APPLICATION FORM FOR GAVI NVS SUPPORT

Submitted by

The Government of Nepal

for

Typhoid conjugate vaccine routine, with catch-up campaign



1 Gavi Grant terms and conditions

1.2 Gavi terms and conditions

1.2.1 Gavi terms and conditions

The terms and conditions of the Partnership Framework Agreement (PFA) between Gavi and the Country, including those provisions regarding anti-corruption and anti-terrorism and money laundering, remain in full effect and shall apply to any and all Gavi support made pursuant to this application. The terms and conditions below do not create additional obligations or supersede those of the PFA. In the event the Country has not yet executed a PFA, the terms and conditions of this application shall apply to any and all Gavi support made pursuant to this application.

GAVI GRANT APPLICATION TERMS AND CONDITIONS

FUNDING USED SOLELY FOR APPROVED PROGRAMMES

The applicant country ("Country") confirms that all funding provided by Gavi will be used and applied for the sole purpose of fulfilling the programme(s) described in the Country's application. Any significant change from the approved programme(s) must be reviewed and approved in advance by Gavi. All funding decisions for the application are made at the discretion of Gavi and are subject to IRC processes and the availability of funds.

AMENDMENT TO THE APPLICATION

The Country will notify Gavi in its Joint Appraisal, or in any other agreed annual reporting mechanism, if it wishes to propose any change to the programme(s) description in its application. Gavi will document any change approved by Gavi according with its guidelines, and the Country's application will be amended.

RETURN OF FUNDS

The Country agrees to reimburse to Gavi all funding amounts that Gavi determines not to have been used for the programme(s) described in its application. The Country's reimbursement must be in US dollars and be provided, unless otherwise decided by Gavi, within sixty (60) days after the Country receives Gavi's request for a reimbursement and be paid to the account or accounts as directed by Gavi.

SUSPENSION/ TERMINATION

Gavi may suspend all or part of its funding to the Country if it has reason to suspect that funds have been used for purpose other than for the programme(s) described in the Country's application, or any Gavi-approved amendment to the application. Gavi retains the right to terminate its support to the Country for the programme(s) described in its application if a misuse of Gavi funds is confirmed.

NO LIABILITY

The Country shall be solely responsible for any liability that may arise in connection with: (i) the implementation of any programme(s) in the Country; and (ii) the use or distribution of vaccines

and related supplies after title to such supplies has passed to the Country.

Neither party shall be responsible for any defect in vaccines and related supplies, which remain

the responsibility of the relevant manufacturer. Gavi shall not be responsible for providing any additional funding to replace any vaccines and related supplies that are, or became, defective or disqualified for whatever reason.

INSURANCE

Unless otherwise agreed with Gavi, the Country shall maintain, where available at a reasonable cost, all risk property insurance on the Programme assets (including vaccines and vaccine related supplies) and comprehensive general liability insurance with financially sound and reputable insurance companies. The insurance coverage will be consistent with that held by similar entities engaged in comparable activities.

ANTI-CORRUPTION

The Country confirms that funds provided by Gavi shall not be offered by the Country to any third person, nor will the Country seek in connection with its application any gift, payment or benefit directly or indirectly that could be construed as an illegal or corrupt practice.

ANTI-TERRORISM AND MONEY LAUNDERING

The Country confirms that funds provided by Gavi shall not be used to support or promote violence, war or the suppression of the general populace of any country, aid terrorists or their activities, conduct money laundering or fund organisations or individuals associated with terrorism or that are involved in money-laundering activities; or to pay or import goods, if such payment or import, to the Country's knowledge or belief, is prohibited by the United Nations Security Council.

AUDITS AND RECORDS

The Country will conduct annual financial audits, and share these with Gavi, as requested. Gavi reserves the right, on its own or through an agent, to perform audits or other financial management assessment to ensure the accountability of funds disbursed to the Country. The Country will maintain accurate accounting records documenting how Gavi funds are used. The Country will maintain its accounting records in accordance with its government-approved accounting standards for at least three years after the date of last disbursement of Gavi funds. If there is any claims of misuse of funds, Country will maintain such records until the audit findings are final. The Country agrees not to assert any documentary privilege against Gavi in connection with any audit.

CONFIRMATION OF LEGAL VALIDITY

The Country and the signatories for the Country confirm that its application, or any other agreed annual reporting mechanism, is accurate and correct and forms legally binding obligations on the Country, under the Country's law, to perform the programme(s) described in its application, as amended, if applicable.

COMPLIANCE WITH GAVI POLICIES

The Country confirms that it is familiar with all Gavi policies, guidelines and processes relevant

to the programme(s), including without limitation the Transparency and Accountability Policy (TAP) and complies with the requirements therein. All programme related policies, guidelines and processes are available on Gavi's official website and/or sent to the Country.

USE OF COMMERCIAL BANK ACCOUNTS

The Country is responsible for undertaking the necessary due diligence on all commercial banks used to manage Gavi cash-based support. The Country confirms that it will take all responsibility for replenishing Gavi cash support lost due to bank insolvency, fraud or any other unforeseen event.

ARBITRATION

Any dispute between the Country and Gavi arising out of or relating to its application that is not settled amicably within a reasonable period of time, will be submitted to arbitration at the request of either Gavi or the Country. The arbitration will be conducted in accordance with the then-current UNCITRAL Arbitration Rules. The parties agree to be bound by the arbitration award, as the final adjudication of any such dispute. The place of arbitration will be Geneva, Switzerland. The languages of the arbitration will be English or French.

For any dispute for which the amount at issue is US\$ 100,000 or less, there will be one arbitrator appointed by Gavi. For any dispute for which the amount at issue is greater than US \$100,000 there will be three arbitrators appointed as follows: Gavi and the Country will each appoint one arbitrator, and the two arbitrators so appointed will jointly appoint a third arbitrator who shall be the chairperson.

