

Application Form for Country Proposals

Providing support for fIPV Switch

Submitted by

The Government of Uganda

Date of submission: 29th October 2020

This form is applicable to applications submitted in 2020

Document date: 24th November 2020

This document replaces all previous versions and incorporates revisions to the cover page only.

The completed application documents must be submitted electronically through the GAVI Country Portal at https://www.gavi.org/our-support/country-portal by the application deadline.

Enquiries to: proposals@gavialliance.org or <u>countryportal@gavi.org</u>. The documents can be shared with GAVI partners, collaborators and general public. The application and attachments must be submitted in English, French, Spanish, or Russian.

Note: Please ensure that the application has been received by the GAVI Secretariat on or before the day of the deadline.

For any questions regarding the portal please contact <u>countryportal@gavi.org</u> or the Gavi Senior Country Manager.

https://www.gavi.org/sites/default/files/document/guidelines-on-reporting-and-renewal-of-gavisupportpdf.pdf

Proposal must be submitted through the portal by selecting:

- Gavi Renewal Request
- "Switch" fIPV
- Add details about request for Tropis Needle-Free Injection System
- Upload Proposal and supporting documentation

The GAVI Secretariat is unable to return submitted documents and attachments to countries. Unless otherwise specified, documents will be shared with the GAVI Alliance partners and the general public.

Contents

Application Form for Country Proposals1	•
Application specification	,
Executive Summary4	ŀ
IPV introduction plan4	ŀ
Program performance5)
Polio Coverages over the years)
Polio coverage over the years5)
Unimmunized for Polio 3 over the years6	,
IPV Coverage over the year by district6	,
Unimmunized for IPV over the years7	,
AFP Surveillance7	,
Justification for the introduction of fIPV in Uganda Programs	1
The key benefits assessed are as follows:	1
Current Immunization Schedule:	
Objective13	,
Specific Objectives	,
IMPLEMENTATION PLAN	,
Planning:13	,
Sensitization:14	ŀ
Training:14	ŀ
Social mobilization:14	ŀ
Vaccine and related supplies quantification and cold chain:14	ŀ
fIPV roll-out plan and requested support:16	,
fIPV roll-out plan and requested support Comparison Table	,
Financial Value proposition17	,
Timelines18	
Budget and financing	,
Budget summary18	,
Signatures19	1
References:	1
Attachments required	•

Application specification

A list of required attachments is included at the end of this form.

Summary

The Government of: Uganda		Date of Submission: 29 th October 2020								
fIPV introduction date 2021 (Me	onthto	fIPV Rou	fIPV Routine Immunization schedule: 6 weeks & 14 weeks							
be determined later)										
Co-financing: No		If co-fina	If co-financing, please specify amount (\$) per dose: N/A							
Procurement mean (UNICEF SD	, PAHO, s	elf-procur	ement): UNICEF SD							
Vaccine preference	Reason	for choice	of presentation	Expected wastage rate*						
(in order of first to third)										
1. 10-dose stand-alone IPV			lose vial has better	5%						
	•	ions on ble wastag								
2. 5-dose stand-alone IPV			ose vial has better	10%						
	•	ions on ble wastag	Cold capacity and ge rate							
	I									
Device preference: needle-free	injection	system, T	ropis by PharmaJet							
PharmaJet Tropis Injectors										
PharmaJet Tropis Syringes			1. 10% Wastage							
PharmaJet Tropis Filling Adapte	rs		2. 10% wastage							

Executive Summary

The introduction of a second dose of Inactivated Polio Vaccine (IPV2) is recommended as the next step towards complete Oral Polio Vacine (OPV) withdrawal, while providing a higher protection against ciculating Vaccine Derived Polio Virus (cVDPV) type 2 which are currently circulating in the Republic of South Sudan and the Demographic Republic of Congo represent a risk in Uganda and the rest of the workd.

As the Government of Uganda already has vaccine allocated, we are requesting device support to switch from from full IPV dose to fIPV using the needle-free Tropis device. Switching from Full dose IM injection to fractional dose will save the country money through reduced supply chain and sharps disposal costs without compromising on the efficacy and coverage. This move will also may betterour chances of 100% coverage through the novel benefits of needle free administration. The Pharmajet Tropis device is easy to use, and is also easy to train thus limited programatic effort will be needed to roll out. The technology is inline with the country's effort to use more baby friendly technology, lower cost of vaccinaton and improve the patient experience as we drive towards erradication of polio in Uganda. Uganda opted for an early protection IPV schedule starting with first dose of fIPV at 6 weeks of age and second dose at 14 weeks of age. This will not increase any cost or visits to the clinic by mothers as it will be accommodated within the current routine vaccinition schedule in Uganda at times in the schedule where the highest coverage is achieved.

