CLINTON HEALTH ACCESS INITIATIVE

Ethiopia Country Profile

2023

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Country overview

Indicators	Status
Population	123M (2022)
Birth Cohort (M)	3.9M (2021)
Under 5 Mortality Rate (# per 1,000 live births)	34, lower than the regional value of Sub-Saharan Africa which is 50 (2021)
EPI Coverage	DTP1: 70%; DTP3: 65% MCV1: 56%; MCV2: 48%
National EPI Manager	Interagency Coordination Committee (ICC) under Ministry of Health
GNI per capita (USD)	$1020 (2022)
Government Health Spend (% per GDP)	1.9% (2019/20)
Gavi Country Status (Y/N, Year of Transition)	Y, Initial self-financing
COVAX country (Y/N)	Y

Source: UN 2022 Estimates; World Bank; WUENIC 2022, cMYP 2021-25

9 vaccines in EPI target children, adolescent girls (9-14 years) and women of reproductive age (15-49 years)

Immunization scheduled based on age							
Birth	6 weeks	10 weeks	14 weeks	9 months	15 months	14 yrs (Girls)*	Women of childbearing age
BCG	OPV1	OPV2	OPV3	Measles (MCV1)	MCV2	HPV1	Td1 (first contact)
OPV0	Penta1	Penta2	Penta3			HPV2 after 6 months	Td2 (1 month after first dose)
	PCV1	PCV2	PCV3				Td3 (6 month after 2nd dose)
	Rota1	Rota2	IPV				Td4 (1 year after 3rd dose)
							Td5 (1 year after 4th dose)

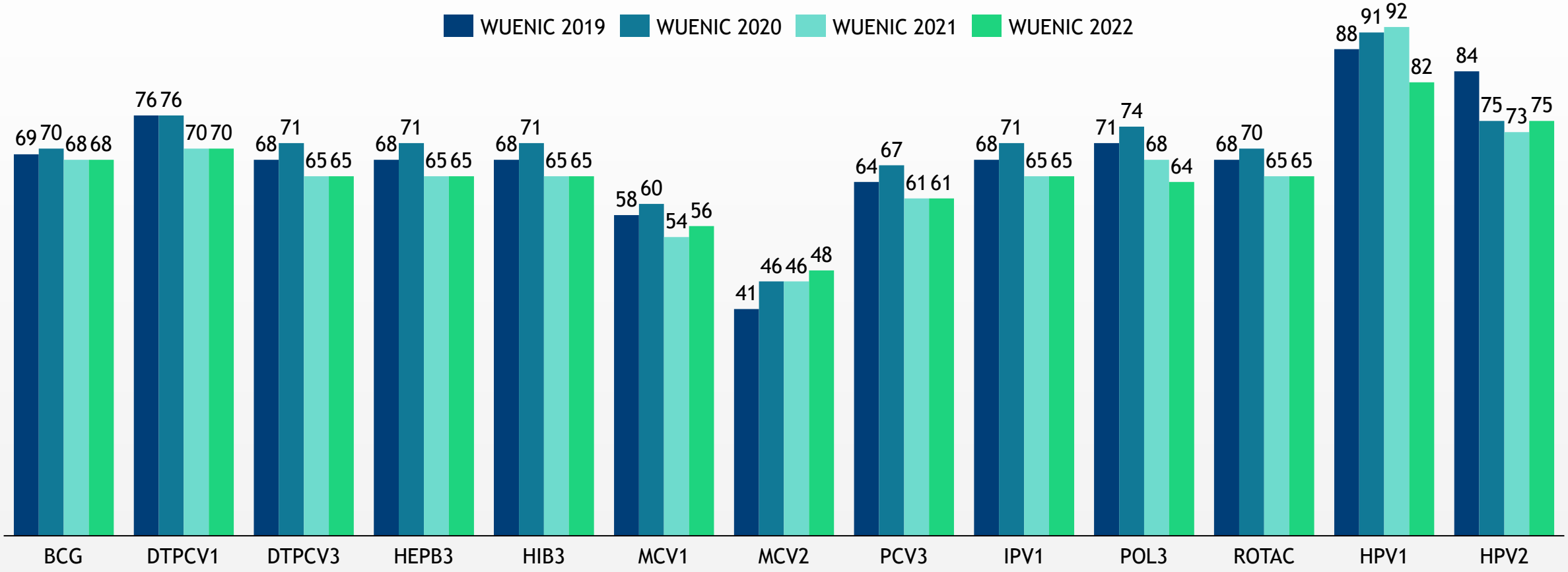
- Immunization services is primarily provided by government health facilities (98.5%); private facilities and NGOs contribute for only 1.0% and 0.5% respectively
- Infants may start vaccination at the facility of their birth but are likely to shift to their nearest government facility for completion