Gavi will not be liable to the country for any claim or loss relating to the programme(s) described in the application, including without limitation, any financial loss, reliance claims, any harm to property, or personal injury or death. The Country is solely responsible for all aspects of managing and implementing the programme(s) described in its application.

1.3 Gavi Guidelines and other helpful downloads

Guidelines and documents for download

Please refer to the relevant guidelines concerning your request for support.

Please ensure to consult and download all documents. It is important to note that some documents must be completed offline, and will need to be uploaded in the final steps of your application.

This application form is designed to collect information needed by Gavi to process requests for support, plan procurement of vaccines, plan technical assistance, track data for future reporting, and more.

A key component of the application is a solid operational plan (New Vaccine Introduction Plan for routine support, or Plan of Action for campaign support), explaining how the country will

introduce the vaccine or conduct the envisaged campaign, with a corresponding budget. The New Vaccine Introduction Plan or Plan of Action must be submitted together with this application form and will be considered as the foundation of the support request.

For more information on the documents to submit with your application and what they should contain, please refer to the appropriate guidelines: http://www.gavi.org/support/process/apply/

2 Review and update country information

2.1 Country profile

2.1.1 Country profile

Eligibility for Gavi support

Eligible

Co-financing group

Initial self-financing

Date of Partnership Framework Agreement with Gavi

11 June 2014

Country tier in Gavi's Partnership Engagement Framework

3

Date of Programme Capacity Assessment

November 2016

2.1.2 Country health and immunisation data

Please ensure your Country health and immunisation data is up to date. If not, please go to the Overall expenditures and financing for immunisation section of the portal to submit this information.

	2019	2020
Total government expenditure	11,848,648,648.65	

Total government	588,288,288.29
health expenditure	
Immunisation budget	23,043,212

2.1.3 National health planning and budgeting cycle, and national planning cycle for immunisation:

The government planning cycle starts on the

16 July			
The current National Hea	alth Sector Plan (NHSP) is		
From	2016		
То	2020		

Your current Comprehensive Multi-Year Plan (cMYP) period is

2017-2021

Is the cMYP we have in our record still current?

Yes⊠	No□	

If you selected "No", please specify the new cMYP period, and upload the new cMYP in country documents section.

Note 1

If any of the above information is not correct, please provide additional/corrected information or other comments here:

No Response

2.1.4 National customs regulations

Please describe local customs regulations, requirements for pre-delivery inspection, and special documentation requirements that are instrumental for the delivery of the vaccine.

Vaccines are received in Nepal by Management Division, Department of Health Services, Ministry of Health and Population. Important documents for each shipment required as per customs regulations are: 1) pre-notice letter, 2) airway bill, 3) invoice, 4) packing list, 5) release

certificate, 6) country of origin document, and 7) quality assurance document. Vaccine shipments are regularly received by Logistics Management Section, Management Division, with complete documentations as mentioned above for each shipment. Therefore, no potential delays are anticipated.

2.1.5 National Regulatory Agency

Please provide information on the National Regulatory Agency in the country, including status (e.g. whether it is WHO-certified). Please mention a point of contact with phone number and e-mail address. UNICEF will support the process and may need to communicate licensing requirements to the vaccine manufacturers where relevant.

National Regulatory Authority of Nepal is the Department of Drug Administration. Department of Drug Administration (DDA), Ministry of Health and Population, Government of Nepal, is Nepal's health technology product regulatory authority mainly responsible for enforcing pharmaceutical sector related objectives and strategies of National Health Policy 2071. In accordance with the objectives of the National Health Policy 1991, to improve and manage by establishing coordination among governmental, non-governmental and private organizations involved in the activities related to drug production, import, export, storage, supply, sales, distribution, quality assessment, regulatory control, rational use and information flow, the National Drug Policy 1995 has been implemented in Nepal. Achieving the aim and objectives of National Drug Policy is another important area for DDA.

Contact:

Mr. Santosh KC, Information Officer, Tel: +977 1 4780227 EXT: 231

Mr. Narayan Prasad Dhakal, Director-General, DDA, email: narayandhakalji@gmail.com;

narayandhakalji@yahoo.com

Website: dda.gov.np

2.2 National Immunisation Programmes

2.2.2 Financial Overview of Active Vaccine Programmes

IPV Routine

Note 2			
	2020	2021	2022
Country Co-			
financing (US\$)			
Gavi support (US\$)	1,421,111	1,448,767	1,446,637

Measles SD Routine - Strat 1

	2020	2021	2022
Country Co-	318,639		
financing (US\$)			
Gavi support	296,308		
(US\$)			

PCV Routine

	2020	2021	2022	2023	2024
Country Co- financing (US\$)	764,766	774,962	356,182	353,781	618,762
Gavi support (US\$)	11,549,706	11,727,748	4,649,551	4,618,211	4,353,229
Pentavalent Ro	outine				
	2020	2021	2022	2023	2024
Country Co- financing (US\$)	885,653	894,727	404,314	401,589	176,498
Gavi support (US\$)	2,362,570	2,385,639	1,115,972	1,108,450	1,333,540
Rota Routine					
	2020	2021	2022	2023	2024
Country Co- financing (US\$)	301,500	247,766	249,480	216,249	308,612
Gavi support (US\$)	3,192,777	2,623,748	2,641,908	2,290,004	2,183,866
Summary of a	ctive Vaccine P	rogrammes			
	2020	2021	2022	2023	2024
Total country co-financing (US\$)	2,270,558	1,917,455	1,009,976	971,619	1,103,872
Total Gavi support (US\$)	18,822,472	18,185,902	9,854,068	8,016,665	7,870,635
Total value (US\$) (Gavi + Country co-financing)	21,093,030	20,103,357	10,864,044	8,988,284	8,974,507

2.3 Coverage and Equity

2.3.1 Coverage and equity situation analysis

Note: If a recent analysis of the coverage and equity analysis is already available, for example as part of a Joint Appraisal report, you may simply reference the report and section where this information can be found.

