

Identifying and materializing opportunities in middle-income countries (MICs)

Presentation to DCVMN
February 2022



Agenda

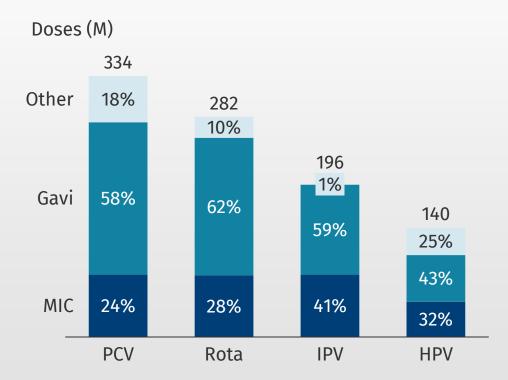
Item	Facilitator	Time
Registration & Introduction	DCVMN	15 minutes
CHAI MICs Opportunity Database: Overview of market opportunities in pneumococcal conjugate vaccines (PCV), human papillomavirus (HPV), Inactivated Polio Virus (IPV) and rotavirus markets	CHAI, K. Mtombeni & J. Zhu	30 minutes
Q&A	All	15 minutes
Case Studies : Tailoring country go-to-market strategies with the MIC Opportunity Database	CHAI, K. Mtombeni & J. Zhu	30 minutes
Q&A	All	15 minutes

CHAI Middle-Income Country (MIC) Opportunity Database

Overview of market opportunities in PCV, HPV, IPV and rotavirus markets

Gavi-transitioned and never-Gavi MICs represent a substantial opportunity for DCVMs, yet penetration into these MIC markets has been limited

By 2025, MICs will make up 20-40% of demand in high-value antigen markets¹



Uptake of DCVM products in MICs has been limited to date²

Gavi countries:

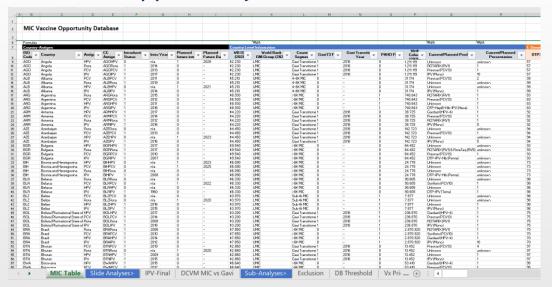
79% of birth cohort lives in countries with high DCVM product usage

Middle-income countries:

28% of birth cohort lives in countries with high DCVM product usage

The opportunity database supports DCVMs analyze, prioritize, and sell to MICs

CHAI MIC opportunity database



4 antigen markets covered:

- HPV
- PCV
- Rota
- IPV

Across 78 Gavi-transitioned & never-Gavi MIC markets:

- 24 in South America
- 19 in Asia
- 17 in Europe
- 10 in Africa
- 8 in Middle East



Comprehensive insights, including ...

- Country-level information, incl. Gavi status, transition etc.
- Introduction status & product use
- Market size
- Procurement modality
- Usage of DCVM products in country
- Assessment of readiness to introduce or switch
- Product preferences

To prioritize market opportunities for DCVMs, we look at four dimensions

Never Gavi + Gavi Trans'd MICs Market Relevance 2

Market size

Country readiness to introduce/switch

4) DCVM product use/interest

Focus on most relevant markets

- Preferring a locally produced product
- With low disease burden and unlikely to introduce a Vx
- Using an incompatible product (IPV only, e.g., using DTaP-IPV)

Focus on medium and large markets

- Relative market value est. based on MI4A price data, country gross national income (GNI), schedule, and population
- Not meant to represent exact market value (as that is dependent on supplier & product)

Analysis of countries' priorities and capacity

- DTP3 coverage
- Coverage backsliding
- COVID-19 coverage
- Recent NVI/switch
- EPI Routine Immunization robustness

Analysis of countries' openness to use DCVM Vx

 Based on partner and CHAI country data

PCV: 30 MICs prioritized which together represent an est. market size of ~\$1,5B1

Country Relevance:

7 countries excluded due lack of market relevance

6 countries excluded b/c they have low disease burden and are unlikely to introduce a vaccine