Introduction of fIPV has financial implications. The vaccine and devices in addition to a portion of the process of fIPV introduction in Uganda will be financed by GAVI. The requested switch grant for introduction of fIPV (attached budget sheet) takes into account National and district activities that will include Coordination meetings, Training, vaccine delivery system, support supervision and monitoring. GAVI policy decision is to provide 100% financing for the vaccine and devices through 2025 thus the country has made a 5 year plan starting January 2021.

IPV introduction plan

Under the current Polio Endgame Strategy 2019-2023, oral polio vaccine (OPV) withdrawal remains one of the goals necessary for complete eradication of all polioviruses of all viruses, wild as well as vaccine derived polioviruses.

To achieve this, in 2013 WHO recommended countries to introduce at least one dose of Inactivated Polio Vaccine (IPV) in their routine immunization schedule to provide an immunity base against paralysis caused by circulating vaccine derived polio virus 2(cVDPV2) and boost immunity against poliovirus types 1 and 3. Uganda achieved this milestone by end of April 2016 following a successful switch from tOPV to bOPV.

The program has been notified on the application for the introduction of a second dose of IPV (IPV2) into routine immunization as the next step towards complete OPV withdrawal and achieving higher protection against cVDPV2.

Following a consultation with ICC and NITAG on the global Polio eradication initiative, the program plans to introduce a second doses of IPV (IPV2) into routine immunization through administration of fIPV at 6 weeks and 14 weeks for all surviving infants (**2,121,964 children**).

The two IPV doses will be provided through fractional intra-dermal IPV injection of 0.1ml as opposed to

the full dose of 0.5mls.

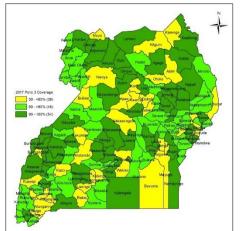
Program performance

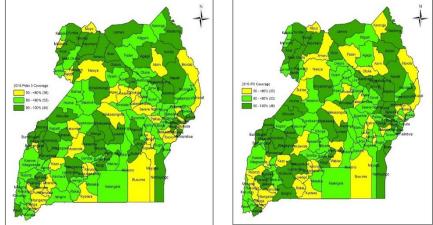
Polio activities in Uganda are conducted through Routine immunization, Supplementary Immunization Activities (SIAs) and Surveillance. Despite certification of WHO African region to be free from the Wild Polio Virus, Uganda is still at risk of circulation of the vaccine Derived Polio Viruses in Africa. Due to the remaining challenges of low population immunity, sub optional AFP surveillance system and porous borders, the country stands the risk of reversing the gains if efforts are not made to intervene the recommended second dose of IPV (IPV2) now. Also, Uganda joins the rest of the world in the efforts to eradicate all polio viruses through the gradual withdrawal of oral polio vaccine from routine immunization.

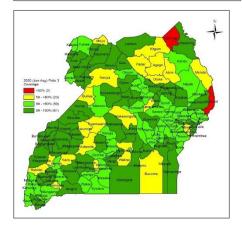
Polio Coverages over the years

The figures below show the subnational trends of Polio 3 coverage. The national average is 95% however it is desirable to all district coverage over 80%. Between 2017 and 2019, we had about 35 districts with coverage below 80%. In 2019, we had 48 districts (35%) with coverage over 90%. Due to the interruption of Covid pandemic, 2020 was affected with a drop in services especially between April and May 2020. However after May 2020, recovery plans were put in place and guidelines sent to the districts to improve Immunisation performance and conduct catch-up activities through the Integrated Child Health Days (ICHDs)

Polio coverage over the years







The figure shows performance for 2020, Jan – August annualized. The district performance shows improved overall coverage with 61 districts with over 90% coverage as compared to 48 districts in 2019.

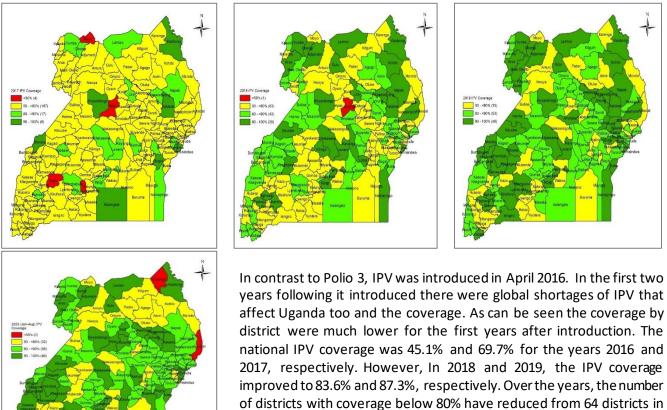
The national level coverage was 91.6% and 88.5% for 2019 and 2020, respectively.

