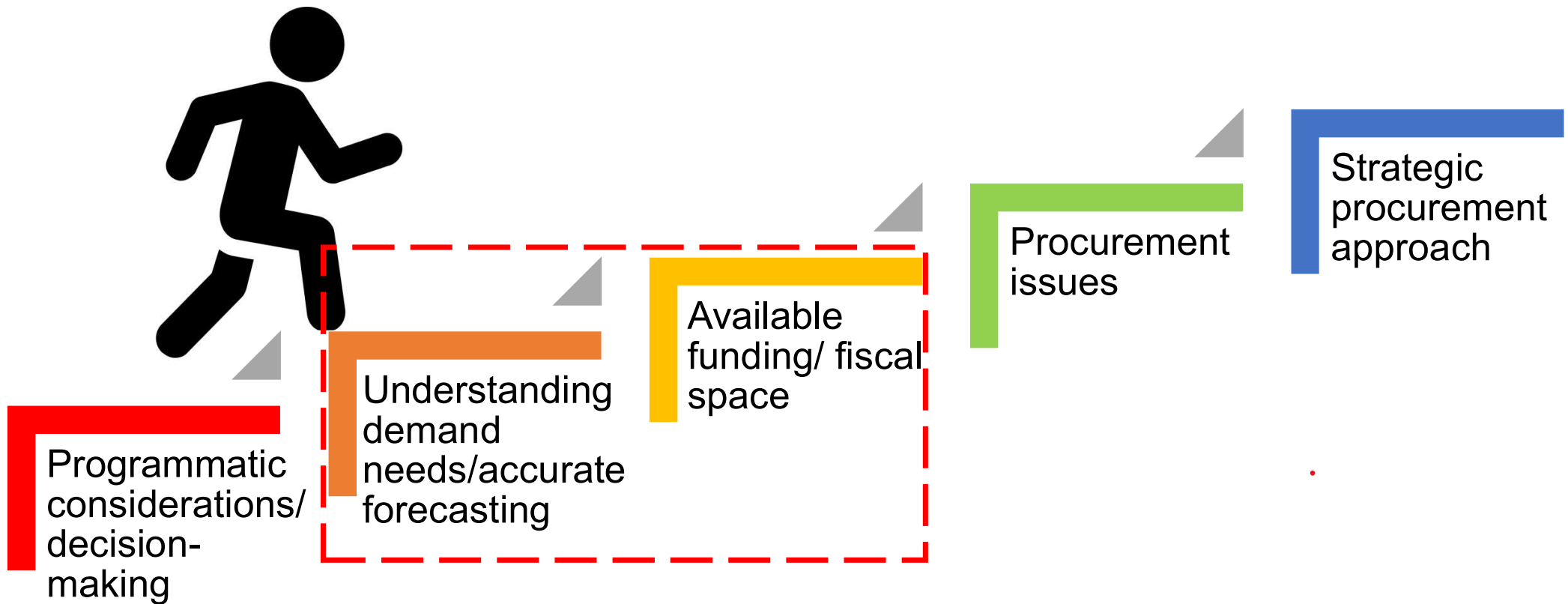


Forecasting, planning & budgeting for new vaccine introductions Ensuring sustainable financing

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Sustainable financing for immunization: how countries can mobilize, allocate, and use adequate and predictable resources in ways that support high-quality delivery of immunization services.

Financing for immunization programs is ideally publicly funded, through pooled financing that is sourced from a mix of domestic and, in LMIC, external resources.

- A country's domestic revenue-raising ability is *not tied to any one program area*
 - is a product of a country's overall macroeconomic and fiscal capacity to raise and allocate revenues
 - Is a product of the prioritization that governments give to the health sector in their resource-allocation decisions
- External resources may be raised specifically for immunization



Sustainable financing for Immunization Agenda 2030 [☆]

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Sustainable financing: Three drivers for immunization financing

Levels of public spending on health

- Ensuring adequate and predictable financing for health and immunization often places pressure on limited public resources
- Most countries' revenues have declined, while spending needs have increased due to COVID-19



- Increase domestic public expenditure on health (economic growth leading to increased overall government revenues)
- Reallocate domestic public expenditure towards health --
- Increase/reallocate external funding

Prioritization of the health and immunization budget

- Governments need to allocate scarce resources across multiple sectors and programs, and immunization provides one of the most cost-effective investments



