Tdap Vaccine
AS BOOSTER IMMUNIZATION AGAINST TETANUS, DIPHTHERIA AND PERTUSSIS

Outline

- Background
- aHTA Eligibility
- Disease Magnitude and Severity
- Vaccination Coverage of the Primary Series Roll-out
- Challenges and Mitigation Plans of the Primary Series Roll-out
- Costing Analysis Based on NIP Implementation Plans
- Summary of Points for Consideration
- Overall Recommendation

BACKGROUND

Tdap Vaccine

	Details	References
Health Technology	**Tetanus, diphtheria, and acellular pertussis (Tdap) vaccine**	Topic Nomination Form
Indication	Booster immunization against tetanus, diphtheria and pertussis	Topic Nomination Form
	Adacel® is indicated for active booster immunization for the prevention of tetanus, diphtheria and pertussis (whooping cough) in persons **4 years of age and older.**	MIMS (Adacel®)
	Boostrix® is indicated for booster vaccination against diphtheria, tetanus and pertussis of individuals from the **age of 4 onwards**.	MIMS (Boostrix®)
	More importantly, Tdap is being proposed to replace Td vaccine, which is currently administered to the following: • **Pregnant women;** • **Children aged 6-7 years old (Grade 1 students); and** • **Children aged 11-12 (Grade 7 students)**	DPCB [communications]
Nominator	DPCB (Cycle 3 - December 2024)	Topic Nomination Form

Rationale for Nomination

Different types of Booster Vaccines for Tetanus, Diphtheria and Pertussis

Booster for ≤7 yo	Booster for >7 yo
• **DTaP:** Diphtheria-tetanus toxoids and acellular pertussis vaccine (PNF-listed) • **Tdap:** Tetanus-diphtheria toxoids and acellular pertussis vaccine (intervention of interest) • **DT:** Diphtheria and tetanus toxoid vaccine (PNF-listed)	• **Tdap:** Tetanus-diphtheria toxoids and acellular pertussis vaccine (intervention of interest) • **Td:** Tetanus and diphtheria toxoid vaccine (PNF-listed) • **TT**: Tetanus toxoid (PNF-listed)

- **Tdap is the only booster vaccine against pertussis for older children, adolescents and pregnant women**

Notes:

- The only booster vaccine (DTaP) in the PNF for tetanus, diphtheria and pertussis is indicated for children just until 7 years old.
- The existing booster vaccine being implemented by DOH only covers tetanus and diphtheria (Td vaccine), and DOH is intending to also cover booster dose for pertussis.

Background

NIP roll-out of Diphtheria, Pertussis and Tetanus containing vaccines

- Primary series with DPT-HepB+Hib vaccine (Pentavalent):
  - 1st dose: 6 weeks
  - 2nd dose: 10 weeks
  - 3rd dose: 14 weeks
- Booster dose with Td vaccine
  - 1st Booster: Grade 1 students (6-7 yo)
  - 2nd Booster: Grade 7 students (11-12yo)
  - Pregnant women

Tdap is proposed to replace Td vaccine

References: NIP Manual of Operations (pp 94-95); PIDSP - Childhood Immunization Schedule for 2025 (p.5)

AHTA ELIGIBILITY

aHTA

aHTA track: for health technology topics (drugs, vaccines and medical devices) identified as **standards of care (SoC)** or **long-standing use in clinical practice**

<u>Requirements for accelerated assessments:</u>

1. Clinical Evidence

- **Existing recommendations or inclusions in the Essential Medicines List (EML)** by the World Health Organization (WHO) (preferably available)
- **DOH-approved Clinical Practice Guidelines (CPG) Recommendation** for the use of the product OR **local CPG developed by the relevant medical society** OR **international CPG adopted by the relevant said relevant medical society** indicating the: potential place of the proposed intervention in the clinical pathway, and proposed dosing schedule or regimen and the treatment pathway, OR **Recommendations in the DOH Omnibus Health Guidelines (OHG)**

2. Economic evidence

- **Local comparative costing with the identified comparator** in the CPG provided (i.e., interventions at the same level in the clinical pathway as the nominated health technology)

aHTA Eligibility: Tdap booster vaccine

	Requirements	**Tetanus, Diphtheria and acellular pertussis vaccine (Tdap)** as an active booster immunization against tetanus, diphtheria and pertussis
CLINICAL EVIDENCE	DOH-approved CPG	✔
	Recommendations in the DOH OHG	✔
	Existing in the WHO EML	✔ **Listed in the WHO EML** *(as individual components)*
ECONOMIC EVIDENCE	Local Comparative Costing	✔ Costing analysis conducted by HTAD

CLINICAL EVIDENCE

Note: DOH is looking at revising the OHG to expand the age groups to be covered by Tdap until 6 years old.

1. *Is Tdap Vaccine included in the DOH Omnibus Health Guidelines? (1 of 3)*

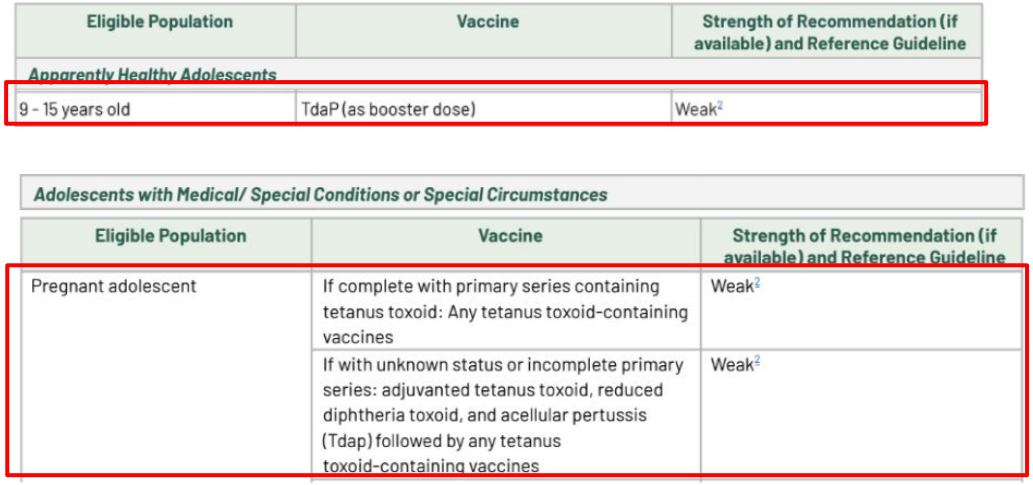
DOH-approved CPG	Included?	Remarks
OHG for Children 2023 (Pages 72-73)	Yes	***Additional vaccines recommended to be received by all healthy children***