Two districts, Karenga and Amudat had very low coverage of below 50%.

Unimmunized for Polio 3 over the years

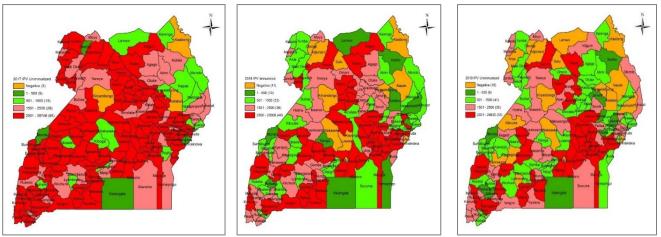
For the past years, the number of unimmunized have reduced but at a slow rate. In 2019, we had 19 districts with over 2,500 children unimmunized. The largest number of the unimmunized are from Wakiso district (24,000 children) that has large population but also charaterized with urban issues.





2018 to 35 districts in 2019. Despite the challenges of Covid 19 in 2020, IPV coverage is at 87% by August 2020. The two districts (Amudat and Karenga) have coverage below 50% as observed earlier for Polio 3.

Unimmunized for IPV over the years



The districts with the high number of unimmunized children for IPV have consistently reduced following its introduction in 2015. As seen in the figures above, 48 districts had over 2,500 children unimmunized in 2018 but this number reduced to 33 districts in 2019. As seen in the other vaccines, Wakiso district having the highest population (2,900,000) in Uganda has the highest number of unimmunized children (24,000).

Indicators	Target	2016	2017	2018	2019	2020
NP-AFP rate per 100,000 < 15 Yrs (actual)	>=2.0	3.71	3.05	3.54	2.87	1.61
Stool adequacy	>=80%	89	87	93	90%	94%
Investigated < 2 days of notification	>=80%	99	98	100	100%	100%
Specimen arriving at lab < 3 days since collection	>=80%	96	95	97	95%	77%
Specimen arriving in good condition	>=90%	99	100	100	100%	100%
Non-polio enterovirus isolation rate	>=10%	9	12	12	15%	13%
Total number of districts in the country		112	116	122	128	135
Proportion of districts with a population of under 15 years < 100,000	%	33	27	30	30	28
Proportion of districts with a non polio AFP rate > = 1 / 100,000	80	99	96	75	91	82
Proportion of districts with a non polio AFP rate > = 2/ 100,000	80	81	70	37	67	42

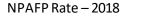
AFP Surveillance

Indicators	Target	2016	2017	2018	2019	2020
Proportion of districts with a surveillance index >= 1.5	80	67	73	64	71	47
Proportion of districts with a stool adequacy rate > = 80%	80	67	65	67	77	72
Proportion of districts with non-polio AFP cases aged 6 – 59 months with > = 3 doses of OPV	80	76	48	65	67	64

Nationwide AFP (acute flaccid paralysis) surveillance is the gold standard for detecting cases of poliomyelitis. The desirable steps of surveillance include; finding and reporting children with acute flaccid paralysis (AFP), transporting stool samples for analysis, isolating and identifying poliovirus in the laboratory, mapping the virus to determine the origin of the virus strain.

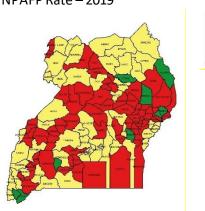
Uganda has a well-structured AFP surveillance system implemented through the Integrated Disease Surveillance and Response (IDSR) approach. The surveillance system is established from national level to district and at each of the health facilities in the district. At each of these levels a surveillance focal point is responsible for AFP surveillance function. The AFP surveillance structure has helped the country in particular at the subnational level to timely detect and respond to any outbreaks including WPV outbreaks. Each district is expected to detect and report at least two cases of AFP in a year per 100,000 population under 15 years. The table above shows the performance for Non-polio AFP rate over the year and 2020 had the lowest at 1.61 as compared to the previous year. The stool adequacy rate is >90%. All the samples notified are investigated within 2 days (100%).

