bangsamoro Autonomous Region in Muslim Mindanao (BARMM) recorded the lowest vaccination coverage of the primary series at 25.22% (769,604 out of 3,051,186). Vaccination coverage of primary series in other regions were considered high to very high (i.e. 40% and above) based on WHO vaccination coverage classification. For booster vaccination coverage, NCR remained as the region with the highest coverage at 21.34% (2,108,772 out of the 9,883,071) while BARMM still had the lowest booster vaccination coverage at 1.54% (47,081 out of 3,051,186). The vaccination coverage for booster doses remains to be low to moderate based on WHO vaccination coverage classification. According to the revised WHO SAGE Roadmap for prioritizing uses of COVID-19 vaccines (21 January 2022), vaccination in medium priority-use groups which includes children and adolescents with comorbidities should only be initiated when at least moderate (10-40%) vaccination coverage has been achieved for both primary series and booster doses of higher priority-use groups. Meanwhile, for lowest priority-use groups which include healthy children and adolescents, vaccination should be initiated when at least high (vaccination coverage (i.e. 40-70%) has been achieved for both primary series and booster doses of higher priority-use groups. The WHO also stated that increasing the booster dose coverage rate for higher priority-use groups will usually yield greater reductions in severe disease and death than use of equivalent vaccine supply to increase the primary vaccination series coverage rates of lower priority-use groups. **HTAC Judgment:** Pediatric vaccination poses inherent challenges because of pre-existing inequities in the healthcare system including: - inequitable access to information in order for parents to provide informed consent and for children to provide assent; - inequitable capacity to diagnose co-morbidities in children, especially for marginalized sectors (e.g., pediatric specialists); - inaccessibility to vaccination sites and inadequate logistical capacity among geographically isolated and disadvantaged areas (GIDAs); - general deficiency in infrastructure, transportation modalities, and health human resources across the different areas in the country.	

		These challenges can be translated to opportunities to improve the vaccination coverage of priority groups (e.g., encouraging unvaccinated parents and/or guardians accompanying pediatric vaccinees to get vaccinated as well, improvement of information, education, and communication (IEC) campaigns, among others). The following measures may be initiated to ensure the success of the implementation of COVID-19 vaccination for children ages 5 to 11 years old: ● emphasize the importance of free and prior informed consent ● emphasize the need for supporting the autonomy of parents, guardians, and the pediatric population towards vaccination ● ensure that IEC and other vaccination-related documents are accessible and comprehensible (i.e., translated into the local language of the target population) Pediatric vaccination shall be rolled out following the country's prioritization criteria, cognizant of the following: ● burden of COVID-19 in the pediatric population, especially those with comorbidities; ● sufficient supply to cover the pediatric population in addition to the higher priority-use groups As for the use of *Pfizer-BioNTech (10ug/dose)* among children ages 5 to 11 years, the less stringent logistic requirements (i.e., 2-8°C for 10 weeks and -90 °C to -60°C for longer periods of time) will not aggravate health inequities related to inoculation of recipients residing in isolated and disadvantaged locations. However, the intricate vaccine handling and preparation of Pfizer-BioNTech may make administration in rural areas without the appropriate capacity more challenging. Based on trial evidence, *Pfizer-BioNTech* 10µg/dose may be used for children ages 5-11 years old as trial evidence has demonstrated its safety and efficacy for this vulnerable population.	