- Ministries of health, civil society and development partners to advocate the multisectoral benefits that come from investing in immunization

Efficient use of resources within the immunization program

- At the program level, there may be considerable scope to increase cost-efficiencies



- better and more effective procurement
- innovations in service delivery
- vaccine technology and cold chain equipment

Strategic interventions for sustainable financing

The IA2030 agenda spells out four important focus areas needed for sustainable financing:

Ensuring sufficient, predictable resources to procure and deliver recommended vaccines universally

- (1) increase spending on health and increase prioritization on PHC → strategies will tend to differ by income group
- (2) Link strategic plans for immunization to national health plans and the medium-term planning process
- (3) Better alignment of external assistance with country needs

Making optimal use of those resources

- (1) Promote incremental reforms to public financial management.
- (2) Align with new budget formulations and structures that are evolving in most countries.
- (3) Strengthen capacity in forecasting, budgeting and procurement to increase procurement efficiency, accuracy, and prevent interruption of vaccine supply
- (4) Integrate immunization programs with other PHC services and priority programs.
- (5) Use of financing, either through strategic purchasing reforms or performance-based financing, can incentivize coverage increases and quality

Aligning partnerships

- (1) Donors can improve alignment for greater aid effectiveness
- (2) Countries can identify opportunities to engage the private sector

Supporting sustainable transitions from external assistance

- (1) Prepare early for transition with appropriate plans.
- (2) Link transition planning with medium-term health sector planning.
- (3) Donor flexibilities may be needed to smooth the transition to self-reliance
- (4) Government leadership is essential for a successful transition

Procurement costs

$P \times q$ = Total vaccine procurement costs

P = Price per dose, including freight expenditures

q = Number of doses supplied

Number of doses for the first year:

$$q = i \times b \times d \times \frac{1}{(1-w)} \times (1+r)$$

i = predicted vaccination coverage

b = number of girls in target cohort/cohorts

d = number of vaccine doses per girl

w = wastage rate (%)

r = reserve/buffer stock (%)

Delivery costs

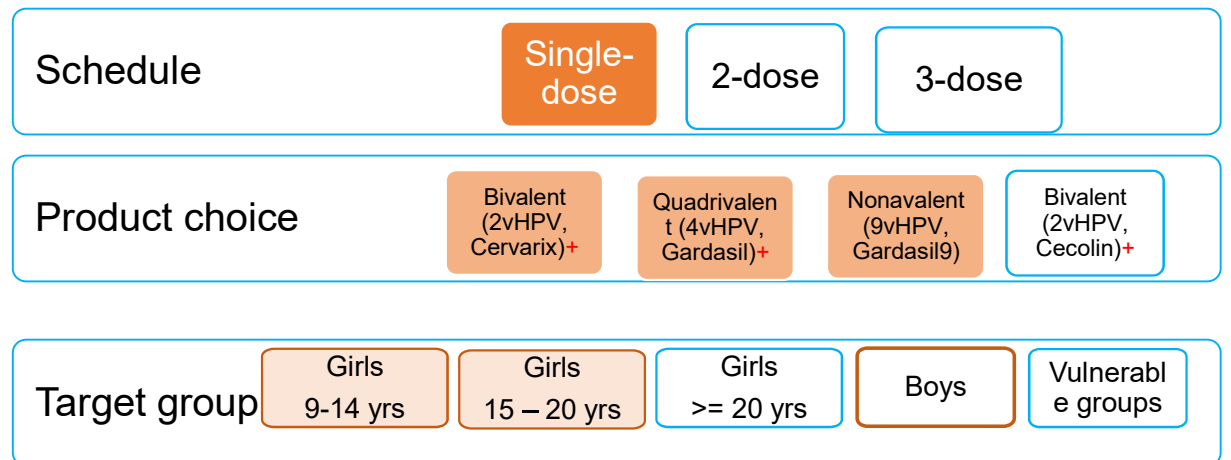
1. Human resources for vaccine delivery
2. Per diem and travel allowances
3. Cold chain equipment
4. Vehicles, transport and fuel
5. Program management
6. Training and capacity building
7. Social mobilization and advocacy
8. Waste management of used syringes
9. Buildings, utilities, and other shared costs
10. Vaccine preventable disease surveillance
11. Monitoring of adverse events following immunization