Eligible Population Group or Condition	Recommended Vaccine	Strength of Recommendation (if available) and Reference Guideline
12 - 23 months old	DTP (as booster dose)	Weak[6]
3 to 5 years old	COVID-19 Vaccine: CoronaVac (Sinovac)	Weak[7]
4 - 7 years old	DTP (as booster dose)	Weak[6]
9 - 15 years old	TdaP (as booster dose)	Weak[6]

CLINICAL EVIDENCE

Covers Grade 7 students (11-12 yo)

1. *Is Tdap Vaccine included in the DOH Omnibus Health Guidelines? (2 of 3)*

DOH-approved CPG	Included?	Remarks
OHG for Adolescents 2023 (Pages 66-67)	Yes	

Eligible Population	Vaccine	Strength of Recommendation (if available) and Reference Guideline
Apparently Healthy Adolescents		
9 - 15 years old	TdaP (as booster dose)	Weak[2]

Adolescents with Medical/ Special Conditions or Special Circumstances		
Eligible Population	**Vaccine**	**Strength of Recommendation (if available) and Reference Guideline**
Pregnant adolescent	If complete with primary series containing tetanus toxoid: Any tetanus toxoid-containing vaccines	Weak[2]
	If with unknown status or incomplete primary series: adjuvanted tetanus toxoid, reduced diphtheria toxoid, and acellular pertussis (Tdap) followed by any tetanus toxoid-containing vaccines	Weak[2]

CLINICAL EVIDENCE

Covers Grade 1 and Grade 7 students

1. *Is Tdap Vaccine included in the DOH Omnibus Health Guidelines? (3 of 3)*

<table>
<tr><th>DOH-approved CPG</th><th>Included?</th><th>Remarks</th></tr>
<tr>
<td>National Immunization Program - Manual Of Operations: Page 94-95</td>
<td>Yes</td>
<td>
<table>
<tr><th colspan="2">Pentavalent vaccine</th></tr>
<tr><td>Primary Series Schedule</td><td>3 doses of Pentavalent Vaccine (given at 6, 10, 14 weeks of age)*
*1st dose starting at six weeks (minimum) with 2nd dose and 3rd dose at intervals of four weeks (minimum) after each dose.</td></tr>
<tr><td>Booster Schedule</td><td>For Tetanus vaccine:
1 booster dose in early childhood (1-6 years) and another (Td) during adolescence (12-15 years) is required. A further dose in adulthood is likely to provide lifelong protection.

For Diphtheria vaccine:
1 booster dose at two years old and two other doses with Td vaccine at school age.</td></tr>
</table>
</td>
</tr>
</table>

CLINICAL EVIDENCE

Covers Grade 1 and Grade 7 students

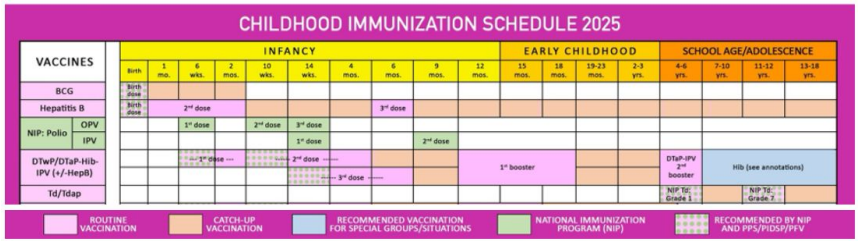
2. Is Tdap Vaccine included in DOH-approved CPGs? (1 of 2)

DOH-approved CPG	Included?	Remarks
PHEx: Pediatric Immunization (2023) (Pages 13-14; 81-89; 112-124)	Yes	**Pertussis Vaccine** We suggest giving a **pertussis-containing vaccine booster dose** among **children and adolescents who completed the 3-dose primary DPT (Diphtheria-Pertussis-Tetanus)** series starting at 12 months of age and following a minimum interval of 6 months after the 3rd dose. (weak recommendation, very low certainty evidence) **Tetanus Vaccine** We suggest giving a tetanus toxoid-containing vaccine **booster dose** among **healthy infants and children who completed a 3-dose primary series of tetanus toxoid-containing vaccines** starting at 12 months of age and following a minimum interval of 6 months after the 3rd dose. (weak recommendation, low certainty evidence

CLINICAL EVIDENCE

Covers Grade 1 and Grade 7 students

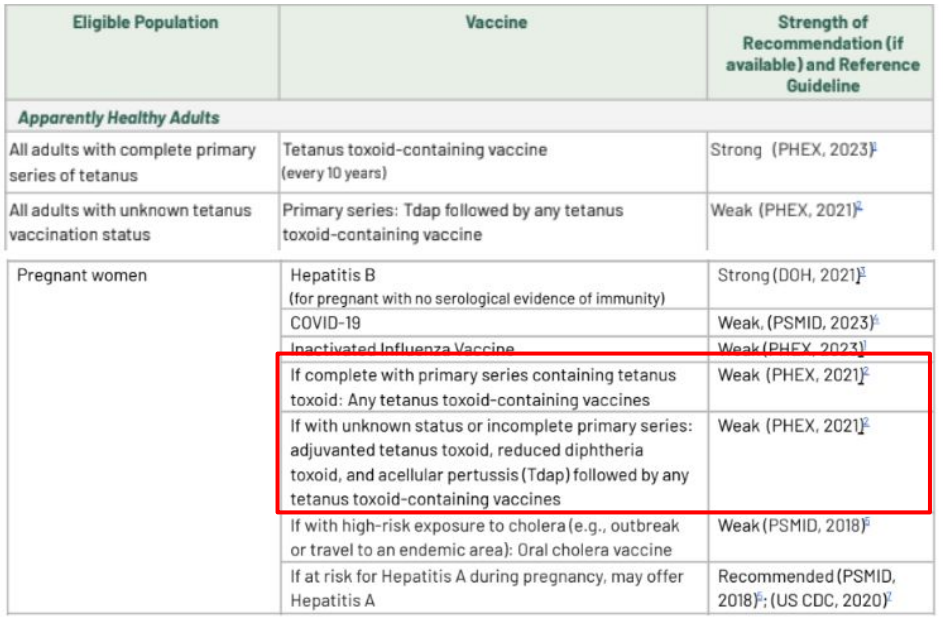
2. *Is Tdap Vaccine included in DOH-approved CPGs? (2 of 2)*

DOH-approved CPG	Included?	Remarks
PIDSP - Childhood Immunization Schedule for 2025	Yes	**Tetanus and Diphtheria Toxoid (Td) / Tetanus and Diphtheria Toxoid and Acellular Pertussis (Tdap) Vaccine** **General Information And Recommendation** ● Minimum age: 7 years ● Routine vaccination: ○ Ages 7-18 years old → 1 dose Tdap (considered as 3rd booster for DTP) ○ Tdap booster doses should be given every 10 years for those who have completed* their DTP doses. **If Tdap is not available, Td can be given.** ○ **The NIP provides Td vaccine at Grade 1 and Grade 7 as part of their school-based immunization program.** *Completed DTP doses → having received 5 doses of DTP, or 4 doses of DTP if the 4th dose was given on or after the 4th birthday. 