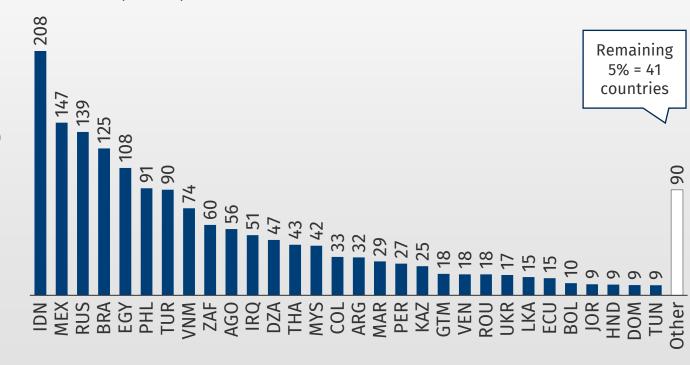
 i.e., Iran, Serbia, Eq Guinea, Jamaica, Bosnia & Herzegovina, Maldives

China excluded due to the country's preference for domestic vaccines

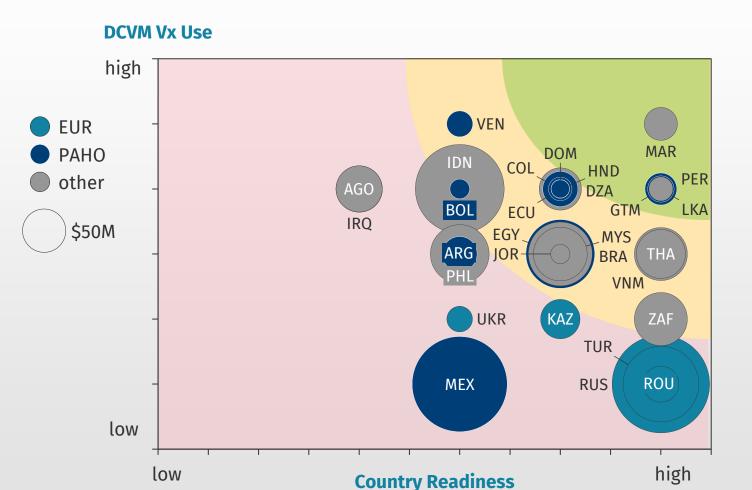
Relative Market Size:

Of the remaining 71 MICs, 30 represent 95% of the estimated market opportunity

Market size (USD M)



PCV: To prioritize go-to-market opportunities, DCVMs should consider the countries' readiness to introduce/switch and their openness to adopt DCVM products



4 countries show near-term opportunities
[green] to introduce/switch to a DCVM product;
combined market size estimated at \$97M
USD/year

11 countries in **PAHO** (\$534M opportunity), all – except Mexico show history of strong DCVM Vx use but some are struggling with low DTP3 coverage and backsliding

 Given a potential market size of >\$230M in Mexico, recommended to explore interest in DCVM Vx

6 countries in the **EUR region** represent \$505M opportunity, mostly with high levels of readiness but low levels of DCVM Vx use (e.g. Russia, Turkey, etc.)

For large markets with high DCVM Vx use but low readiness, **readiness expected to improve over time**, so pursuing registration now is still recommended

IPV: 23 MICs prioritized which together represent an est. market size of ~\$155M1

Country Relevance:

19 countries excluded due lack of market relevance

18 countries excluded b/c they use a combo-IPV vaccine

• e.g., South Africa

1 country excluded due to local vaccine preference

• e.g., China

Relative Market Size:

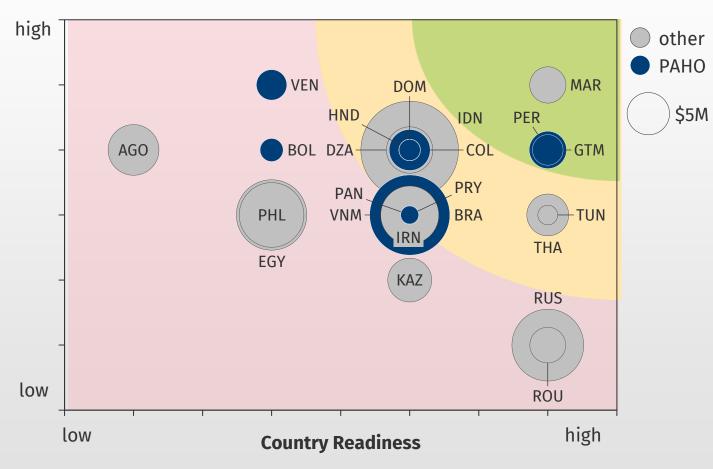
Of the remaining 59 MICs, 23 represent 95% of the estimated market opportunity