Planning and budgeting for different policy options

Vaccination schedule by age	Number of doses previous WHO position (2017)	Current WHO Position (2022)
Primary target group	Girls aged 9-14yrs	Girls aged 9-14yrs
9-14 years	2 doses	Either 1* or 2 doses
15-20 years	3 doses	Either 1* or 2 doses
>=20 years	3 doses	2 doses*
Immuno-compromised – any age	3 doses	Should be prioritized and receive at least 2 doses*, but ideally 3 doses if programmatically feasible

*off-label recommendations for girls and boys

HPV Vaccine Technical Support Partners, June 2023



+Gavi detailed product profiles

Financial considerations for HPV introduction

	Introduce 1-dose	Switch to 1-dose	Introduce or stay with 2-dose
Decision-making: <ul style="list-style-type: none"> costs and cost-effective analysis; competing priorities Timeline Fiscal space 	Lack of knowledge about risk of diseases and importance of public health problem	Managing public perceptions, and political decisions Reaching more cohorts of girls with single dose will prevent more cases of cervical cancer than vaccinating fewer girls with a second dose	Evidence on the persistence of protection and long-term follow
Financing options <ul style="list-style-type: none"> Gavi eligible Self-financing Other 	Easier to budget for and justify	Gavi-eligible: 9-valent not in schedule	Higher budget needed
Procurement <ul style="list-style-type: none"> Availability of supply Prices per dose 	3 products to choose from, can introduce more than one type of product? Can plan for larger volumes	Requires a switch of product 9-valent can be used to continue or complete the vaccine schedule	Higher cost per person
Delivery costs <ul style="list-style-type: none"> Facility-based, School-based, Outreach, Mixed Implementation: Phased 	Easier delivery through multiple platforms	May not require major planning changes, and efficiency savings from switch Scale-up through different platforms	Delivering two regimens to target population, not typically part of RI

HPV Introduction	Kenya	Kosovo	Ghana
Year of introduction	2019	2023	No decision yet
Target age group	Girls 9-14		
Schedule	2 doses (6 month)	1 dose	
Delivery strategy	Facility-based		
Catch up of multiple cohorts	Yes, in 2020: 9-14 year-olds		
Financing	Gavi-Accelerated transition	Never Gavi, but now benefitting from Gavi MICs approach	

1. What are your challenges for ensuring sustainable financing of HPV?
2. What is the budgeting process for vaccine procurement and delivery?
3. What interventions are needed or can be explored to address financing challenges?



KENYA NATIONAL VACCINE & IMMUNIZATION PROGRAM (NVIP)



NVIP Mission and Vision



Vision

A Nation free from vaccine preventable diseases.

Mission

To provide appropriate, accessible, affordable and equitable quality immunization services to the people of Kenya.

Mandate

To coordinate vaccination services for all vaccine preventable diseases through provision of policy and guidelines, selected priority vaccines and related biologicals (sera, Immunoglobulins)



NVIP –Who are we?



- NVIP is a unit within the MOH mandated to provide childhood **quality** vaccines to every Kenyan child across the country
- Ensuring consistent product availability is key to the success of the program
- 15 antigens currently offered routinely; BCG, OPV, DTP-HEPB-HIB combination, IPV,PCV, Rota, MR, Yellow fever and Tetanus for pregnant women, HPV and Malaria.
- The program also periodically procures some of these antigens for mass campaigns and outbreak response e.g. Covid-19
- Procurement of syringes and cold chain equipment



Kenya Immunization schedule



Vaccinate to Protect.

Vaccine	Ages of administration	Entire country	Parts of the country
BCG	At birth	✓	
OPV	At birth, 6wks, 10wks, 14wks	✓	
DPT-HepB-Hib	6wks, 10wks, 14wks	✓	
IPV	14 wks	✓	
Measles Rubella 1	9 months	✓	
Measles Rubella 2	18 Months	✓	
Yellow fever	9 months		4 counties
PCV 10	6wks, 10wks, 14wks	✓	
Rota	6wks, 10wks	✓	
HPV	10 year old girls	✓	

* HPV for girls aged 10-14. Other Non EPI Vaccines offered: Yellow fever for travellers, Typhoid Vaccine, Hepatitis B, Anti-snake Venom, Anti-rabies



