



SUSTAINABLE ACCESS TO VACCINES IN MIDDLE INCOME COUNTRIES

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Outline

PART 1: Introduction to the MIC Strategy

PART 2: Price transparency - the V3P

PART 3: Exchanging global supply, demand and regulatory intelligence

PART 4: Enhancing country procurement processes



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The mandate and membership of the MIC Task Force

Task Force mandate (since 2014)

- 1. Review the performance of MICs in immunization and refine our understanding of their needs
- **Take stock** of ongoing activities to address these needs
- 3. **Define** a shared strategy, action plan, and monitoring and evaluation framework to enhance sustainable access to vaccines in MICs
- 4. Act as an information-sharing and coordination forum across immunization agencies active in MICs

Task Force membership





















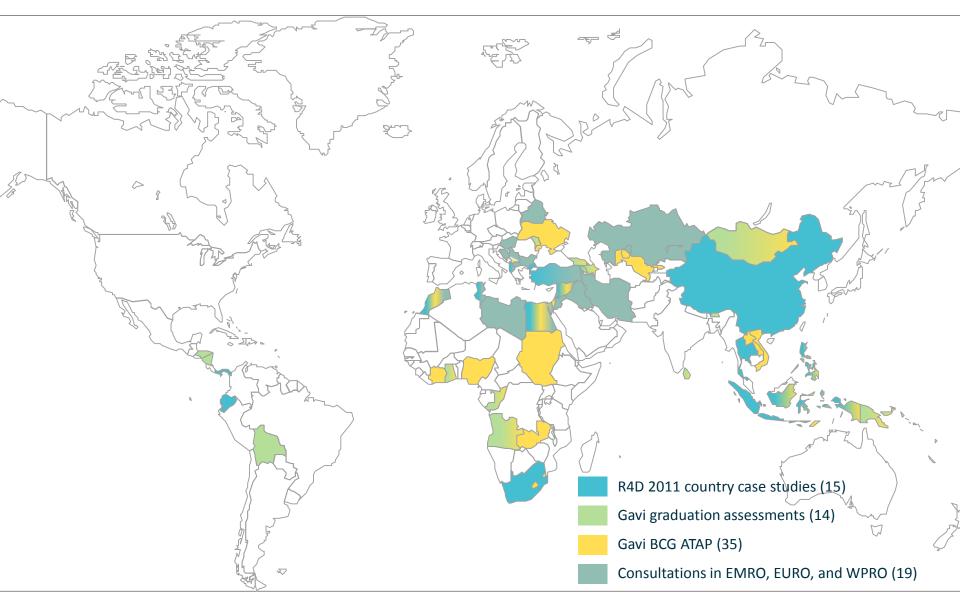




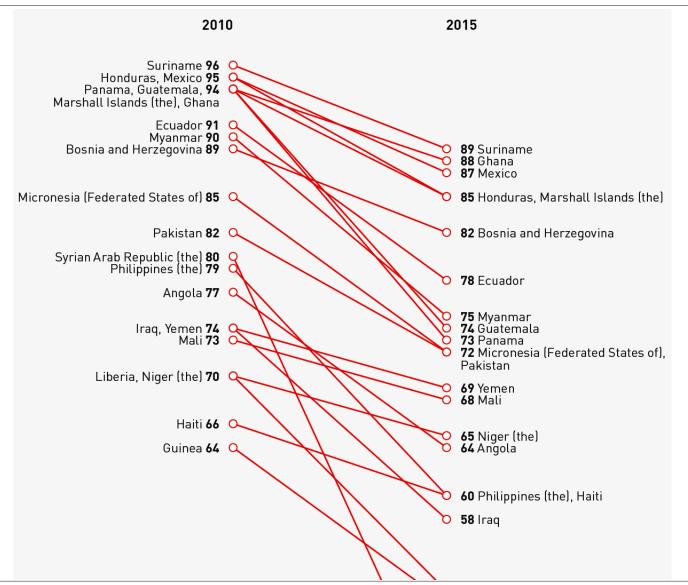
(Supporting analytical work for the Task Force)