Sub national performance of the AFP Indicators (NPAFP Rate)

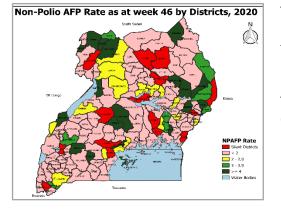


NPAFP Rate – 2019





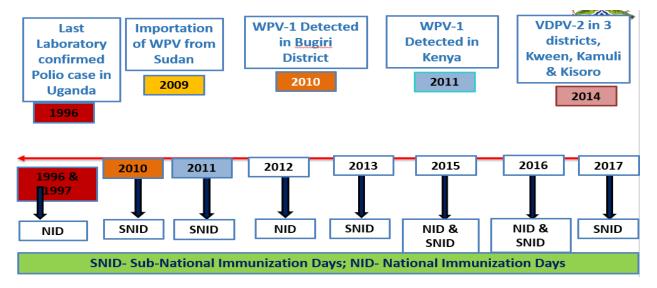
< 0.5 0.5 - 1 1.1 - 1.99 =>2



NPAFP Rate - 2020 (As at Week 46)

The district performance for AFP surveillance in 2020 indicate a reduction in Non-polio AFP rate to 1.61 below the desired minimum of 2 cases per 100,000 children below 15 years by week 46 (November). By November 2020, only 42 districts (31%) had NPAFP rate of atleast 2. The drop in active service surveillance is attributed to the Covid19 pandemic where most of the surveillance focal persons were fully involved in Covid 19 response activities

Uganda's Outbreak history:



Justification for the introduction of fIPV in Uganda Programs

fIPV, delivered intra-dermally, is antigen-sparing and can be used to extend IPV supplies. When administered in a two-dose schedule it has been demonstrated to be more immunogenic than a single dose of intramuscular IPV, both in terms of seroconversion and antibody titres and shown as equivalent to two doses of IPV under some schedules⁹. Available evidence suggests that fIPV is as effective at boosting mucosal immunity as intramuscular IPV in those who had previously received OPV¹⁰

The key benefits assessed are as follows:

- Intradermal (ID) administration of a fractional dose of IPV (fIPV) is safe, effective and immunogenic.¹
- fIPV can benefit children previously vaccinated for polio AND zero-dose children. For children who have previously received oral polio vaccine (OPV), fIPV will help to "boost" their immunity.¹
- fIPV can be given alone or at the same time as any OPV vaccine. Accelerated routine immunization with two doses of IPV or fIPV has been recommended to reduce the risk of emergence of VDPVs.

This application is opting for an early protection two dose fIPV schedule starting with the first dose at 6 weeks and the second dose at 14 weeks as part of the Polio eradication initiative. In addition, this Switch Grant will be utilized to address the training and changes needed to introduce the second dose of IPV and switch to fractional dose.

The table below presents the current and proposed (new) immunization schedule.

Current Immunization Schedule:

Vaccine Antigen	Dosage	Doses	Min. Interval per dosage	Min. Age at Start	Mode of Administ ration	Site of Administr ation	Storage Temperature	Remarks
BCG	0.05ml up to 11mo, 0.10ml after 11Mo.	1	N/A	At birth(or first contact)	Intra dermal	Rt. Upper arm	+2 to +8	Only use diluent provided
DPT-Hep- Hib	0.5 ml	3	4 weeks	At 6 weeks (or first contact after that age)	IM	Lt thigh upper outer aspect	+2 to +8	Do not freeze
IPV	0.5ml	1	N/A	At 14 weeks after birth	IM	Rt thigh upper outer aspect	+2 to +8	Do not freeze
Measles	0.5ml	1	N/A	At 9 Mo (or first contact after that age)	sc	Lt Upper Arm	+2 to +8	Only use diluent provided
PCV	0.5ml	3	4 weeks	At 6 wks (or first contact after that age)	IM	Rt. Thigh outer upper aspect	+2 to +8	
HPV	0.5ml	2	6 months	At first contact with a10-year-old girl	IM	Left upper Arm	+2 to +8	Do not freeze

Rota	1.5 ml	2	1 months (4 weeks)	At 6 weeks	Orally - slow administr ation on inner Aspect of the check	Mouth	+2 to +8	Do not freeze
Tetanus Toxoid with Diptheria	0.5ml	5	Td1&Td2: One Month Td2&Td3 : Six Months Td3 & Td4: One year Td4 & Td5: One year	At first contact with pregnant woman or Women of Child Bearing Age (15 - 45 yrs)	IM	Upper Arm	+2 to +8	Do not freeze

Uganda is currently providing the IPV single full dose at 14 weeks as demonstrated in the Table above. The plan is to 1) switch from the full dose to the fIPV dose and 2) add the second dose of fIPV into the routine immunization schedule. The second dose will be provided at 6 weeks for all the surviving infants.