Key areas of focus National Vaccines and Immunization Program



- Increase and sustain high coverage and equitable utilization of vaccines
- Reduce the number of zero-dose children
- Ensure uninterrupted last mile availability of high quality, safe and effective vaccines
- Effective and efficient integrated immunization service delivery mechanisms
- Introduce new vaccines to tackle and reduce morbidity and mortality
- Create a robust data culture with improved data quality, reporting and utilization of data
- Achieve and sustain Polio Eradication in the country
- Attain control and elimination status of targeted and emerging VPDs & monitor impact of vaccines



Operations of Immunization Systems



1. Vaccine Supply, Quality, Logistics and Tax Exemption
2. Service Delivery and Capacity Building
3. Vaccine Preventable Disease Surveillance
4. Monitoring, Evaluation and Reporting
5. Advocacy, Communication and Community Mobilization



Organisation of Immunization Program Delivery System in Kenya



- **Administrative**
 - 47 Counties Gov. and 1 National Government
 - Population Projection 2023: 53 Million
- **Target Population**
 - Under 1yr: 1.5 Million
 - Under 5 Years: 7.3 Million
 - Adult and Children 12-18 years: 34.9 Million (COVID-19 Vaccine)
 - Girls 10 years: 700,000 (HPV)
- **Vaccine Infrastructure**
 - Cold chain linkages: 1 CVS, 9RVS, 304 SCVS
 - Immunizing Facilities - 8,500 out of 10,000 HFs
- **Health Facility, Community & Environmental Surveillance for Public Health events**



Responsibilities of national and county governments in immunization supply chain management



• **National roles and responsibilities**

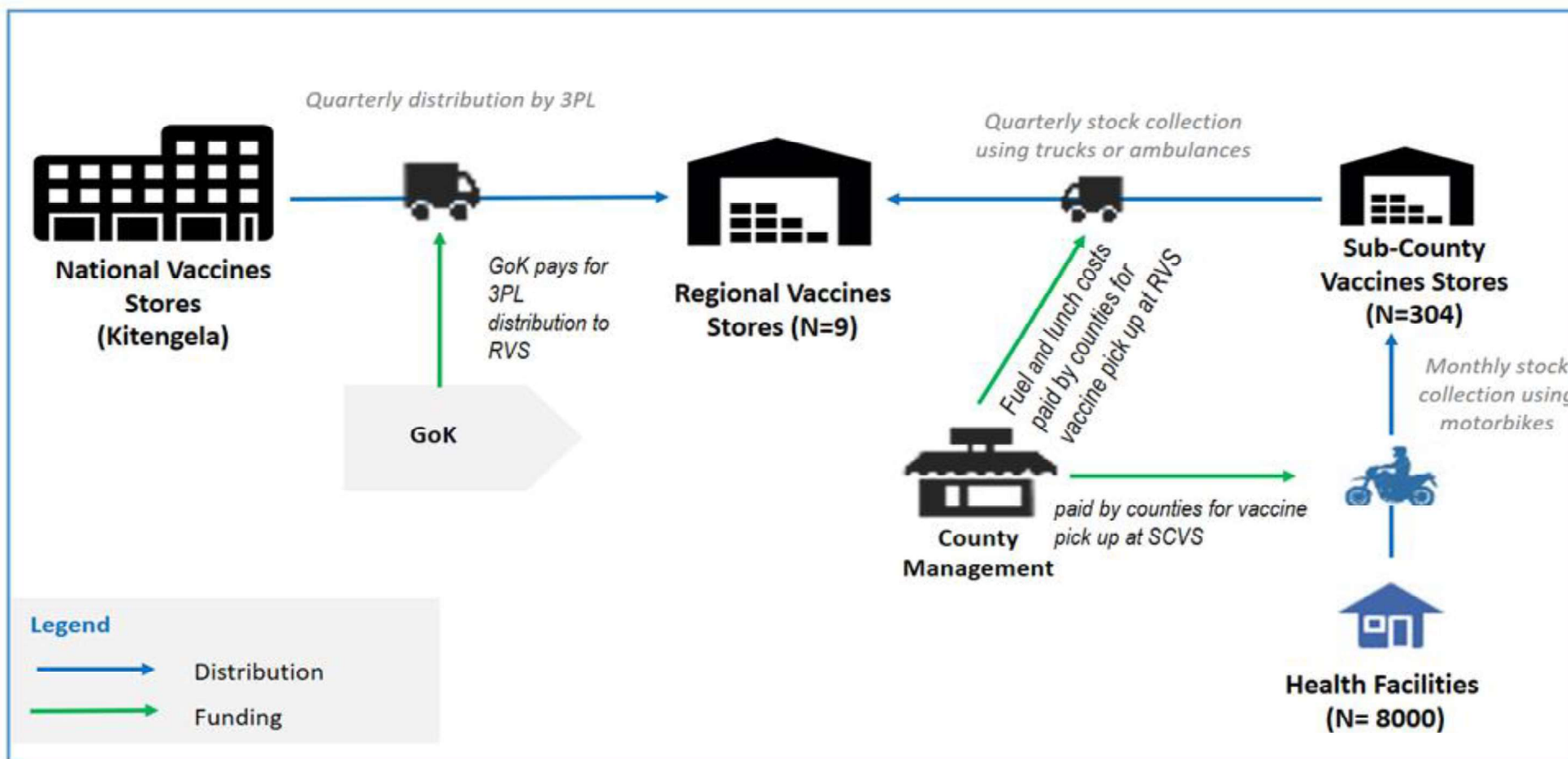
- Overall policy and technical capacity building
- Procurement of vaccines
- Maintaining and operating national and regional stores
- Resource mobilization and partnerships
- Disease surveillance and monitoring- Shared responsibility