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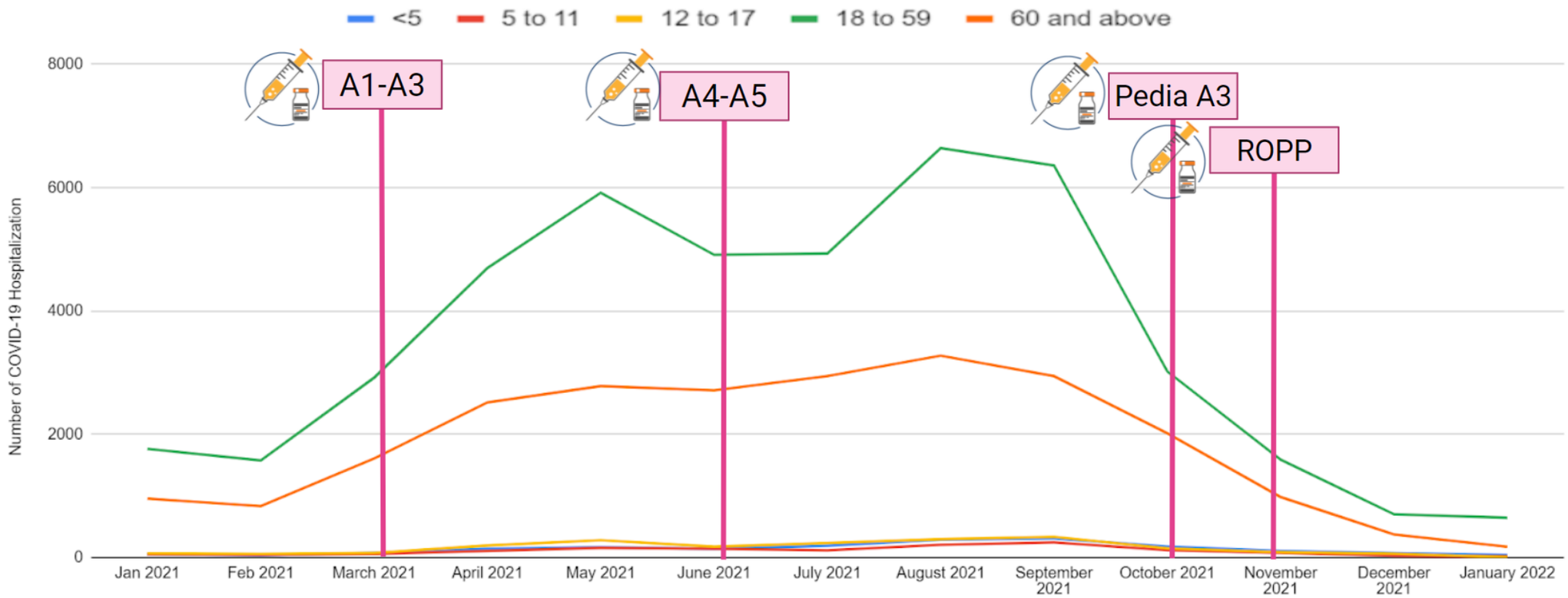
- Department of Finance (DOF)
- National Center for Vaccines Operation (NVOC)
- Philippine Living Clinical Practice Guidelines Group (LCPG Group)
- Salvacion Gatchalian Registry
- Philippine Insurance Corporation (PhilHealth)

Appendix 1: Trends in Hospitalization in the Philippines, by age group



Appendix 2: LCPG Report on Clinical Efficacy, Effectiveness, and Safety

Link to LCPG Report: https://docs.google.com/document/d/1Zw6qs3-W6kMpbpNwbXQay1Pxu4HIfJkt/edit?rtpof=true

Appendix 3: Search Strategy

		Related Terms	Search Terms
Population	children aged 5 to 11 years old	child, children, pediatric, pediatric population, COVID-19, SARS-CoV-2 infection, SARS-CoV-2	[SARS-CoV-2 OR SARS-CoV-2 infection OR COVID-19 OR COVID] AND [child OR children OR pedia OR pediatric] AND [Pfizer-BioNTech COVID-19 Vaccine OR Pfizer-BioNTech OR Comirnaty OR Tozinameran OR Pfizer]
Intervention	Pfizer-BioNTech COVID-19 vaccine (10μg/dose)	Pfizer-BioNTech, COVID-19 Vaccine, Comirnaty, Tozinameran, Pfizer	
Comparator	placebo, unvaccinated, adolescents/adults, other COVID-19 vaccines	N/A (Open comparator for search strategy)	
Outcomes	symptomatic COVID-19, severe COVID-19, hospitalization due to COVID-19, asymptomatic COVID-19, AEs, SR, LR, all-cause mortality, SAE, immunogenicity studies	N/A (Open outcomes for search strategy)	
Databases	PubMed, medRxiv, bioRxiv, and Cochrane Library		
Search Date	21 January 2022		

