IMMUNIZATION AGENDA 2030

THE IMMUNITY BOOST: BENEFITS OF DTP-CONTAINING VACCINE BOOSTER DOSES

Global NITAG Network webinar

26 February 2025

But first, a few questions to the audience:

Please let us know, in which WHO region is your country?

A. AFRO
B. AMRO/PAHO
C. EMRO
D. EURO
E. SEARO
F. WPRO

How many (and which) of the WHO-recommended DTP boosters are included in the national immunization schedule in your country?

A. All 3 boosters (3 primary + 3 childhood/adolescent boosters)
B. 2/3 – 2YL + 4-7 yr
C. 2/3 – 2YL + adolescent
D. 2/3 – 4-7 yr + adolescent
E. Only the 2YL booster
F. Only the childhood 4-7yr
G. Only the adolescent
H. No boosters (yet!)

If your country has at least one booster:

Were you on the NITAG at the time of this recommendation?

A. Yes, I was involved in putting forth the recommendation
B. No – the recommendation was made before my tenure

If you were involved (or are aware of) the context of the recommendation:

What was/were the main drivers for recommending a DTPcv booster?

You may select multiple responses!

A. Sustaining MNTE

B. Equity – tetanus protection for all (incl. boys and men)

C. Preventing diphtheria outbreaks

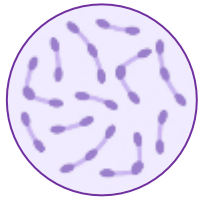
D. Preventing pertussis outbreaks

E. Other (please put in chat!)

OUTLINE

1	Background, WHO recommended booster schedule, and global status of booster introductions	**WHO**	Stephanie Shendale
2	Opportunities for programme integration: 2YL, school platforms, HPV/adolescent health	**UNICEF**	Niklas Danielsson
3	Gavi eligibility and application process	**Gavi**	Amina Ismail
4	Vaccine supply considerations	**UNICEF Supply Division**	Nuria Amich
5	Summary and key resources	**WHO**	Stephanie Shendale

OVERVIEW – DIPHTHERIA, TETANUS AND PERTUSSIS



DIPTHERIA is a contagious disease caused by a toxin-producing bacterium *Corynebacterium diphtheriae* that affects, most commonly, the upper respiratory tract. Infection can cause difficulty breathing, heart failure, paralysis, or death.

TETANUS is an acute infectious disease caused by toxigenic strains of the bacterium *Clostridium tetani,* when spores enter the body through contaminated skin wounds or tissue injuries. Untreated, the case-fatality rate approaches 100%.

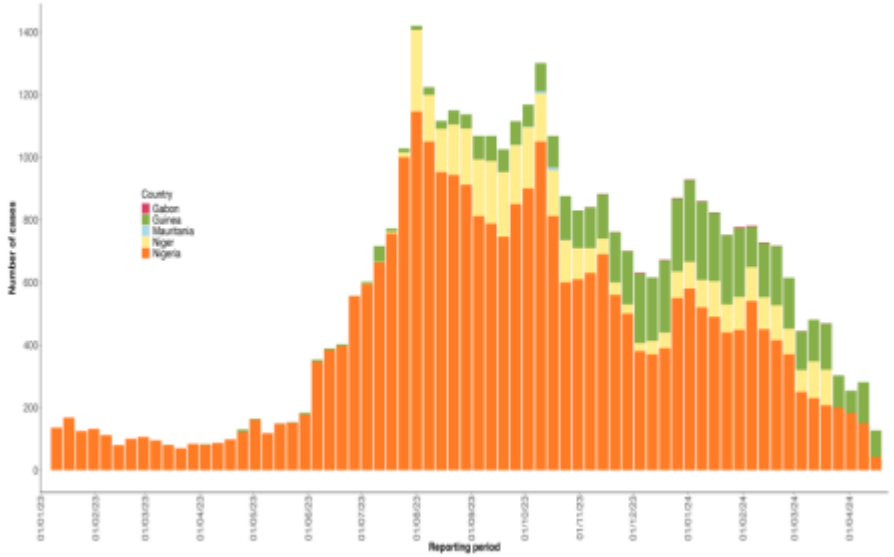
PERTUSSIS (whooping cough) is caused by the bacterium *Bordetella pertussis* and is endemic in all countries. Even in countries with high vaccination coverage, pertussis is an important cause of morbidity and mortality in infants worldwide.

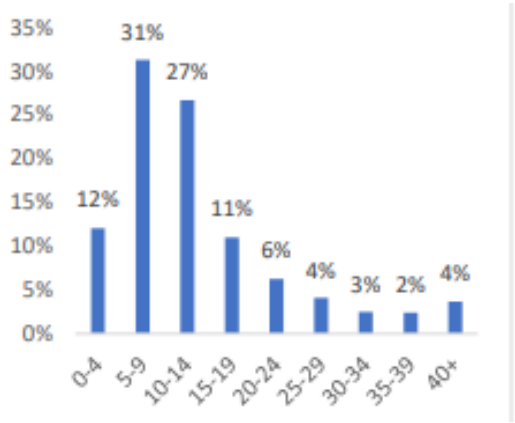
- In 2019, diphtheria, tetanus and pertussis caused an estimated 167,000 deaths and loss of ~14.9M DALYs (over 80% of deaths due to pertussis, ~20% due to tetanus, and <1% due to diphtheria)
- All three diseases are **vaccine preventable.** But immunity from a 3-dose primary series alone **wanes to non-protective levels**, thus requiring further boosting

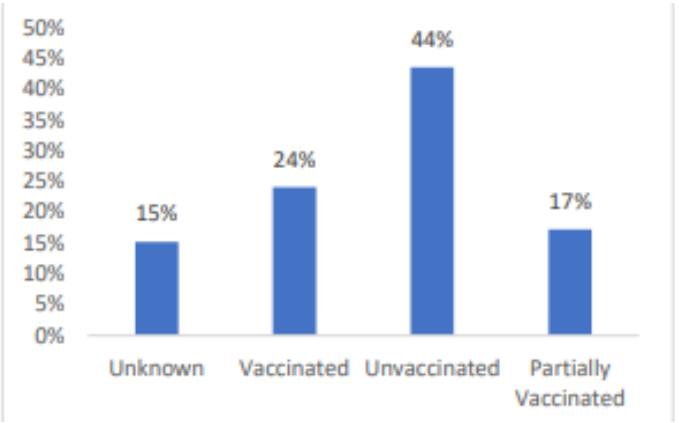
WHO RECOMMENDATIONS ON DIPHTHERIA VACCINATION

- 3-dose primary series is **highly effective**, however boosters are needed to ensure **continued protection**
- WHO recommends 3 primary doses and 3 booster doses; data indicates that 3 boosters should **confer high levels of sero-protection**, at least up to adulthood and likely longer
- Evidence of **waning immunity** after primary series demonstrated in recent **diphtheria outbreaks** where cases appearing among vaccinated individuals and the majority in older age-groups