	IFVZ
ANTIGEN	AGE
BCG, Polio 0	At Birth
Polio 1, DTP-HepB-Hib1, PCV 1, Rota 1, fIPV1	6 Weeks
Polio 2, DTP-HepB-Hib2, PCV 2, Rota 2	10 weeks
Polio 3, DTP-HepB-Hib3, PCV3, fIPV2	14 weeks
Measles Rubella 1	9 months
TD 1	Women of Childbearing age (At 15 to 49 years)
TD 2	I Month after 1 st dose
TD 3	6 Months after 2nd dose
TD 4	12 Months after 3 rd dose
TD 5	12 Months after 4th dose
HPV 1	Girls at 10 years of age, in and out of school
HPV 2	6 Months after 1 st dose

Routine Immunization schedule after Introduction of IPV2

Objective

To introduce the second of dose of IPV required to achieve 90% individual protection against polio types 1, 2 and 3

Specific Objectives

- 1) Switch from IPV full dose to fIPV
- 2) Introduce the second of dose of IPV into routine immunization
- 3) Strengthen routine immunization and surveillance for Vaccine Preventable Diseases (VPDs).

IMPLEMENTATION PLAN

New vaccines introduction and in specific the switch form full dose to the fractional dose has logistics and programmatic implications that needs system planning, consultation and execution.

Planning:

National level

This will be done at the national level through coordination of partners through the National Coordination Committee (25 members) and its respective subcommittees. Five (5) meetings will be provided (Communication (Airtime) for coordination purposes to be given to the activity holder, Transport refund and refreshments).

The subcommittees are five (5) each with ten (10) members. Five (5) meetings will be provided (Transport refund, refreshments and communication (Airtime) for coordination purposes to be given to the activity holder).

District level

District coordination committees chaired by the CAO will be facilitated to plan for the introduction. One (1) coordination committees meeting will be provided for at district level (15 members—CAO and other DHT members)—Communication (Airtime) for coordination purposes to be given to the ADHO, refreshments.

Sensitization:

Need to involve the professional bodies and key stakeholders to increase awareness and promote easy uptake at community level. This grant will cater for One (1) meeting for members from the following professional bodies; UMA, UPA, UMNC, UHF, Media each with 25 members. Needs: Hall hire, refreshments, Communication (Airtime) for coordination purposes and transport

refund

Training:

National level

This will be a cascaded training starting with one (1) day training at the national level for 150 members (TOT).

Needs: 6 workshops – 30 members per group, 5 Hall hires, refreshments, Per diem for 45 members, transport refund.

Training needs: Facilitator and Driver per diem for 5 days, fuel.

District level

Thereafter, a district level training of the DHT and sub county representatives

Social mobilization:

National level

This will involve development of communication plans involving of materials (Promotional messages through newspapers and TV, social media influencers, boosting of social content, development and printing of IEC Fact sheets)

District Level

The districts will be supported with funds for community mobilization and sensitization by the district leadership as we as one (1) radio talk shows and six (6) radio announcement. Extra airtime will be provided by the office of the RDC

Vaccine and related supplies quantification and cold chain:

The target for introduction is surviving infants estimated at 2,121,964 in 2021. In consideration of the switch from full dose to fIPV, this plan is premised on the current vaccine quantification, existing stock and the forecasted supplies. This therefore is not additional vaccine request but a plan to utilize the existing vaccine using a lower dose in a fractionated vaccine administration.

Consequently, under this switch plan, there is no additional request or significant implication on cold chain requirements since the cold chain is the same, and with foreseeable reduction in the overall annual IPV requirements for Routine Immunization.

The Government of Uganda requests to switch from the currently approved IPV presentation, IPV intramuscular injection of full dose to IPV intradermal injection of fractional dose (fIPV) using the needle-

free injection system, therefore a special device for vaccine delivery able to deliver 0.1ml fractions instead of the current injectable method. The country decided to introduce fIPV using Tropic with the aim of reducing injections in children.

This switch is driven by Uganda's voluntary assessment that the introduction of fIPV using needle-free injection provides the best solution to contribute towards the eradication of polio as reflected in the Global Polio Eradication Initiative.