Countries self-diagnosed issues, gaps and needs



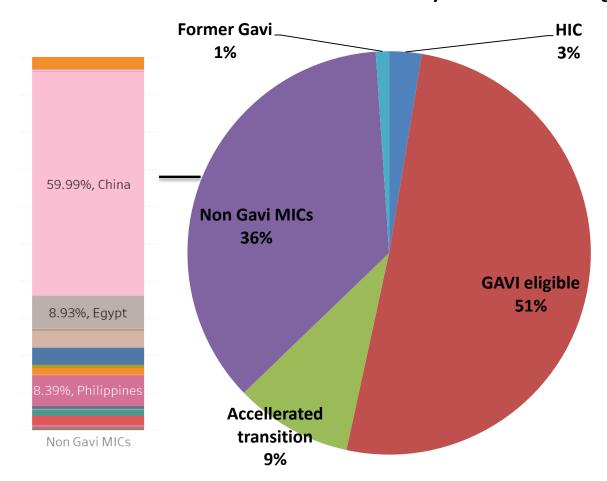
2016 Mid Term Review of GVAP



- DTP3 coverage declined in 25 countries (2010-2015)
- Most of these countries are non-Gavi MICs
- Some countries had very sharp declines from already low coverage

Equitable access requires leaving no country behind

Distribution of PCV unvaccinated children by income & Gavi eligibility in 2015



Unvaccinated children are calculated using WHO-UNICEF coverage estimates (WUENIC, 2016) and surviving infants (2016) from all countries, with PCV in in schedule or not

Efforts to help non-Gavi MICs have, to date, been substantial but fragmented and uncoordinated

(E)

Gavi-eligible MICs:

Sustainable Immunization Financing (SIF)

World Bank Innovative financing

Disease dashboard

LOGIVAC

SIVAC

GAVI graduation assessment missions

"Better Immunization Data" (BID)

CHAI: Technical and Management **Assistance**

Decade of Vaccines Economics (DOVE) analyses

Selected non-Gavi MICs: CHAI Cold chain & Logistics (CCL)

Global immunisation supply chain strategy

ProVac

African Medicines Regulatory Harmonization Programme (AMRH)

NRA strengthening

AHO Revolving Fund

UNICEF MIC Tender

(Visibility for Vaccines)

VIVA project

Global

Medicines

Regulatory

(GMRH)

initiative

Harmonization

EMRO

PVP

Vaccine

Independence

Initiative (VII)

Non-Gavi MICs:

ATAP: Access to Appropriate Prices

HERMES

SAGE Endorsed Partner-shared MIC strategy 2015-2020

Enhance sustainable access to vaccines for populations in middle-income countries to meet GVAP targets Goal • Uphold GVAP principles of country ownership, shared responsibility, integration, sustainability and innovation. Address inequities within and among countries Maximize health impact Consider technical and political feasibility Maximize value for money by complementing existing and planned efforts Geography All MICs not supported through the Gavi Alliance **Objective** Raise and sustain high and equitable immunization coverage and enable new vaccine introductions (1) Strengthened (3) Enhanced demand for (4) Improved access to (2) Increased political decision-making for commitment and financial and equitable delivery of affordable and timely timely and evidencesustainability of immunization services supply based immunization immunization programmes · Addressing vaccine Increasing procurement policy and programmatic Strengthening legislative basis hesitancy and building skills and knowledge for immunization community demand · Increasing access to choices Advocating for immunization · Strengthening in country revolving funds Focus areas Establishing and to achieve set immunization supply chain and data Harmonizing product choice strengthening NITAGs spending targets systems & registration processes Strengthening national Mobilizing national resources Increasing price information capacity to generate and increasing efficiency in Ensure external evidence for decisionprocurement options are resource use making Increasing MICs funding effective and fit for purpose credibility through innovative · Influencing market financial platforms dynamics Country commitment and cost sharing **Strategic** Coordination among international and local partners International and national advocacy and country-to-country peer learning enablers

Strong monitoring and evaluation efforts

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Vaccine price is an important element of sustainable immunization programmes

- Vaccine price is an important component of immunization budgets
- Required budget is a major factor in decisions to adopt and to sustain new vaccines
- → BUT countries lack visibility into vaccine prices for decision making
- Some countries are uncertain about whether they are getting equitable and fair prices

Vaccine price is an important component of immunization budgets

Indicator	Measure
Government Expenditure on Vaccines	28.41 USD per live birth
Government Expenditure on Routine Immunization	34.85 USD per live birth
% Government Expenditure on RI spent on Vaccines	81.54%

Sources: JRF 2016 (2015 data). Note that figures may be significantly different from previous years due to some changes in methodology and updated/corrected data. Figures are only reflective of the 107 countries that have been included in the final cohort for analysis.