Market size (USD M)



IPV: 3 countries across PAHO and North Africa w/ high level of readiness & experience with DCVM products; several other markets less likely, but of interest due to market size

DCVM Vx Use



3 countries show near-term opportunities [green] to introduce/switch to a DCVM IPV product represent a market opportunity of \$10M USD

Engagement with **PAHO** recommended as 8 PAHO countries show mostly moderate readiness and higher DCVM Vx use (\$33M opportunity)

Large markets (PHL, AGO, EGY = \$32M) facing significant readiness challenges

Readiness is expected to improve as countries address EPI challenges so registration and engagement with larger countries is still recommended

Key Takeaways

- ✓ MICs represent a significant market opportunity for DCVMs. CHAI has developed a database to help suppliers identify opportunities and developed tailored marketing strategies
- ✓ Just 10 countries represent 70-80% of market opportunities across HPV, PCV, Rota, and IPV markets; suppliers should focus developing targeted marketing strategies in these countries
- ✓ MICs demonstrate significant variation in DCVM Vx use and country readiness
- ✓ Across all four antigen markets, a group of 3-5 countries shows a high readiness to switch <u>and</u> demonstrates high DCVM product use (e.g. Morocco, Peru, Guatemala)
- ✓ Large markets like Philippines and Egypt show high DCVM Vx use but limited current readiness to switch/introduce; Readiness is expected to improve over time so timely registration still recommended
- ✓ Large markets like Mexico, Russia and Turkey show high readiness, but given limited DCVM Vx use tailored advocacy, registration, and government engagement strategies required

Q&A Session #1



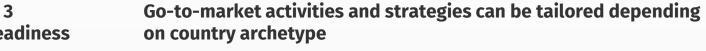
Case Studies

Tailoring country go-to-market strategies with the MIC Opportunity Database

The MIC Database can help tailor go-to-market strategy across 3 archetypes

The MIC Database can split countries into 3 archetypes, based on DCVM Vx use and Readiness

DCVM Vx Use



DCVI	Devi-1 vx ose		
high	2. Longe	r-term 1. Near-ter DZA	MAR
low		3. Exploratory	TUR
	low	Country Readiness	high

	Activity Areas	Definition
	Registration	Submit required documents and other activities required to receive approval by NRA to sell Vx in country
	Marketing	Conduct market research and develop country- specific marketing materials and product messaging
	Govt. Affairs & Market Access	Engage govt. stakeholders to understand tender timelines & requirements, submit tender, and negotiate terms
	Sales	Build Vx awareness among key opinion leaders, identify distribution partner, and define sales models (e.g. distribution & sales force).

In 'Near-term' countries, accelerating registration efforts and proactive engagement with MoH & key opinion leaders is critical to winning tenders

'Near-Term' opportunities demonstrate high programmatic readiness and a history of high DCVM Vx use. These countries are more likely to be actively considering NVI/product switch soon.



- Quickly ensure tender eligibility by pursuing registration and other tender requirements (e.g. company/distributor registration, HTA assessment)
- Timely, proactive engagement with MoH & key opinion leaders to ensure (1) awareness of product availability and (2) communicate product's unique value-add



Archetype Specific Tactics

Registration

- Proactively drive registration and immediately respond to NRA requests
- Pursue fast-track registration (e.g. MoH recommendation, WHO collaborative registration)
- Contract with local agents to help with navigating regulatory processes

Marketing

- Understand stakeholder Vx preferences (MoH, MDs, academics, NGOs, HCW associations, civil society)
- Tailor country-specific marketing materials based on research