• **County roles and responsibilities**

- Procurement of injection devices
- Maintaining and operating sub county and facility stores
- Procurement and maintenance of cold chain Equipment
- Immunization services in all facilities
- Human resource management
- Reporting on service delivery
- Disease surveillance and monitoring – Shared responsibility



Vaccine flow through a four-tier system





Vaccine Supply and Logistics Management levels and activities





Tax Exemption Process for Vaccines



- Head, NVIP makes formal requests for Exemption from Import & Excise Duties, VAT, IDF and RDL to the PS for vaccines and other supplies either donated or on grant agreement arrangement
- These requests are processed by Head, Tax Exemption Unit.
- Head, Tax Exemption goes through the Masterlist generated for the grant agreement and writes a letter to the National Treasury or KRA depending on whether goods or services.
- Process from MoH, NT and finally KRA takes one week.



Enablers of efficient vaccine supply operations



- Adequate and timely financing
- Good data management at all levels
- eLMIS (Chanjo®) provides good data visibility, which triggers action
- Adequate and well trained staff that will manage supplies throughout the chain
- Good transportation systems
- Great linkages and communication systems



Background on Kenya EPI



<p>1978 Alma Ata Declaration by World Health Assembly</p>	<p>1980 KEPI established to target 6 childhood killer diseases</p>	<p>2006 MOH consolidated all vaccination services under one roof – DVI</p>
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New Vaccine Introductions						
2002 Penta-valent	2011 PCV 10	2013 Measles 2 nd dose	2014 Rota-virus	2015 IPV	2019 HPV (girls 10 yrs)	2023 Malaria (select counties)
<p style="text-align: center;">2016 Switched from Measles-only to Measles-Rubella</p>						

1980 - present
MOH continues to improve, expand and intensify immunization services in Kenya.





New Vaccine Introduction Lessons Learnt (HPV)



- HPV vaccine was introduced in 2019 nationally through a facility based strategy targeting about 700,000 girls aged 10 years.
- HPV vaccine is a two dose schedule given six months apart.
- Gardasil is used in Kenya which protects against the 4 types of HPV.
- HPV Vaccine is a single dose with no preservative, freeze and light sensitive and should be stored between 2-8 Celsius degrees.
- Since 2022, a multi age cohort of 10-14 year old girls were targeted through mixed strategy of school, community and health facility.



New Vaccine Introduction Lessons Learnt (Malaria)



- Malaria Vaccine was rolled out as a pilot in 3 countries- Kenya, Ghana and Malawi in 2019
- It was initially carried out in 26 sub counties identified with the highest prevalence in Kenya.
- Malaria vaccine has a 4 dose schedule which is administered at 6, 7, 9 and 24 months with a minimum of 4 weeks between doses.
- RTS,S is the antigen presented as a lyophilized powder and A01 is the diluent adjuvant. One vial has 2 doses. Malaria vaccine is freeze and light sensitive and should be stored between 2-8 Celsius degrees. It has no preservative and the VVM is placed on the diluent.
- An expansion to 25 sub counties was done in March 2023 in the 8 counties with the highest disease counties.