There have been repeated requests for price transparency at the World Health Assembly (WHA)

Since 2001

World Health Assembly asking for increased availability of vaccine pricing information

2014 WHA

Request for **greater price transparency** and information on **cost of production**

2015 WHA

Resolution 68.6 on the GVAP* - access to sustainable supplies of affordable vaccines, including the promotion of vaccine price transparency



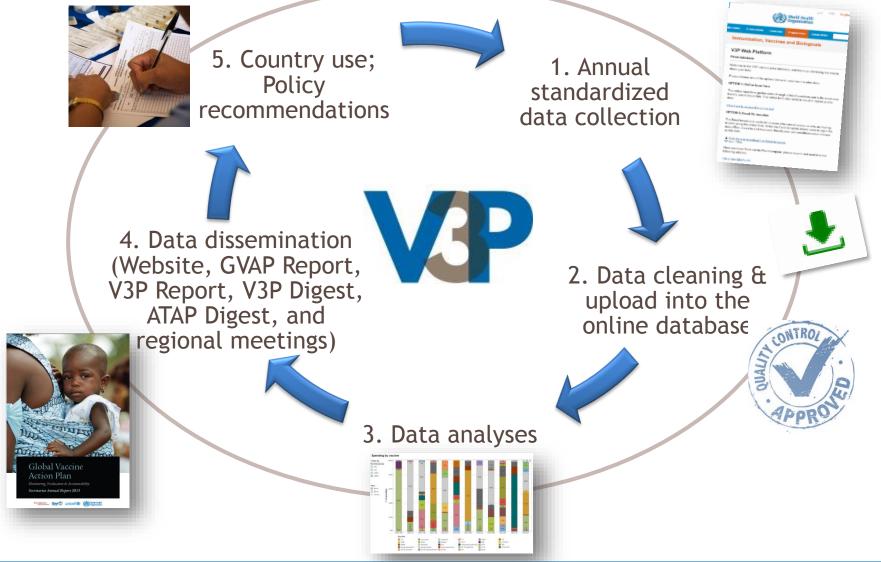
WHO should provide support for countries in the area of procurement and vaccine affordability.

-Member State (WHA/67)