*Ethiopia NITAG is currently considering moving to a 1-dose HPV vaccination programme

Source: Ethiopia EPI, cMYP 2021-25

WUENIC reports that 2022 immunization coverage is still below pre-Covid levels of 2019 except for MCV2; HPV reports the largest gap

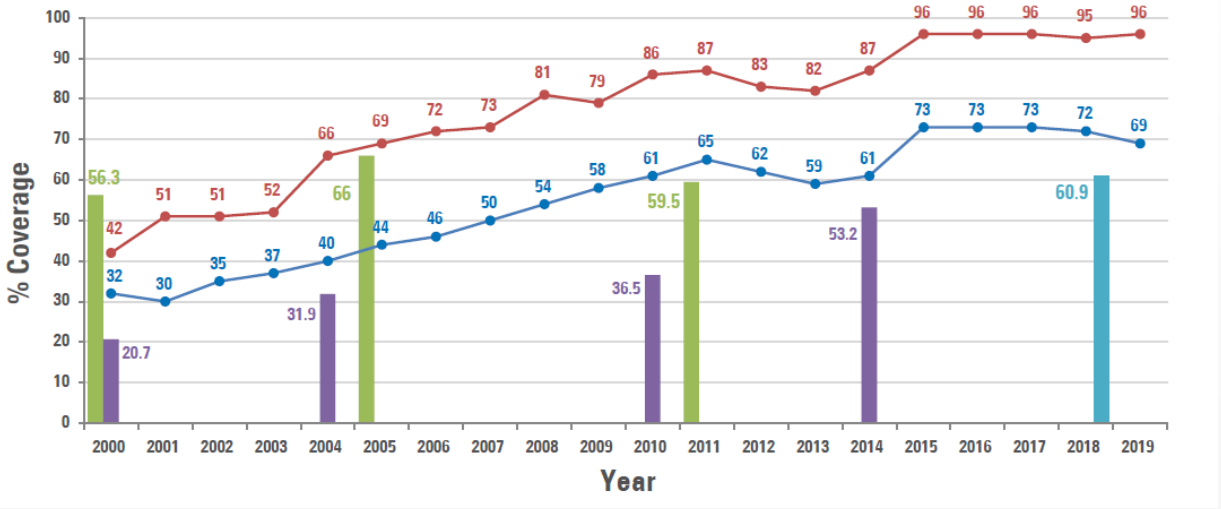
Coverage Estimates (%)