Appendix 4: Risk of Bias (RoB) Assessment

The RoB assessment of the LCPG Group on the Walter, et al. (2022) RCT was used as a basis for the HTAC RoB which was adjusted to follow HTAC specifications which allows for the use of interim results with at least 2 months of follow up period.

ROB Domains	LCPG		HTAC	
	RoB rating	**Basis**	**RoB rating**	**Basis**
Random sequence generation	Low	Yes (Interactive web-based system)	Low	Yes (Interactive web-based system)
Allocation concealment	Low	Yes (Interactive web-based system)	Low	Yes (Interactive web-based system)
Blinding of participants and personnel	Low	Yes (triple-blinded)	Low	Yes (triple-blinded)
Blinding of outcome assessment	Low	Yes (triple-blinded)	Low	Yes (triple-blinded)
Missing outcome data (efficacy)	High / unclear*	Interim report, 2.3 month median follow up data reported	Low	Based on HTAC specifications, a minimum of 2 months follow up may be acceptable for interim results of RCTs
Missing outcome data (safety)	High / unclear* *planned 6 months assessment*	Interim report, 2.3 month median follow up data reported	Low/High	• Based on HTAC specifications, a minimum of 2 months follow up may be acceptable for interim results of RCTs for short term outcomes • High for long term outcomes
Selective reporting	Low	All planned outcomes reported	Low	Agree with LCPG RoB assessment
Overall RoB rating	**High/unclear**		**Low - short term outcomes** **High - long term outcomes**	

Appendix 5: GRADE Table (HTAC)

Table A1.2. Summary of Findings Table for the Efficacy of Pfizer-BioNTech (*10µg/dose*)

Efficacy Outcome (at ≥7 days after dose2)	**N** Study design	**Quality Assessment**					**Summary of Findings**			**Certainty**
		Risk of Bias	**Inconsistency**	**Indirectness**	**Imprecision**	**Other Considerations**	**Vaccine n/N (%)**	**Control n/N (%)**	**Vaccine Efficacy (CI)**	
1: Symptomatic COVID-19, without previous evidence of infection *(Cohort 1)*	1 RCT	Not serious	Cannot be assessed	Not serious	Not serious	None	3/1305 (0.23%)	16/663 (2.41%)	90.7 (67.7 to 98.3)	++++ High
2 : Symptomatic COVID-19 infection, without previous evidence of infection *(Cohort 1)*	1 RCT	Not serious	Cannot be assessed	Not serious	Not serious	None	3/1461(0.2%)	16/714 (2.2%)	90.9 (68.3 to 98.3) *Note: ACIP reported a VE for this outcome with longer follow up period (3.3 months)*	++++ High
3 : Severe COVID-19 or MIS-C *(Cohort 1)*	1 RCT	Cannot be assessed	Cannot be assessed	Cannot be assessed	Cannot be assessed	None	0 (Zero) events	0 (Zero) events	Not applicable	Cannot be assessed
4: Death	1 RCT	Cannot be assessed	Cannot be assessed	Cannot be assessed	Cannot be assessed	None	0 (Zero) events	0 (Zero) events	Not applicable	Cannot be assessed