Describe national and sub-national evidence on the coverage and equity of immunisation in the country and constraints to improvement. In particular, identify the areas and groups of low coverage or high inequity linked to geographic, socioeconomic, cultural or female literacy considerations, as well as systematically marginalized communities. Specify both the areas and/or populations with low coverage (%) and those with the largest absolute numbers of un/under-vaccinated children. Among data sources, consider administrative data, coverage surveys, DHS/MCS, equity analyses, Knowledge-Attitude-Practice surveys, and patterns of diseases like measles.

Describe the challenges underlying the performance of the immunisation system, such as:

- o Health work force: availability and distribution;
- o Supply chain readiness;
- o Gender-related barriers: any specific issues related to access by women to the health system:
- o Data quality and availability;
- o Demand generation / demand for immunisation services, immunisation schedules, etc;
- Leadership, management and coordination: such as key bottlenecks associated with the management of the immunisation programme, the performance of the national/ regional EPI teams, management and supervision of immunisation services, or broader sectoral governance issues;
- o Financing issues related to the immunisation programme that impact the ability to increase coverage, including bottlenecks related to planning, budgeting, disbursement and execution of resources;
- Other critical aspects: any other aspect identified, for example based on the cMYP, EPI review, PIE, EVM or other country plans, or key findings from available independent evaluations reports.

Describe lessons learned and best practices on the effectiveness of implemented activities to improve coverage and equity; recommendations on changes or new interventions that might be required to accelerate progress (include data to support any findings or recommendations).

Please see the "Vaccine Equity" section of the attached Plan of Action for TCV, which details vaccine coverage trends; inequities across wealth quintile, mothers' education levels, and geographic areas; and various immunization strategies that have been implemented with the goal of reaching every child.

Please see "Expanded Program on Immunization in Nepal" section of the POA for sub-sections detailing current function and challenges for service delivery, human resources for health, supply chain and vaccine management, EPI monitoring and evaluation, advocacy, communications, and social mobilization, and cold chain.

The "Lessons learned from past campaigns and new introductions" section in the attached POA details lessons learned and provides recommendations on programmatic changes and new interventions to improve coverage.

2.4 Country documents

Upload country documents

Please provide **country documents** that are relevant for the national immunisation programme and for multiple vaccines, to be taken into account in the review of your application. If you have already provided one or more of these country documents, you do not need to upload it/them again unless the document version changed. If documents cannot be provided, please use the comment functionality to explain why, or by when they will be available.

Note that only general country documents are uploaded here; at the end of section 3 (subsection "Upload new application documents") you will be required to provide those documents that are specific to the support requested (for example the new vaccine introduction plan and/or campaign plan of action, new budget, application endorsements etc.)

Country and planning documents

✓	Country strategic multi-year
	plan

cMYP20172021_19-04-18_12.49.52.pdf

Comprehensive Multi-Year Plan for Immunisation (cMYP) or equivalent country strategic plan

Country strategic multi-year plan / cMYP costing tool

<u>Information on cMYP 201721 costing 09-09-</u> <u>20 16.03.49.pdf</u>

Effective Vaccine Management (EVM) assessment

Final Nepal EVM Assessmentreport2017_09-09-20_16.12.07.doc

Effective Vaccine Management (EVM): most recent

improvement plan progress report

<u>Implementation status of EVM Improvement</u> Plan 2017 09-09-20 16.13.20.docx

Data quality and survey documents: Final report from most recent survey containing immunisation coverage

indicators

NDHS 2016 FINAL_09-09-20_16.15.01.pdf

Data quality and survey documents: Immunisation data quality improvement plan

No file uploaded

Data quality and survey documents: Report from most recent desk review of immunisation data quality

No file uploaded

Data quality and survey documents: Report from most recent in-depth data quality evaluation including immunisation

No file uploaded

Human Resources pay scale

No file uploaded

If support to the payment of salaries, salary top ups, incentives and other allowances is requested

Coordination and advisory groups documents

National Coordination Forum Terms of Reference

ICC Functions and Members 10-09-20_10.48.07.pdf

ICC, HSCC or equivalent



National Coordination Forum meeting minutes of the past 12 months

NIAC and ICC mtg min12 Sep 2019FINAL_09-09-20_16.37.27.pdf

ICC meeting minutes 29 April 2019NVS renewal 2019_09-09-20_16.36.49.pdf

Other documents

Other documents (optional)

No file uploaded

Please also provide other country documents to support the review of the applications, for example Health Facility Assessment Reports, Knowledge-Attitude-Practice surveys or other demand-related surveys, if available.

3 Typhoid conjugate vaccine routine, with catch-up campaign

3.1 Vaccine and programmatic data

Choice of presentation and dates

For each type of support please specify start and end date, and preferred presentations.

Typhoid conjugate vaccine routine

Preferred presentation	TCV, 5 doses/vial, Liquid		
Is the presentation licensed or registered?	Yes ⊠	No □	
2nd preferred presentation			
Is the presentation licensed or registered?	Yes ⊠	No □	
Required date for vaccine and supplies to arrive	2 October 2	2021	

Planned launch date	1 February 2022		
Support requested until	2025		
Typhoid conjugate vaccii	ne catch-up campaign		
Preferred presentation	TCV, 5 doses/vial, Liquid		
Is the presentation licensed or registered?	Yes ⊠ No □		
2nd preferred presentation			
Is the presentation licensed or registered?	Yes ⊠ No □		
Required date for vaccine and supplies to arrive	2 October 2021		
Planned launch date	1 February 2022		
Tialinea laurion date	Trobluary 2022		
Support requested until	2022		

3.1.2 Vaccine presentation registration or licensing

If any of the selected presentations are not yet licensed or registered, please describe the duration of the registration or licensing procedure, whether the country's regulations allow the expedited procedure for national registration of WHO-pre-qualified vaccines, and confirm whether the licensing procedure will be completed ahead of the introduction or campaign.