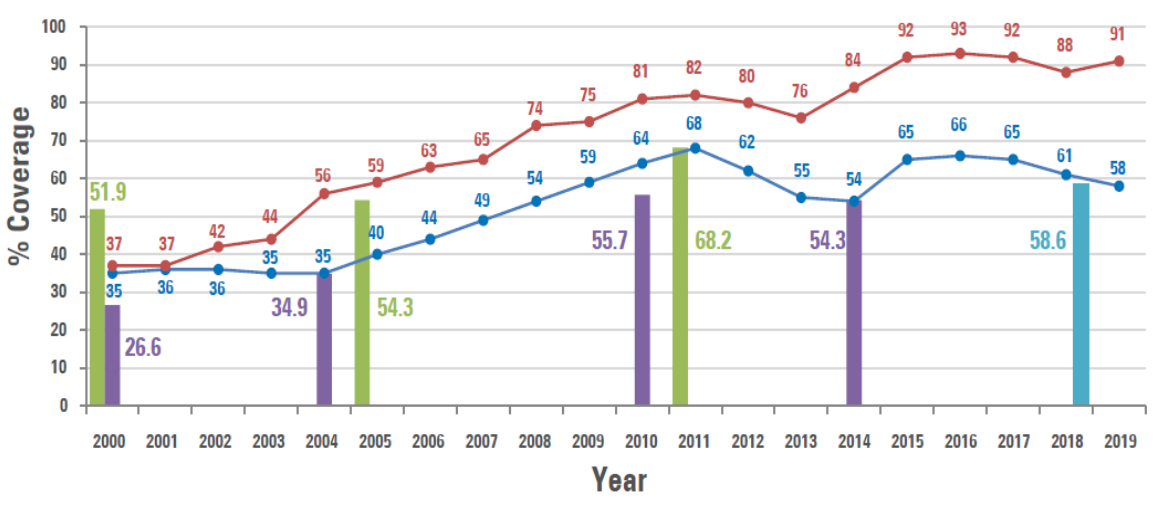
Source: WUENIC 2022

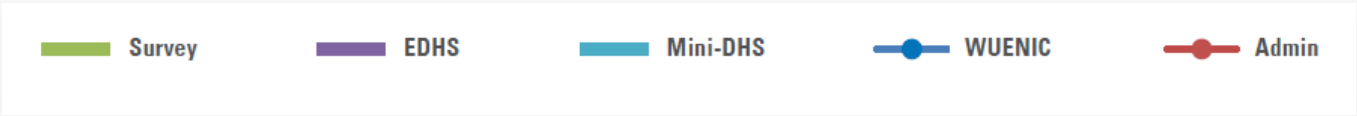
But the immunization data in Ethiopia varies greatly by sources - administrative, WUENIC, and surveys - posing a challenge for targeted action to boost coverage

Trends of Penta 3 coverage by different data sources, 2000-19



Trends of MCV1 coverage by different data sources, 2000-19





- The variation is largely due to differences in methodology in data collection, use of inaccurate and dissimilar denominators, and inadequacy in recording and reporting
- As highlighted in cMYP 2021-25, an “information revolution” is one of the four transformation agendas stipulated in the HSTP I and HSTP II to address these challenges

Source: WUENIC 2022, EDHS: Ethiopia Demographic and Health Survey

Ethiopia has planned 5 NVIs during the 2021-25 cMYP period, including an OCV campaign, of which none have been implemented to date

5-year demand forecast for expected introductions (in million doses)[1]

	Year post introduction				
Vaccine	Year1	Year2	Year3	Year4	Year5
HepB (Birth dose)	2.73	3.64	3.57	3.65	3.73
MenA	1.76	3.95	4.31	4.49	4.72
Yellow Fever	3.56	4.86	4.80	4.90	4.99
MR	7.82	8.15	8.42	8.55	8.69
Total IPV after IPV2 introduction (excludes zero dose catchup)	6.79	7.17	7.20	7.36	7.51

Ethiopia has an official cholera elimination plan which has not materialized as of 2023, probably due to vaccine shortages

	Year post introduction				
Vaccine	Year1	Year2	Year3	Year4	Year5
Target Population (in million)	3.03	3.00	3.00	2.97	3.49
OCV doses required (in million)	6.06	6.00	6.00	5.95	6.98

Source: cMYP 2021-25, Cholera elimination plan for 2022-28, [1]Linksbridge Demand

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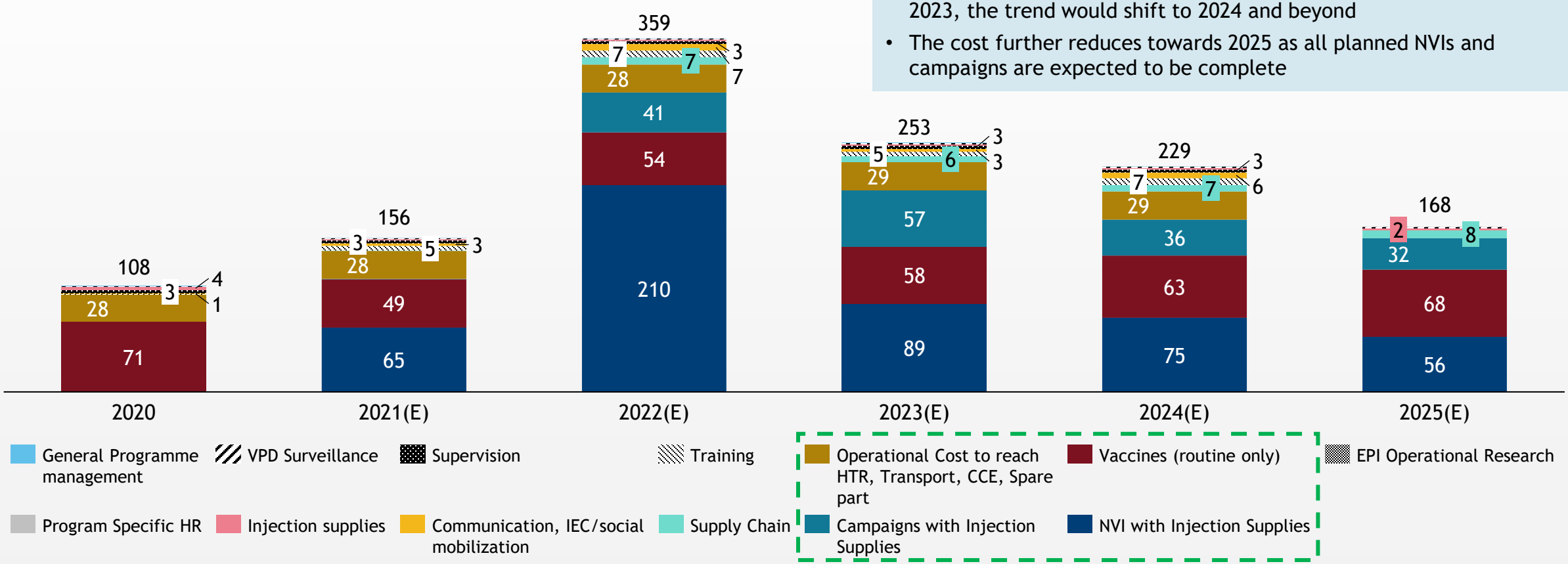
[Vx Spending]: NVI and campaigns are estimated to be the largest cost drivers during 2021-25 followed by routine Vx and operational cost