CLINICAL EVIDENCE

Covers Pregnant Women

1. Is Tdap Vaccine included in the DOH Omnibus Health Guidelines?

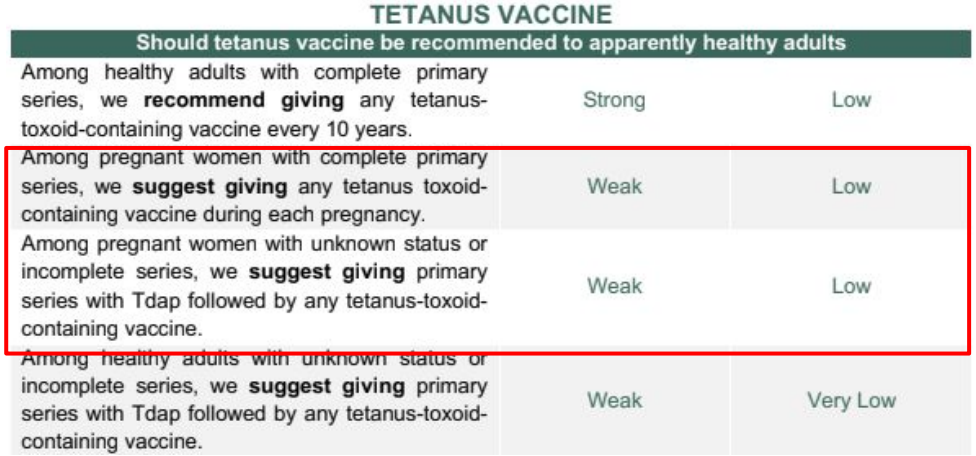
DOH-approved CPG	Included?	Remarks
OHG for Adults 2023 (Pages 66-67)	Yes	

Eligible Population	Vaccine	Strength of Recommendation (if available) and Reference Guideline
Apparently Healthy Adults		
All adults with complete primary series of tetanus	Tetanus toxoid-containing vaccine (every 10 years)	Strong (PHEX, 2023)
All adults with unknown tetanus vaccination status	Primary series: Tdap followed by any tetanus toxoid-containing vaccine	Weak (PHEX, 2021)
Pregnant women	Hepatitis B (for pregnant with no serological evidence of immunity)	Strong (DOH, 2021)
	COVID-19	Weak, (PSMID, 2023)
	Inactivated Influenza Vaccine	Weak (PHEX, 2023)
	If complete with primary series containing tetanus toxoid: Any tetanus toxoid-containing vaccines	Weak (PHEX, 2021)
	If with unknown status or incomplete primary series: adjuvanted tetanus toxoid, reduced diphtheria toxoid, and acellular pertussis (Tdap) followed by any tetanus toxoid-containing vaccines	Weak (PHEX, 2021)
	If with high-risk exposure to cholera (e.g., outbreak or travel to an endemic area): Oral cholera vaccine	Weak (PSMID, 2018)
	If at risk for Hepatitis A during pregnancy, may offer Hepatitis A	Recommended (PSMID, 2018); (US CDC, 2020)

Covers Pregnant Women

CLINICAL EVIDENCE

2. Is Tdap Vaccine included in DOH-approved CPGs? (1 of 5)

DOH-approved CPG	Included?	Remarks
PHEx: Adult Immunization (2023) (Pages 17; 156-167)	Yes	

TETANUS VACCINE

Should tetanus vaccine be recommended to apparently healthy adults		
Among healthy adults with complete primary series, we **recommend giving** any tetanus-toxoid-containing vaccine every 10 years.	Strong	Low
Among pregnant women with complete primary series, we **suggest giving** any tetanus toxoid-containing vaccine during each pregnancy.	Weak	Low
Among pregnant women with unknown status or incomplete series, we **suggest giving** primary series with Tdap followed by any tetanus-toxoid-containing vaccine.	Weak	Low
Among healthy adults with unknown status or incomplete series, we **suggest giving** primary series with Tdap followed by any tetanus-toxoid-containing vaccine.	Weak	Very Low

Covers Pregnant Women

CLINICAL EVIDENCE

2. *Is Tdap Vaccine included in DOH-approved CPGs? (2 of 5)*

DOH-approved CPG	Included?	Remarks
PIDSP - Childhood Immunization Schedule for 2025	Yes	**Tetanus and Diphtheria Toxoid (Td) / Tetanus and Diphtheria Toxoid and Acellular Pertussis (Tdap) Vaccine** **Pregnant Adolescents** 2. **Pregnant Adolescents** • Give 1 dose of Tdap for every pregnancy. • Previously vaccinated pregnant adolescents with DTP/Td/Tdap, administer 1 dose of Tdap vaccine at 27 to 36 weeks AOG. • Unimmunized pregnant adolescents, administer a 5-dose tetanus-diphtheria (Td)-containing vaccine following a 0-,1-, 6-,18-, and 30-month schedule. Use Tdap as one of the 5 doses, preferably given at 27-36 weeks AOG.

Covers Pregnant Women

CLINICAL EVIDENCE

2. *Is Tdap Vaccine included in DOH-approved CPGs? (3 of 5)*

DOH-approved CPG	Included?	Remarks
PSMID - CPG for Adult Immunization 2018 **Tetanus, diphtheria, pertussis vaccine for adults**	Yes	• Immunity against pertussis wanes approximately 5-10 years after completion of childhood vaccination, leaving adolescents and adults susceptible to the disease.[5] The acellular vaccine composed of inactivated components of *B. pertussis* cells is the recommended vaccine for adults.