https://iris.who.int/bitstream/handle/10665/258681/WER9231.pdf





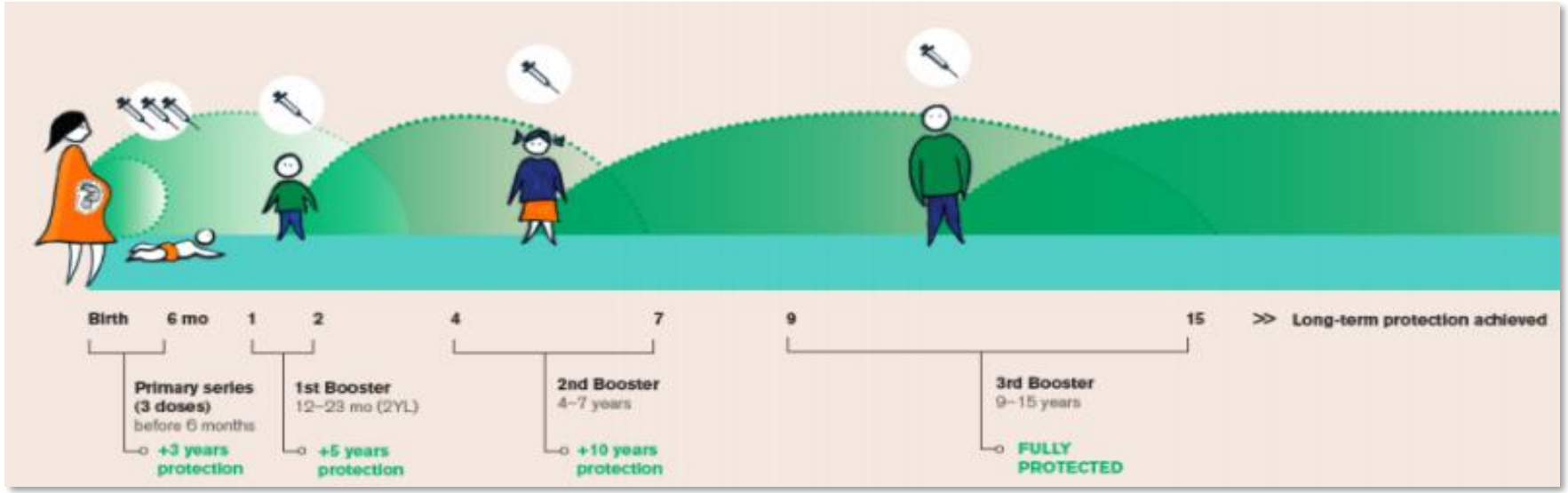


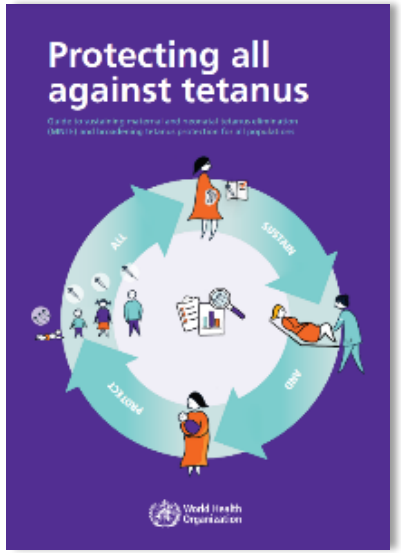
Epi curve and case characteristics of reported diphtheria cases in Gabon, Guinea, Mauritania, Niger, and Nigeria (reporting period 01/01/23-15/05/24) - https://iris.who.int/bitstream/handle/10665/376981/AFRO.Diphtheria.Sitrep008-20240526.pdf

WHO RECOMMENDATIONS ON TETANUS VACCINATION

https://www.who.int/publications/i/item/WHO-WER9206

- There is no natural immunity to tetanus, and *C. tetani* spores are found everywhere!
- A **3-dose primary series** induces protective immunity in almost **100%** of vaccinated infants, however, **antibody levels decline over time**.
- Data from serological studies suggest that a primary series in infancy + a booster during the second year of life will provide **3-5 years of protection.**
- A further booster dose (early childhood) will provide protection into adolescence.
- Six doses of TTCV by adolescence are expected to protect for at least 20-30 years (thus protecting women throughout the reproductive age).
- Six routine doses also contribute to **equity** by ensuring boys and adult males are protected as well





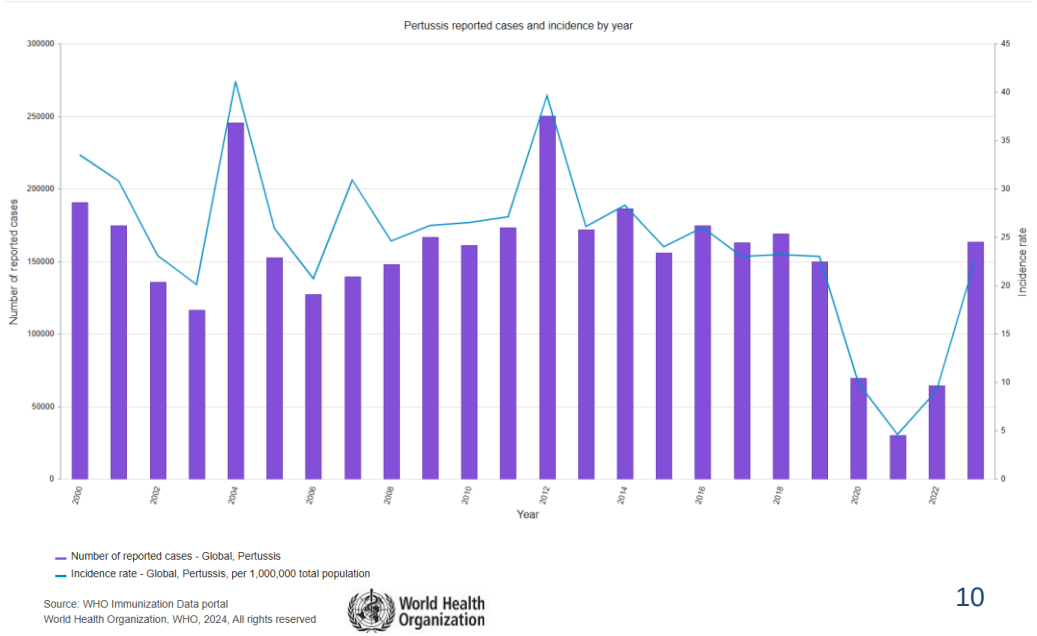
https://www.who.int/publications/i/item/protecting-all-against-tetanus
English and French

WHO RECOMMENDATIONS ON PERTUSSIS VACCINATION


Weekly epidemiological record
Relevé épidémiologique hebdomadaire

https://iris.who.int/bitstream/handle/10665/242416/WER9035.PDF

- Pertussis is endemic in all countries – true burden is difficult to assess due to suboptimal surveillance and reporting
- Main aim of pertussis vaccination is protecting **infants and young children.**
- WHO recommends a primary series of 3 doses, from 6 weeks followed by a booster, preferably in the second year of life (2YL).
- Duration of protection following 3p varies considerably across settings.
- High coverage with 3 doses **plus a 2YL booster** will reduce severe disease in children in the **<5 year age**.
- More rapid waning of immunity and possibly reduced impact on transmission with acellular (aP) relative to whole-cell (wP) vaccines.
- National programmes should not switch from wP to aP vaccine.
- A booster dose in adolescence* has been shown to decrease disease in adolescents but is not recommended as a means of controlling pertussis in infants.



*only aP-containing vaccines should be used above 7 years of age

WHO RECOMMENDED DTP-CV SCHEDULE

1961: FIRST SCHEDULE PUBLISHED BY WHO CALLED FOR A DTP BOOSTER

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Report of technical discussions at 13th WHA (1961)

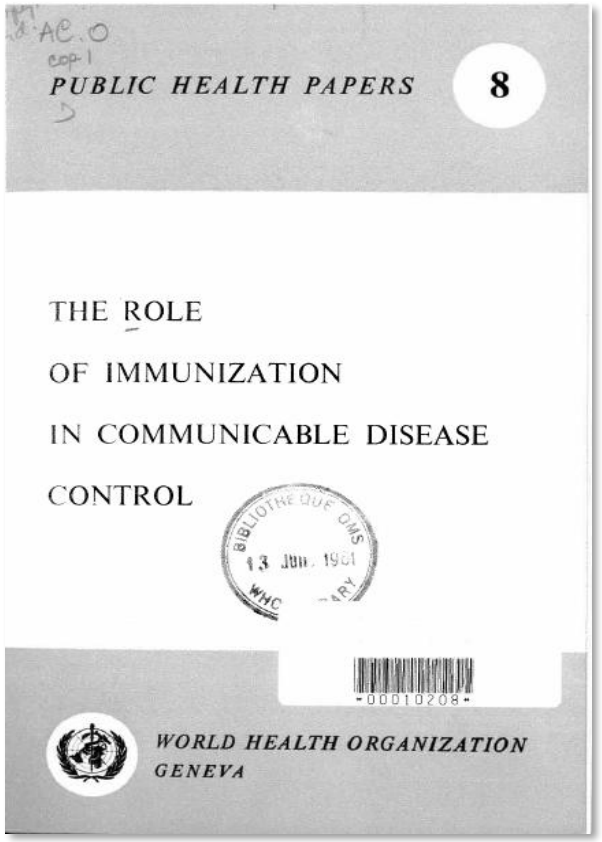

TABLE 2. SUGGESTED SCHEDULE OF IMMUNIZATION IN AREAS WITH INADEQUATE MEDICAL SERVICES; TO BE MODIFIED AS REQUIRED TO SUIT LOCAL CONDITIONS