New Vaccine Introduction Lessons Learnt (Malaria)



SUCSESSES

- Strong coordination and stakeholder engagement from planning to implementation of the pilot introduction
- Well publicized national launch
- High acceptance of the vaccine, good uptake of dose 1-3 with over 60% coverage.
- Overall documentations for vaccines were available and in use
- Health care workers (87%) remain the main source of information about malaria Vaccine to care givers followed by radio (47%).
- 93% of Health care workers reported malaria vaccine to have improved EPI services and 79% indicated the pilot introduction process was very smooth.
- 43% of health care workers who attended the introduction training were still working in the MCH



New Vaccine Introduction Lessons Learnt (Malaria)



CHALLENGES

- 36% of health facilities remained completely closed in the month of January 2021 due to health care workers strike.
- The delay in CHV training was identified as a major challenge and affected demand creation and defaulter tracing activities
- Shortage of Mother Child health booklets in most facilities.
- 57% of health facilities received supervision visits in the past 6 months before the evaluation
- High dropout of 16% for dose 4 malaria vaccine



New Vaccine Introduction Lessons Learnt (Rotavirus)



- Kenya introduced Rotavirus vaccine in 2014
- The vaccine manufactured by GSK has been in use since then (Rotarix®). The vaccine is a single oral dose is given as a two dose schedule at 6 weeks and 10 weeks.
- In 2022, Kenya switched from Rotarix® to Rotavaq® 5D which is 3 oral dose schedule at 6, 10 and 14 weeks.
- As a result of global shortages in 2022, there was huge uptake of Rotavaq® due to catch-up of the missed population.
- The multi dose vial switch positively affected the cold chain space as there was a 61% reduction in size.



New Vaccine Introduction Lessons Learnt (Rotavirus)



- Different manufacturing processes and formulation significantly change the way the two vaccines are stored, transported and administered
- There was need to change inventory management practices of the New formulation.
- Inadequate Finances for cascade training of the Health care workers on proper administration and storage of the new vaccine.
- Due to global shortages in 2022, there was huge uptake of Rotavaq® due to catch-up of the missed population.
- The multi dose vial switch positively affected the cold chain space as there was a 61% reduction in size.



Cross cutting Lessons learnt on New vaccine introductions



- Adequate time allocation for planning activities
- Multi sectoral collaboration is key for successful implementation for any new vaccine and sustained high performance in the immunization coverage
- Training of the service providers is essential
- Social mobilization and stakeholder engagement are key for high coverage
- Availability, Quality and Efficiency in the vaccines build community trust

Thank you



Fiscal Space analysis for Routine Immunization including New Vaccines Introduction in Kosovo



June 21, 2023

Summary of Costs (2024-2028), in US\$

Year	New Vaccines	Syringes	RI Vaccines	Syringes	Total
2024	1,526,999	0	306,192	19,047	1,852,238
2025	2,081,975	5,175	285,757	18,094	2,391,001
2026	2,174,244	5,051	282,969	19,066	2,481,329
2027	2,185,192	4,761	280,197	18,732	2,488,882
2028	2,194,209	4,678	151,444	9,790	2,360,122
Grand Total, US\$	10,162,619	19,665	1,306,559	84,729	11,573,572
Yearly Average, US\$	2,032,524	3,933	261,312	16,946	2,314,714

GAVI Support: next slide

Analysis (in US\$)

- Public Expenditure on Health: 3.6% of GDP ~ \$338 million
- RI Costs for Five years: \$1.30 million, Yearly Average: \$0.26 million
- Costs for Newer Vaccines for Five Years: \$10.1 million, Yearly Average: \$2 million
- Total RI Costs including New Vaccines for Five Years: \$11.5 million, Yearly Average: \$2.3 million
- Annual Current Total RI Costs as part of Public Expenditure on Health for RI: \$0.26 million
- Annual Resource Gap: \$2.0 million (approx.)

	2021	2022	2023
Ministry of Health	97,182,643	60,403,320	81,006,877
KHUCS	104,236,139	129,616,523	139,665,909
Health Insurance Fund	7,901,062	8,162,998	8,938,806
Government Health Grant for Municipalities	62,525,127	62,595,335	70,531,503
Budget allocated for health	271,844,971	260,778,176	300,143,095
Immunization	1,202,950	1,202,950	1,624,063
Share of budget for immunization, from health budget	0.44%	0.62%	0.54%





COFFEE BREAK

Please return
in 15 minutes

GLOBAL VPPEF
20 & 21 June 2023
Copenhagen, Denmark



Questions and Discussion