CLINICAL EVIDENCE

Covers Pregnant Women

2. *Is Tdap Vaccine included in DOH-approved CPGs? (4 of 5)*

DOH-approved CPG	Included?	Remarks
PSMID - CPG for Adult Immunization 2018 **Tetanus, diphtheria, pertussis vaccine for adults**	Yes	See table below

Recommendation, indication/target population	• Adults who have not been vaccinated or are incompletely vaccinated with tetanus-diphtheria combination 3-dose primary series should receive the complete primary series that includes 1 dose of Tdap to prevent tetanus, diphtheria, and pertussis. *Strong recommendation; low to moderate quality of evidence*
	• Td vaccination every 10 years may be given to adults aged 19-64 years old, if the last vaccination was at least 10 years ago. *Weak recommendation; low quality of evidence*
	• Adults who anticipate to have close contact with an infant <12 months old may receive one dose of Tdap to prevent transmission of pertussis. *Weak recommendation; very low quality of evidence*
	• Adults who sustained wounds assessed to be tetanus-prone should be given Td with or without tetanus immunoglobulin to prevent tetanus infection. *Strong recommendation; low quality of evidence*
Schedule	• Td of 0.5 ml each should be given intramuscularly with the second dose given 4-8 weeks after the first dose, and the third dose given at 6-12 months after the second dose. • Adults of all ages who have never received Tdap as an adolescent or adult, or for whom vaccine status is unknown, should receive Tdap as their first dose, followed by Td to complete their primary series.[20]

This includes pregnant women.

CLINICAL EVIDENCE

3. Is Tdap vaccine included in the WHO Essential Medicines List? (1 of 2)

WHO EML	Included?	Remarks
WHO EML	Yes *Tdap is not recommended as a combination (to avoid unduly complicating the WHO list since various combination products intended for different groups of people) but each component is recommended by the WHO for EPI program.*	**Summary of evidence and Expert Committee recommendations** *The Committee accepted the recommendation of the WHO Department of Vaccines and Biologicals to modify the list of essential vaccines to list the antigens but not the specific vaccine mixtures.* ***The reason is that there are various combination products intended for different groups of people and that listing all of the recommended vaccines would unduly complicate the list.*** *Specific therapeutic recommendations for vaccines containing single antigens or mixtures of antigens are found in the policy statements of the WHO Department of Vaccines and Biologicals.*

CLINICAL EVIDENCE

3. Is Tdap vaccine included in the WHO Essential Medicines List? (2 of 2)

WHO EML	Included?	Remarks
WHO EML	Yes *Tdap is not recommended as a combination (to avoid unduly complicating the WHO list since various combination products intended for different groups of people) but each component is recommended by the WHO for EPI program.*	**WHO Essential Programme on Immunization** There are now 13 vaccines (antigens) recommended by WHO for the EPI programme. They are: Bacillus Calmette-Guérin (BCG), **diphtheria, pertussis, tetanus,** *Haemophilus influenzae* type B (Hib), Hepatitis B (HepB), polio, measles, rubella, pneumococcal disease (PNC), rotavirus (Rota), human papillomavirus (HPV), and COVID-19 (for adults). **WHO recommendations for routine immunization (2024)**

Table 1: Summary of WHO Position Papers - Recommendations for Routine Immunization

Antigen	Children (see Table 2 for details)		Adolescents	Adults	Considerations (see footnotes for details)
Recommendations for all immunization programmes					
BCG [1]	1 dose				Birth dose and HIV; Universal vs selective vaccination; Co-administration; Vaccination of older age groups; Pregnancy
Hepatitis B [2]	3-4-doses (see footnote for schedule options)		3 doses (for high-risk groups if not previously immunized) (see footnote)		Birth dose Premature and low birth weight Co-administration and combination vaccine Definition high-risk
Polio [3]	3-5 doses (at least 2 doses of IPV) with DTPCV				bOPV birth dose; Type of vaccine; Fractional dose IPV; Transmission and importation risk; Local epidemiology, programmatic implications and feasibility for "early" option
DTP-containing vaccine (DTPCV) [4]	3 doses	2 boosters 12-23 months (DTPCV) and 4-7 years (Td/DT containing vaccine, see footnote)	1 booster 9-15 yrs (Td)		Delayed/interrupted schedule Combination vaccine Maternal immunization

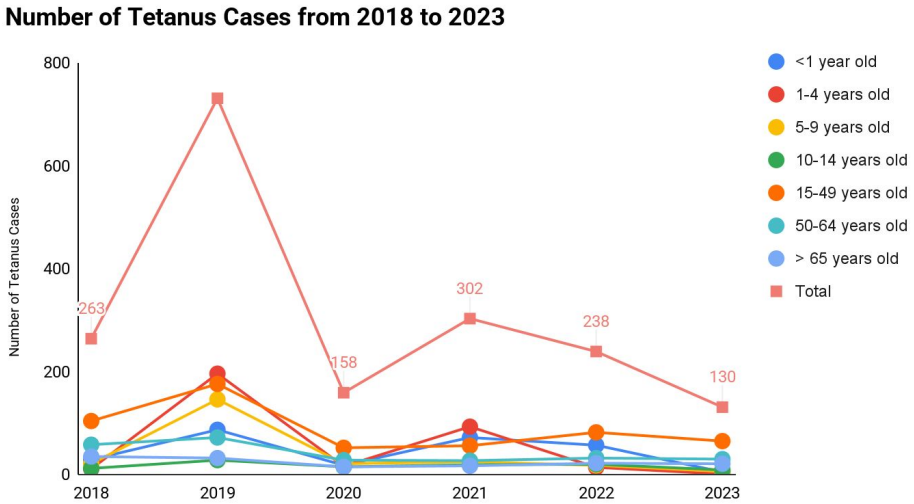
aHTA Eligibility: Tdap booster vaccine

1. *Is Tdap Vaccine included in DOH Omnibus Health Guidelines?* ***YES.***
2. *Is Tdap Vaccine included in DOH-approved CPGs?* ***YES.***
3. *Is Tdap Vaccine included in the WHO Essential Medicines List?* ***YES.***