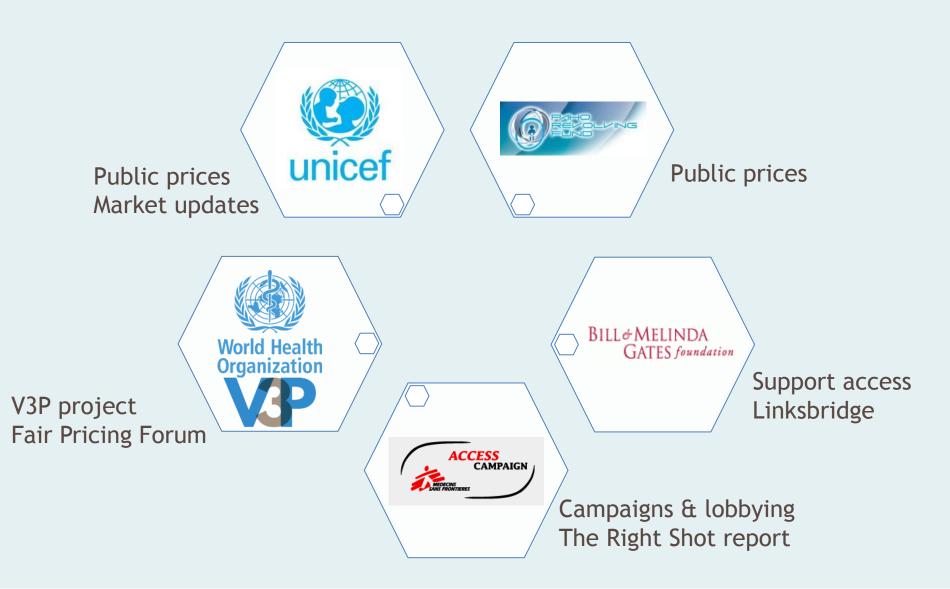


^{*} GVAP: Global Vaccine Action Plan Sources: WHA/54, WHA/66, WHA/67, WHA/68

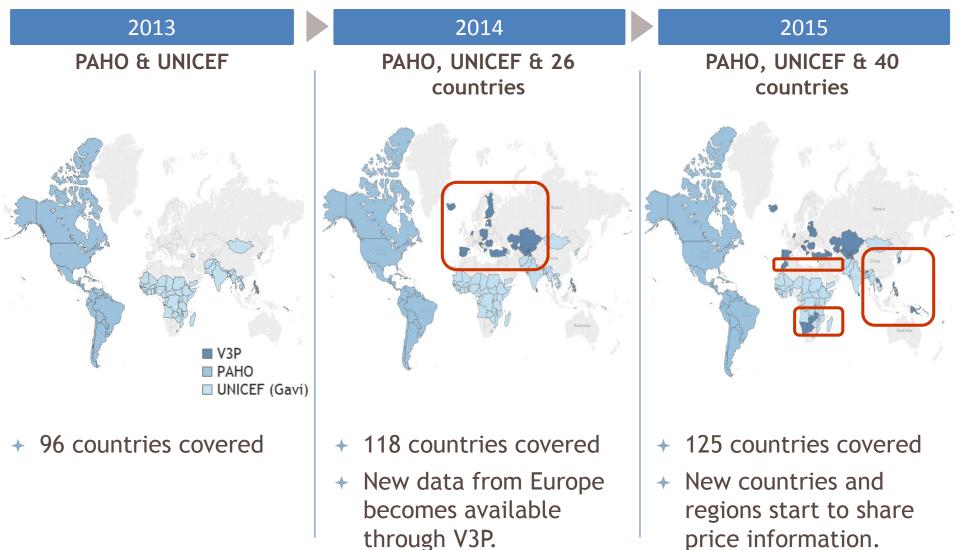
A standardized process to achieve sustainability of price transparency is in place



Several immunization partners are active on vaccine price transparency



Participation of countries in V3P has doubled in 2 years

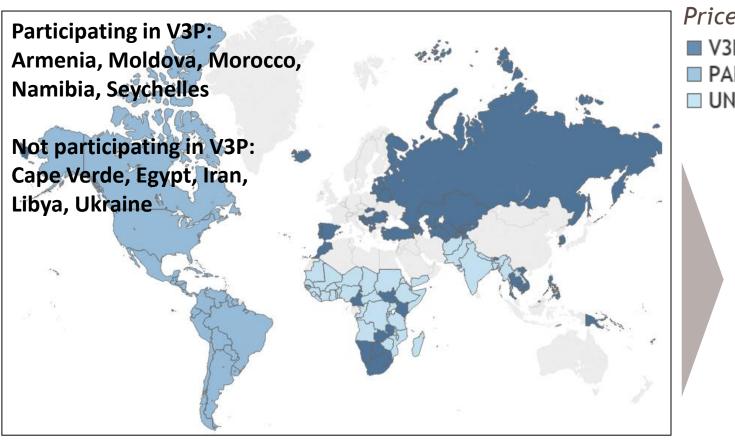




through V3P.

Vaccine price transparency for 70% of the world is achieved in 2016

Map of countries sharing prices in 2016



Price sharing sources:

V3P

■ PAHO

UNICEF (Gavi)

131 countries are covered by prices available through V3P or about 70% of the world*

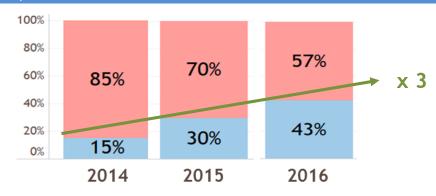
Note: "PAHO" includes all countries of the region of the Americas, as they could potentially access vaccines through the Revolving Fund. "UNICEF (Gavi)" includes all countries that are Gavi eligible or in-transition and known to procure all or part of their vaccines through UNICEF are included. * Including data from PAHO, UNICEF and countries

Participation from non-PAHO and non-Gavi countries is a priority

Non-PAHO and non-Gavi countries* included in the V3P database in 2016, by income level



Evolution of participation in V3P of non-PAHO and non-Gavi MICs*, 2014-2016



- In 2016: V3P database covers 43% of the non-Gavi and non-PAHO MICs (20 countries) and 34% of HICs (16 countries).
- Participation is steadily increasing.