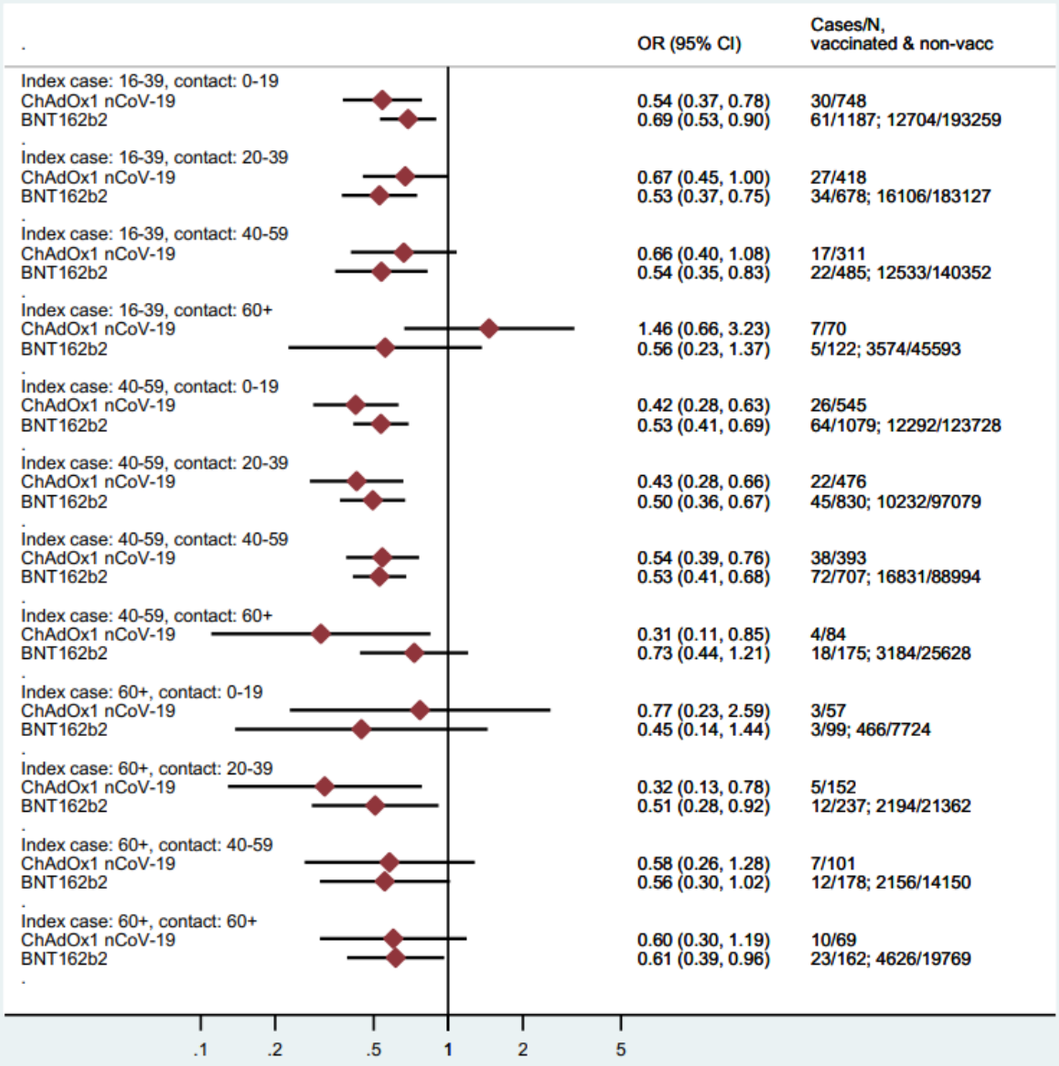
Table A1.3. Summary of Findings Table for the Safety of Pfizer-BioNTech (*10µg/dose*)

Safety Outcome	**N** Study design	**Quality Assessment**					**Summary of Findings**			**Certainty**
		Risk of Bias	**Inconsistency**	**Indirectness**	**Imprecision**	**Other Considerations**	**Vaccine n/N (%)**	**Control n/N (%)**	**Relative Risk (95%CI)**	
1a: Local adverse reaction within 7 days after dose 1 *(US FDA Briefing Document) (Cohort 1 + Cohort 2)*	1 RCT	Not serious	Cannot be assessed	Not serious	Not serious	None	1150/1511 (76.11%)	254/749 (33.91%)	2.24 (2.02 to 2.49)	++++ High