ELIGIBLE FOR aPNF INCLUSION

DISEASE MAGNITUDE AND SEVERITY

C1: Tetanus in the Philippines

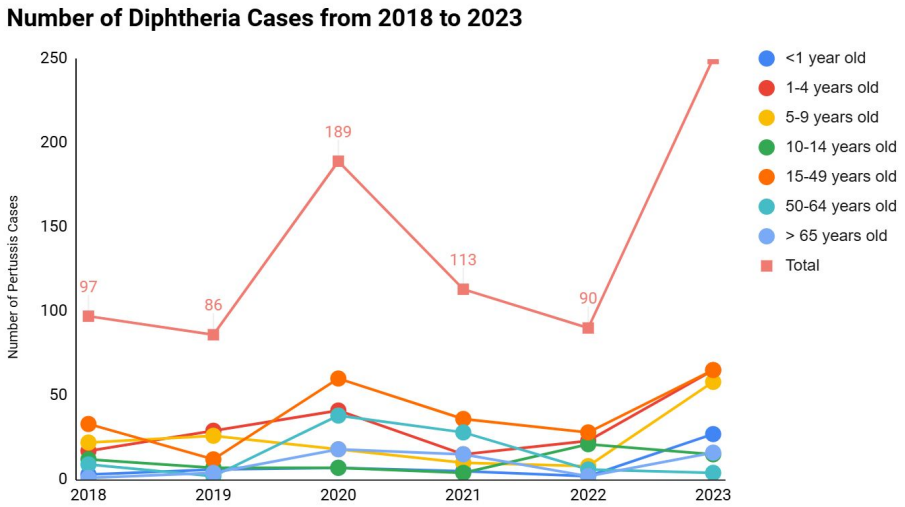


Key Findings: The total number of reported cases decreased from 2019 to 2020 from 730 to 158. From 2020 to 2021, cases increased to 302. Cases declined again in 2022 and 2023 to 238 and 130 cases, respectively. Cases were highest among the 15 to 49 yo, 1-4 yo and 5-9 yo age groups.
Reference: Field Health Services Information System FHSIS [national field-based surveillance]

Cases	2018	2019	2020	2021	2022	2023
<1 yo	28	86	17	71	56	4
1-4 yo	10	195	15	92	13	0
5-9 yo	20	145	20	24	17	5
10-14 yo	11	27	14	18	19	8
15-49 yo	103	175	51	55	81	64
50-64 yo	57	71	27	26	31	29
> 65 yo	34	31	14	16	21	20
Total	263	730	158	302	238	130

Note: No data on deaths due to Tetanus infection in the FHSIS report.

C1: Diphtheria in the Philippines



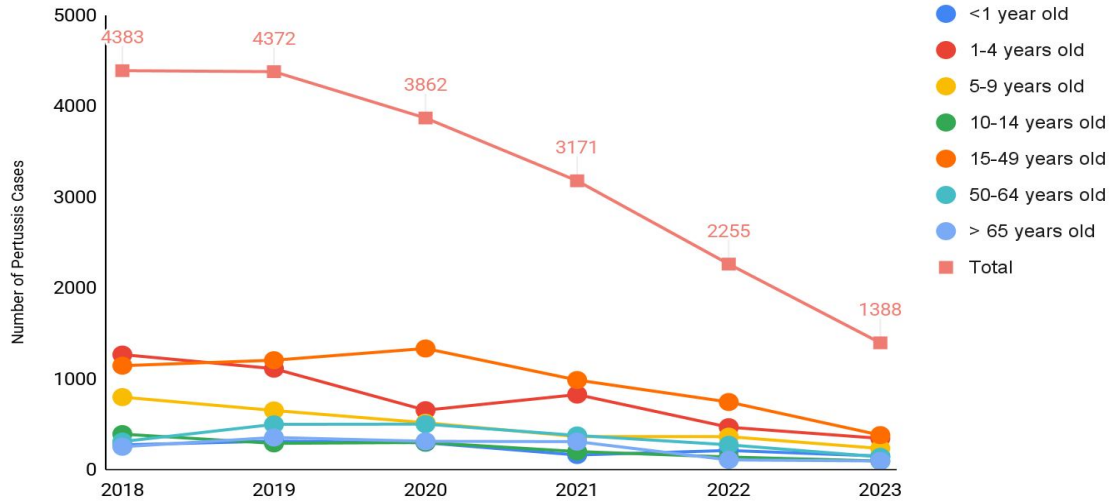
Key Findings: The total number of reported cases increase from 2019 to 2020 from 86 to 189 cases. From 2020 to 2022, cases decreased down to 90. However, number cases increased to 250 in 2023. Cases were highest among the 15 to 49 yo, 1-4 yo and 5-9 yo age groups.
Reference: Field Health Services Information System FHSIS [national field-based surveillance]

Cases	2018	2019	2020	2021	2022	2023
<1 yo	3	6	7	5	2	27
1-4 yo	17	29	41	15	23	65
5-9 yo	22	26	18	10	8	58
10-14 yo	12	7	7	4	21	15
15-49 yo	33	12	60	36	28	65
50-64 yo	9	2	38	28	6	4
> 65 yo	1	4	18	15	2	16
Total	97	86	189	113	90	250

Note: No data on deaths due to Diptheria in the FHSIS report.

C1: Pertussis in the Philippines

Number of Pertussis Cases from 2018 to 2023



Cases	2018	2019	2020	2021	2022	2023
<1 yo	265	307	289	154	204	142
1-4 yo	1259	1104	647	819	460	337
5-9 yo	791	644	509	357	356	226
10-14 yo	384	282	292	192	132	88
15-49 yo	1137	1197	1326	979	737	373
50-64 yo	302	491	494	369	266	134
> 65 yo	245	347	305	301	100	88
Total	4383	4372	3862	3171	2255	1388

Key Findings: The total number of reported pertussis cases decreased from 2018 to 2023. Cases were highest among the 15 to 49 yo, 1-4 yo and 5-9 yo age groups.

Reference: Field Health Services Information System FHSIS [national field-based surveillance]

Note: No data on deaths due to Pertussis in the FHSIS report.

C1: Pertussis in the Philippines

In its report, the DOH said the number is almost six times higher than the 760 cases recorded in the same period in 2023.

PPA Pool photos by Revoli Cortez

MANILA, Philippines — The Department of Health (DOH) has recorded 4,518 cases of pertussis nationwide as of Dec. 14.

In its report, the DOH said the number is almost six times higher than the 760 cases recorded in the same period in 2023.