No direct participationDirect participation in V3P

^{*} Used as a proxy for countries that are more likely to mix or self-procure

Countries use data to inform decisions

NEED V3P ENABLER ACTION

To facilitate country planning and budgeting (eg. introduction of new vaccines)

To understand what factors can be influenced in order to get a better price

To enhance fair pricing

Identify price ranges and budget spending

Understand the market and what factors influence prices

Compare prices with countries in similar conditions

Decisions & planning



Market & procurement

50 34.37 40 15.68 20 14.12 15.11 0 PAHO Self procuring MIGS

Fair pricing

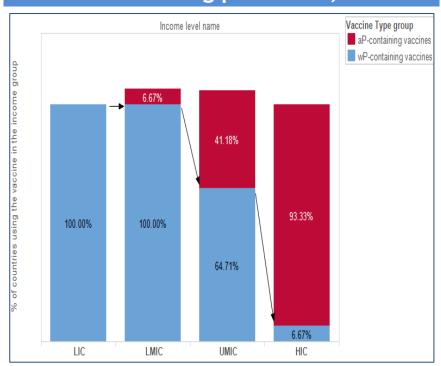






Decisions & planning: example of aP & wP-containing vaccines

Percentage of countries using wP and aP-containing products*, 2015



WAP* in USD per dose for wP and aP-containing products, 2015



Using price information for decision-making:

- Many MICs are switching from wP-containing products to aP-containing products.
- → Countries need to take into account in their decision the high difference in price between these vaccine products.

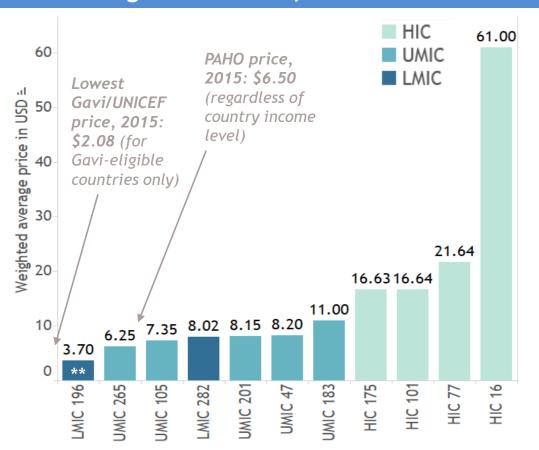
*Weighted Average Price, USD per dose. Note that the percentage cabbe greater than 100% if a country uses both wP and aP-containing vaccines





Market & procurement: Rotavirus vaccine

Weighed Average Price (WAP*) of rotavirus vaccine in non-Gavi eligible countries, 2015



PROCUREMENT FACTORS:

- Gavi-eligibility(1.88€/dose).
- → PAHO RF (\$6.50/dose).
- + High-volume (\$6.25/dose).

MARKET FACTORS:

- Duopoly with clear market leader.
- + Tiered pricing applied.

Explore pool procurement and alternative product.

Source: V3P database - www.who.int/immunization/v3p (extract on 25 August 2016).