No Response

3.1.3 Vaccine procurement

Gavi expects that most countries will procure vaccine and injection supplies through UNICEF or PAHO's Revolving Fund.Does the country request an alternative mechanism for procurement and delivery of vaccine supply (financed by the country or Gavi)?

Υ	es□	No⊠

If you have answered yes, please attach the following in the document upload section:* A description of the mechanism, and the vaccines or commodities to be procured by the country through this mechanism.* A confirmation that vaccines will be procured from the WHO list of pre-qualified vaccines, indicating the specific vaccine from the list of pre-qualification. OR, for the procurement of locally-produced vaccines directly from a manufacturer which may not have been prequalified by WHO, a confirmation should be provided that the vaccines purchased comply with WHO's definition of quality vaccines, for which there are no unresolved quality problems reported to WHO, and for which compliance is assured by a fully functional National Regulatory Authority (NRA), as assessed by WHO in the countries where they are manufactured and where they are purchased.

3.2 Target Information

3.2.1 Targets for routine vaccination

Please describe the target age cohort for the routine immunisation:

Note 4				
619,386				
	2022	2023	2024	2025
Population in the target age cohort (#)	516,155	626,757	633,902	640,875
Target population to be vaccinated (first dose) (#)	516,155	626,757	633,902	640,875
Estimated wastage rates for preferred presentation (%)	10	10	10	10

3.2.2 Targets for campaign vaccination

Please describe the target age cohort for the campaign: e.g. 9 months to < 15 years.Gavi will only provide support up to 15 years of age.

15 months to < 15 years

	2022
Population in the	8,479,640
target age cohort	
(#)	

Target population	8,479,640
to be vaccinated	
(first dose) (#)	
Estimated wastage	10
rates for preferred	
presentation (%)	

3.3 Co-financing information

3.3.1 Vaccine and commodities prices

Price per dose (US\$) - Typhoid conjugate vaccine routine

	2022	2023	2024	2025	
5 doses/vial,liq	1.35	1.2	1.2	1.2	

Commodities Price (US\$) - Typhoid conjugate vaccine routine

	2022	2023	2024	2025
AD syringes	0.036	0.036	0.036	0.036
Reconstitution				
syringes				
Safety boxes	0.005	0.005	0.005	0.005
Freight cost as a % of device value	2.22	2.5	2.5	2.5

Price per dose (US\$) - Typhoid conjugate vaccine catch-up campaign

	2022	
5 doses/vial,liq	1.35	

Commodities Price (US\$) - Typhoid conjugate vaccine catch-up campaign (applies only to preferred presentation)

	2022
AD syringes	0.036
Reconstitution	
syringes	
Safety boxes	0.005
Freight cost as a	2.22
% of device value	

3.3.2 Country choice of co-financing amount per vaccine dose

The table below shows the estimated financial commitment for the procurement of vaccines and supplies for the country, and the portion of Gavi support.

Please note that the values represented in this table do not account for any switches in cofinancing group. The calculations for the entire five year period are based on the countries cofinancing group in the first year.

Note 6

	2022	2023	2024	2025
Country co-	14.81	16.67	16.67	16.67
financing share				
per dose (%)				
Minimum Country	0.2	0.2	0.2	
co-financing per				
dose (US\$)				
Country co-	0.2	0.2	0.2	0.2
financing per dose				
(enter an amount				
equal or above				
minimum)(US\$)				

3.3.3 Estimated values to be financed by the country and Gavi for the procurement of supply

Typhoid conjugate vaccine routine

	2022	2023	2024	2025
Vaccine doses				
financed by Gavi				
(#)				
Vaccine doses				
co-financed by				
Country (#)				
AD syringes				
financed by Gavi				
_(#)				
Total value to be				
financed (US\$)				
AD syringes co-				
financed by				
Country (#)				
Safety boxes				
financed by Gavi				
(#)				
Safety boxes co-				
financed by				
Country (#)				

Freight charges financed by Gavi (\$)				
Freight charges co-financed by Country (\$)				
	2022	2023	2024	2025
Total value to be co-financed (US\$) Country				
Total value to be financed (US\$)				

Typhoid conjugate vaccine catch-up campaign

	2022
Vaccine doses financed by Gavi (#)	9,412,500
AD syringes financed by Gavi (#)	9,327,700
Safety boxes financed by Gavi (#)	102,625
Freight charges financed by Gavi (\$)	257,551
	2022
Total value to be financed (US\$) Gavi	13,348,500
Total value to be financed (US\$)	13,348,500

3.3.4 Co-financing payment

Please indicate the process for ensuring that the co-financing payments are made in a timely manner.

After receiving the decision letter for TCV catch-up campaign and routine support, the program division will put the co-financing fund amount in the immunization program AWPB 2021/2022 and will pay the co-financed amounts.

If your country is in the accelerated transition phase for Gavi support, please answer the following question:

Please provide evidence that the co-financing obligations for the new introduction have been budgeted for, and elaborate on how the country plans to pay for the fully self-financing amounts. Please discuss the extent to which medium-term immunisation/health plans and medium-term expenditure frameworks incorporate the additional costs associated with this introduction. Discuss any co-financing defaults that may have happened in the last five years.