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Philippines

Measles and pertussis outbreaks a wake-up call for the Philippines

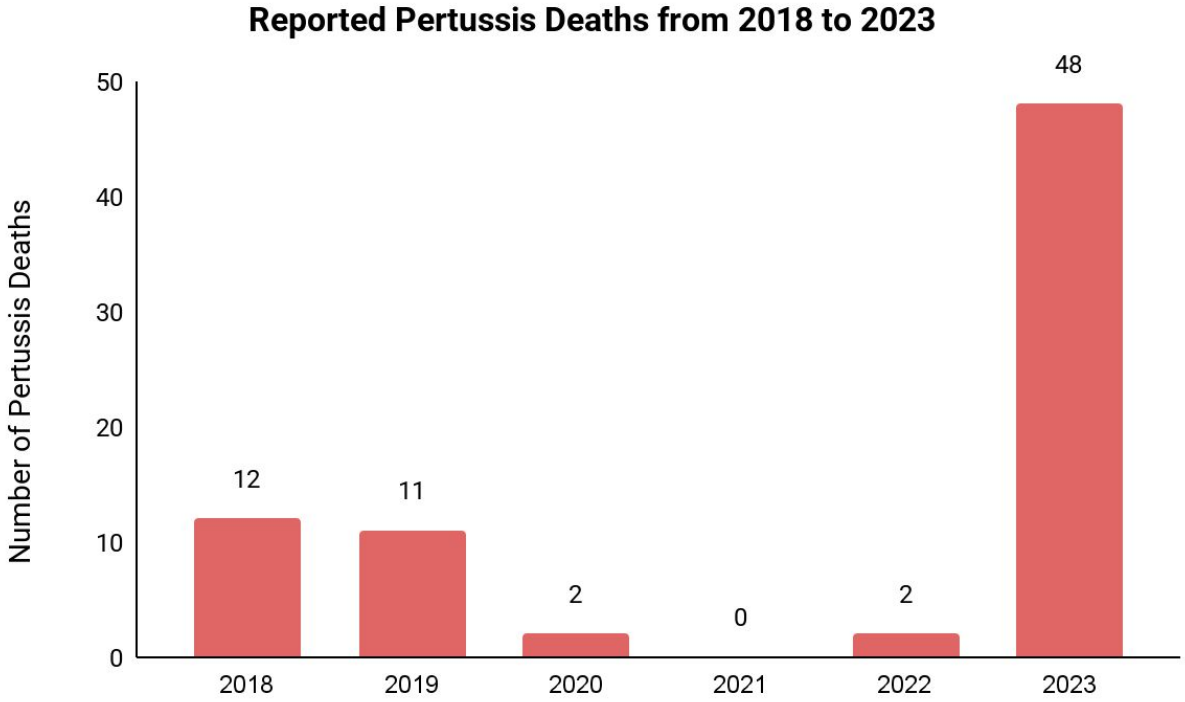
Declaration Of Pertussis Outbreak In Quezon City

BY QCESD - Mar 21, 2024 8:00 AM

Although official report from the DOH on the number of pertussis cases in 2024 is not yet posted, **pertussis outbreak was declared in certain cities/provinces in the country**.

References: Unicef, 2024; PhilStar 2024

C1: Pertussis in the Philippines



Key Findings: The number of reported pertussis deaths decreased from 2018 to 2021. Meanwhile, form 2022 to 2023, there a sudden increase in the number of reported deaths from 2 to 48.

Reference: Philippine Integrated Disease Surveillance and Response (PIDSR) [Case-based surveillance]

PRIMARY SERIES ROLL-OUT: VACCINATION COVERAGE

Vaccination coverage of the primary series of DPT-containing vaccines from 2018 to 2024.

Vaccine Dose	Vaccination Coverage (%)						
	2018	2019	2020	2021	2022	2023	2024
Dose 1 : DPT-HiB-HepB 1	66.47	72.83	77.77	70.09	77.41	78.02	68.09%
Dose 2 : DPT-HiB-HepB 2	65.90	72.10	76.32	69.27	76.37	77.57	64.20%
Dose 3: DPT-HiB-HepB 2	65.10	71.08	74.80	68.34	74.64	76.81	58.27%

WHO position

The main aim of pertussis vaccination is to reduce the risk of severe pertussis in infants and young children, due to the high morbidity and mortality caused by the disease in this age group. All children worldwide, including HIV-positive individuals, should be immunized against pertussis. Every country should seek to achieve early and timely vaccination initiated at 6 weeks and no later than 8 weeks of age, and maintain high coverage (≥90%) with at least 3 doses of assured quality pertussis vaccine at all levels (national and subnational). This will ensure high levels of protection in children in the <5 year age group. Any reduction in overall coverage can lead to an increase in cases of pertussis.

Vaccination coverage of the primary series (dose 1 to dose 3) of DTP-containing vaccine **did not reach** **high coverage (≥90%)**.

References:

- Pertussis vaccines - WHO position paper (August 2015)
- FHSIS report (2018-2023)

PRIMARY SERIES ROLL-OUT: CHALLENGES AND MITIGATION PLANS

Implementation of Primary Series Vaccination with DTP- containing vaccines

Challenges encountered resulting in the low coverage of primary series vaccination of DTP-containing vaccines	Plans to address low primary series vaccination coverage of DTP-containing vaccines
Demand side challenges	
• Cultural beliefs and a lack of awareness about available healthcare services	• Strengthen of health education campaigns to combat vaccine hesitancy, using community engagement and trusted local leaders to promote immunization
• Economic constraints, such as transportation costs and lost wages, discouraging families from completing required vaccine doses.	• Provide financial and logistical support, including transportation assistance and incentives
	• Intensify catch-up vaccination campaigns, following WHO recommendations
	• Integrate immunization with other essential health services
	• Improve collaboration between national and local governments, private organizations, and international health agencies

Implementation of Primary Series Vaccination with DTP- containing vaccines

Challenges encountered resulting in the low coverage of primary series vaccination of DTP-containing vaccines	Plans to address low primary series vaccination coverage of DTP-containing vaccines
Supply side challenges	
• Supply shortages, with certain years experiencing stockouts (nationwide stockout in 2024)	• Improve vaccine supply chain management to prevent stockouts and ensure consistent availability in all health facilities
• Many remote areas face difficulties in accessing healthcare facilities	• Expand mobile vaccination teams and house-to-house immunization drives to reach remote and underserved areas

COSTING ANALYSIS BASED ON NIP IMPLEMENTATION PLANS

COSTING ANALYSIS: *Assumptions/conditions applied*

- There are two Philippine FDA-approved Tdap Vaccines. Costing for these two brands was performed.
  - *Adacel*® - Manufactured by Sanofi
  - *Boostrix*® - Manufactured by GSK

- According to the DPCB, Tdap is being proposed to replace Td vaccine, thus, costing for Td was also performed

Vaccine Cost per Dose		
Adacel®	*Boostrix*®	Td vaccine
Php 660.33	Php 1,205.00	Php 11.90

Note: There is no available pertussis-only booster vaccine for the adult population.