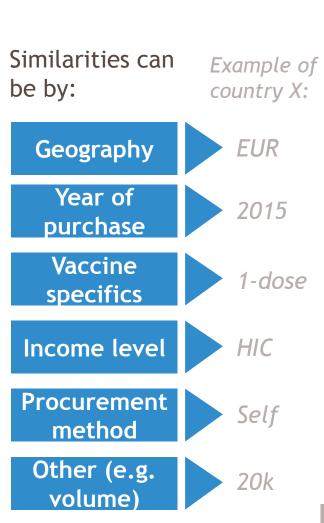


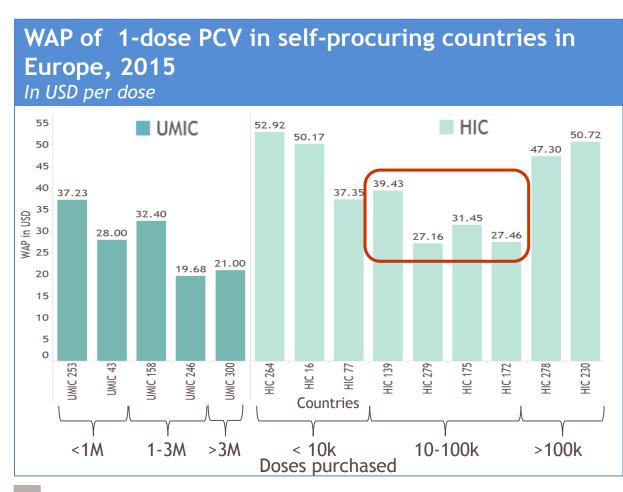
^{*} WAP by volume, in USD per dose / ** 3-dose schedule Note: Difference in price may be due to exchange rate fluctuations

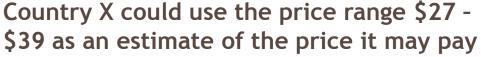


Fair pricing: Pneumococcal Vaccine (PCV)

<u>Definition</u>: using prices from similar countries to inform negotiations & tender limits.









At the regional/global level, data can be used to inform strategies

Type of use

- Global market analysis
- Inform immunization partners policies and market shaping strategies

- Inform regional strategies for access to supply
- Fill in information gap for international procurement

Examples

- → GVAP report: 'price differentiation led by income, overlapping tiers'
- What prices will Gavi countries access as they lose external support?
- V3P can help inform tender strategies of international procurement entities
- Most European countries purchase from the same manufacturer: possible risks of shortages, opportunities for harmonization
- Informing procurement costs and negotiations for the purchase of hexavalent vaccine for vaccination of refugees coming to Europe



How to access V3P?

Got to www.who.int/immunization/v3p

You will find three main Gateways:



 Price database: to compare prices across countries



 Knowledge repository: to get information about the V3P project and related articles, reports and analyses



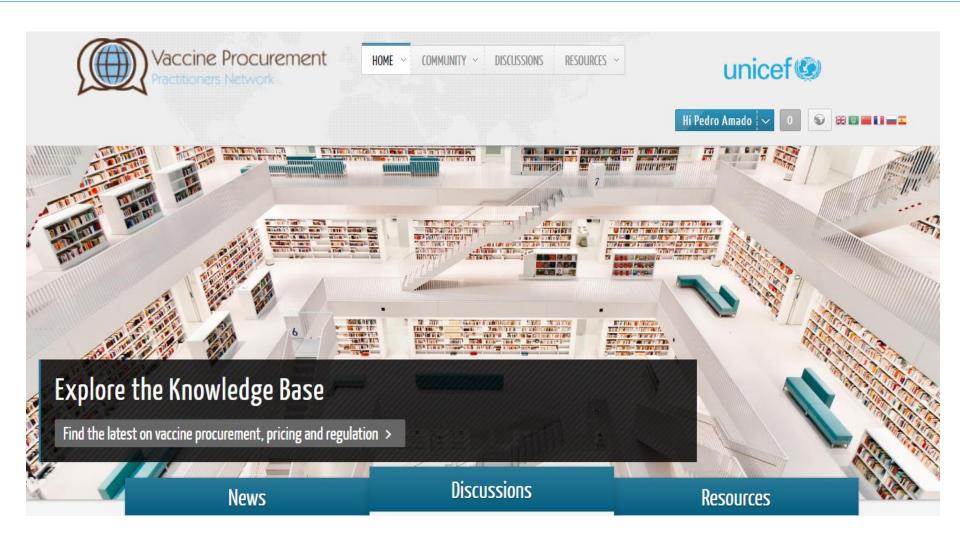
Resource gateway: to access the full range of online resources on vaccine products, prices, and procurement (incl. links to partners' websites)



The V3P mechanism was designed to help middle-income and GAVI-graduating countries, but any country can participate.