No Response

Following the regulations October
of the internal budgeting
and financing cycles the
Government will annually
release its portion of the
co-financing funds in the
month of:

The payment for the first year of co-financed support will be made in the month of:

Month November

Year 2021

3.4 Financial support from Gavi

3.4.1 Routine Vaccine Introduction Grant(s)

Typhoid conjugate vaccine routine

Live births (year of introduction)

619,386

Gavi contribution per live birth (US\$)

8.0

Total in (US\$)

495,508.8

Funding needed in country by

1 May 2021

3.4.2 Campaign Operational Costs Support grant(s)

Typhoid conjugate vaccine catch-up campaign

Population in the target age cohort (#)

Note 7

8,479,640

Gavi contribution per person in the target age cohort (US\$)

0.65

Total in (US\$)

5,511,766

Funding needed in country by

1 May 2021

3.4.3 Operational budget

Please complete the Gavi budgeting and planning template to document how the Gavi Vaccine Introduction Grant and the Campaign Operational Costs support grant will be used to facilitate the timely and effective implementation of critical activities in advance of and during the campaign and the introduction of the new vaccine. Please ensure to upload the completed budgeting and planning template as part of this application.

If Gavi's support is not enough to cover the full needs please indicate how much and who will be complementing the funds needed in the Operational Budget template. In the following fields please provide an overview of your request.

Total amount - Gov. Funding / Country Co-financing (US\$)

1572726

Total amount - Other donors (US\$)

0

Total amount - Gavi support (US\$)

6007275

Amount per target person - Gov. Funding / Country Co-financing (US\$)

0.17

Amount per target person - Other donors (US\$)

0

Amount per target person - Gavi support (US\$)

0.66

3.4.4 Key Budget Activities

List the key budgeted activities to be undertaken in implementing the requested support. Please provide details on the key cost drivers, inputs and assumptions required for these activities.

In the attached Gavi budgeting and planning template, details about the budgeted activities for both TCV campaign operations support and vaccine introduction grant for federal, provincial and district levels are given. Further, campaign operations budget for local level (palika/municipality level) is also provided (US\$ 1,569,581) which will be funded by the Government. Additional two budget sheets (for campaign operations and VIG each) are attached which shows budget assumptions and calculations in detail. Out of the total budget request to Gavi, US \$ 235,563 is requested for WHO and US\$ 528,515 is requested for UNICEF. The budgeted activities include all key activities to successfully implement the TCV campaign and TCV introduction in routine immunization including advocacy, communication, and social mobilization activities; orientation, training and micro-planning activities; supervision and monitoring; vaccine and logistics transport; review and evaluation activities, campaign operations activities, etc.

3.4.5 Financial management procedures

Please describe the financial management procedures that will be applied for the management of the NVS direct financial support, including any procurement to be incurred.

The grants will be managed as per existing Government financial rules. Part of the grants requested for partners (WHO and UNICEF) will be managed as per their organizational financial management procedures.

3.4.6 Compliance with guidelines for use of Gavi financial support for human resources (HR) costs

Does the submitted application and budget comply with existing guidelines, criteria and requirements for use of Gavi financial support for human resources (HR) costs?

1000	Yes⊠	No□	
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Please provide further information and justification concerning human resources costs, particularly when issues and challenges have been raised regarding the compliance with Gavi guidelines.

Please see the attached budget sheets for details about budgeted activities.

3.4.7 Fiduciary management

Please indicate whether funds for operational costs should be transferred to the government or WHO and/or UNICEF and when funding is expected to be needed in country. Attach banking form if funding should be transferred to the government. Please note that UNICEF and WHO will require administrative fees as follows.

UNICEF Tripartite Agreement: 5%
 UNICEF Bilateral Agreement: 8%
 WHO Bilateral Agreement: 7%.

The total budget request to Gavi is US\$ 6,007,275 (US\$ 5,511,766 for campaign and US\$ 495,509 for VIG). Out of these, US\$ 235,563 is requested for transfer to WHO, and US\$ 528,515 for transfer to UNICEF. The rest (US\$ 5,243,197) is requested for transfer to the Government. The Government account details for funds transfer will be shared before the time of transfer. Since the campaign and vaccine launch is planned in Q1 of 2022, funding will be required in country preferably by May/June/July 2021 to effectively plan and prepare. For the Government, decision letter may be required by March 2021 to include the TCV campaign and RI activities in the AWPB of FY 2021/2022.

3.4.8 Use of financial support to fund additional Technical Assistance needs

Gavi funds through its Partner Engagement Framework / TCA, tailored and differentiated technical assistance in response to specific country needs. Please review the currently approved technical assistance plan (also referred to as the "One TA plan") with a view to assess that required support for the implementation of the new vaccine support is contained in the approved technical assistance plan. If gaps in technical assistance are identified for the new vaccine support, the additionally required technical assistance may be funded through the vaccine introduction grant or campaign operational costs support. In this case, the relevant costs must be reflected in the budgeting and planning template. In addition, please indicate the programmatic areas for additional technical assistance needs and the respective agencies providing the technical assistance (if already identified) below.

Note 9

Additional Targeted Country Assistance needs will be reflected in the respective year TCA request.

3.5 Strategic considerations

3.5.1 Rationale for this request

Describe the rationale for requesting these new programme(s), including the burden of disease. If already included in detail in the Vaccine Introduction Plan or Campaign Plan of Action, please cite the sections only.

Please see the "Typhoid Burden" and "Background and Decision-Making Process" sections in the attached Plan of Action.

3.5.2 Alignment with country strategic multi-year plan / comprehensive multi-year plan (cMYP)

Please describe how the plans and key assumptions in this request align with the most recent country strategic multi-year plan (cMYP) and other national health and immunisation plans.

One of the strategic objectives of Nepal's cMYP 2017-2021 is to "reach every child for full immunization". This strategic objective has several strategic approaches, one of which is introduction of new vaccines. Introduction of typhoid vaccine in routine immunization is a priority for new vaccine introduction, and will be reflected in the next cMYP as well.

