Vaccine Deep Dive: Typhoid Conjugate Vaccine (TCV)

Vaccine Deep Dive: 2023 Gavi Funding & Process Briefings

27 July 2023

gavi.org

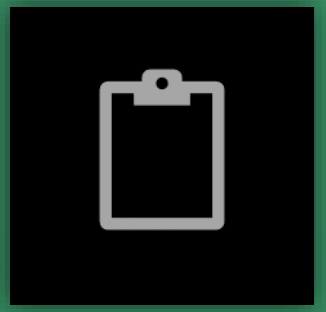
Housekeeping

English-French translation available
Anglais-Francais traduction disponible

Use chat feature to post links and/or reactions

Use Q&A function to post questions

Please no use of AI notetakers; A full transcript with highlights will be provided with the recording



Link to poll shared at the end of the session

Slideshow & recording shared following the session

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Photo: PATH/Asad Zaidi

Contents:

1. Typhoid Epidemiology, Vaccine & WHO recommendations
2. Gavi support and application process
3. Country support available from TyVAC

1

Typhoid epidemiology, vaccines & WHO recommendations

Adwoa Bentsi-Enchill

WHO/Immunization, Vaccines & Biologicals (IVB)

Typhoid & paratyphoid fever epidemiology

Global distribution

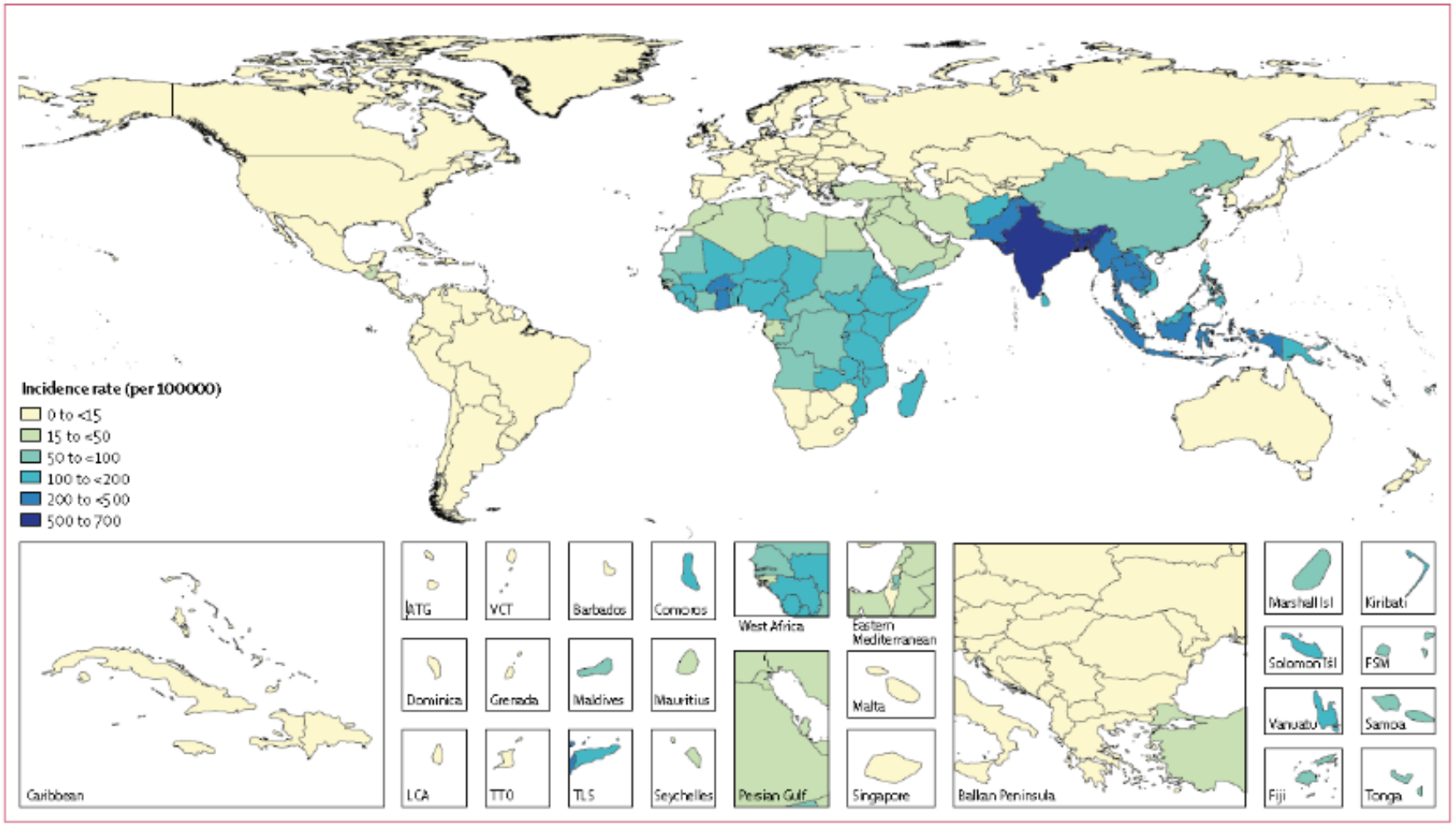

Figure 1: Incidence rates (per 100 000) of typhoid and paratyphoid fevers, by country, in 2017
Unfilled locations are those for which GBD does not produce estimates. The inset maps detail smaller locations. ATG=Antigua and Barbuda. FSM=Federated States of Micronesia. GBD=Global Burden of Diseases, Injuries, and Risk Factors Study. Isl=Islands. LCA=Saint Lucia. TLS=Timor-Leste. TTO=Trinidad and Tobago. VCT=Saint Vincent and the Grenadines.

Typhoid

- 9 million cases/year, 110,000 deaths/year*
- Peak incidence 5 - 19 yrs of age**
- ~30% of typhoid cases in children <5 years occur in <2 yrs of age***

Paratyphoid

- 6 million cases/yr
- 54 000 deaths/yr

*Global Burden of Disease Collaborative Network. Global Burden of Disease Study 2019. Seattle (WA): Institute for Health Metrics and Evaluation; 2020
**Meeting of the Strategic Advisory Group of Experts on Immunization, April 2022: conclusions and recommendations. WER. 2022, 97, 261-276.
***TCV position paper, 2018

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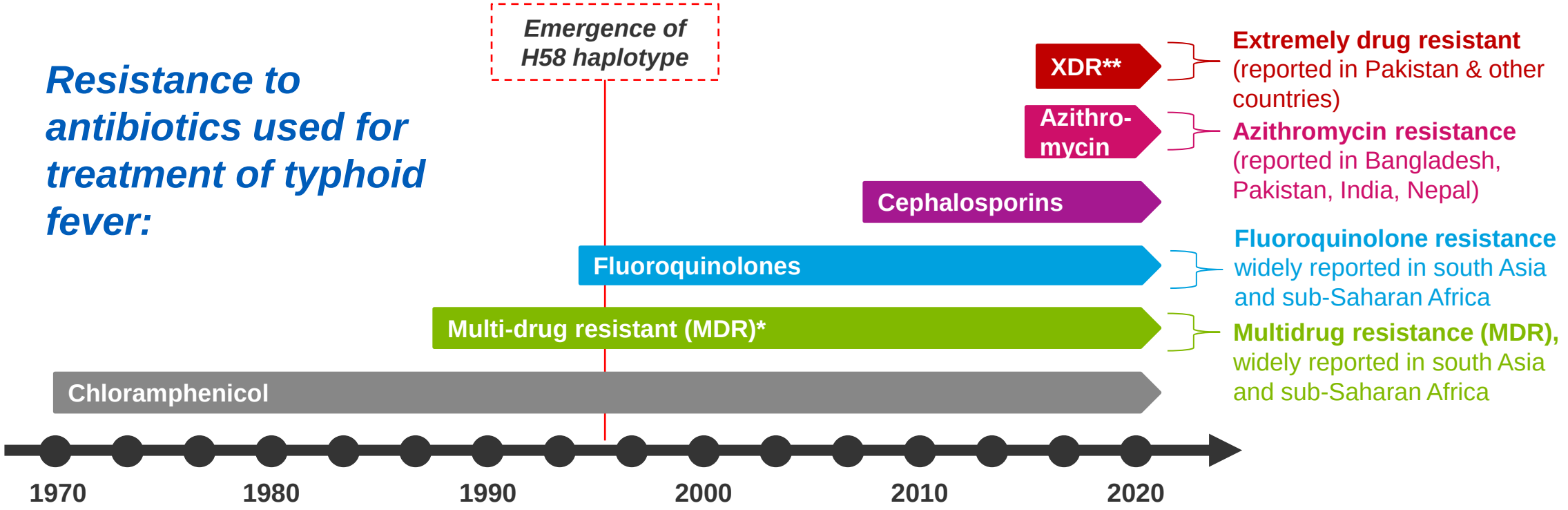
S. Typhi strains are becoming increasingly resistant to available antibiotics