Access the V3P page from the VPPN



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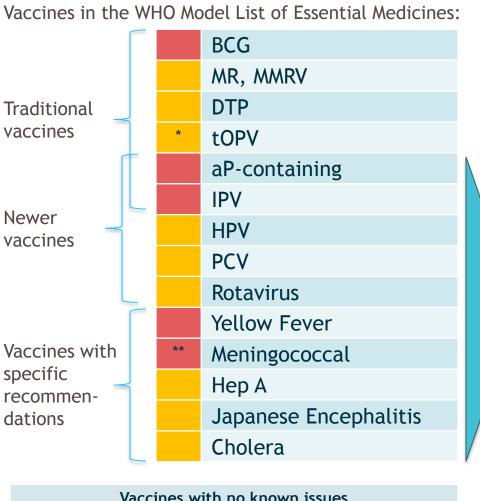
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Several vaccines are currently in short supply or at risk of a shortage



Vaccines with no known issues

Measles; Hib; HepB; DTP-HepB-Hib; TT; Td; Rabies;

Typhoid; MMR, Seasonal influenza

Legend:

- Known shortages in several countries and regions
- Known shortages in a few countries, or vaccine at risk of shortage (eg. with 2 or less manufacturers)

* Due to the switch to bOPV ** Short supply of multivalent vaccines

- 15 out of 25 vaccines in shortage or at risk of a shortage (60%).
- Issues for newer vaccines are mainly linked to mono/duopoly situations.
- Issues are more complex for traditional vaccines and vaccines with specific recommendations.
- Other biologicals also in shortages (e.g. diptheria antitoxin, snake antivenoms).



There are several actors working on supply and demand

Main international partners

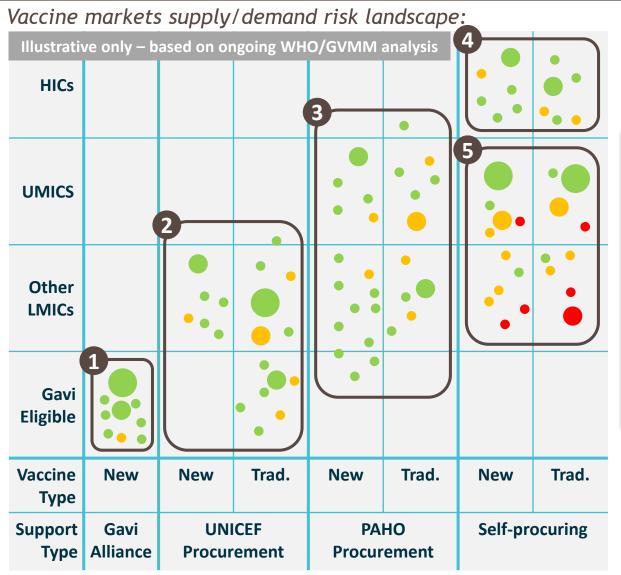
	Demand					Supply			Information
	Demand Management			Operations/Procurement		Long-term Supply			Information &
Actor	Policy/ Introduction	Forecasting	Delivery	Supply Management	Tendering	Industry Incentives	Product Development	Market Strategies	communication
BMGF/its technical grantees						0	0	6	•
Gavi					•				•
UNICEF						6			
WHO	//	•	-			•	/	/	•
РАНО						•			•

Several global actors across areas

 Most actors have a specific focus (e.g. PAHO on PAHO countries, Gavi on Gavi countries/vaccines) Legend: Gavi
Non-Gavi
PAHO

Size of circle indicates level of focus

Supply/demand risk is highest in self-procuring **Middle Income Countries (MICs)**



Self-procuring MICs have mixed prospects. With several countries vulnerable to markets not being able to meet their demand at affordable prices.



Towards more intelligence and enhanced dialogue

WHO IVB & EMP working with BMGF and Linksbridge to:

- Map information available across WHO on demand, supply, regulatory matters
- Analyse potential information gaps across main immunization partners
- Propose potential mechanisms to address gap and enhance information sharing and dialogue for enhanced demand-supply management

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Procurement issues in UN & Self-procuring countries

Preliminary analysis of Gavi transition assessments shows that:

- 73% of countries under study, independently of procurement method, have identified at least one issue in their current procurement practices
- Several procurement issues are raised by countries:
 - Weak forecasting
 - No procurement team
 - Weak procurement processes
 - Limited procurement experience
 - Supplier preference
 - Weak market knowledge
 - Weak staff training

- Inappropriate buffer stock
- Insufficient funding and/or untimely funding
- Procurement by price
- Inadequate price referencing
- Importation: customs and port clearance issues
- Inability to conduct multiyear tenders



WHO will play a supporting role in this area

- WHO is looking into the possibility of developing procurement guidelines and assessment tools to guide countries in strengthening of procurement processes
- WHO Regional Offices are providing some opportunities for regional