COSTING ANALYSIS: *Assumptions/conditions applied*

DPCB Plans for Implementation of Tdap Booster Vaccination

- According to the DPCB, Tdap is being proposed to replace Td vaccine, which is currently administered to [1] Children aged 6-7 years old (Grade 1 students), [2] children aged 11-12 (Grade 7 students) and [3] Pregnant women.

Strategy 1: Phased transition per population

- Year 1-2: transition from Td to Tdap for pregnant women
- Year 3-4: transition from Td to Tdap for Grade 1 students
- Year 5 and onwards: transition from Td to Tdap for Grade 7 student

Strategy 2: Phased transition by priority regions

- Phased transition per priority region with the highest pertussis cases

COSTING ANALYSIS: *Assumptions/conditions applied*

Target Population	Given	Projections made
Strategy 1 - Phased transition by Population		
Pregnant women	Number of pregnant women for Year 1 (2025)	Year 2 = Year 1 * PH growth rate (1.02%) Year 3 = Year 2 * PH growth rate (1.02%) …
Grade 1	Population, disaggregated by singular age (2020)	Year 1 = Number of children aged 1 yo in 2020 = Number of children aged 6 yo in 2025 (eligible Grade 1) Year 2 = Number of children under 1 yo in 2020 = Number of children aged 6 yo in 2026 Year 3 onwards = projection using growth rate
Grade 7		Year 1 = Number of children aged 7 yo in 2020 = Number of children aged 12 yo in 2025 (eligible Grade 7) Year 2 = Number of children aged 6 yo in 2020 = Number of children aged 12 yo in 2026 Year 3 = Number of children aged 5 yo in 2020 = Number of children aged 12 yo in 2027 Year 4 = Number of children aged 4 yo in 2020 = Number of children aged 12 yo in 2028 Year 5 = Number of children aged 3 yo in 2020 = Number of children aged 12 yo in 2029

COSTING ANALYSIS: *Number of Target Population*

Strategy 1 - Phased transition by Population					
Target Population/ Number of doses	**Year 1**	**Year 2**	**Year 3**	**Year 4**	**Year 5**
	Pregnant women only		**Pregnant women + Grade 1 Students**		**Pregnant women + Grade 1 Students + Grade 7 Students**
Pregnant (2 doses)	2,200,865	2,223,314	2,245,992	2,268,901	2,292,044
Grade 1 (1 dose)	0	0	2,178,753	2,222,328	2,266,774
Grade 7 (1 dose)	0	0	0	0	2,236,525
Total number of doses needed (including wastage)	4,621,817	4,668,959	7,004,273	7,098,136	9,541,756

COSTING ANALYSIS: *Assumptions/conditions applied*

Strategy 2 - Phased transition by Region		
Year 1	Top 3 regions with the highest cases of pertussis	Region 6, 11, 4A
Year 2	Top 6 regions with the highest cases of pertussis	New cohort from top 3 regions + Region 8, 10, BARMM
Year 3	Top 9 regions with the highest pertussis cases	New cohort from top 6 regions + NCR, Region 7, 12
Year 4	Top 11 regions with the highest pertussis cases	New cohort from top 9 regions + Region 5, 4B
Year 5	Rest of the regions	New cohort from top 11 regions + CAR, CARAGA, Region 1, 2, 3 9* *all additional regions have zero cases of Pertussis in 2023

Reference: 2023 FHSIS Report

COSTING ANALYSIS: *Assumptions/conditions applied*

Target Population	Given	Projections made
Strategy 2 - Phased transition by Region		
Pregnant women	Population, disaggregated by region Total national population	Year 1 = Number of pregnant women* in strategy 1 x (population in the top 3 regions in pertussis incidence / total national population) Year 2 = Number of pregnant women* in strategy 1 x (population in the top 6 regions in pertussis incidence / total national population) Year 3 = Number of pregnant women* in strategy 1 x (population in the top 9 regions in pertussis incidence / total national population) Year 4 = Number of pregnant women* in strategy 1 x (population in the top 11 regions in pertussis incidence / total national population) Year 5 = Number of pregnant women* in strategy 1 x 100% of total national population
Grade 1		*Similar formula with pregnant women* **Number of Grade 1 students in strategy 1*
Grade 7		*Similar formula with pregnant women* **Number of Grade 7 students in strategy 1*

COSTING ANALYSIS: *Number of Target Population*

Strategy 2 - Phased transition by Region					
Target Population/ Number of doses	**Year 1**	**Year 2**	**Year 3**	**Year 4**	**Year 5**
Pregnant (2 doses)	593,312	895,335	1,438,550	1,646,973	2,292,044
Grade 1 (1 dose)	593,034	860,187	1,395,484	1,613,166	2,266,774
Grade 7 (1 dose)	617,252	891,119	1,392,197	1,653,848	2,236,525
Total number of doses needed (including wastage)	2,516,755	3,719,075	5,948,021	6,889,008	9,541,756

COSTING ANALYSIS SUMMARY

Parameter	*Adacel*® (Sanofi)				
	Year 1	Year 2	Year 3	Year 4	Year 5
Strategy 1 - Phased transition by Population					
Cost of Vaccination per individual					
Pregnant Women	Php 1,396.63				
Grade 1 Students	Php 698.31				
Grade 7 Students	Php 698.31				
GRAND TOTAL *(Php, total cost for all target populations)*	3.23 B	3.26 B	4.89 B	4.96 B	6.66 B
% cost of Tdap from total NIP budget	59.22%	59.82%	89.75%	90.95%	122.26%
% cost of Tdap from Td budget allocation	1,548.04%	1,563.84%	2,346.02%	2,377.46%	3,195.92%

Total NIP Budget: Php 5.45 Billion
NIP Budget Allocation for Td Vaccine: Php 208.488 Million
Assumption: Same NIP budget and Td vaccine budget from year 1-5

COSTING ANALYSIS SUMMARY

Parameter	*Boostrix*® (GSK)				
	Year 1	Year 2	Year 3	Year 4	Year 5
Strategy 1 - Phased transition by Population					
Cost of Vaccination per individual					
Pregnant Women	Php 2,570.16				
Grade 1 Students	Php 1,285.08				
Grade 7 Students	Php 1,285.08				
GRAND TOTAL *(Php, total cost for all target populations)*	5.94 B	6.00 B	9.00 B	9.12 B	12.26 B
% cost of Tdap from total NIP budget	108.98%	110.09%	165.16%	167.37%	224.99%
% cost of Tdap from Td budget allocation	2,848.80%	2,877.86%	4,317.31%	4,375.15%	5,881.36%

Total NIP Budget: Php 5.45 Billion
NIP Budget Allocation for Td Vaccine: Php 208.488 Million
Assumption: Same NIP budget and Td vaccine budget from year 1-5