Resistance to antibiotics used for treatment of typhoid fever:



*** Multidrug resistant (MDR):** *S.* Typhi strain resistant to chloramphenicol, ampicillin and cotrimoxazole
**** Extremely drug resistant (XDR):** *S.* Typhi strain resistant to chloramphenicol, ampicillin and cotrimoxazole, fluoroquinolones and 3rd generation cephalosporins

WHO position paper on TCV (2018) – key points

World Health Organization
Organisation mondiale de la Santé

Weekly epidemiological record
Relevé épidémiologique hebdomadaire

Contents

Typhoid vaccines: WHO position paper – March 2018

Introduction

Vaccins antityphoïdiques: note de synthèse de l'OMS – mars 2018

Introduction

- **TCV preferred** to existing typhoid vaccines *(ViPS and Ty21a)* in view of improved immunological properties, suitability in younger children and expected longer duration of protection.
- **Single IM dose** for infants and children from 6 mths of age and adults up to 45 yrs in typhoid endemic regions.
- Routine programmatic use at 9 months of age, or in the 2nd yr of life.
- **Catch up** to 15 yrs of age at introduction (burden of disease and programmatic feasibility are greater in this age range than in adults)
- TCV introduction to be prioritized in countries with the **highest burden** of typhoid disease or a **high burden of antimicrobial resistant *S. Typhi***.
- Vaccination recommended in **response to confirmed outbreaks** … [countries] should consider introduction/strengthening of routine immunization.

Reference: https://www.who.int/publications/i/item/whio-wer9313

World Health Organization
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Current evidence on TCV - Summary

- ✓ Single dose Typbar-TCV is highly **efficacious & effective** in children 6 mths to 15 yrs
  - Efficacy:
    - 81-85% in Bangladesh, Nepal, Malawi Typhoid Vaccine Acceleration Consortium (TyVAC) studies; 2 years follow-up
    - 78% in children 9 months to 12 years, Malawi; 4 years follow-up (pre-print Lancet, April 2023)
  - Effectiveness: 95-97% (Navi Mumbai, Hyderabad/Pakistan); 84% (Zimbabwe)
- ✓ Updated immunogenicity data
  - Persisting antibody response to Typbar-TCV® 7 years following primary vaccination with/without a booster dose
  - Immunological non-inferiority of TyphiBEV to Typbar-TCV (Phase IV VE studies ongoing for TyphiBEV)
- ✓ **Reassuring safety profile** with no signals of serious adverse events
  - TyVAC trials with full DSMB reviews found TCV well-tolerated and reactogenicity profile similar to control vaccines
  - Review of safety data by the Global Advisory Committee on Vaccine Safety (GACVS)*
- ✓ **No interference in co-administration** with other routine childhood vaccines
  - Co-administration data available for MCV (M, MR, MMR), MenA and yellow fever vaccines
- ✓ Extended age indication for Typbar-TCV - licensed and PQ'd - for use in adults up to 65 years (since 2022)

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Two conjugated vaccine products are WHO PQ'd and available through Gavi support

Consider opportunity to combine with MR 10-dose → 5-dose vial switch

Manufacturer	Bharat Biotech International	Biological E. Ltd
Vaccine trade name	Typbar-TCV	TYPHIBEV
Presentation	5 dose vial, liquid	
Routine and/or campaign	Both	
Price per dose (USD) = Price per fully immunized person. (weighted average price (WAP) 2023)	$1.39	
Doses per fully immunised person	1	
Indicative wastage rate	10%	
2023 wastage adjusted vaccine cost per fully immunized person (USD) (WAP)	**$1.53**	
Shelf-life	36 months at 2-8°C	24 months at 2-8°C
Cold chain volume per dose	2.8 cm^3	2.9cm^3
Vaccine vial monitor type	VVM 30	
Handling open vials	WHO recommends that opened vials of this vaccine may be kept for use in subsequent immunization sessions up to a maximum of 28 days provided the conditions outlined in the WHO Policy Statement "Multi-Dose Vial Policy" are met, and vaccine is <u>not</u> used under CTC.	WHO recommends that opened vials of this vaccine may be kept for use in subsequent immunization sessions up to a maximum of 28 days provided the conditions outlined in the WHO Policy Statement "Multi-Dose Vial Policy" are met.

Refer to: Gavi Detailed Product Profiles & WHO Summary of key characteristics of WHO prequalified TCVs

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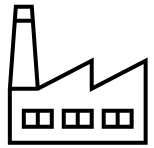
TCV supply and market updates

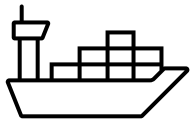


Suppliers

- Two manufacturers supply the Gavi market (Bharat Biotech International Limited (BBIL) & Biological E Ltd (BioE)

Product updates

- Two available products have similar age targets for routine administration (≥6 months) and dosing (single IM injection). Primary difference is the carrier protein.
- The products are considered programmatically equivalent and therefore UNICEF allocates products to countries according to market dynamics



Procurement timeline

- UNICEF SD tender agreement in place for 2022-2024 for TCV doses

Q&A

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Gavi support and application process

Allyson Russell

Vaccine Programmes Team, Gavi

Gavi support available for TCV introduction

Activity	Vaccine support	Financial support	Programmatic guidance
Introduction of single-dose into **routine immunisation (RI)**	Doses **co-financed between Gavi and country**	**Vaccine introduction grant** to support start-up investment costs (ceiling based on transition status) **HSS, EAF, TCA** funds for improving routine coverage	Recommend routine TCV administration be **timed with an existing routine immunization visit**
One time single-dose **catch-up campaign** at time of RI introduction*	Doses **fully financed by Gavi**	**Operational cost grant** to support implementation of catch-up campaign (ceiling based on transition status)	Catch-up campaign with target population of **9 months to <15 years old**

Additional considerations

- Countries should use a triangulation of **assessment of disease burden, surveillance data, operational feasibility and affordability** to inform introduction and strategy decisions (i.e., routine or routine + catch-up campaign; national vs. risk-based; phased implementation)
- Gavi also offers support to use TCV to respond to **confirmed typhoid outbreaks**, however advises countries with outbreaks to consider routine introduction and strengthening routine delivery platforms and demand generation

**Gavi support for catch-up campaign is only available as part of TCV introduction into routine immunisation.*

Reminder: Leverage all Gavi funding channels

Full Portfolio Plan

Health systems & immunization strengthening	• Improving coverage of TCV in routine immunization post-introduction with support for health care delivery costs; management; data systems, analysis and use; supply chain improvement; demand generation • Surveillance system strengthening
Equity Accelerator Funding	• Expanding immunization services to areas typically underserved and unreached by health care system
Innovation Fund	• Top-up grant to enable expansion of tested innovations to improve vaccine coverage and quality of immunization services (e.g., digital tracking systems)
Cold chain equipment optimization platform	• Improving hardware and cold chain system functionality
Targeted Country Assistance	• Technical assistance in-country to support many aspects of immunization system strengthening and new vaccine introductions
Vaccine Grants: Vaccine Introduction Grant (VIG); Campaign Operational Cost (Ops); Switch	•Campaign operational cost grants including post-campaign coverage surveys •Vaccine introduction into routine immunization system including post-introduction evaluation
Learning Activities	•Priority research to inform future vaccination strategies
Diagnostic Support	•*Forthcoming*