Age	Vaccination	Visit
0-4 weeks	(1) BCG vaccination	1st
3-9 months	(2) Smallpox vaccination (3) Diphtheria-pertussis-tetanus (triple vaccine with alum): 2 doses at an interval of one month The first injection could be given at the time of smallpox vaccination. Smallpox vaccination is verified at the second visit. Failures of smallpox vaccination are revaccinated.	2nd and 3rd
School entry or soon thereafter	(4) Diphtheria/tetanus booster (plain or with alum) (5) TAB vaccination (where necessary): 2 doses at an interval of one month (6) Smallpox revaccination: at the time of second TAB injection	4th and 5th
10-14 years	(7) BCG revaccination (in tuberculin-negative reactors) (8) Smallpox revaccination (9) TAB booster	6th and 7th

WHO RECOMMENDED 6 DOSE SCHEDULE FOR DTP-CONTAINING VACCINES

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	Primary Series	Booster 1	Booster 2	Booster 3
Recommended Age[1]	**3 doses (from 6w-)**	**2YL (12-23 months)**	**4-7 years**	**9-15 years**
Recommended vaccine[2]	**3 doses of DTP-containing vaccine** - Tetanus toxoid - Full diphtheria toxoid - Pertussis *In most countries this is given as Penta or Hexa combination	**1 dose of DTP-containing vaccine** - Tetanus toxoid - Full diphtheria toxoid - Pertussis	**1 dose of DT/Td- containing vaccine (with or without P)** - Tetanus toxoid - Full or reduced diphtheria toxoid - With or without pertussis	**1 dose of Td-containing-vaccine (with or without P)** - Tetanus toxoid - Reduced diphtheria toxoid - With or without pertussis
Product options[3]	• DTwP or DTaP • Quadravalent (with HepB, Hib, IVP) • **Pentavalent (DTP-Hib-HepB,** DTP-Hib-IPV) • **Hexavalent (DTP-Hib-HepB-IPV)**	• **DTwP** or DTaP • Quadravalent (with HepB, Hib, IPV) • **Pentavalent (DTP-Hib-HepB**, DTP-Hib-IPV) • **Hexavalent (DTP-Hib-HepB-IPV)**	• **Td** (from ≥4yrs) or DT (if <7yrs) • DTP, TdaP	• Td • TdaP

Indicates a Gavi-supported option

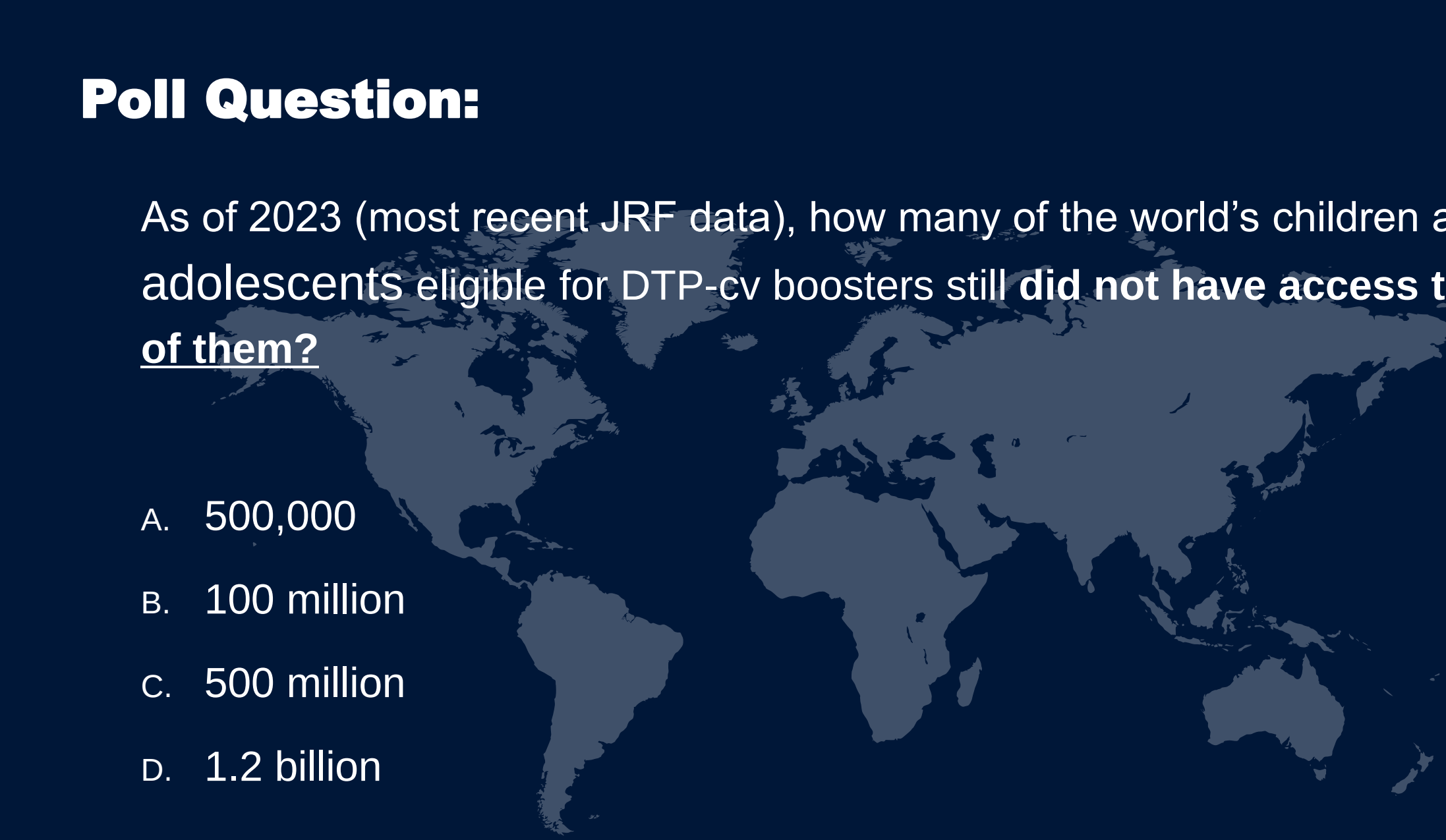
1. Depending on local epidemiology; For WHO recommended schedules see: www.who.int/teams/immunization-vaccines-and-biologicals/policies/who-recommendations-for-routine-immunization---summary-tables
2. WHO recommends a tetanus-diphtheria-pertussis-containing combination vaccine for the 2YL booster, plus 2 additional tetanus-diphtheria-containing boosters
3. **Countries currently using whole-cell pertussis vaccine (wP) for the primary series should continue to do so**.

For up-to-date product information prequalified by WHO always check: https://extranet.who.int/prequal/vaccines/prequalified-vaccines .
For up-to-date information on UNICEF Supply Division vaccine prices see: https://www.unicef.org/supply/index_57476.html .

GLOBAL STATUS OF DTP-CV BOOSTER INTRODUCTIONS

Poll Question:

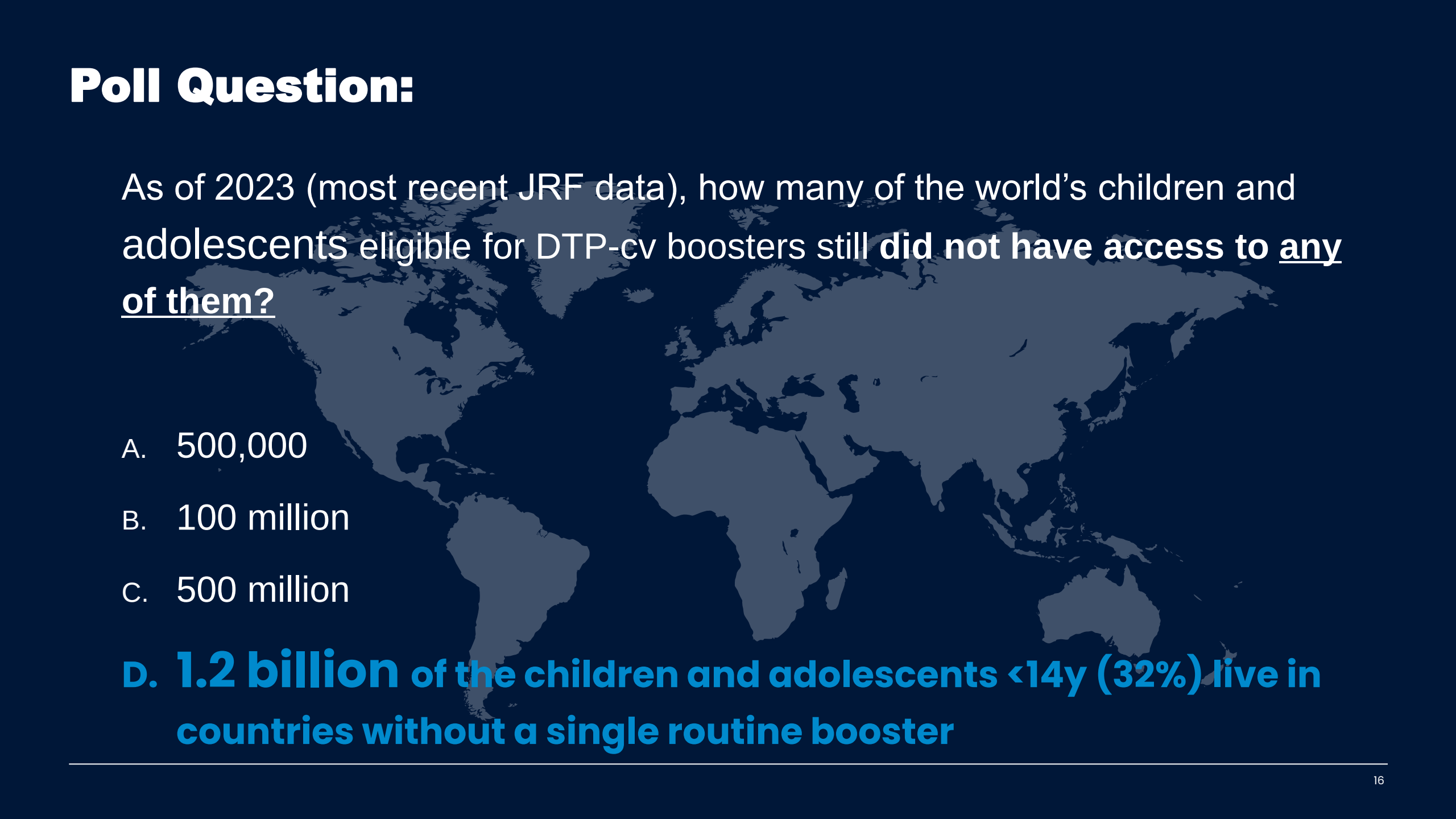
As of 2023 (most recent JRF data), how many of the world's children and adolescents eligible for DTP-cv boosters still **did not have access to <u>any of them?</u>**



A. 500,000
B. 100 million
C. 500 million
D. 1.2 billion

Poll Question:

As of 2023 (most recent JRF data), how many of the world's children and adolescents eligible for DTP-cv boosters still **did not have access to <u>any of them?</u>**



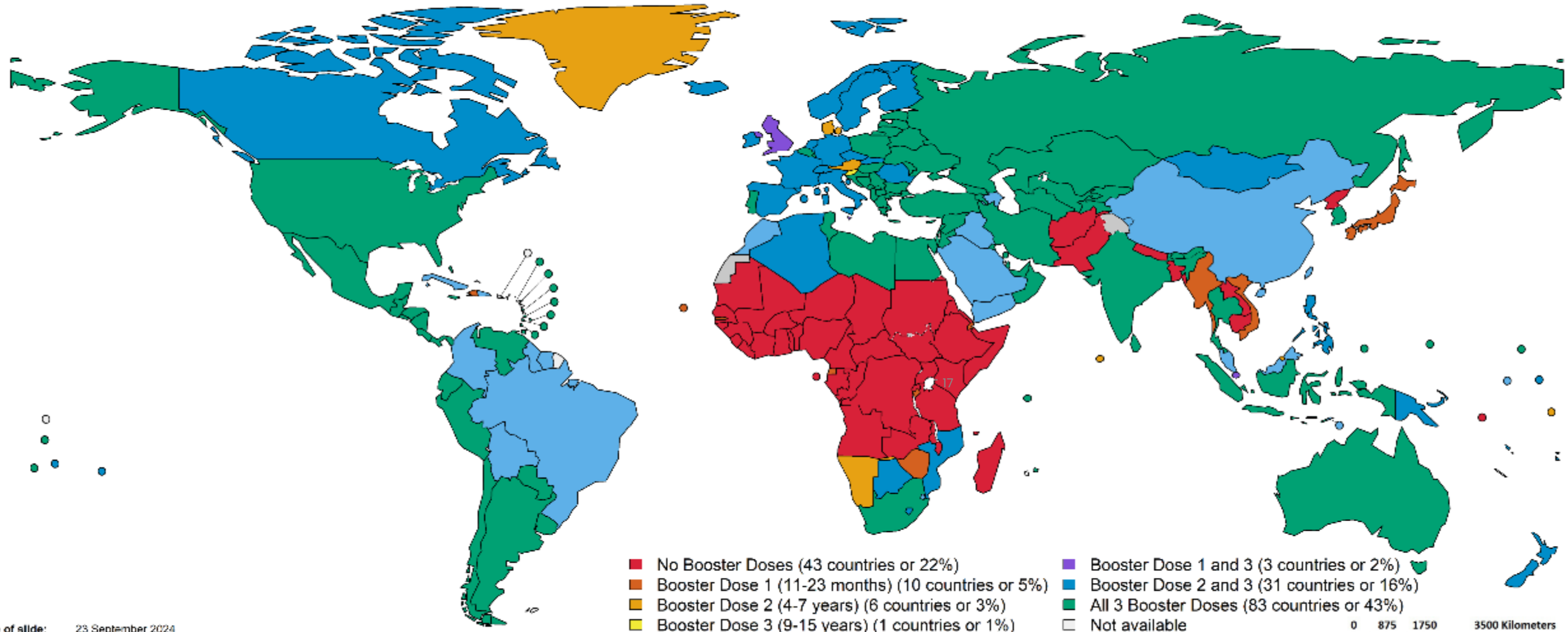
A. 500,000

B. 100 million

C. 500 million

D. 1.2 billion of the children and adolescents <14y (32%) live in countries without a single routine booster

GLOBAL DISTRIBUTION OF DTPCV BOOSTER DOSES, 2023



Date of slide: 23 September 2024
Map production: Immunization, Vaccines and Biologicals (IVB), World Health Organization (WHO)
Data source: IVB database as at 23 September 2024

Disclaimer:
The boundaries and names shown and the designations used on this map do not imply the expression of any opinion whatsoever on the part of the World Health Organization concerning the legal status of any country, territory, city or area nor of its authorities, or concerning the delimitation of its frontiers or boundaries. Dotted and dashed lines on maps represent approximate border lines for which there may not yet be full agreement.

World Health Organization

STRATEGIES AND OPPORTUNITIES FOR PROGRAMME INTEGRATION

Poll Question:

TRUTH or MYTH : Programmes must introduce booster doses in order – i.e. start with the 2YL, then childhood, then adolescent…

A. TRUTH

B. MYTH

Poll Question:

TRUTH or MYTH : Programmes must introduce booster doses in order – i.e. start with the 2YL, then childhood, then adolescent…

A. TRUTH

B. MYTH

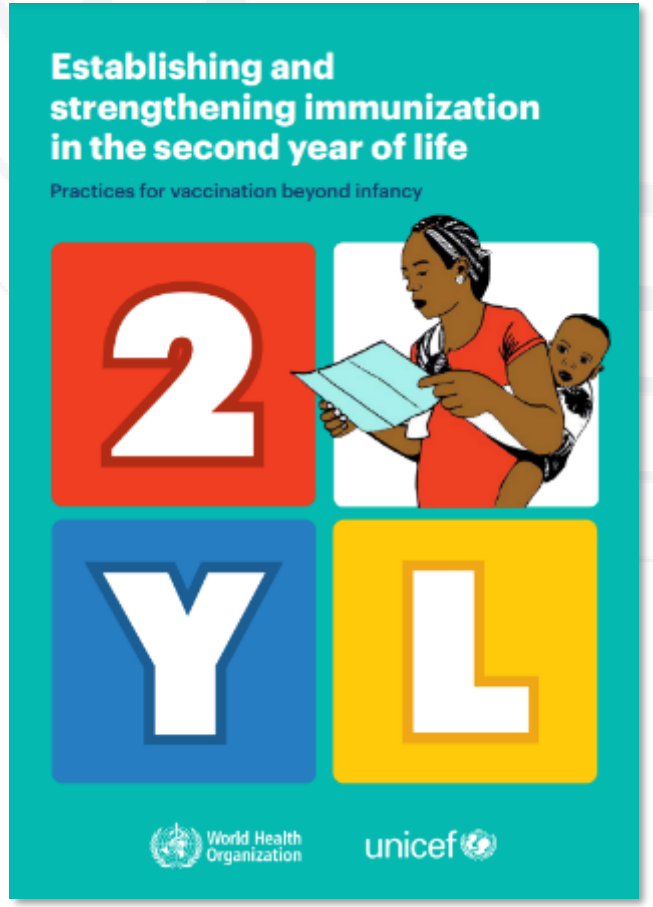
Countries can introduce boosters in any order; every booster provides incremental benefit, and any booster is better than none.