3.5.3 Coordination Forum (ICC, HSCC or equivalent) and technical advisory committee (NITAG)

Provide a description of the roles of the national Coordination Forum (ICC, HSCC or equivalent body) and national immunization technical advisory group (NITAG) in developing this request.

If any of Gavi's requirements to ensure basic functionality of the relevant national Coordination Forum (ICC, HSCC or equivalent) were not met, please describe the reasons and the approach to address this. Requirements can be found in the general application guidelines.

In the absence of a NITAG, countries should clarify the role and functioning of the advisory group and describe plans to establish a NITAG.

Based on compelling evidence of Nepal's high typhoid burden, high risk factors for typhoid, and encouraging TCV study results, national TCV introduction (both campaign and introduction in RI) was recommended by the Nepal's National Immunization Advisory Committee (NIAC) in August 2020, and the program division was requested to proceed with preparing the application for submission to Gavi. NIAC is an advisory body for immunization mandated by the Immunization Act 2072 of Nepal. Following this, Inter-Agency Coordination Committee (ICC) reviewed and endorsed the NIAC recommendations and Gavi application in September 2020.

3.5.4 Financial sustainability

Please discuss the financing-related implications of the new vaccine programs requested, particularly how the government intends to fund the additional co-financing obligations. Please mention if any defaults occurred in the last three years and, if so, describe any mitigation measures that have been implemented to avoid future defaults. Additionally has the country taken into account future transition from Gavi support?

The Immunization Program is the priority program (P1) of the Government of Nepal. The government will fund the additional co-financing amount through its own funds. The country has taken into account future transition from Gavi support by establishing the Immunization Fund through Nepal's Immunization Act.

3.5.5 Programmatic challenges

Summarise programmatic challenges that need to be addressed to successfully implement the requested vaccine support, and describe plans for addressing those. These may include plans to address the barriers identified in the coverage and equity situation analysis section, and include vaccine supply chain, demand generation/community mobilisation, data quality/availability/ use and leadership, management and coordination, etc.

Nepal recently underwent transition to federalization. Following this, Nepal's first nation-wide vaccination campaign in the new federal structure was successfully conducted in 2020 (Gavi

supported MR campaign). In the current federal structure, there are three tier system of the Government which includes federal, provincial and local level. The local level is the new level/structure of the government. Therefore, capacity building (in health/health management) of the local level will be required, and accordingly activities have been put in the local level for the TCV campaign by the Government.

COVID-19 has posed programmatic challenges by creating delays in previously-planned immunization strengthening activities. An Effective Vaccine Management (EVM) assessment was originally planned in 2019; however, it was delayed due to challenges in conducting the assessment during the ongoing restructuring and decentralization of the health system under the new federal structure, as well as a national measles-rubella (MR) campaign in early 2020. Due to COVID-19 situation and lock-downs, it has been delayed till now in 2020. However, EVM assessment is prioritized to be completed within 2020 and initial planning meeting has been held in the first week of September 2020 immediately after second lock-down was lifted. A National Immunization Supply Chain Action plan, also delayed due to COVID-19, is being developed in collaboration with WHO and UNICEF with targeted completion by Q1 2021. These plans and assessments will be completed before TCV preparations start in Q2/Q3 2021 and gaps addressed before TCV introduction in Q1 2022.

3.5.6 Improving coverage and equity of routine immunisation

Explain how the proposed NVS support will be used to improve the coverage and equity of routine immunisation, by detailing how the proposed activities and budget will contribute to overcoming key barriers.

In the attached Plan of Action, 'Strengthening routine immunization through TCV campaign' and Strategies and activities to reach unimmunized and under immunized population (reaching the unreached)' sections detail how the support will be utilized to improve coverage and equity of routine immunization. Advocacy and information about routine immunization will be included in all advocacy, communication and social mobilization activities in the campaign. Mass media (TV, radio, newspaper, SMS system, etc) use for TCV campaign will include information on routine immunization and hygiene promotion. Backside of the campaign invitation cards, which will be delivered house-to-house to eligible households including in hard-to-reach areas, will have information on routine immunization (importance, safety and schedule) and hygiene promotion. Through this, households and communities will not only have information about the campaign but also about routine immunization. Backside of the campaign vaccination cards which will be given to everyone vaccinated in the campaign will have information on routine immunization (importance, safety and schedule) and hygiene promotion. The campaign vaccination card for 15 - 23 months aged children will have routine immunization status recorded for follow-up and immunization after campaign completion to progress towards full immunization palika declaration. Further, training and orientation activities to immunization coordination committees at all levels, FCHVs, school teachers, stakeholders. etc., will also include training on routine immunization. Micro-planning will be focussed on finding hard-toreach and under-served populations. Data from monitoring activities such as rapid convenience monitoring will be utilized to improve routine immunization service such as outreach areas.

3.5.7 Synergies

Describe potential synergies across planned and existing Gavi support, including planned introductions, campaigns and HSS support. If relevant, comment on capacity

and appropriate systems to introduce multiple vaccines. Also describe how the country will mitigate any programmatic and financial risks associated with multiple introductions. Furthermore, how is the requested support complementary and creating synergies with the support of other Global Health Initiatives, such as the Global Fund and GFF?

Note 10

The TCV catch-up campaign and TCV introduction in routine immunization will have synergistic effect. As TCV campaign will have more budget and, therefore, more activities covering more areas or number such as trainings, ACSM activities, supervision and monitoring, it will also benefit TCV introduction in routine immunization as many activities are integrated and routine immunization strengthening component are also embedded in these activities.

3.5.8 Chosen Immunisation Strategy

Please provide an explanation of the chosen immunisation strategy (routine only versus routine and catch-up) and the target age of vaccination; if this information is provided in the NVIP / POA, please cite sections only.