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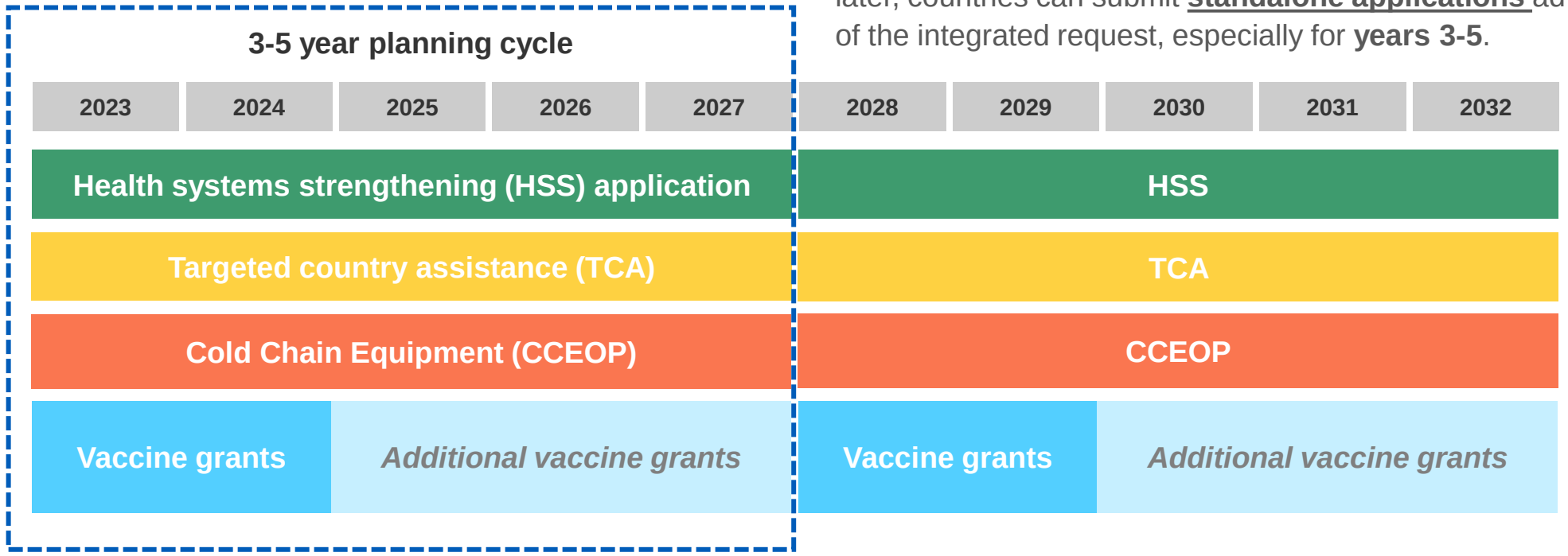
Reminder: Applying for Gavi grants using multi-year planning

Countries encouraged to plan an **integrated request (i.e., full portfolio plan – FPP)** across all support types anticipated they will need during 3–5-year grant period

Vaccines and diagnostics to be implemented **in first two years** of planning cycle should aim to submit jointly.

However, if bandwidth is too stretched or unforeseen need arises later, countries can submit **standalone applications** ad hoc outside of the integrated request, especially for **years 3-5**.



1 application spanning multiple support types and multiple years and **1 review** by Independent Review Committee (IRC)

Resources:
Gavi guidelines

Gavi Guidelines can be found by visiting:

Gavi.org → Programmes & Impact → How our support works → Gavi Support Guidelines

Includes:

Application Process Guidelines

Directives pour le processus de demande de Gavi

Programme Funding Guidelines

Directives de financement du programme Gavi

Vaccine Funding Guidelines

Directives de Gavi pour le financement du soutien aux vaccins

Budget Eligibility Guide

Guide d'éligibilité budgétaire de Gavi

&

Templates, Instructions, 'Standalone' application materials

Resources: Vaccine Funding Guidelines *KEY*

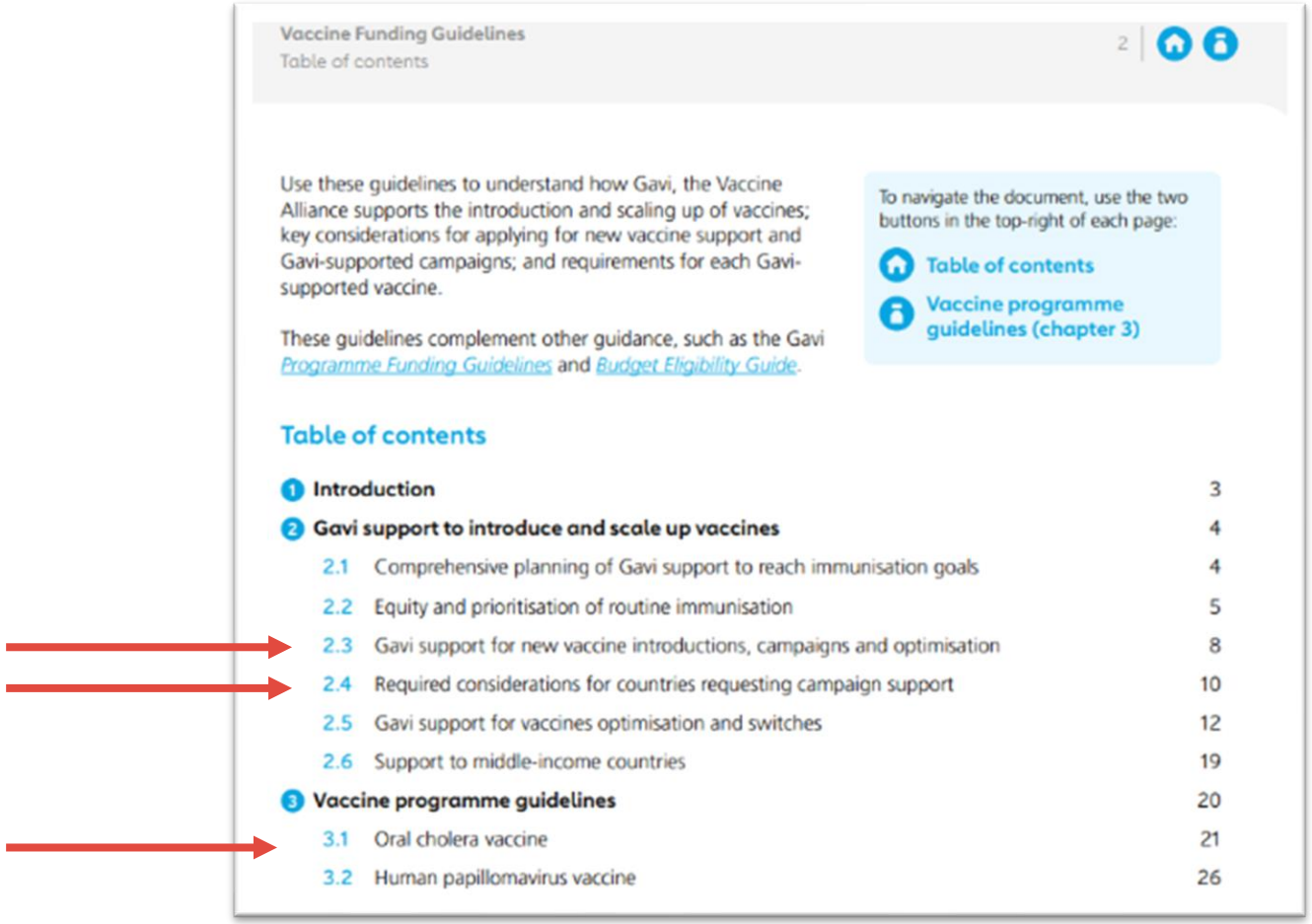
Purpose: Guiding document for how to apply for Gavi vaccine grants (i.e., new vaccine introduction or campaigns), with specific requirements by vaccine

Key sections:

Section 2: Gavi support for vaccines and campaigns. Details expectations and requirements for vaccine applications.