STRATEGIES AND OPPORTUNITIES FOR PROGRAMME ALIGNMENT

	Booster 1	Booster 2	Booster 3
Recommended Age	2YL (12-23 months)	4-7 years	9-15 years
Opportunities/ Linkages	– Opportunity to strengthen/reinforce a **2YL platform** – 2nd dose of measles-containing vaccine (**MCV2**) – **meningitis** – alternative 2+1 schedules **PCV** – **malaria** vaccine – 4th dose of **Hexavalent** – **well-child visit**, vitamin A supplementation, and/or deworming – **catch-up opportunity** for any missing first year of life antigens	– A **day care or school-based vaccination strategy**, as 4-7 years is the age when many children are in care or begin primary school – Opportunity to implement **school-entry vaccination screening** at the time of enrolment	- Important group approaching reproductive years - For coverage equity, **boys** also need to be protected for injuries and surgical procedures - **Mitigate false rumors** about female sterilization and contraception when both boys and girls are vaccinated - **HPV vaccine** (which targets the same age group) - **Adolescent health interventions** and education - Strengthen **school** health platforms

2YL BOOSTER

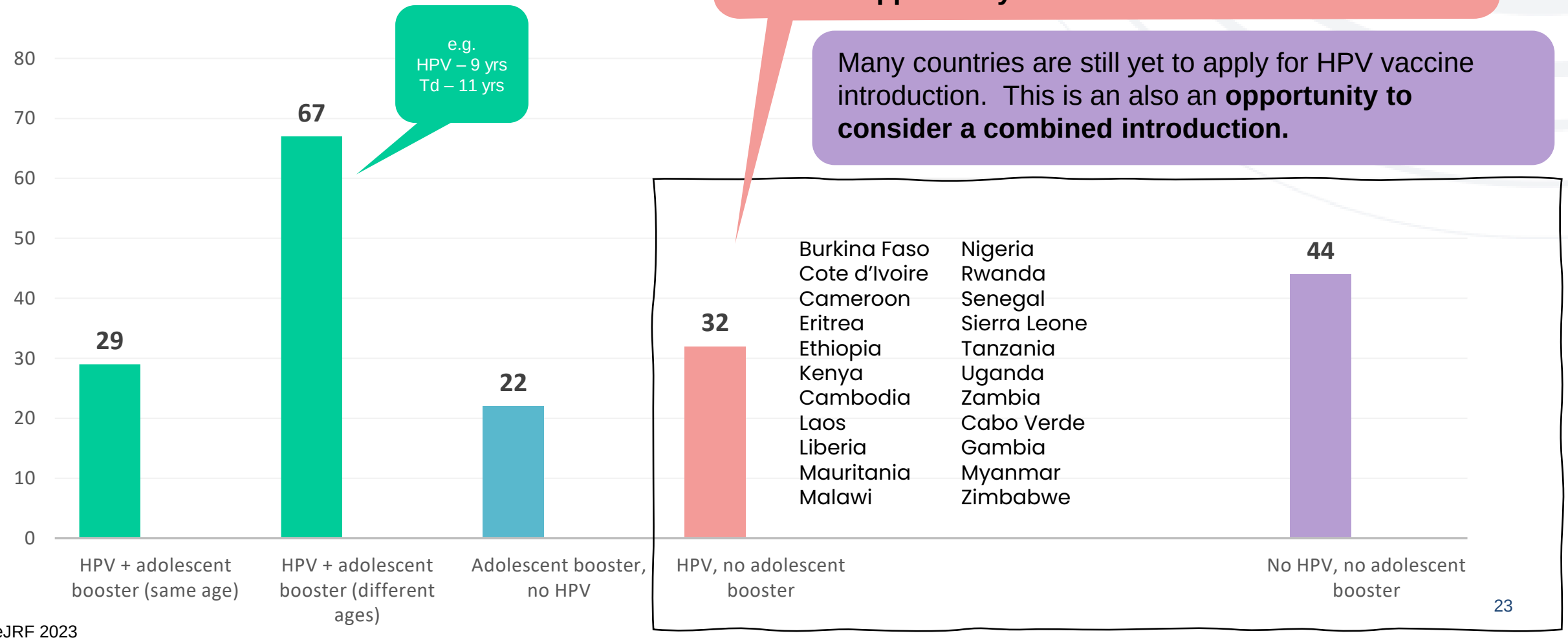
- A strong platform in the 2YL is the first important step in extending immunization beyond infancy and encouraging the continuity of routine vaccination into preschool, school, adolescent and adult populations.
- The 2YL DTPcv booster can be given as: **DTP** or as a fourth shot of **pentavalent** or **hexavalent** vaccines – programmatic considerations for each choice
- A booster in the 2YL can be co-administered with other 2YL vaccines (e.g. MCV2, meningitis, malaria 4th dose, etc.)
- Provides opportunity for integrated delivery of other preventive health services: well-child visit, vitamin A supplementation, deworming
- A well-functioning 2YL platform can also expand opportunities for **catch-up vaccination** of doses missed in infancy



Vaccination in the second year of life tools and resources
www.who.int/teams/immunization-vaccines-and-biologicals/essential-programme-on-immunization/integration/vaccination-in-the-second-year-of-life-(2yl)

OPPORTUNITIES FOR INTEGRATING HPV AND ADOLESCENT BOOSTERS ARE NOT BEING SUFFICIENTLY LEVERAGED

96 countries are offering both HPV and an adolescent booster (all high or upper-middle income countries):