1b. Local adverse reaction within 7 days after dose 2 *(US FDA Briefing Document)* *(Cohort 1 + Cohort 2)*	1 RCT	Not serious	Cannot be assessed	Not serious	Not serious	None	1096/1501 (73.02%)	237/741 (31.98%)	2.28 (2.05 to 2.55)	++++ High
2a: Systemic adverse reaction within 7 days after dose 1 *(US FDA Briefing Document)* *(Cohort 1 + Cohort 2)*	1 RCT	Not serious	Cannot be assessed	Not serious	Serious *CI crosses the null value*	None	715/1511 (47.32%)	334/749 (44.59%)	1.06 (0.96 to 1.17)	+++ Moderate
2b: Systemic adverse reaction within 7 days after dose 2 *(US FDA Briefing Document)* *(Cohort 1 + Cohort 2)*	1 RCT	Not serious	Cannot be assessed	Not serious	Not serious	None	771/1501 (51.37%)	272/741 (36.71%)	1.40 (1.26 to 1.56)	++++ High
3. Any adverse event from dose 1 to 1 month after dose 2 *(US FDA Briefing Document)* *(Cohort 1 + Cohort 2)*	1 RCT	Not serious	Cannot be assessed	Not serious	Serious *CI crosses the null value*	None	166/1518 (10.94%)	69/750 (9.20%)	1.19 (0.91 to 1.55)	+++ Moderate
4: Serious adverse event from dose 1 through cut-off/unblinding *(US FDA Briefing Document)* *(Cohort 1 + Cohort 2)*	1 RCT	Serious *short follow up period*	Cannot be assessed	Not serious	Very Serious *Wide CI and CI crosses the null value*	None	4/3109 (0.13%)	1/1538 (0.07%)	1.98 (0.22 to 17.69	+ Very low
5. All-cause mortality *(Cohort 1 + Cohort 2)*	1 RCT	Cannot be assessed	Cannot be assessed	Cannot be assessed	Cannot be assessed	None	0 (Zero) events	0 (Zero) events	Not applicable	Cannot be assessed