Section 3: Specific guidance for each vaccine on what Gavi funds, expectations for applications, and required documents

English | Français



Vaccine Funding Guidelines
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Use these guidelines to understand how Gavi, the Vaccine Alliance supports the introduction and scaling up of vaccines; key considerations for applying for new vaccine support and Gavi-supported campaigns; and requirements for each Gavi-supported vaccine.

These guidelines complement other guidance, such as the Gavi *Programme Funding Guidelines* and *Budget Eligibility Guide*.

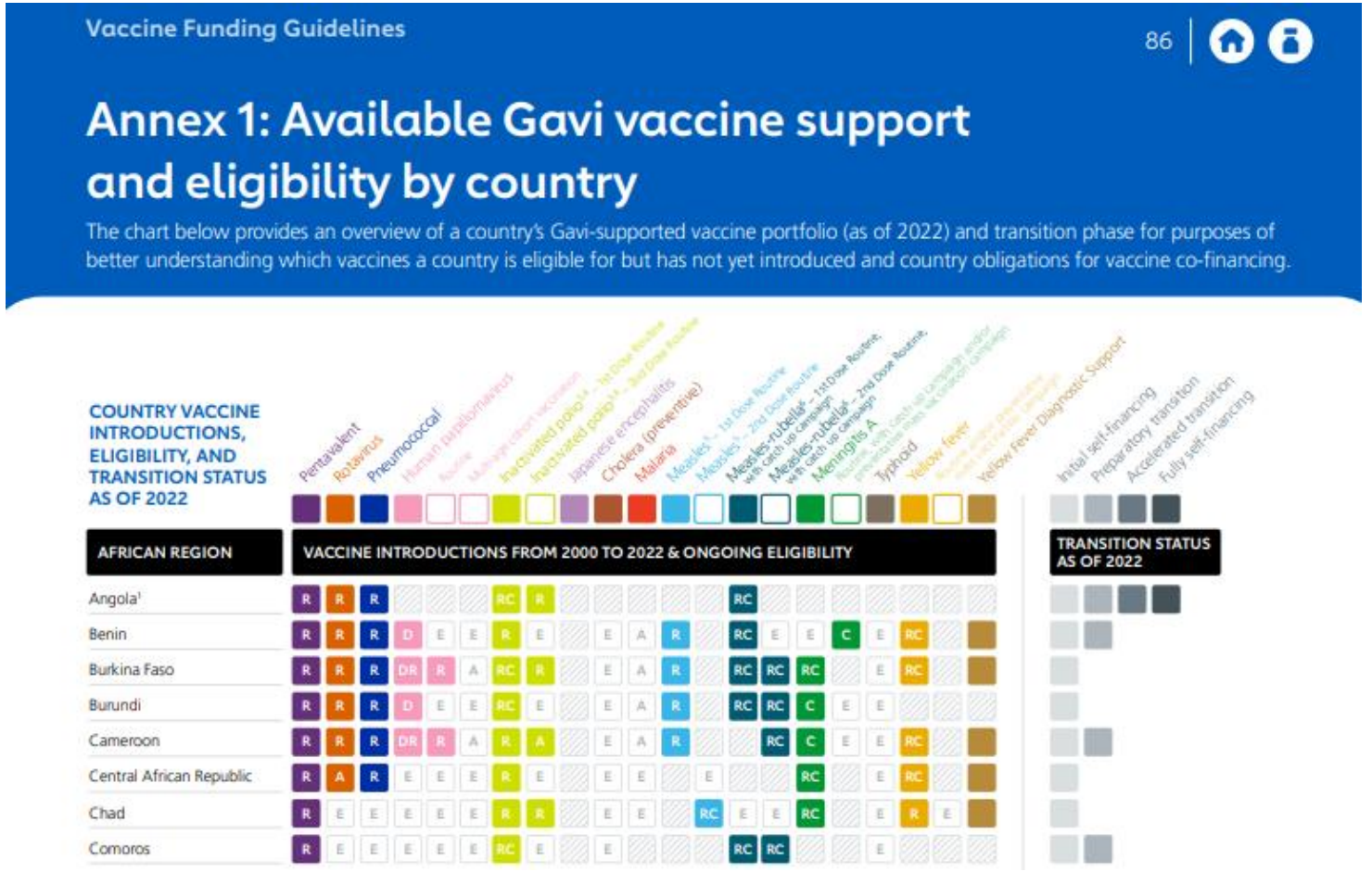
To navigate the document, use the two buttons in the top-right of each page:
Table of contents
Vaccine programme guidelines (chapter 3)

Table of contents

Resources: Vaccine Funding Guidelines *KEY*

Eligibility for new vaccine introduction with Gavi support

English | Français



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Annex 1: Available Gavi vaccine support and eligibility by country

The chart below provides an overview of a country's Gavi-supported vaccine portfolio (as of 2022) and transition phase for purposes of better understanding which vaccines a country is eligible for but has not yet introduced and country obligations for vaccine co-financing.