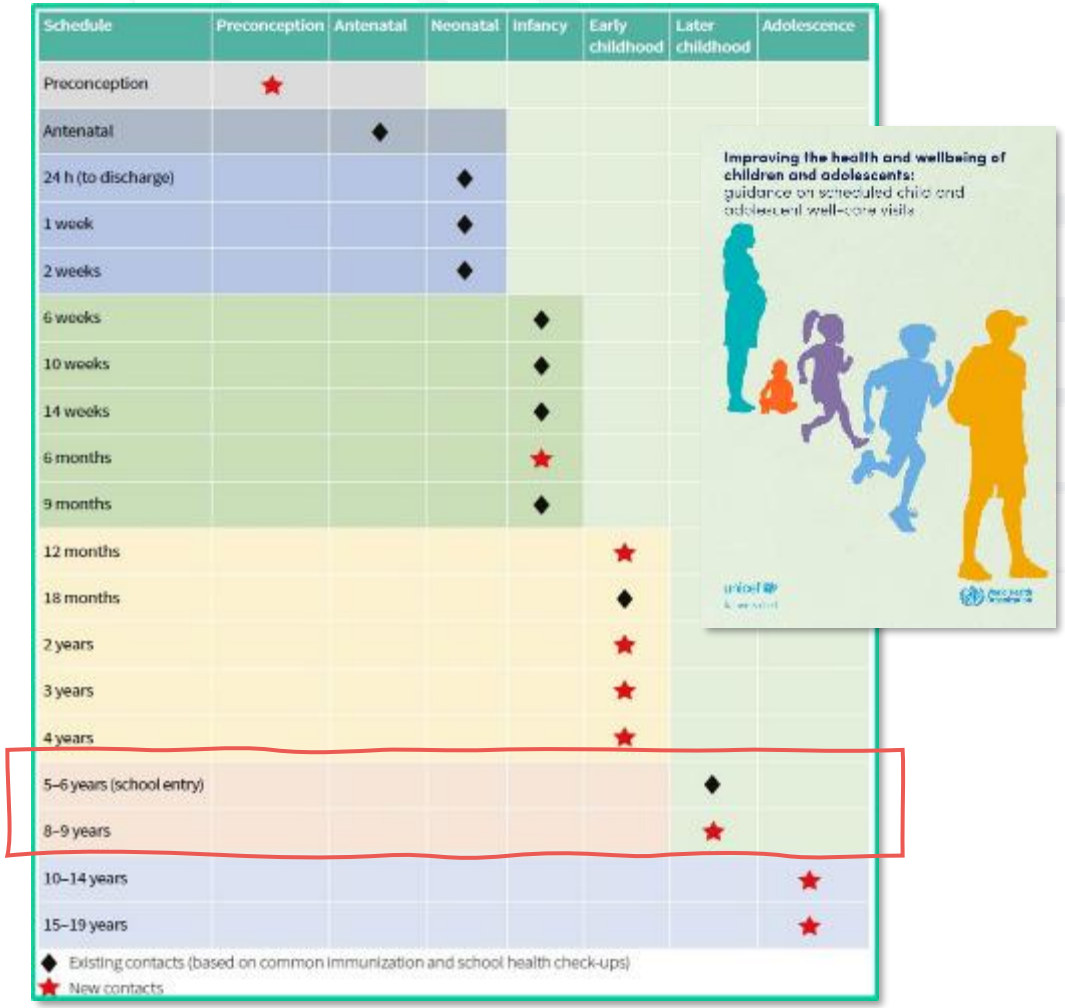
However, **32 countries** are already reaching this age group with HPV, but with no adolescent booster… this is a **missed opportunity**

Many countries are still yet to apply for HPV vaccine introduction. This is an also an **opportunity to consider a combined introduction.**

Source: eJRF 2023

CHILDHOOD BOOSTER (4-7 YEARS OLD)

- Many countries do not yet have an EPI contact in this age range
- This is a challenge but also **an opportunity** to create a new contact point with the health system and/or link this to school vaccination platforms (including school entry vaccination checks)
- WHO-UNICEF guidance on scheduled routine child and adolescent well-care visits recommends at least **2 contacts** in this age range, and up to **3** in the adolescent (9-15 year) range *(next slide)*



https://iris.who.int/handle/10665/376159

WHO resources on school vaccination:
https://www.who.int/teams/immunization-vaccines-and-biologicals/essential-programme-on-immunization/integration/school-vaccination

LONG TERM: TRANSITION TOWARDS SCREENING DURING ANC (AVOID OVERVACCINATION)

TTCV vaccination schedule for pregnant women and adults who are partially vaccinated during childhood and adolescence

Age of last vaccination	Previous vaccinations (from vaccination record)	Recommended TTCV doses	
		At present ANC contact/pregnancy	Later (with interval of at least one year)
Infancy	3 TTCV primary doses	2 doses of TTCV (minimum 4 week interval between doses)	1 dose of TTCV
Early childhood/ school age	3 TTCV primary doses + 1 booster (total of 4 TTCV doses)	1 dose of TTCV	1 dose of TTCV
School age	3 TTCV primary doses + 2 boosters (total of 5 TTCV doses)	1 dose of TTCV	None (fully protected)
Adoles-cence	3 TTCV primary doses + 3 boosters (total of 6 TTCV doses)	None (fully protected)	None (fully protected)

All doses given should be properly recorded in the home-based record or ANC/maternal health card and in the standard facility register and tally sheet.

Accurate recording by dose number (i.e. TTCV2, TTCV3, etc.) is important so that repeated unnecessary vaccinations can be avoided.

https://www.who.int/publications/i/item/WHO-WER9206

GAVI SUPPORT:

ELIGIBILITY AND APPLICATION PROCESS

Eligibility*: DTP booster doses* among Gavi74

Most Gavi-eligible countries currently don't have the 3 DTP boosters recommended by WHO

Countries with no boosters

Afghanistan
Burkina Faso
CAR
DRC
Eritrea
Ethiopia
Madagascar
Mali
South Sudan

Benin
Cameroon
Comoros
Cambodia
Guinea

Niger
DPRK
Rwanda
Sudan
Sierra Leone
Somalia
Guinea-Bissau
Liberia

Mauritania
Nepal
Pakistan
Senegal
Tanzania
Myanmar
Zambia

Chad
Togo
Uganda
Malawi

Bangladesh
Cote d'Ivoire
Sao Tome
Ghana
Kenya
Nigeria
Solomon Islands
Lao
Congo

Angola

Countries with 1 or 2 boosters

Booster 1 12-23 months	Booster 2 4-7 years	Booster 3 9-15 years	Boosters 1&2	Boosters 2&3
Burundi Gambia			Yemen	Lesotho Mozambique PNG Kiribati Mongolia
Haiti Zimbabwe			Azerbaijan Bolivia Cuba Guyana East Timor Vietnam	
Djibouti				

Gavi-eligible countries
Initial self-financing
Preparatory transition
Accelerated transition

Former Gavi countries
Fully self-financing

Compliant w/ WHO recommendations

Countries with all 3 boosters

Syria

Tajikistan
Kyrgyzstan

Armenia
Bhutan
Georgia
Honduras
Indonesia
India
Sri Lanka
Moldova
Nicaragua
Ukraine
Uzbekistan

(*): Official data reported by Member States through the WHO/UNICEF joint reporting Form as at 13/09/24; Gavi Eligibility status update 1 July 2024

Only Gavi-eligible countries are eligible for VIG support and 2YL vx support

TYPES OF SUPPORT AVAILABLE FOR DTPCV BOOSTERS

Gavi Vaccine Funding Guidelines

Vaccine dose procurement and associated supplies: under current co-financing principles, for the 2YL booster dose (DTwP, pentavalent or hexavalent) **only.**

Vaccine financing support will not be provided for tetanus-diphtheria (Td) – recommended for boosters at 4–7 years and 9–15 years – as long as the price remains equal to or below US$ 0.20 per dose, which is the minimum country co-financing based on the current Gavi policy.

Vaccine Introduction Grant (VIG): For Gavi-eligible countries introducing DTP-containing vaccine boosters (DTwP, Td, pentavalent and/or hexavalent), Gavi will provide a one-time VIG for each new booster

Countries that currently have a booster programme are not eligible for support for that existing contact, except for those deciding to switch from DTP to pentavalent or hexavalent in the 2YL

Health system strengthening (HSS) support: Countries can decide to use their HSS grants (within the existing ceiling) to complement the funds provided under the VIG to support the sustained implementation of the DTPcv boosters programme after accounting for other programmatic priorities.

Allowable HSS support is detailed in the Gavi Programme Funding Guidelines.

Countries are encouraged to explore other complementary funding, including domestic financing, to strengthen contacts beyond the first year of life.

Targeted Country Assistance (TCA) support: TCA from in-country, regional and global partners to support the planning and implementation of the DTP-containing vaccine boosters programme may be available. Countries are encouraged to contact their Gavi Senior Country Manager for details.