COSTING ANALYSIS SUMMARY

Parameter	*Td vaccine (DPCB)*				
	Year 1	Year 2	Year 3	Year 4	Year 5
Strategy 1 - Phased transition by Population					
Cost of Vaccination (cost of vaccines + other costs)					
Pregnant Women	Php 70.87				
Grade 1 Students	Php 35.44				
Grade 7 Students	Php 35.44				
GRAND TOTAL *(Php, total cost for all target populations)*	163.78 M	165.45 M	248.21 M	251.53 M	338.12 M
% cost of Td from total NIP budget	3.01%	3.04%	4.55%	4.62%	6.20%
% cost of Td from Td budget allocation	78.55%	79.36%	119.05%	120.64%	162.18%

Total NIP Budget: Php 5.45 Billion
NIP Budget Allocation for Td Vaccine: Php 208.488 Million
Assumption: Same NIP budget and Td vaccine budget from year 1-5

COSTING ANALYSIS SUMMARY

Parameter	*Adacel*® (Sanofi)				
	Year 1	Year 2	Year 3	Year 4	Year 5
Strategy 2 - Phased transition by Region					
Cost of Vaccination (cost of vaccines + other costs)					
Pregnant Women	Php 1,396.64				
Grade 1 Students	Php 698.32				
Grade 7 Students	Php 698.32				
GRAND TOTAL *(Php, total cost for all target populations)*	1.76 B	2.60 B	4.15 B	4.81 B	6.66 B
% cost of Tdap from total NIP budget	32.53%	47.65%	76.21%	88.27%	122.26%
% cost of Tdap from Td budget allocation	842.97%	1,245.68%	1,992.24%	2,307.41%	3,195.92%

Total NIP Budget: Php 5.45 Billion
NIP Budget Allocation for Td Vaccine: Php 208.488 Million
Assumption: Same NIP budget and Td vaccine budget from year 1-5

COSTING ANALYSIS SUMMARY

Parameter	*Boostrix*® (GSK)				
	Year 1	Year 2	Year 3	Year 4	Year 5
Strategy 2 - Phased transition by Region					
Cost of Vaccination (cost of vaccines + other costs)					
Pregnant Women	Php 2,570.17				
Grade 1 Students	Php 1,285.08				
Grade 7 Students	Php 1,285.08				
GRAND TOTAL *(Php, total cost for all target populations)*	3.23 B	4.78 B	7.64 B	8.85 B	12.26 B
% cost of Tdap from total NIP budget	59.34%	87.69%	140.25%	162.44%	224.99%
% cost of Tdap from Td budget allocation	1,551.30%	2,292.37%	3,666.24%	4,246.26%	5,881.36%

Total NIP Budget: Php 5.45 Billion
NIP Budget Allocation for Td Vaccine: Php 208.488 Million
Assumption: Same NIP budget and Td vaccine budget from year 1-5

COSTING ANALYSIS SUMMARY

Parameter	*Td Vaccine (DPCB)*				
	Year 1	Year 2	Year 3	Year 4	Year 5
Strategy 2 - Phased transition by Region					
Cost of Vaccination (cost of vaccines + other costs)					
Pregnant Women	Php 70.88				
Grade 1 Students	Php 35.44				
Grade 7 Students	Php 35.44				
GRAND TOTAL *(Php, total cost for all target populations)*	89.19 M	131.79 M	210.78 M	244.11 M	338.12 M
% cost of Td from total NIP budget	1.64%	2.42%	3.87%	4.48%	6.20%
% cost of Td from Td budget allocation	42.78%	63.21%	101.10%	117.08%	162.18%

Total NIP Budget: Php 5.45 Billion
NIP Budget Allocation for Td Vaccine: Php 208.488 Million
Assumption: Same NIP budget and Td vaccine budget from year 1-5

COSTING ANALYSIS SUMMARY

Overall ranking of strategy and vaccine brand

- **Most costly strategy:** Strategy 1 (Phased by Population) Boostrix [Php 5.94B to Php 12.26B]
- **Least costly strategy:** Strategy 2 (Phased by Regions) Td vaccine [Php 89.19M to Php 338.12M]

Total cost for all target populations			
DPCB Implementation Plan	**Interventions**		**Comparator**
	Boostrix ®	**Adacel ®**	**Td vaccine**
Strategy 1 (Phased by Population)	Php 5.94 B - Php 12.26 B >	Php 3.23 B - Php 6.66 B >	Php 163.78 M - Php 338.12 M
Strategy 2 (Phased by Region)	Php 3.23 B - Php 12.26 B >	Php 1.76 B - Php 6.66 B >	Php 89.19 M - Php 338.12 M

Total NIP Budget: Php 5.45 Billion

Note:

- **Red cell:** exceeds total NIP budget
- **Orange cell:** covers a large portion of the total NIP budget which may displace funds for other vaccines
- **Green cell:** does not exceed total NIP budget and does not cover large portion of the budget

SUMMARY OF POINTS FOR CONSIDERATION

SUMMARY OF POINTS FOR CONSIDERATION

Points for Positive Recommendation	Points for Negative Recommendation
Aside from Tdap, there is no booster vaccine containing pertussis for the adult population	Low vaccination coverage (< 90%) of the primary series - Acellular booster would require high coverage of primary series with whole cell pertussis vaccine
Pertussis outbreak in 2024	• **Adacel ®** ○ **Both Strategy 1 and 2 exceed the allocated budget for Td vaccination and will cover a large portion of the total NIP budget** which may displace funds for other vaccines • **Boostrix ®** ○ **Strategy 1 exceeds both the total NIP budget and allocated Td vaccination budget** ○ **Strategy 2 will exceed the allocated budget for Td vaccination and will cover a large portion of the total NIP budget** which may displace funds for other vaccines
Tdap is a standard of care for pregnant women (2023 OHG for Adults, citing 2021 PHEX review)	
With feasible plans to improve primary vaccination coverage	

OVERALL RECOMMENDATION

Negative recommendation for Tdap as booster immunization against tetanus, diphtheria and pertussis for Grade 1 students (6-7 yo), Grade 7 students (11-12 yo) and pregnant women, at this time given that the primary series coverage is still low and that there is insufficient NIP budget to cover the shift from Td to Tdap. In order to fully realize the protective benefits of Tdap, the HTA Council recommends to prioritize improving the primary series coverage and sufficient financial resources for Tdap vaccine implementation, before considering the shift from Td to Tdap booster vaccination program.

THANK YOU!