COUNTRY VACCINE INTRODUCTIONS, ELIGIBILITY, AND TRANSITION STATUS AS OF 2022

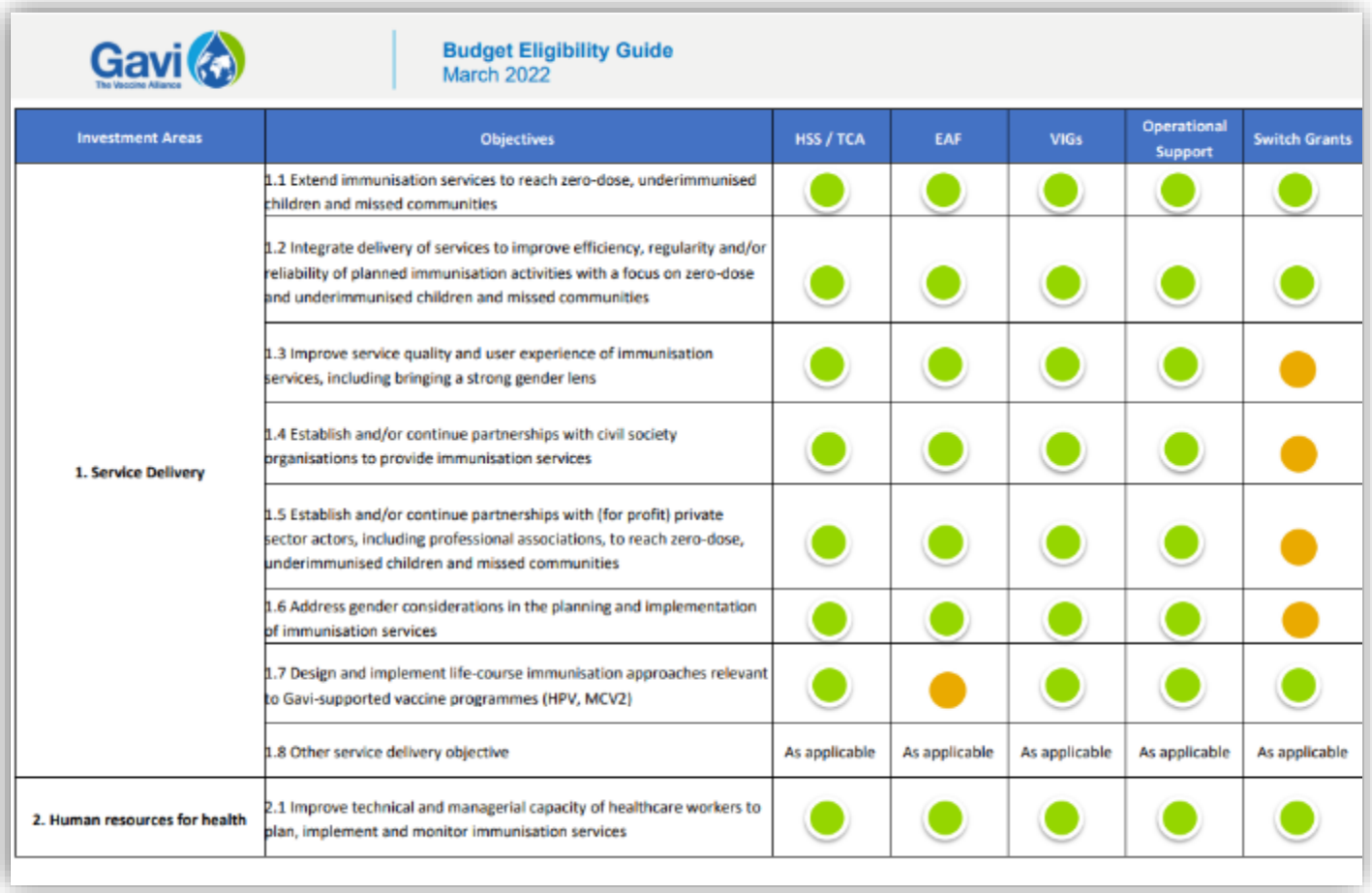
Pentavalent; Rotavirus; Pneumococcal; Human papillomavirus; Routine; Multidose inject vaccination; Inactivated polio 1st dose Routine; Inactivated polio 2nd dose Routine; Japanese encephalitis; Cholera (preventive); Malaria; Measles 1st Dose Routine; Measles 2nd Dose Routine; Measles-rubella 1st Dose Routine, with catch up campaign; Measles-rubella 2nd Dose Routine, with catch up campaign; Meningitis A; Routine, with catch up campaign and/or preventive mass vaccination campaign; Typhoid; Yellow fever; Routine, with catch up campaign and/or preventive mass vaccination campaign; Yellow Fever Diagnostic Support; Initial self-financing; Preparatory transition; Accelerated transition; Fully self-financing

AFRICAN REGION	VACCINE INTRODUCTIONS FROM 2000 TO 2022 & ONGOING ELIGIBILITY	TRANSITION STATUS AS OF 2022
Angola[1]	R R R RC R RC	
Benin	R R R D E E R E E A R RC E E C E RC	
Burkina Faso	R R R DR R A RC R E A R RC RC RC E RC	
Burundi	R R R D E E RC E E A R RC RC C E E	
Cameroon	R R R DR R A R A E A R RC C E E RC	
Central African Republic	R A R E E E R E E E E RC E RC	
Chad	R E E E E E R R E E RC E E RC E R E	
Comoros	R E E E E E RC E E RC RC E	

Resources: Budget Eligibility Guide

Budget Eligibility Guide remains a central reference guide, which guides on:

1. Which objectives can be financed by which grant types
2. Which costs are eligible for each grant type



Gavi The Vaccine Alliance | Budget Eligibility Guide March 2022

Investment Areas	Objectives	HSS / TCA	EAF	VIGs	Operational Support	Switch Grants
1. Service Delivery	1.1 Extend immunisation services to reach zero-dose, underimmunised children and missed communities	●	●	●	●	●
	1.2 Integrate delivery of services to improve efficiency, regularity and/or reliability of planned immunisation activities with a focus on zero-dose and underimmunised children and missed communities	●	●	●	●	●
	1.3 Improve service quality and user experience of immunisation services, including bringing a strong gender lens	●	●	●	●	●
	1.4 Establish and/or continue partnerships with civil society organisations to provide immunisation services	●	●	●	●	●
	1.5 Establish and/or continue partnerships with (for profit) private sector actors, including professional associations, to reach zero-dose, underimmunised children and missed communities	●	●	●	●	●
	1.6 Address gender considerations in the planning and implementation of immunisation services	●	●	●	●	●
	1.7 Design and implement life-course immunisation approaches relevant to Gavi-supported vaccine programmes (HPV, MCV2)	●	●	●	●	●
	1.8 Other service delivery objective	As applicable	As applicable	As applicable	As applicable	As applicable
2. Human resources for health	2.1 Improve technical and managerial capacity of healthcare workers to plan, implement and monitor immunisation services	●	●	●	●	●

English | Français

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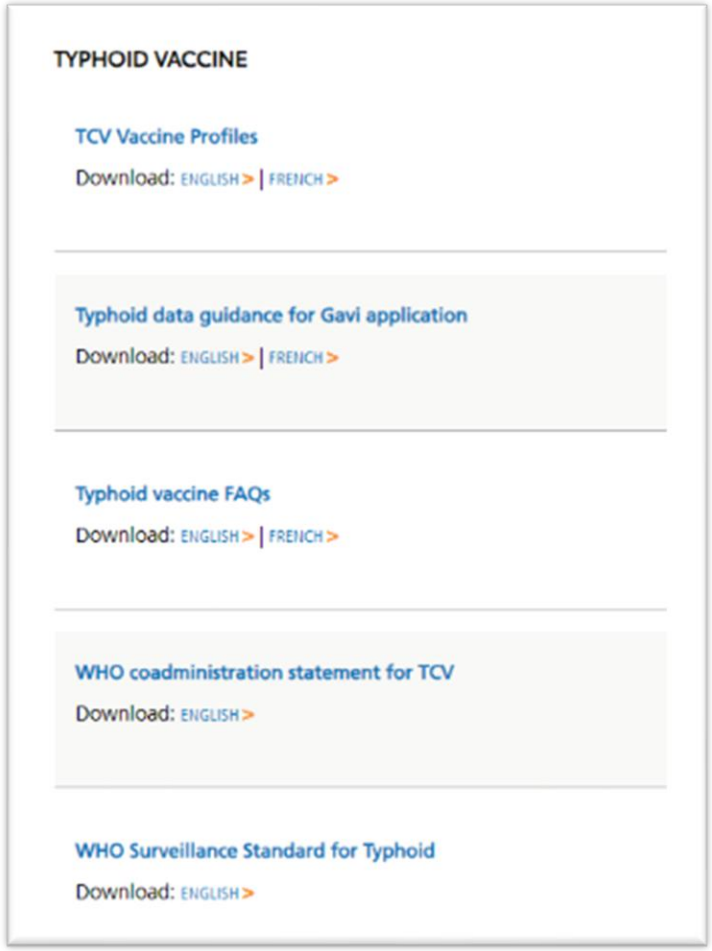
Resources: Typhoid vaccine specific documents

Please navigate to this section of Gavi's website to access typhoid vaccine specific documents and guidance:



TYPHOID VACCINE

TCV Vaccine Profiles

Download: ENGLISH > | FRENCH >

Typhoid data guidance for Gavi application

Download: ENGLISH > | FRENCH >

Typhoid vaccine FAQs

Download: ENGLISH > | FRENCH >

WHO coadministration statement for TCV

Download: ENGLISH >

WHO Surveillance Standard for Typhoid

Download: ENGLISH >

Where to go if you need guidance?