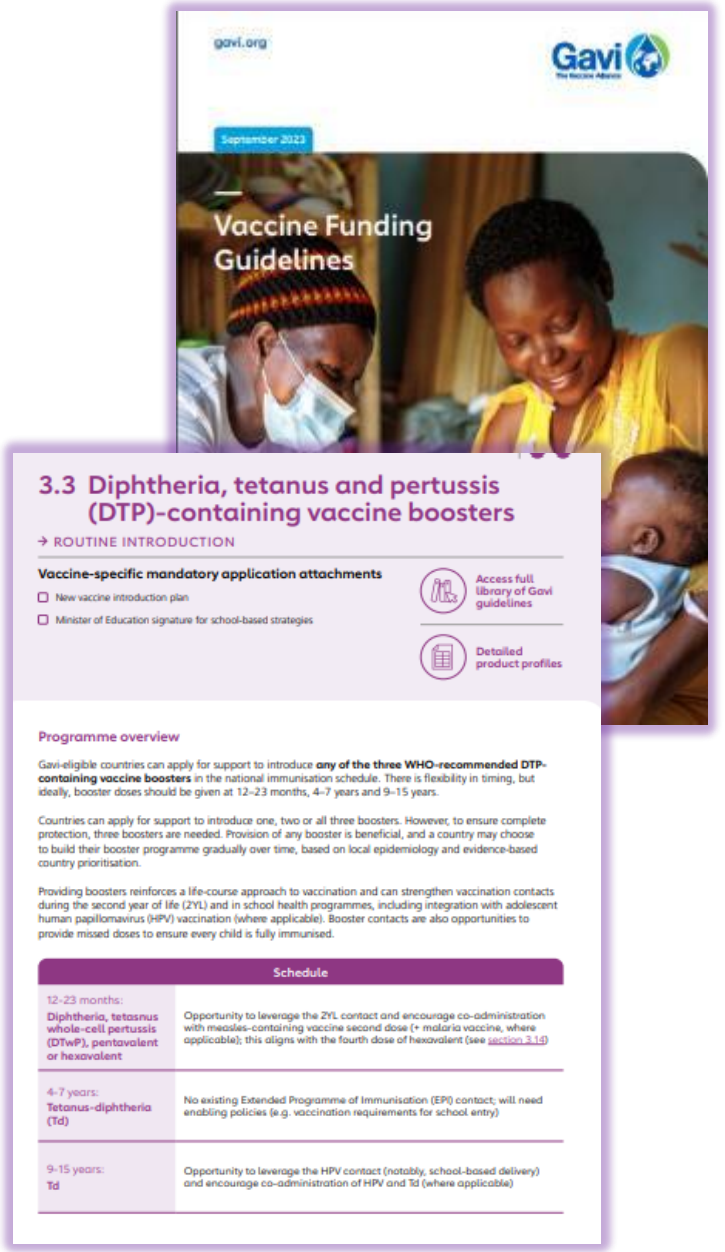
FINANCIAL SUPPORT

Calculation of financial support for new introductions and campaigns and switches			
Transition phase	**VIGs**	**Ops grants**	**Switch**
Initial self-financing	US$ 0.80 per infant in the birth cohort (i.e. live births in the year of introduction) or a lump sum of US$ 100,000, whichever is higher	US$ 0.65 per targeted person	US$ 0.25 per infant in the birth cohort or a lump sum of US$ 30,000, whichever is higher
Preparatory transition	US$ 0.70 per infant in the birth cohort or a lump sum of US$ 100,000, whichever is higher	US$ 0.55 per targeted person	US$ 0.25 per infant in the birth cohort or a lump sum of US$ 30,000, whichever is higher
Accelerated transition	US$ 0.60 per infant in the birth cohort or a lump sum of US$ 100,000, whichever is higher	US$ 0.45 per targeted person	US$ 0.25 per infant in the birth cohort or a lump sum of US$ 30,000, whichever is higher

GAVI DTP-CV BOOSTERS PROGRAMME

- Countries eligible for Gavi support can apply to introduce **each booster** under Gavi Product Menu **either individually** OR **any combination** of boosters together.
- Application window is **now open**:

	Deadline for submission	Independent Review Committee (IRC) review indicative dates
~~**2mths prior**~~	~~22 January 2025~~	10–21 March 2025
~2mths prior	1 May 2025	16–27 June 2025
~2mths prior	16 September 2025	3–14 November 2025



https://www.gavi.org/sites/default/files/support/guidelines-2024/GAVI-Vaccine-Funding-Guidelines-aug2024.pdf

COSTING TOOL AVAILABLE FOR COUNTRY DECISION SUPPORT

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Country X: 4 doses of hexavalent and 2 doses of Td

Introducing Td boosters is expected to result in additional injections, increased cold chain requirements, increased vaccine costs, and increased program costs. *This is an indicative assessment and may require further analysis to inform decision-making.*

Number of injections

- Introducing DTP-containing boosters alongside a 4-dose hexavalent vaccine schedule would increase total vaccinations by 2 Td doses per person
- In a given year, approximately XXM additional doses would be administered, and this would result in an estimated XXM additional injections over a 10-year period

Cold chain requirements

- With an assumed wastage rate of XX% with the 10-dose vial Td vaccine, the total cold chain volume for country X will be approximately XXM cm3 more per year when adding Td boosters

Vaccine costs

Program costs

All costs are in USD$

Country X: DTP Booster Switch Analysis (DTwP + 2 Td)

Introducing DTP-containing boosters is expected to result in additional injections, increased cold chain requirements, increased vaccine costs, and increased program costs. *This is an indicative assessment and may require further analysis to inform decision-making.*

Number of injections

- Introducing DTP-containing boosters alongside a 3-dose penta (or hexa) vaccine schedule would increase total vaccinations by 3 doses (1 DTwP + 2 Td) per person
- In a given year, approximately XXM additional doses of DTP and XXM of Td would be administered. This would result in an estimated XXM additional injections over a 10-year period

Cold chain requirements

- With an assumed wastage rate of XX% with the 10-dose vial Td vaccine, the total cold chain volume for country X will be approximately XXM cm3 more per year when adding DTP and Td boosters,

Vaccine costs

- With an assumed 10-dose DTP vial at $0.19 per dose (Source: UNICEF), the estimated DTP vaccine procurement costs for Country X in 2025 are expected to be $XXM
- With an assumed 10-dose Td vial at $0.13 per dose (Source: UNICEF), the estimated Td vaccine procurement costs for Country X in 2025 are expected to be $XXM
- This adds up to $XXM in additional vaccine procurement costs for the country over a 10-year period

Program costs

- The total vaccine program costs for Country X will be $XXM to introduce DTP boosters ($XXM over a 10-year period) and $XXM to introduce Td boosters ($XXM over a 10-year period) This includes both financial and economic costs
- As a Gavi-eligibly country, Country X is eligible for a one-time Gavi Vaccine Introduction Grant of $XX

All costs are in USD$

Gavi

KEY PRIORITIES 2025

Development of guidance materials:

- Communication and advocacy materials
- NITAG information kit and decision support tools
- Implementation guidance and training

Provision of TA:

- Consolidate existing capacities (e.g. modeling and cost of illness tools)
- Planning and application support (TCA)

Learning agenda & Case Studies:

- Support evidence generation for programme implementation

Advocate for **community of practice for 2YL** and other contact points

Explore **intersection with HPV programme/child & adolescent health**

VACCINE SUPPLY CONSIDERATIONS

GENERAL SUPPLY CONSIDERATIONS

- Importance of countries defining which boosters to implement, the specific timelines and the vaccine of choice to allow managing these interdependent markets.

- **Vaccines available for procurement through UNICEF:**
  - *Booster 1 options (for the second year of life): DTwP, pentavalent (wP) and hexavalent (wP) vaccines,*
  - *Booster 2 options (for 4-7 years): DTwP and Td vaccines,*
  - *Booster 3 option (for 9-15 years): Td vaccine.*

- Defining the forecast for each of the vaccines is key to ensure supply availability and appropriate timelines.

- UNICEF and partners will be **managing the demand generation process of DTwP containing vaccines (DTwP-cv)** under the Hexavalent and DTPcv booster programs:
  - to adequately **balance demand and supply availability of the DTwP-cv**,
  - while ensuring the **long-term health of the DTwP-cv markets**.

SUPPLY CONSIDERATIONS – DTP VACCINE

- **Three** manufacturers have WHO prequalified whole cell DTP (DTwP) vaccines and ample capacity for DTwP bulk and DTwP-cv production.
  - These three suppliers also have a WHO prequalified Penta vaccine & one of them has a WHO prequalified Hexa vaccine
  - **Decisions on DTwP bulk allocation are made based on long-term demand scenarios**

- UNICEF is currently supplying DTwP vaccine in **10-dose vials**:
    - Based on **LTAs with two WHO PQ-ed manufacturers**, for the period 2023-2027
- Relatively low procurement through UNICEF (Average 7M doses on annual basis)
  - Significant changes in DTwP demand would require time for the supply market to adapt.

SUPPLY CONSIDERATIONS – PENTAVALENT VACCINE

- **Five** manufacturers have **WHO PQ-ed *whole cell* pentavalent vaccines**.