Govt. Affairs & Market Access

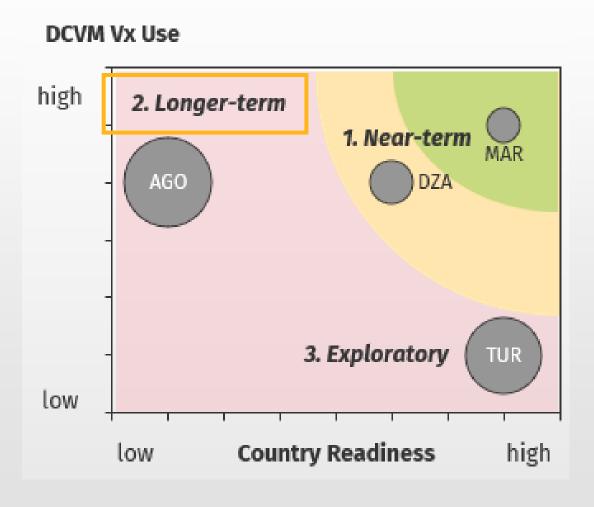
- Meet with stakeholders to demonstrate interest, ability to supply, and your Vx's unique value-add vs competitors
- Understand and possibly influence tender requirements (e.g. serotype)
- Internally prepare for tender to enable rapid response

Sales

Build local distribution partnerships to enhance govt. market access



"Longer-term" Countries



In 'Longer-term' countries , take advantage of longer window of time before NVI/ switch to develop country-specific marketing and messaging strategies

'Longer-term' opportunities demonstrate a history of high DCVM Vx use but are currently prioritizing activities like C19 coverage or backsliding and may have limited capacity to consider NVIs/switches soon



Key Success Factors

- Take advantage of longertime period to frontload administrative requirements and more effectively market to MoH/KoLs
- **Understand and communicate** how your product will support addressing or avoid aggravating current Vx challenges





Archetype Specific Tactics

Registration

- Immediate registration recommended in priority countries to increase ability to engage stakeholders
- Ensure timely registration in other countries to meet tender timelines (e.g. risk of product backlog, extra reg. requirements)

Marketing

- Develop targeted marketing materials, including addressing current EPI challenges (e.g. backsliding, C19 impacts, cold chain)
- Increase Vx familiarity within private market and non-EPI stakeholders

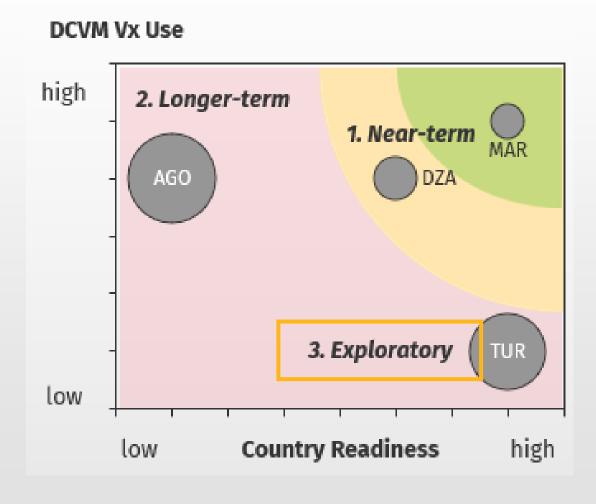
Govt. Affairs & Market Access

- Monitor EPI strategy & activities to understand NVI/switch timelines
- Develop (in)formal communication channels to ensure that govt. can engage when ready
- Ensure partners (e.g. CHAI, WHO) know your interest & ability to supply

Sales

Build distribution partnerships to facilitate public and private sales

"Exploratory" MICs



In 'Opportunistic' countries, suppliers must first address barriers to DCVM Vx use

'Opportunistic' countries demonstrate a low DCVM Vx use likely driven by lack of familiarity with non-MNC Vx landscape, negative perceptions of DCVM vaccine quality and safety, lack of knowledge about potential benefits



- Understand and address country barriers preventing greater DCVM Vx use
- Ensure awareness of your products existence and benefits
- Increase govt. confidence in the safety and efficacy of your DCVM product



Archetype Specific Tactics

Registration

- Understand unique NRA criteria required for approval (e.g. EMA approval)
- Present data within NRA submission package to address key concerns

Marketing

- Identify if country preferences match your Vx or are negotiable
- Tailor marketing materials to address country concerns; leverage evidence where possible (e.g. journal articles, clinical trials, case studies)
- Pre-empt MoH concerns by building private market and key opinion leader familiarity with your Vx