				2 · · · · · · · · · · · · · · · · · · ·						
Tropis Needle Free Rollout										
		2021		2,022		2023		2024		2025
# Children IPV		-		-		-		-		-
# Children fIPV		1,910,063		1,962,037		2,022,801		2,084,535	*	2,148,947
			_		_				_	
IPV doses for IM		-		-		-		-		-
IPV doses for NF		764,025	·	784,815		809,120		833,814		859,579
IPV doses - Wastage @15%	<u> </u>	114,604		117,722	r	121,368	*	125,072	r	128,937
Tropis Injectors		16,800		-						
Tropis Syringes		3,820,126		3,924,074		4,045,602		4,169,070		4,297,894
Tropis Adapters		246,460	·	253,166		261,007		268,972	·	277,284
Total Product Cost	\$	11,576,227	\$	4,721,572	\$	4,867,799	\$	5,016,360	\$	5,171,365
IPV Freight Cost @5%	\$	111,586	\$	114,622	\$	118,172	\$	121,779	\$	125,541
Total Cost	\$	11,687,813	\$	4,836,195	\$	4,985,971	\$	5,138,138	\$	5,296,907

Five-year Cost estimates for Vaccines and Injection Devices

We estimate that 16,800 devices are sufficient for all immunization sites (~8383) with sufficient coverage to accommodate back-up needs. We have adjusted the request to receive all injectors in 2021. The advices have taken into consideration the mode of delivery of vaccines at static (health facility) and outreach. It is assumed that while we expect immunizing sites to operate daily, outreaches should also be able to provide fIPV with tropis device hence the need for at least 2 devices per immunizing site.

Based on 4 million injections per year and 16,800 devices, it will take 17 years for each device to reach 10,000 injections, thus not requiring replacement during this forecast period.

The introduction will not have additional cold chain capacity implications. Any emerging additional needs will be addressed by the ongoing CCEOP cold chain equipment installation.

Distribution of vaccines and related supplies will ride on the existing routine distribution schedule in the National Medical Stores (NMS).

Tropis Needle Free Rollout										
		2021		2,022		2023		2024		2025
# Children IPV		-		-		-		-		-
# Children fIPV		1,910,063		1,962,037		2,022,801		2,084,535	•	2,148,947
IPV doses for IM	•	-	•	-	•	-	•	-	•	-
IPV doses for NF	•	764,025		784,815	•	809,120	•	833,814	r	859,579
IPV doses - Wastage @15%	•	114,604		117,722	•	121,368	•	125,072	r	128,937
Tropis Injectors		16,800		-						
Tropis Syringes		3,820,126		3,924,074		4,045,602		4,169,070		4,297,894
Tropis Adapters		246,460		253,166		261,007	•	268,972		277,284
Total Product Cost	\$	11,576,227	\$	4,721,572	\$	4,867,799	\$	5,016,360	\$	5,171,365
IPV Freight Cost @5%	\$	111,586	\$	114,622	\$	118,172	\$	121,779	\$	125,541
Total Cost	\$	11,687,813	\$	4,836,195	\$	4,985,971	\$	5,138,138	\$	5,296,907

fIPV roll-out plan and requested support:

The requested support above is a net cost benefit for Gavi, as fIPV with Tropis has been shown to be more cost effective than full dose IM administration as validated by a study completed by PATH/WHO:

fIPV roll-out plan and requested support Comparison Table

IM Full Dose										
		2021		2,022		2023		2024		2025
# Children IPV		2,025,170		2,126,428		2,232,750		2,344,387		2,461,607
# Children fIPV		-		-		-		-		-
IPV doses for IM	•	4,050,340	•	4,252,857	•	4,465,499		4,688,774	•	4,923,213
IPV doses for NF		-		-		-		-		-
IPV doses - Wastage @15%	r	607,551		637,928		669,825	·	703,316	r	738,482
Needle		4,050,340		4,252,857	-	4,465,499		4,688,774		4,923,213
			_							
Total Product Cost	\$	11,993,056	\$	12,592,709	\$	13,222,344	\$	13,883,461	\$	14,577,634
IPV Freight Cost @5%	\$	591,552	\$	621,130	\$	652,186	\$	684,796	\$	719,035
Total Cost	\$	12,584,608	\$	13,213,838	\$	13,874,530	\$	14,568,257	\$	15,296,670