- Your best resource is your Gavi Senior Country Manager
- Other persons you can contact are:
  - WHO focal point for new vaccine introduction
  - PATH's TyVAC team

https://www.gavi.org/our-support/guidelines

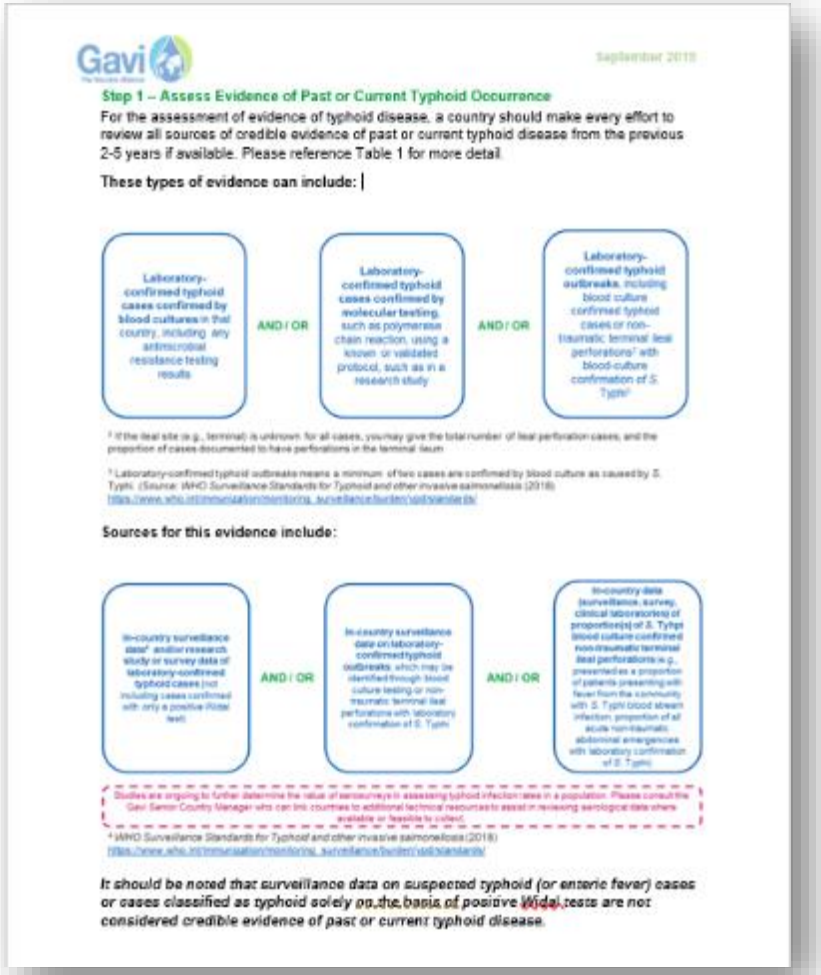
Resources: Guidance on TCV Burden Evidence & Targeting

Data sources to inform TCV introduction & vaccination strategy:

- If available, lab-confirmed typhoid disease incidence data (e.g. blood culture, including antimicrobial resistance and non-traumatic ileal perforation data) from surveillance, medical reports, or research studies.
- In absence of lab-confirmed typhoid data, countries should assess risk of typhoid occurrence using other available data (e.g., modelled burden, distribution of typhoid risk factors, outbreaks of other water-borne diseases, regional burden estimates)
- NB: It is assumed not all of these data types will be available, and the country will use a combination of available data to present the rationale for TCV introduction.

Targeting

- **National**: If evidence points to high nation-wide risk, OR if lacking national data but risk factors exist nationwide, to ensure equity where cases not detected.
- **Sub-national**: If evidence points to higher risk in particular region AND minimal or no risk for rest of the country.



Gavi

Step 1 – Assess Evidence of Past or Current Typhoid Occurrence

For the assessment of evidence of typhoid disease, a country should make every effort to review all sources of credible evidence of past or current typhoid disease from the previous 2-5 years if available. Please reference Table 1 for more detail.

These types of evidence can include:

Laboratory-confirmed typhoid cases confirmed by blood cultures in that country, including any antimicrobial resistance testing results

AND / OR

Laboratory-confirmed typhoid cases confirmed by molecular testing, such as polymerase chain reaction, using a known or validated protocol, such as in a research study

AND / OR

Laboratory-confirmed typhoid outbreaks, including blood culture confirmed typhoid cases or non-traumatic terminal ileal perforations[1] with blood culture confirmation of *S. Typhi*[2]

[1] If the ileal site (e.g., terminal) is unknown for all cases, you may give the total number of ileal perforation cases, and the proportion of cases documented to have perforations in the terminal ileum

[2] Laboratory-confirmed typhoid outbreaks means a minimum of two cases are confirmed by blood culture as caused by *S. Typhi*. (Source: *WHO Surveillance Standards for Typhoid and other invasive salmonellosis* (2018) https://www.who.int/immunization/monitoring_surveillance/burden/vpd/standards/)

Sources for this evidence include:

In-country surveillance data[3] and/or research study or survey data of laboratory-confirmed typhoid cases (not including cases confirmed with only a positive Widal test)

AND / OR

In-country surveillance data on laboratory-confirmed typhoid outbreaks, which may be identified through blood culture testing or non-traumatic terminal ileal perforations with laboratory confirmation of *S. Typhi*

AND / OR

In-country data (surveillance, survey, clinical laboratories) of proportion(s) of *S. Typhi* blood culture confirmed non-traumatic terminal ileal perforations (e.g., presented as a proportion of patients presenting with fever from the community with *S. Typhi* blood stream infection; proportion of all acute non-traumatic abdominal emergencies with laboratory confirmation of *S. Typhi*)

Studies are ongoing to further determine the value of serosurveys in assessing typhoid infection rates in a population. Please consult the Gavi Senior Country Manager who can link countries to additional technical resources to assist in reviewing serological data where available or feasible to collect.

[3] *WHO Surveillance Standards for Typhoid and other invasive salmonellosis* (2018) https://www.who.int/immunization/monitoring_surveillance/burden/vpd/standards/

It should be noted that surveillance data on suspected typhoid (or enteric fever) cases or cases classified as typhoid solely on the basis of positive Widal tests are not considered credible evidence of past or current typhoid disease.

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Process overview: Components of the TCV application

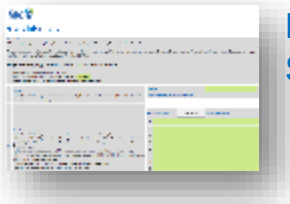
Standalone Vaccine Application

TCV application form
Timing, dose requirements, vaccine registration, financing overview

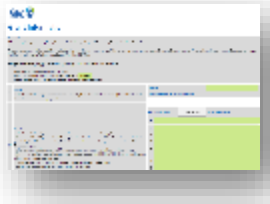
Workplan
High level activity timeline and budget required

Targeted Areas
Identifies which sub-national levels are targeted if sub-national (pre-populated list of districts)

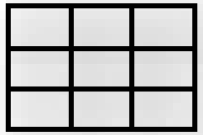
Budgeting & Reporting



Budget Summary



Detailed Budget



Budget calculations – country format

Vaccine specific attachments

1. New Vaccine Introduction Plan & Campaign Plan of Action

Key document

2. NITAG recommendation
3. ICC Approval
4. MOH and MOF endorsement signatures

Process overview: Standard Gavi Forms and Guidelines

Please navigate to this section of Gavi's website to access standard forms, instructions, and budget eligibility guidance.

Templates

Guidelines

STANDALONE VACCINE APPLICATION MATERIALS & GUIDELINES

Gavi Budgeting & Reporting Template

Download: ENGLISH > | FRENCH >

Standalone Vaccine Application Template & Instructions

Download: ENGLISH > | FRENCH >

Gavi Support Detail Instructions

Download: ENGLISH > | FRENCH >

Gavi Budget Eligibility Guide

Download: ENGLISH > | FRENCH >

https://www.gavi.org/our-support/guidelines

Budgeting & Reporting

Budget Summary

Detailed Budget

Standalone Vaccine Application

Workplan

High level activity timeline and budget required

Targeted Areas

Identifies which sub-national levels are targeted (pre-populated list of districts)

Application deep dive: Key items in Plan of Action

Rationale & Strategies

- Does the epidemiological rationale justify the introduction approach?
- Is the proposed vaccination schedule and campaign approach and timing in line with SAGE and NITAG recommendations?
- Are the strategies proposed for vaccination teams and implementation adequate to reach typically underimmunized communities, feasible to implement, and cost-effective?
- Does the campaign approach include sufficient plans to reach typically under-immunized communities and individuals with TCV?
- Is the Ministry of Education sufficiently included and represented in the planning phases for a successful school-based campaign?
- *If feasible and necessary given country context:* Have opportunities to catch up children and adolescents with other antigens been considered?
- Did the country identify the key lessons learned from past campaigns, and reflect these in the planned activity?