Govt. Affairs & Market Access

- Identify gatekeepers to greater DCVM Vx use and address concerns
- Create awareness of your product's comparative advantage
- Leverage your government's economic and trade orgs to establish new relationships with target country stakeholders

Sales

Build local distribution partnerships to enhance govt. market access and increase private market penetration



Key Takeaways

- ✓ Due to fragmented procurement landscape, MICs require pro-active, tailored go-to-market strategies
- ✓ Different MIC archetypes ('Near-term', 'Longer-term', and 'Opportunistic') require different registration, marketing, government affairs, and sales tactics
- ✓ MICs go-to-market strategies differ from Gavi countries in the following ways:

Activity	Differences vs Gavi countries	
Registration	 Fewer countries accept WHO PQ as a regulatory standard, SRA or PIC/S approval maybe required Strong relationsihps with local agents may help DCVMs navigate more complicated regulatory rules 	
Marketing	 MIC socio-economic and EPI contexts vary considerably Country tailored 'value for money' marketing required 	
Govt. Affairs & Market Access	 Decision making can be less centralized, role of non-government KoLS can be critical Greater DCVM engagement with MoH/KoLs required 	
Sales	• Larger private sector increases both its commercial importance and influence on RI product choice	

How is CHAI helping DCVMs succeed in middle-income markets?

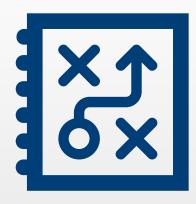
Sharing relevant market intelligence



Key results of this analysis are available to DCVMN via the CHAI website (will be shared after the webinar)

- Results presentation
- Simplified Excel

Bilateral CHAI business planning support



CHAI provides tailored business planning support to DCVMs to improve access to vaccines in Gavi and in MIC markets

- Targeting engagements with significant winwin outcomes for global health and suppliers
- Access to additional country intelligence: detailed country product preferences (e.g., serotype, price, NRA origin), procurement process, registration information, etc.

Q&A Session #2



Thank you for your participation!

Please contact **Jason Zhu** (<u>jzhu@clintonhealthaccess.org</u>) and **Khanyisa Mtombeni** (<u>kmtombeni@clintonhealthaccess.org</u>) with any questions



www.clintonhealthaccess.org



Appendix

HPV: 31 MICs prioritized which together represent a market opportunity of ~\$351M1

Country relevance: 4 countries excluded due lack of market relevance

3 countries excluded b/c they have low disease burden and are unlikely to introduce a vaccine

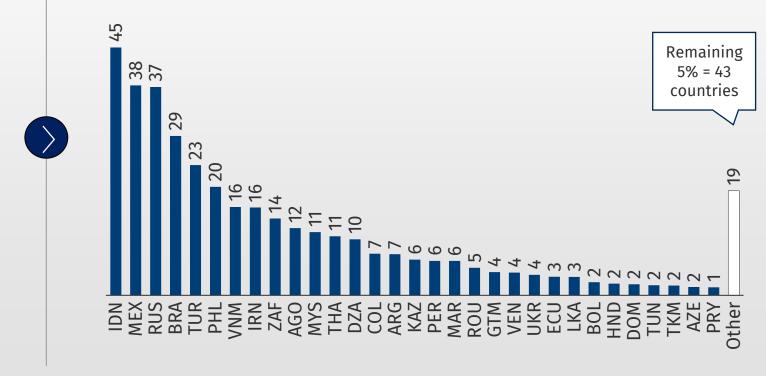
i.e., Egypt, Iraq, Jordan

China excluded due to the country's preference for domestic vaccines

Market size:

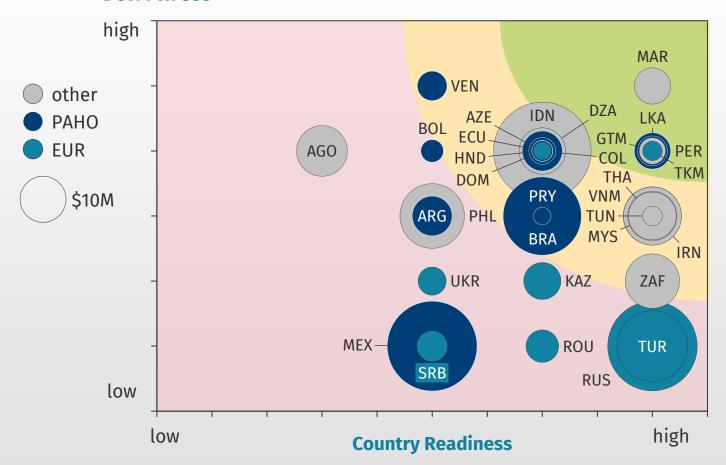
Of the remaining 74 MICs, 31 represent 95% of the estimated market