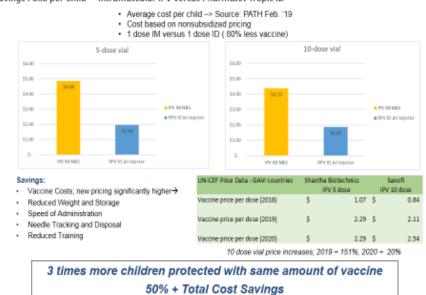
IM Full Dose										
		2021		2,022		2023		2024		2025
# Children IPV		1,910,063		1,962,037		2,022,801		2,084,535		2,148,947
# Children fIPV		-		-		-		-		-
IPV doses for IM	r	3,820,126	,	3,924,074	•	4,045,602	•	4,169,070	•	4,297,894
IPV doses for NF		-		-		-		-		-
IPV doses - Wastage @15%	r	573,019		588,611	•	606,840	•	625,361	r	644,684
Needle		3,820,126		3,924,074		4,045,602		4,169,070		4,297,894
Total Product Cost	\$	11,311,393	\$	11,619,183	\$	11,979,028	\$	12,344,616	\$	12,726,065
IPV Freight Cost @5%	\$	557,929	\$	573,111	\$	590,860	\$	608,893	\$	627,707
Total Cost	\$	11,869,322	\$	12,192,294	\$	12,569,888	\$	12,953,509	\$	13,353,772

fIPV will save nearly 50% of the cost as shown in the above 2 tables, thus ensuring that the children are covered well at a reduced cost.

Financial Value proposition

Financial Value Proposition - Two doses IPV vs 2 dose fIPV

Total Costs Savings Polio per Child – Intramuscular IPV versus PharmaJet Tropis ID



Timelines

ask Name	- Duration	✓ Start	➡ Finish
Governement of Uganda fIPV Implementation	1524 days	Fri 2/28/20	Wed 12/31/25
Proposal - Gavi	143 days	Fri 2/28/20	Tue 9/15/20
Complete Proposal	0 days	Tue 9/15/20	Tue 9/15/20
Program Management and Coordination	42 days	Mon 8/17/20	Tue 10/13/20
Complete Program Management	0 days	Tue 10/13/20	Tue 10/13/20
Planning and preparations	22 days	Mon 9/14/20	Tue 10/13/20
Training and meetings - PharmaJet to support	35 days	Mon 9/14/20	Fri 10/30/20
Complete Training and meetings	0 days	Fri 10/30/20	Fri 10/30/20
Social mobilization, IEC, advocacy	15 days	Mon 9/14/20	Fri 10/2/20
Complete Social mobilization	0 days	Fri 10/2/20	Fri 10/2/20
Reproduction of materials	17 days	Mon 10/12/20	Tue 11/3/20
Complete reproduction of materials	0 days	Tue 11/3/20	Tue 11/3/20
2021 - rollout	303 days	Wed 11/4/20	Fri 12/31/21
2022 - rollout	261 days	Mon 1/3/22	Mon 1/2/23
2023 - rollout	260 days	Tue 1/3/23	Mon 1/1/24
2024 - rollout	262 days	Tue 1/2/24	Wed 1/1/25
2025 - rollout	260 days	Thu 1/2/25	Wed 12/31/25
Surveillance and monitoring	1043 days	Thu 3/19/20	Mon 3/18/24
Complete Surveillance and monitoring	0 days	Mon 3/18/24	Mon 3/18/24

Budget and financing

To introduce the second dose of IPV, Uganda will require **USD 11,687,813** for switch grant as per the implementation plan above; budget attached.

Budget summary

The Government of Uganda is requesting full support from GAVI for fIPV and supplies without any country co-financing. Uganda would need the innovative fIPV delivery system Tropis device Thus, GAVI will pay USD 31,945,023 to cover the fIPV delivery technology, Vaccines and freight of 5%. For the next 5 years

Signatures

Government

The Government of Uganda acknowledges that this vaccine switch introduction is intended to contribute to the eradication of polio as reflected the Global Polio Eradication Initiative's Polio Eradication and Endgame Strategic Plan.

The Government of Uganda therefore requests support from Gavia grant to introduce a second dose of IPV that will be delivered through intradermal inactivated polio vaccine to be administered with the PharmaJet Tropis Needle-Free Injection System.

Minister of Health (or delegated authority)				
Name	Dr. Jane Ruth ACENG			
Date				
Signature				

This application has been compiled by:

Full Name	Position	Telephone	Email
Dr. Henry G.	Director General	+256772221291	Henry.mwebesa@gmail.com
MWEBESA	of Health (DG)		
Dr. Diana ATWINE	Permanent	+256 775324462	Diana.atwine@health.go.ug
	Secretary		

National Coordinating Body - Inter Agency-Coordinating Committee (ICC) for Immunization or equivalent

The ICC, National steering committee met on 30th July, 2020 to review this proposal. By the terms of reference for our committee, we endorsed this proposal at that meeting, based on the supporting documentation attached. The endorsed minutes of this meeting are attached as Attachment 3.