The selected immunization strategy is a catch-up campaign for children 15 months to under 15 years, followed by routine introduction at 15 months. Please see POA, "Rationale and Background for Introduction" section for further details.

3.5.9 Risk-Based or Phasing and Explanation

Will a risk based or phased introduction approach be adopted?

Yes⊠ No□]
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If a risk-based or phased approach will be adopted, please provide an explanation for this approach, if this information is provided in the NVIP / POA, please cite sections only.

A two-phased approach will be adopted for the TCV campaign, covering three provinces in the first phase and four provinces in the second phase. This approach is detailed in the Plan of Action, "Two-phase approach to typhoid conjugate vaccine introduction" section. Both phases of the campaign is expected to be completed within Q1 of 2022.

3.6 Report on Grant Performance Framework

Grant Performance Framework – Application Instructions

The Grant Performance Framework (GPF) contains all indicators that will be used to monitor programmatic performance for your requested type of support. Targets that were entered for number to be vaccinated in section 3 on the Target Information tab, have been carried over into their respective indicators in the GPF. Based on these numbers, coverage and dropout rate targets were calculated (where applicable). These appear as "calculated targets". If you wish to revise these target values, please revise in the application form – they are not editable in the

performance framework. In addition, as a part of your application, there are several items to be filled directly into the GPF. These are broken into required and optional items, below:

Required

- 1. In addition to the calculated targets, country targets are required to be submitted for outcome indicators. These targets should align to those in your cMYP or NHSP. If these targets are not in your cMYP or NHSP, or are the same as the calculated targets, please enter "NA" for each target value.
- 2. Additional indicators that appear in the Performance Framework that are not included in the application form. Please enter targets for these indicators.
- 3. For many indicators, reporting dates have been pre-populated. For those that have not yet been pre-populated, please add reporting dates.

Optional

- 1. Adding data sources to existing indicators: If there are data sources for indicators that you would like to include, you may add an additional source by clicking on the pencil icon next to the indicator name.
- 2. Adding new indicators: Gavi requires all countries to report on core indicators, which are already included in the GPF. If you wish to add supplemental indicators to monitor performance, you may do so by clicking the "Add indicator" button at the respective performance level (Outcome, Intermediate Result, or Process).

Please note that the GPF is filtered by default to only show indicators that are relevant to the specific types of support contained in the application. You may view the entire GPF by using the "Grant Status" filter. Please ensure your pop-up blocker is disabled when launching the GPF.

If you have any questions, please send an email to countryportal@gavi.org.

3.7 Upload new application documents

3.7.1 Upload new application documents

Below is the list of **application specific documents** that must be provided with your application.

In the case a document cannot be provided, please use the comment box to explain why, or by when it will be available.

Application documents



New vaccine introduction plan (NVIP) and/or campaign plan of action (PoA), including checklist & activity list and timeline

NepalTCV POANVIPFINALSep 2020FINAL_18-09-20_20.31.13.docx

If support for a campaign and routine introduction is requested at the same time, the new vaccine introduction plan and campaign plan of action can be combined into one document to minimise duplication.

Most recent assessment of burden of relevant disease

No file uploaded

If not already included in detail in the Introduction Plan or Plan of Action.

- Gavi budgeting and planning template
- 2. TCV RI intro 2022 proposed budgetall levelsNepalFINAL10 September 2020 16-09-20 16.56.49.xlsx
- 1. TCV campaign 2022 proposed budgetall levelsNepalFINAL10 September 2020 16-09-20 16.56.14.xlsx

Budgeting and Planning
TemplateTCVNepalFINAL_16-0920_16.54.00.xlsm

Sources and justification of campaign target population estimates (if applicable)

No file uploaded

Endorsement by coordination and advisory groups



National coordination forum meeting minutes, with endorsement of application, and including signatures

ICC mtg minute11 September 2020NepalFINAL_14-09-20_15.53.48.pdf



NITAG meeting minutes

with specific recommendations on the NVS introduction or campaign

NIAC mtg minute14 Aug 2020FinalNepal_16-09-20_16.47.38.pdf

Other documents

Other documents (optional) No file uploaded

4 Review and submit application

4.1 Submission Details

Country vaccine funding summary

Please review the estimated projections for new vaccine programmes included in this application.

Active Vaccine Programmes

Note 11

IPV Routine

	2020	2021	2022
Country Co-			
financing (US\$)			
Gavi support (US\$)	1,421,111	1,448,767	1,446,637

Measles SD Routine - Strat 1

	2020	2021	2022
Country Co-	318,639		
financing (US\$)			
Gavi support	296,308		
(US\$)			

PCV Routine

	2020	2021	2022	2023	2024
Country Co- financing (US\$)	764,766	774,962	356,182	353,781	618,762
Gavi support (US\$)	11,549,706	11,727,748	4,649,551	4,618,211	4,353,229

Pentavalent Routine

	2020	2021	2022	2023	2024
Country Co- financing (US\$)	885,653	894,727	404,314	401,589	176,498
Gavi support (US\$)	2,362,570	2,385,639	1,115,972	1,108,450	1,333,540

Rota Routine

	2020	2021	2022	2023	2024
Country Co- financing (US\$)	301,500	247,766	249,480	216,249	308,612
Gavi support (US\$)	3,192,777	2,623,748	2,641,908	2,290,004	2,183,866

Total Active Vaccine Programmes

	2020	2021	2022	2023	2024
Total country co-financing (US\$)	2,270,558	1,917,455	1,009,976	971,619	1,103,872
Total Gavi support (US\$)	18,822,472	18,185,902	9,854,068	8,016,665	7,870,635
Total value (US\$) (Gavi + Country co-financing)	21,093,030	20,103,357	10,864,044	8,988,284	8,974,507

New Vaccine Programme Support Requested

Typhoid conjugate vaccine routine, with catch-up campaign

	2022	2023	2024	2025
Country Co-				
financing (US\$)				
Gavi support (US\$)	13,348,500			

Total country co-		
financing (US\$)		

Total Gavi	
support (US\$)	
Total value (US\$)	
(Gavi + Country	
co-financing)	

Total Portfolio Overview – Existing Programs + New Vaccine Support Requested (US\$)

	2020	2021	2022	2023	2024
Total country co-financing (US\$)	4,150,558	2,983,955	1,009,976	971,619	1,103,872
Total Gavi support (US\$)	38,214,972	26,987,402	23,202,568	8,016,665	7,870,635
Total value (US\$) (Gavi + Country co-financing)	42,365,530	29,971,357	24,212,544	8,988,284	8,974,507

Contacts

Person(s) who should be contacted in case Gavi needs to ask for more information in regard to the application.