Country Readiness

- Is cold chain capacity adequate for the plan proposed (or will be by the time of implementation)? If not, are plans described to increase permanent or surge capacity through Ops or other funding mechanisms to meet the need?
- Are there sufficient human resources available in the country to implement the campaign according to the plan proposed?
- Are there plans articulated for updating the HMIS to capture the new antigen?

Monitoring & Evaluation

- Is there an adequate strategy for real-time monitoring during campaign implementation to inform daily activities and mop up?
- Is there a plan for monitoring the roll out of routine introduction via HMIS?
- Is a post campaign coverage survey planned and adequately budgeted for following WHO guidelines?

Budget

- Do the budgeted activities align with the plans detailed in the POA/NVIP?
- Are costs proposed justifiable and sufficient to successfully implement the activities proposed?

Application deep-dive: Strengths of submitted applications

Demonstration of high **political commitment**

Use of available **data on equity** to determine overall strategies

Introduction rationale and approach (national vs. subnational; phased versus all at once) well justified on epidemiological, AMR and cost-effectiveness grounds

Plans for **strengthening of RI** through the introduction

Learnings from previous introductions & campaigns reflected in plan

Analysis of **vaccine storage capacity** and articulation of contingency plans

Continuous improvement plan described and budgeted

World Health Organization

Gavi The Vaccine Alliance

Application deep-dive: common areas needing improvement

Section of application	Areas of concern
Plan of action	• Elements of operational aspect not well described: supervision structure and roles, vaccination team structure and strategy, available TA and roles • **Vaccination teams not allocated based on size of target population**, vaccination strategy, and equity considerations. Campaign structure does not meet WHO norms for SIA (e.g., daily vaccination target) • Opportunities for integration not fully taken into consideration or described; lack of synergies between programmes where there should be • AEFI systems in place are weak, with limited plan to improve for the introduction • Weak description of how surveillance and diagnostics will be improved after routine introduction (links with HSS grants)
Equity / intersectionality analysis	• **Unclear strategy to identify and reach marginalized groups** (e.g. refugees, women, out-of-school children)
Timeline / phasing	• **Timelines for implementation are unrealistic** to be able to prepare a high-quality campaign and introduction • Campaign and routine immunization introduction are spaced far apart

Application deep-dive: common areas needing improvement

Section of application	Areas of concern
Budget	• **Budget does not align with strategy** outlined in POA (e.g., number of vaccinators) • **Lump sums** are requested rather than breakdown (e.g., community engagement or surveillance) • Resources not used as efficiently as possible (e.g., integrated activities) or allocated according to need (e.g., more resourced in hard-to-reach areas) • Detailed budget showing calculations missing and/or budget elements poorly explained or justified • Incorrect cost classifications
Human resources costs	• Human resources costs that are not adequately justified, especially for higher levels of supervision and management
Supply chain & waste management	• Storage capacity analysis does not consider potential **concurrent arrival of other vaccines** • **Waste management** costs not accounted for
Effective Vaccine Management (EVM)	• EVM older than 5 years or progress report / improvement plan missing
Data Quality Assessment (DQA)	• Incomplete compliance with DQA requirements
Government approvals	• NITAG or ICC minutes (translated) and signatures missing; MOH/MOF signatures missing

Best practices: Implementation successes

Coordination	• Strong government commitment and coordination among stakeholders
Capacity-building	• Training on strategies for conducting a wide-age injectable campaign • Additional AEFI trainings and AEFI surveillance strengthening
Private sector	• Engaged **private pediatricians** and general practitioners as key influencers
Planning, monitoring	• Capitalized on prior **measles-rubella and polio vaccination campaign experience and data systems** for microplanning and readiness assessments
Integration	• Leveraged EPI and public health interventions **to increase immunization coverage and deliver complementary interventions**: zero-dose identification and co- administration initiatives, mop-up vaccination sessions, school vaccination, national immunization weeks, WASH activities & SBCC
Advocacy, comms, social mobilization	• Strong community awareness for TCV introduction: media involvement and **effective social mobilization key** • Used school vaccination sessions with **early/strong coordination and advocacy with Dept. of Education** including school health coordinators and parents

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Best practices: Implementation challenges & lessons learned

COVID-19 pandemic	• Delays due to COVID-19 priorities • Heightened vaccine misinformation and confusion related to concurrent COVID-19 vaccine introduction
Resource limitations	• **Insufficient human resources for large campaigns**, especially skilled vaccinators • (Especially in integrated campaigns) Vaccinators dissatisfied with pay conditions and/or not well equipped to educate families on all components of all vaccines
School-based vaccination	• School closures disrupted microplans • Out-of-school children were difficult to quantify in microplanning • School reluctance to vaccinate students • Need for increased engagement of both public and private schools, including training and communication materials to ensure consistent messaging
Lack of acceptance and hesitancy	• Myths and misconceptions about the vaccines being administered; concerns that children would be administered a COVID-19 vaccine disguised as TCV • Vaccination refusals and misinformation circulating on social media; need for more robust vaccine safety messaging

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Q&A

3

Country support available from Typhoid Vaccine Acceleration Consortium (TyVAC)

Emmanuel Mugisha

PATH's TyVAC Director

Why now?

TCV introduction is urgent for many reasons:

- Increasing spread of drug-resistant strains.
- Climate change causes weather extremes (drought, flooding) that will increase typhoid risks.
- Rapid urbanization and more crowded informal settlements enable typhoid to spread more easily.
- Countries are positioned to optimize Gavi support ahead of transition and changes to eligibility status.
- We have enough quantities of the TCV vaccine.

Photo: PATH/Kundzai Tinago

The Typhoid Vaccine Acceleration Consortium (TyVAC) is led by the Center for Vaccine Development and Global Health at the University of Maryland School of Medicine, the Oxford Vaccine Group at the University of Oxford, and PATH. TyVAC is funded by the Bill & Melinda Gates Foundation.