In case the GAVI Secretariat has queries on this submission, please contact:

Enter family name in capital letters.

Name	Dr. Alfred Driwale		Head: Uganda National Expanded Program on Immunization
Tel no	+256772515222	Title	Ministry of Health, Uganda
Fax no	Nil	Address	Ministry of Health, Uganda
Email	Driwalealfred2019@gmail.com		

References:

11th Meeting of SAGE Polio Working Group: conclusions and recommendations. 19–20 January 2015

(<u>http://www.who.int/immunization/sage/meetings/2016/april/1_11th_Meeting_SAGE_Polio</u> _Working_Group_January_2016.pdf).

2. Use of fractional dose IPV in routine immunization programmes: considerations for decisionmaking. March 2017;

(http://www.who.int/immunization/diseases/poliomyelitis/endgame_objective2/inactivated _polio_vaccine/fIPV_considerations_for_decision-making_March2017.pdf?ua=1), accessed 10/04/2017.

- Okayasu, H, SeinC, Chang Blanc D, et al. Intradermal administration of fractional doses of inactivated poliovirus vaccine: a dose-sparing option for polio immunization. J Infect Dis2017; 216:161–7.
- 4. YousafzaiMT, SaleemAF, Mach O, Baig A, Sutter RW, Zaidi AKM. Feasibility of conducting intradermal vaccination campaign with inactivated poliovirus vaccine using Tropis intradermal needle free injection system, Karachi, Pakistan. *Heliyon* 2017; 3:e00395
- SaleemAF, MachO, Yousafzai MT, et al. Needle adapters for intradermal administration of fractional dose of inactivated poliovirus vaccine: evaluation of immunogenicity and programmatic feasibility in Pakistan. *Vaccine*2017; 35:3209–14
- **6.** UNICEF. Inactivated Polio Vaccine: Supply Update. Copenhagen: UNICEF; May 2018. Available from: https://www.unicef.org/supply/files/Inactivated_Polio_Vaccine_Supply_Update.pdf.
- World Health Organization. Meeting of the Strategic Advisory Group of Experts on immunization, April 2018 – conclusions and recommendations. Wkly Epidemiol Rec. No 23, 2018, 93, 329–344. Geneva: WHO; 2018. Available at: http://www.who.int/wer/2018/wer9323/en/.
- XXIV Meeting of the Technical Advisory Group (TAG) on Vaccine-preventable Diseases. 2017 Jul 12-14; Panama City, Panama. Available from: https://www.paho.org/hq/index.php?option=com_docman&view=download&category_slug=ta g-final-reports-1626&alias=42498-24-tag-final-report-2017-498&Itemid=270&lang=en.
- **9.** Anand A, Molodecky NA, Pallansch MA, Sutter RW. Immunogenicity to poliovirus type 2 following two doses of fractional intradermal inactivated poliovirus vaccine: A novel dose sparing immunization schedule. Vaccine. 2017 May 19;35(22):2993–2998.

- Gamage D, Mach O, Palihawadana P, Zhang Y, Weldon WC, Oberste MS, et al. Boosting of Mucosal Immunity After Fractional-Dose Inactivated Poliovirus Vaccine. J Infect Dis. 2018 Nov 5;218(12):1876-1882.
- 7 World Health Organization [Internet]. Fractional dose IPV page. Available from: http://www.who.int/immunization/diseases/poliomyelitis/endgame_objective2/inactivated_pol io_vaccine/fractional_dose/en/.
- 12. 8 Pan American Health Organization, World Health Organization [Internet]. Fractional doses of the inactivated poliovirus vaccine (fIPV) page. Available from: https://www.paho.org/hq/index.php?option=com_content&view=article&id=14058:fractional-doses-of-the-ipv<emid=1707&lang=en.
- **13.** 9 Gamage D, Ginige S, Palihawadana P, et al. National introduction of fractional-dose inactivated polio vaccine in Sri Lanka following the global "switch". WHO South-East Asia J Public Health. September 2018;7(2):79-83.

Attachments required

- Attachment 1. Detailed timeline for key activities of the fIPV introduction plan
- Attachment 2. Completed budget and financing
- Attachment 3. Minutes of ICC meeting endorsing the fIPV introduction plan
- Attachment 4. A copy of the most recent comprehensive multi-year plan (cMYP). The cMYP does not need to include fIPV; however, countries should specify a plan for inclusion of fIPV into their next cMYP, including date for revision.