Cost of different components under cMYP 2021-25, M USD

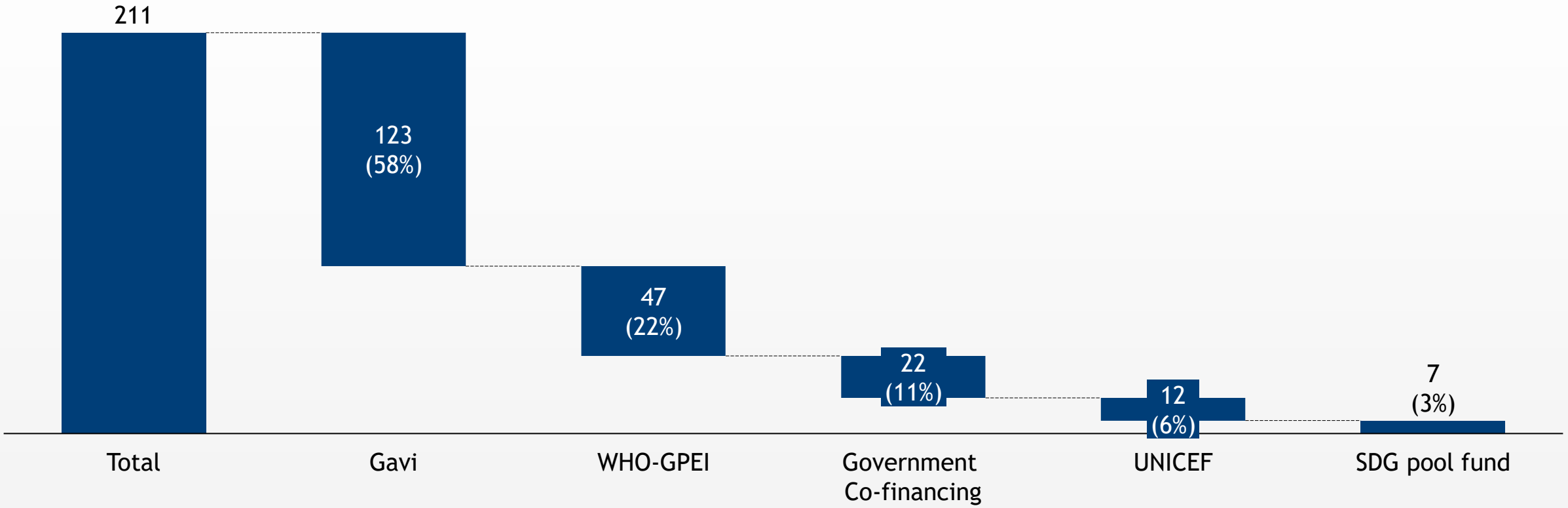
- Most of the planned NVIs and campaigns were anticipated for 2022 resulting in highest cost for that year
- As none of the introductions/campaigns have materialized as of 2023, the trend would shift to 2024 and beyond
- The cost further reduces towards 2025 as all planned NVIs and campaigns are expected to be complete



Source: cMYP 2021-25, HTR: Hard to Reach

[Budget support]: During 2016-20, Gavi funding represented 58% of EPI budget support - continued funding will be crucial to achieving the objectives for 2021-25