Name	Position	Phone Number	Email	Organisation
Dr. Rahul Pradhan	Immunization	+977 9801246690	pradhanr@who.int	WHO, Nepal
	Cluster Lead,			
	National			
	Professional Office	r		
Dr. Jhalak S.	Chief, Child Health	+977 9851195553	jgautamdr@gmail.com	Family Welfare
Gautam	and Immunization			Division
	Services			

Comments

Please let us know if you have any comments about this application

No Response

Government signature form

The Government of Nepal would like to expand the existing partnership with Gavi for the improvement of the immunisation programme of the country, and specifically hereby requests Gavi support for:

Typhoid conjugate vaccine routine, with catch-up campaign

The Government of Nepal commits itself to developing national immunisation services on a sustainable basis in accordance with the national health and immunisation strategic plans. The Government requests that Gavi and its partners contribute financial and technical assistance to support immunisation of children as outlined in this application.

The co-financing commitments in this application include the amount of support in either supplies or cash that is requested from Gavi, and the financial commitment of the Government for the procurement of this new vaccine.

Please note that Gavi will not review this application without the signatures of both the Minister of Health and Minister of Finance (and Minister of Education, if applicable) or their delegated authority.

We, the undersigned, affirm that the objectives and activities in this request are fully aligned with the national health and immunisation strategic plans (or equivalent), and that funds for implementing all activities, including domestic funds and any needed vaccine co-financing will be included in the annual budget of the Ministry of Health.

We, the undersigned, further affirm that the requested funding for salaries, salary topups/allowances, per diems and incentives does not duplicate funding from other sources (e.g. from other donors).

We, the undersigned, further affirm that the terms and conditions of the Partnership Framework Agreement between Gavi and the Country remain in full effect and shall apply to any and all Gavi support made pursuant to this application.¹

Minister of Health (or delegated authority)	Minister of Finance (or delegated authority)
Name	Name
Date	Date
Signature	Signature
For countries requesting HPV support, with a seminister of Education (or delegated authority) is	
Minister of Education (or delegated authority)	
Name	
Date	
Signature	

¹ In the event the Country has not yet executed a Partnership Framework Agreement, the terms and conditions of this application shall apply to any and all Gavi support made pursuant to this application.

Appendix

NOTE 1

The new cMYP must be uploaded in the country document section.

NOTE 2

The purpose of these estimates is to provide visibility into the current and future vaccine funding requirements. The values reflected here are a combination of actuals and estimates. Specifically, current year values reflect values approved by the secretariat, while future values are based on data provided by the country – when data isn't available we rely on extrapolations to estimate funding needs. Please note that any future values might be subject to change, and for the official obligations a country should refer to its active Decision Letter.

NOTE 3

- * For more information on the vaccine presentations available, please refer to the detailed product profiles available here: http://www.gavi.org/library/gavi-documents/supply-procurement/detailed-product-profiles/
- * Please note Gavi may not be in a position to accommodate all countries first product preferences. In such cases, Gavi will contact the country and partners to explore options.
- * Due to a variety of factors, the launch date may vary compared to the date stipulated in the application. Gavi will work closely with countries and their partners to address these issues.
- * For routine vaccine introduction, support is usually requested until the end of the country's valid cMYP, as per the guidelines and may be extended in the future. If you wish to request Gavi support for a shorter time period than the end of your cMYP you may do so.
- * For campaigns the "support requested until" field will normally be one calendar year from the launch date, but can be extended for a phased campaign.

NOTE 4

- * The population in the target age cohort represents 100% of people in the specified age range in your country.
- * The target population to be vaccinated is the number of people in the cohort that are expected to be vaccinated.
- * For indicative wastage rates, please refer to the detailed product profiles available here: http://www.gavi.org/about/market-shaping/detailed-product-profiles/
- * The wastage rate applies to first and last dose.

NOTE 5

- * The target population to be vaccinated is the number of people in the cohort that are expected to be vaccinated.
- * For indicative wastage rates, please refer to the detailed product profiles available here: http://www.gavi.org/library/gavi-documents/supply-procurement/detailed-product-profiles/

NOTE 6

Co-financing requirements are specified in the guidelines.

NOTE 7

Note: The population in the target age cohort used here is the number you entered for year one in the target information section.

NOTE 8

https://www.gavi.org/support/process/apply/additional-guidance/#leadership

NOTE 9

A list of potential technical assistance activities in each programmatic area is available here: http://www.gavi.org/support/pef/targeted-country-assistance/

NOTE 10

E.g. if two introductions are planned in the same year, there should be synergies at least in training and social mobilisation events.

NOTE 11

The purpose of these estimates is to provide visibility into the current and future vaccine funding requirements. The values reflected here are a combination of actuals and estimates. Specifically, current year values reflect values approved by the secretariat, while future values are based on data provided by the country – when data isn't available we rely on extrapolations to estimate funding needs. Please note that any future values might be subject to change, and for the official obligations a country should refer to its active Decision Letter.