- UNICEF is currently supplying pentavalent vaccine in **1-dose and in 10-dose vials**:
  - Based on **LTAs with 4 WHO PQ-ed manufacturers**, for the period 2023-2027,
  - Between 150 and 175 million doses annually,
  - For supply to Gavi and non-Gavi supported countries.

- UNICEF will be **complementing current LTA awards for 2026 and 2027, based on updated demand forecasts** considering the interdependencies with hexavalent and DTwP vaccine markets.

- **Adequate supply availability and production capacity** to accommodate changes in pentavalent demand in the context of the DTwP booster program (for the second year of life booster).

SUPPLY CONSIDERATIONS – HEXAVALENT VACCINE

- **One** manufacturer has a **WHO prequalified *whole cell* hexavalent vaccine**.
- Two WHO PQs are expected in 2026 and another one in 2027.

- **UNICEF** has established **two LTAs for 2024 & 2025**:
  - 1 for Gavi eligible countries for hexavalent support (10-dose vial),
  - 1 for middle-income countries (MICs) and Gavi countries non-eligible for hexavalent support, (1 and 10 dose vial).

- UNICEF will implement **additional awards for 2026 and 2027, based on updated demand forecasts** considering the interdependencies with pentavalent and DTwP vaccine markets.
- ***Supply availability will be gradual, driven by demand*** in the early years of the Hexavalent and DTwP booster programs.

SUPPLY CONSIDERATIONS – TD VACCINE

- **Five** manufacturers have a **WHO prequalified Td vaccine**, with ample overall production capacity
- UNICEF is currently supplying Td vaccine in **10-dose and 20-dose vials** based on **four LTAs with WHO prequalified suppliers**
- High procurement through UNICEF (130-140M doses)
- **Adequate supply availability and production capacity** to accommodate changes in Td demand moving forward in the context of the DTwP booster program (for the second and third booster).

SUMMARY: WHY INTRODUCE DTP-CV BOOSTERS?

Improve global equity in protection against diphtheria, tetanus and pertussis

Provide and sustain lifelong protection

Prevent diphtheria and pertussis outbreaks

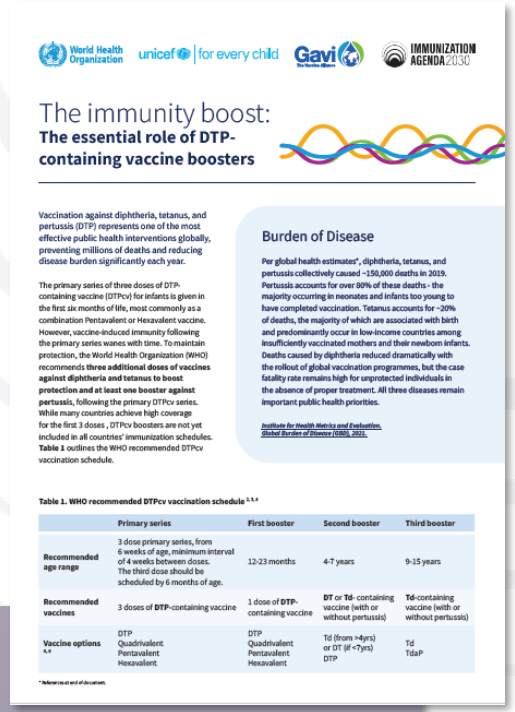
Sustain Maternal & Neonatal Tetanus Elimination (MNTE) status and make room for new maternal vaccines

Address gender inequity for tetanus vaccination among boys/males

Strengthen health systems through integration opportunities

KEY TAKE-AWAYS

- To maintain **long-term protection** against diphtheria, tetanus, and pertussis (DTP), **booster doses are needed** beyond the primary infant series.
- WHO recommends three diphtheria and tetanus boosters and at least one pertussis booster during childhood and adolescence, given as combination vaccines.
- **As of December 2023, Gavi-eligible countries can apply for support to introduce any of the three WHO-recommended DTP-containing vaccine boosters.**
- **Countries can apply for support to introduce one, two or all three boosters –** every booster provides benefit.
- Vaccine options available through UNICEF: **DTwP**, **pentavalent (wP)**, **hexavalent (wP)**, and **Td** vaccines
- Each booster provides opportunities for integration and programme synergies with its delivery platform: 2YL, school-entry, HPV/adolescent health.



World Health Organization | unicef | for every child | Gavi | IMMUNIZATION AGENDA 2030

The immunity boost:
The essential role of DTP-containing vaccine boosters

Vaccination against diphtheria, tetanus, and pertussis (DTP) represents one of the most effective public health interventions globally, preventing millions of deaths and reducing disease burden significantly each year.

The primary series of three doses of DTP-containing vaccine (DTPcv) for infants is given in the first six months of life, most commonly as a combination Pentavalent or Hexavalent vaccine. However, vaccine-induced immunity following the primary series wanes with time. To maintain protection, the World Health Organization (WHO) recommends **three additional doses of vaccines against diphtheria and tetanus to boost protection and at least one booster against pertussis**, following the primary DTPcv series. While many countries achieve high coverage for the first 3 doses , DTPcv boosters are not yet included in all countries' immunization schedules. **Table 1** outlines the WHO recommended DTPcv vaccination schedule.

Burden of Disease

Per global health estimates*, diphtheria, tetanus, and pertussis collectively caused ~150,000 deaths in 2019. Pertussis accounts for over 80% of these deaths - the majority occurring in neonates and infants too young to have completed vaccination. Tetanus accounts for ~20% of deaths, the majority of which are associated with birth and predominantly occur in low-income countries among insufficiently vaccinated mothers and their newborn infants. Deaths caused by diphtheria reduced dramatically with the rollout of global vaccination programmes, but the case fatality rate remains high for unprotected individuals in the absence of proper treatment. All three diseases remain important public health priorities.

Institute for Health Metrics and Evaluation. Global Burden of Disease (GBD), 2021.

Table 1. WHO recommended DTPcv vaccination schedule [1,3,4]

	Primary series	First booster	Second booster	Third booster
Recommended age range	3 dose primary series, from 6 weeks of age, minimum interval of 4 weeks between doses. The third dose should be scheduled by 6 months of age.	12-23 months	4-7 years	9-15 years
Recommended vaccines	3 doses of **DTP**-containing vaccine	1 dose of **DTP**-containing vaccine	**DT** or **Td**- containing vaccine (with or without pertussis)	**Td**-containing vaccine (with or without pertussis)
Vaccine options [4,6]	DTP Quadrivalent Pentavalent Hexavalent	DTP Quadrivalent Pentavalent Hexavalent	Td (from >4yrs) or DT (if <7yrs) DTP	Td TdaP

* Reference at end of document.

For more information:

Gavi Vaccine Funding Guidelines: DTP-cv Boosters

WHO position papers on:
Diphtheria
Tetanus
Pertussis

RESOURCES

WHO Position papers and supplementary materials

- WHO Position Paper on Diphtheria vaccines
- WHO Position Paper on Tetanus vaccines
- WHO Position Paper on Pertussis vaccines

WHO Immunological Basis for Immunization Series

- **Diphtheria** (2009 update)
- **Tetanus** (2018 update)
- **Pertussis** (2017 update)

WHO Vaccine Preventable Disease Surveillance Standards (2018 revision)

- Diphtheria surveillance standards
- Non-neonatal tetanus surveillance standards
- Tetanus serosurveys
- Pertussis surveillance standards

Vaccine supply

- WHO list of prequalified vaccines
- UNICEF vaccine pricing data

Vaccine safety

- WHO Global Vaccine Safety - DTP vaccines info
- Global Advisory Committee on Vaccine Safety

Gavi programme funding

- Gavi Vaccine Funding Guidelines – DTPcv boosters
- Gavi Product Menu

Burden of Disease databases

- WHO annual reported VPD cases
- Global Burden of Disease modeled estimates (2021 revision)

Implementation/programmatic resources

- WHO Routine Immunization Schedule Recommendations
- Use of tetanus-diphtheria (Td) vaccine in children 4–7 years of age – WHO expert consultation
- Protecting All Against Tetanus - WHO
- Establishing and strengthening vaccination in the second year of life (2YL) – WHO, UNICEF

IMMUNIZATION AGENDA 2030

THANK YOU!

MERCI !

Materials and recordings will be shared

Children in Mongolia photographed for Generation ImmUnity. Credit: Khasar Sandag