TyVAC works closely with global partners

TyVAC's multidisciplinary strategy to combat typhoid

Convene, coordinate, and engage international partners and the typhoid community

Maintain momentum and attention on typhoid

Generate evidence to guide vaccine policy and sustainable programs

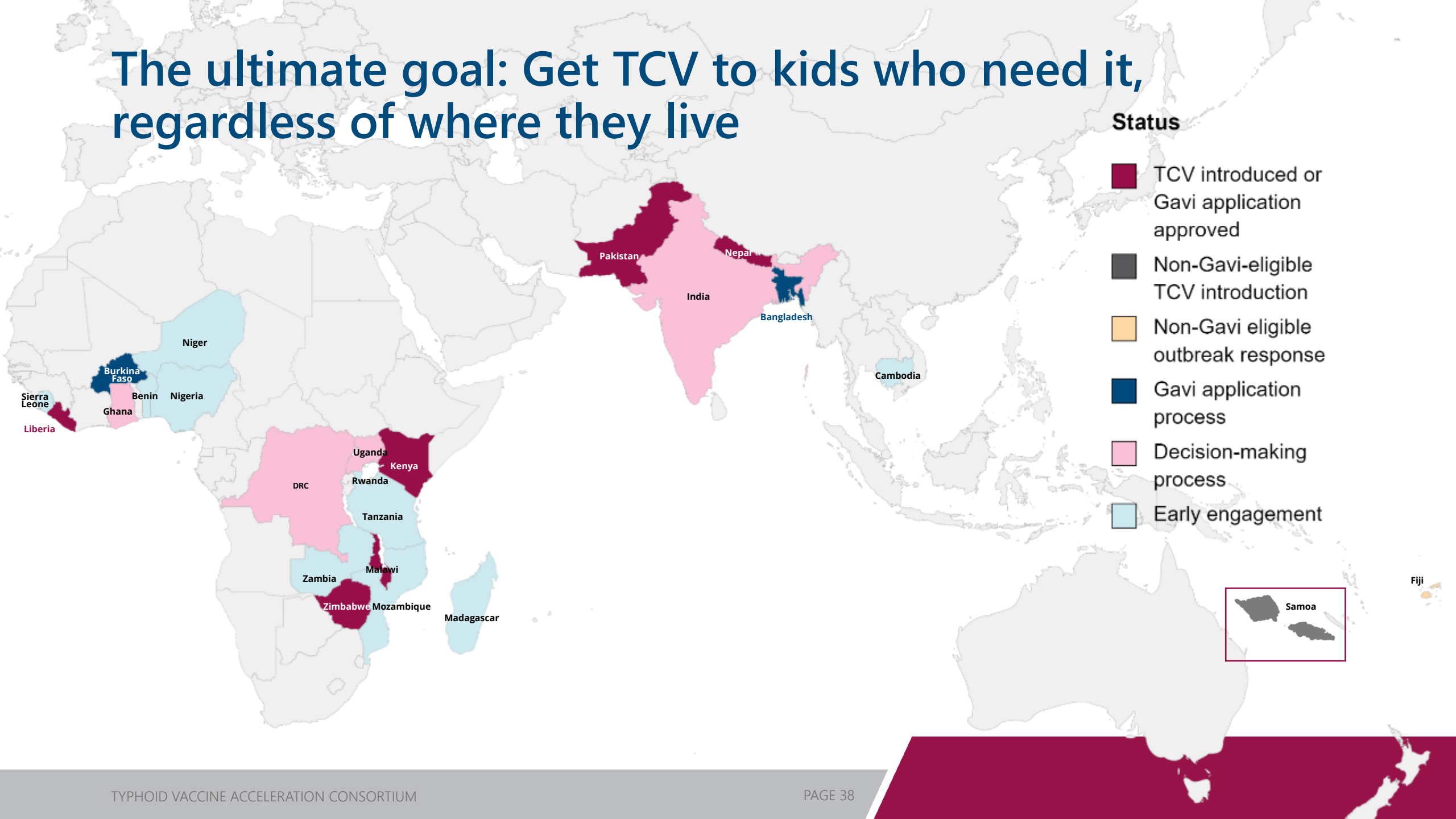
Ensure widespread and sustainable TCV introductions

Ensure widespread and sustainable TCV introductions

- Support the use and application of new surveillance tools/assessment methods for TCV introduction decision-making.
- Ensure countries have the latest vaccine performance and health economics data to enable an information-based decision for TCV introduction.
- Provide technical support as needed for countries to submit strong Gavi applications and conduct quality TCV introductions.
- Support TCV program sustainability.

Photo: PATH/Kundzai Tinago

The ultimate goal: Get TCV to kids who need it, regardless of where they live



TyVAC supports TCV decision-making and introduction

Phase 1  **Scoping/Prep and Application**

- Provide resources and support for regional and national level stakeholder forums on typhoid and TCVs.
- Assist with collating and reviewing typhoid burden data.
- Develop advocacy and communications materials to support decision-making.
- Help with Gavi application and facilitate post-application responses from Gavi.
- Assess country-specific cost-effectiveness analyses and estimate prospective vaccine program costs.

Phase 2  **Introduction**

- Support microplanning activities.
- Collaborate with Gavi and UNICEF to develop training and information, education, and communication materials.
- Support AEFI surveillance training.

Phase 3  **Post-Introduction**

- Share lessons learned to inform EPI programming and improve policies, coverage, delivery, and equity.

TyVAC is available to support policymakers

- National data can come from many sources (not only confirmed blood culture). TyVAC will triangulate data to give a reasonable indication of typhoid burden.
    - Intestinal perforation; outbreaks; drug-resistance; risk factors (i.e., WASH, climate change); modelled data
- Perfect is the enemy of the good.
    - Waiting for "more" or "perfect" data, risks avoidable morbidity/mortality and ongoing transmission of increasingly drug-resistant typhoid.
- After a positive NITAG, ICC, and key signatory approval, TyVAC supports Gavi application process with planning & coordination meetings and application drafting.
- As needed, support may continue through the Gavi Independent Review Board questions.
- TyVAC offers support for campaign planning and introduction as funding allows.

TyVAC support evolves as global context changes

- TyVAC has re-calibrated based on where countries need or request the most support.
- TyVAC leverages lessons learned and solutions from previous decision-making and introduction countries to help mitigate challenges. For example:
  - Changes to campaign introductions in a post-COVID-19 context, including identification of integrated campaign opportunities.
  - Considerations to reach school-aged children using campaigns at schools.
  - Sharing accurate and contextually appropriate messages to combat misinformation and rumors, particularly considering COVID-19 vaccine confusion and drop in RI coverage.
  - Microplanning to focus on zero-dose children and hard-to-reach communities.
- Routine immunization schedule will continue to grow (RTS,S; MMCV; others). TyVAC continues to help countries prioritize, consider routine schedule revisions, etc.
- Build capacity of local partners to support government, work with CSOs to message typhoid prevention and importance of vaccines to have impact in the near-term.

Summary

- TyVAC has successfully packaged data and evidence for national and sub-national decision-makers in the African and Asian regions.
  - Data on local burden is most often requested. TyVAC works to pull data from national surveillance records, HMIS, facilities, and published literature to make the most comprehensive case with existing evidence.
- The TyVAC model has been refined over the last five years and is highly adaptable to best fit the needs of individual decision-makers and country-led processes.
- The next several years are crucial for TCV introduction to help combat drug-resistant typhoid and to protect against changes in burden brought along by climate change and migration.
- TyVAC has a model that encourages decision-makers to begin the process now, even if in the early stages, so that support can be provided during time of Gavi eligibility.

Q&A

2023 Gavi Funding & Process Briefing Series

7 June	How the Gavi Alliance Works	
14 June	How to Access Gavi Support	
21 June	Programme Application Types	
22 June	Deep Dive: Vaccine Portfolio Optimisation	
28 June	The Gavi Budget	
5 July	Vaccine Support Application Types	
12 July	Programmatic Deep Dive 1: Behavioural & Institutional Change	
13 July	Deep Dive: Cholera Vaccine & Diagnostics Support	
19 July	Programmatic Deep Dive 2: Supply Side Improvements & Optimising Systems	
20 July	Deep Dive: Measles Vaccine Support	
26 July	Gavi's Monitoring & Learning Approach	
27 July	Deep Dive: Typhoid Vaccine Support	
	August Break	
6 Sept	Facilitation Skills for Successful Programme Planning	***New Date***
13 Sept	Gavi Private Sector Engagement	***New***
20 Sept	Gavi Targeted Country Assistance (TCA) Support	***New***
27 Sept	Gavi Middle Income Country (MICs) Support	***New***
28 Sept	Deep Dive: Hexavalent Support	***New***

See you at the next briefing session in **September**!

Feedback Wanted

Please help us improve our series by providing feedback through our survey here:

English Survey | Enquête française

(the link to the survey will also be provided in the chat)

Spread the word!

Please forward the invite/zoom details to all partners, consultants, country team members, and anyone who might benefit!

Materials

Access this and previous session recordings and slide decks here.

Annexes

Who is the Independent Review Committee & how does it work?

Key characteristics of the IRC:

- the review committee is independent*

  **Members are not from Vaccine Alliance member organizations, nor involved in preparing the applications*

- the committee relies upon a wide range of experts in public health, epidemiology, development, finance and economics
- the committee is based on a system of peer review

Current member bios, governance structures, and recent IRC reports are available here: https://www.gavi.org/our-support/irc

At each review session,