2016-20 EPI budget support from selected EPI partners, M USD



- In addition to co-financing, the Gavi financial support includes specific funding for Health system strengthening (HSS), HPV intro, MCV2 intro, Measles SIA, PCV switch, Cold Chain Equipment Optimization Platform (CCEOP), Civil society organization support and Gavi Targeted country assistance

Source: cMYP 2021-25

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Most Vx are supplied by DCVMs but MNCs still supply major vaccines - PCV, HPV and Rota - which could be an additional opportunity for DCVMs

Manufacturers supplying different vaccines to Ethiopia during 2022

Vaccine	Supplier	Supplier Type
BCG	Serum Institute of India (SII)	DCVM
DTP containing		DCVM
Measles containing		DCVM
Tetanus-Diphtheria (Td)		DCVM
OCV	EuBiologics	DCVM
bOPV	Bharat Biotech International Limited (BBIL)	DCVM
IPV	AJ Vaccines	Others (IPV R&D funded by BMGF)
PCV	Pfizer (PCV13)	MNC
HPV	Merck Vaccines (HPV4)	MNC
Rota	GlaxoSmithKline Biologicals SA	MNC

- Out of the 6 vaccines supplied by DCVMs, SII supplies 4 major ones
- No information on Chinese vaccines used to date except that SinoPharm's COVID-19 vaccine was imported from China[1]

Source: MI4A data 2023, [1]CHAI country team

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Decision making for NVIs and vaccine switches follow a similar process and take approximately 12-18 months from product selection to implementation

Ethiopia NVI/Switch process

12-18 months

Product selection	Approval	Implementation
• EPI technical working groups, along with the NITAG, review the evidence to support the introduction of a Vx or switch to a particular Vx product • NITAG develops a recommendation for NVI/Switch and selects product(s) as applicable	Approval by ICC and NITAG followed by Gavi application submission and approval	EPI plans and executes NVI/switch incl. HCW trainings

- The 12–18-month timeline for switches is due to the time required to gather evidence for decision-making, ensuring NITAG/EPI/ICC are aligned on the decision, and the additional training required for HCWs
- Opportunities to expedite this process can come from prioritization amongst MOH and key stakeholders

Source: MoH handbook for health workers; AMC 2020 Report; CHAI country team

Vx registration process considers WHO PQ and/or approval by SRAs; Ethiopia also participates in the Collaborative Procedure for Accelerated Registration (WHO)

Regulatory Standards:

National Regulatory Authority	Ethiopia FDA
NRA Maturity Level	ML2
Direct Recognition of SRA/ WHO PQ	☑

Participates in the WHO CRP	☑
Dossier submission required for products with WHO PQ or SRA approval	☑
Local agent for MAH required	☑

- **Ethiopian Food and Drug Authority (EFDA) is the NRA in Ethiopia.**
  - EFDA currently operates at maturity level 2 (ML2)
  - EFDA recognizes NRAs from the US, Canada, Australia, EMA, Norway, Finland, France, Denmark, Netherlands, Austria, Japan, Switzerland, Belgium, Germany, Italy, Ireland, UK, and WHO PQ
  - EFDA also participates in the WHO Collaborative Registration Procedure for products that are WHO-prequalified and adopts WHO PQ'd products
- **Ethiopia is Gavi-eligible and procures all vaccines and related supply through UNICEF SD**
  - The government contributes 0.2 USD for each dose of GAVI supported vaccines as co-financing
  - Financing of the BCG, Polio, and Td vaccines is 100% borne by the government
- **Ethiopian Pharmaceutical Supply Service (EPSS), under the MoH, is the central procurement agency for pharmaceutical and medical products other than vaccines, and responsible for distributing vaccines to all regions of Ethiopia post custom clearance.**
- **The procurement process in Ethiopia is governed by the Public Procurement & Property Administration Agency (PPPAA). RPPA is responsible for issuing procurement guidelines, supervising procurement activities, and ensuring compliance with procurement laws and regulations via a competitive bidding process.**

Source: Ethiopian Public Health Institute; Ethiopian Public Health Institute, Production of Cell Culture-Based Anti- rabies Vaccine in Ethiopia, Guidelines for the Registration of Vaccines, NMRA's Participating in the WHO Collaborative Procedure, Vaccine Registration Guidelines; Ministry of Health, Ethiopian Pharmaceutical Supply Service (EPSS), Ethiopian Pharmaceutical Supply Service

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