Market size (USD M)



HPV: Five countries with high level of readiness & proven interest in DCVM products; other large markets ready, but will have to be convinced of DCVM product use

DCVM Vx Use



5 countries show near-term opportunities[green] to introduce/ switch to a DCVM product represent a market opportunity of \$22M

11 countries in **PAHO** (\$69M opportunity), all – except Mexico & Argentina - show moderate to high levels of readiness to introduce/switch and DCVM use

7 countries in the **EUR region** represent ~\$80M opportunity, with high to medium levels of readiness

 But largest markets Russia and Turkey haven't used a lot of DCVM vaccines yet

For other large markets, **readiness to introduce/ switch is expected to improve over time**, early registration and engagement is recommended

Rota: 27 MICs prioritized which together represent a market opportunity of ~\$310M1

11 countries excluded due lack of market relevance

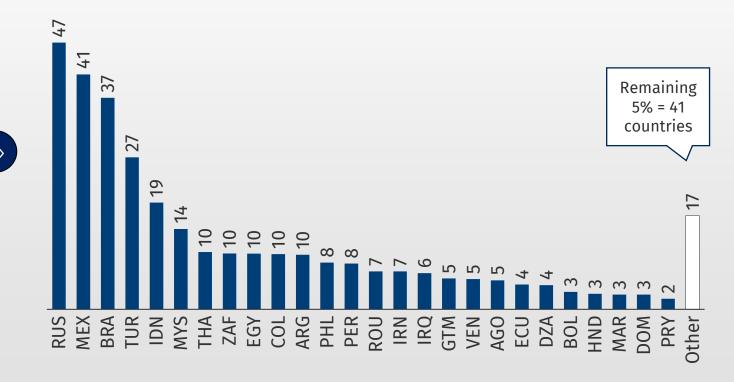
9 countries excluded b/c they have low disease burden and unlikely to introduce a Vx

• e.g., Tunisia

2 country excluded due to local vaccine preference

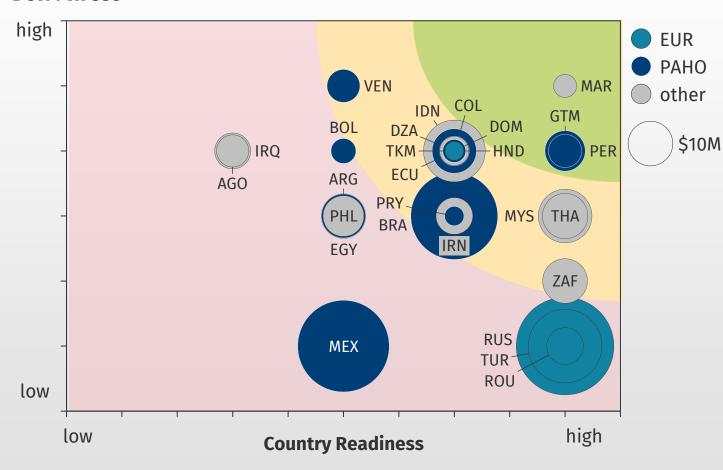
e.g., China & Vietnam

Of the remaining 67 MICs, 27 represent 95% of the estimated market Market size (USD M)



Rota: Three countries w/ high level of readiness & experience with DCVM products; Russia, Turkey and Mexico require advocacy for DCVM products

DCVM Vx Use



Together the 3 countries with highest likelihood [green] to introduce/ switch to a DCVM product represent a market opportunity of \$16M

11 countries in **PAHO** (\$90M opportunity), all – except Mexico & Argentina - show moderate to high levels of readiness and DCVM use

4 countries in the **EUR region** represent ~\$80M opportunity, with high level of readiness, but little experience with DCVM Vx products—advocacy required

For other sizeable markets (e.g., Egypt, Indonesia), readiness is expected to improve over time, so timely registration and engagement recommended