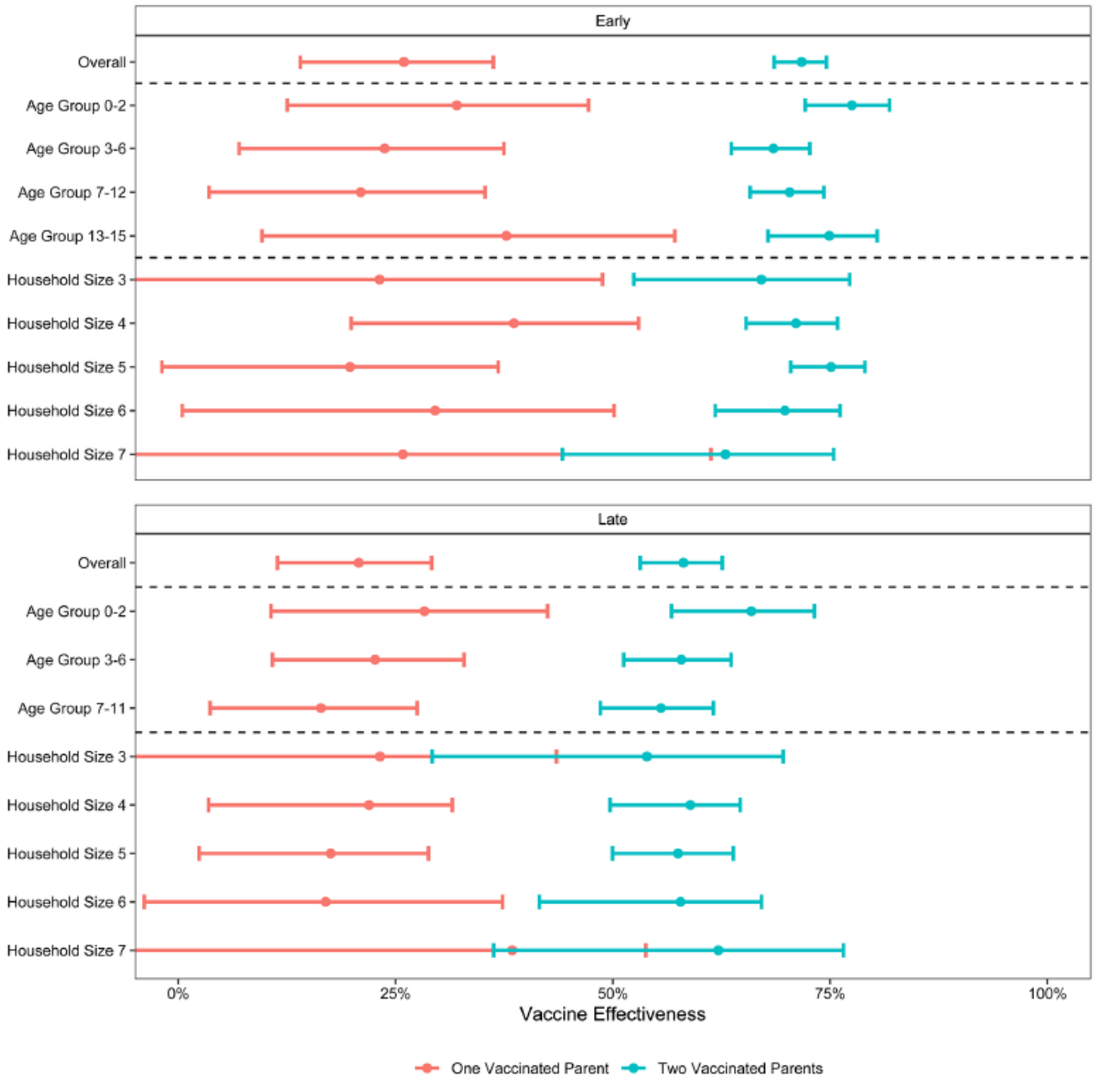
Appendix 6: Odds ratio on transmission per age group (Harris et al., 2021)

The forest plot below reported by the Harris et al., 2021 study shows the odds ratios for household contacts in becoming a secondary case if the index case was vaccinated with *ChAdOx1 nCoV-19 (AZ) or BNT162b2(Pfizer-BioNTech 30 µg/dose)* ≥21 days before testing positive vs. contacts of unvaccinated index cases. Results were aggregated per age of index case and contacts from multivariable logistic regression.



Appendix 7: Vaccine effectiveness against transmission by age group and household number (Hayek et al., 2021)

The forest plot below reported by Hayek et al., 2021 shows the indirect vaccine effectiveness calculated using the formula 1-IRR, of one or two vaccinated parents on the probability of infection of a susceptible, unvaccinated child. The early period represents the period when the Alpha variant was dominant in Israel while the late period represents the Delta surge.



Appendix 8: Costing Table

Cost of implementing *Pfizer-BioNTech (10µg/dose)*

In projecting the costs for implementing the COVID-19 Vaccination program in 2022 using *Pfizer-BioNTech (10µg/dose),* the following cost items were identified in calculating for the total resource requirement: *Pfizer-BioNTech (10µg/dose)* and vaccine consumables; logistics (hauling and storage); and operations (mobilization and training of vaccinators). The source of these costs were derived from the DOH - Disease Prevention and Control Bureau's (DPCB) overall vaccine budget plan. Overall, the projected cost of vaccine and consumables, logistics and operations to vaccinate 13.93 million pediatric Filipinos 5 to 11 years old [90% of the PSA 2022 projected population for this age group] with *Pfizer-BioNTech (10µg/dose)* is **Php 9.90B**.

For the sources of cost value inputs, we used the unit cost of vaccines based on the price offered to the government (as disclosed in confidence by the DOH-BIHC). Meanwhile, the cost inputs (i.e., cost items, cost values, and resource utilization) to estimate the cost of consumables, logistics, and operations were all referenced from the DOH-NIP, DOH-SCMS, and the manufacturer.

The paragraphs below will detail the costing calculation for cost components.

Vaccine and Consumables

The total cost of vaccines and consumables for 13.93 million pediatric Filipinos 5 to 11 years old with *Pfizer-BioNTech (10µg/dose)* is Php 9.90B. This amount accounts for the cost of two doses of *Pfizer-BioNTech (10µg/dose)* for every vaccinee, with 1% estimated wastage of vaccines, and 10% estimated wastage for vaccine consumables. Vaccine consumables include tuberculin syringes, mixing syringes, diluent, and safety collector boxes. The DOH-NIP noted that negotiations with possible manufacturers of 0.2 mL syringes are underway. However, the more readily available tuberculin syringes (1mL) will be procured as an alternative for now. As for personal protective equipment (PPE) of the vaccination team, these costs will be incurred by the LGU as this will be incorporated in their routine vaccination program.

Logistics

Included under logistics are hauling and storage costs. Hauling cost includes the rental and transport cost of tertiary packaging that can contain 600 vials each. Given an assumed weight of 31.4 kg per tertiary packaging, the total cost for hauling *Pfizer-BioNTech (10µg/dose)* is estimated at Php 282,625,807.32. This amount also includes a 1% valuation cost. For cold-chain storage, it is estimated to cost Php 78.40 per liter per month, resulting in a total storage cost of Php 4,864,517.77 per month. The overall cost for logistics is estimated to be at Php 287,490,325.09.

Operations

Operations cost includes mobilization, hiring costs, as well as training for vaccine implementation. However, since COVID-19 Vaccination in 2022 has been incorporated in the routine immunization program of LGUs, operations costs shall be incurred by the LGU.

Table A3.1 summarizes the resource requirement costs and assumptions in the roll-out of Pfizer-BioNTech (10µg/dose) for pediatric Filipinos ages 5-11 years old in the Philippines in 2022.

Table A3.1. Resource requirement costs in the roll-out of Pfizer-BioNTech (10µg/dose) in the Philippines in 2022

Description	Cost	Assumptions/Notes	Source
Vaccine and Vaccine Consumables	**Php 9,612,569,454.31**	For two doses, with 1% wastage for vaccines; consumables include syringes, diluent, and safety collector boxes, with 10% wastage for vaccine consumables *(estimated costs for vaccinating 13.93 million pediatric Filipinos based on identified target for Pfizer-BioNTech in 5-11 year-olds in 2022)*	DOF, DPCB, NIP, SCMS
Logistics	**Php 287,490,325.09**	This includes hauling and storage costs. *(estimated costs for vaccinating 13.93 million pediatric Filipinos based on identified target for Pfizer-BioNTech in 5-11 year-olds in 2022)*	SCMS, Manufacturer (*Pfizer Philippines, Inc.*)
Operations	**Php 0**	Operations cost will be incurred by the LGUs as this will be incorporated in their routine vaccination program.	DPCB
TOTAL COST	**Php 9.90 B**		
PROPORTION OF THE COST TO THE 2021 and 2022 TOTAL COVID-19 VACCINATION BUDGET	**7.90%** **[Allocated from the 2021 and 2022 budget]**		

Acronym: **DPCB:** Disease Prevention and Control Bureau | **DOF:** Department of Finance | **NIP:** National Immunization Program | **SCMS:** Supply Chain Management Service

Based on the projected calculations, the total cost of rolling out vaccination with *Pfizer-BioNTech (10µg/dose)* for 13.93 million pediatric Filipinos 5 to 11 years old would amount to Php 9,900,059,779.40. This would entail utilization of 7.90% of the total allocated budget for vaccination in 2021 and 2022 and will cover 8.96% of the total doses to be procured for the different vaccination policies being implemented.