CLINTON HEALTH ACCESS INITIATIVE

HCV Market Report and Preliminary HBV Market Insights
Highlights and Key Takeaways

CHAI – External webinar

Agenda

- Introduction *(Craig McClure, CHAI) – 10 mins*
- Welcome Remarks *(David Ripin, CHAI) – 3 mins*
- Message from WHO *(Meg Doherty, WHO) – 15 mins*
- HCV Diagnostics Highlights *(Emi Okamoto, CHAI) – 10 mins*
- HCV Treatment Highlights *(Ritubhan Gautam, CHAI) – 7 mins*
- HCV Pediatrics Market *(Christian Ramers, CHAI) – 10 mins*
- HBV Market Insights *(Oriel Fernandes, CHAI) – 10 mins*
- Country Examples
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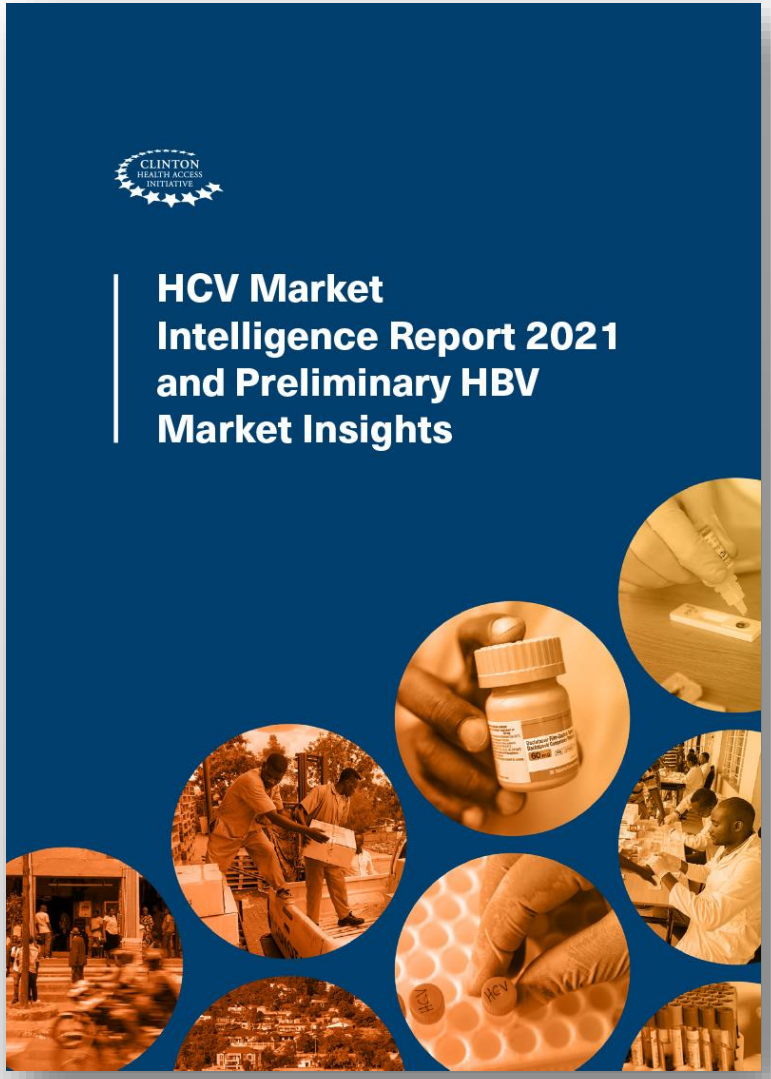
  - *Indonesia DAA Price Reduction (Caroline Thomas, Yayasan Peduli Hati Bangsa) – 5 mins*
- Q&A *– 15 mins*

After the successful release of the first ever market report for HCV in 2020, CHAI is excited to share the latest updates and new topics in this 2nd edition



New Topics Covered In The Report

- **Impact of COVID-19**
- **Products and pricing of diagnostics for liver staging**
- **Use of dried samples for HCV VL testing**
- **Emerging markets for retreatment and pediatrics including addressable pediatrics market-sizing estimates**
- **Preliminary information on HBV market**

The report targets a range of stakeholders and can be leveraged to drive affordable access to quality viral hepatitis commodities

Manufacturers & Distributors

Inform market development strategies based on volumes, pricing trends, in-country price mark-ups across different geographies

Country Governments & Health Programs

Identify opportunities to optimize pricing and volumes based on market trends

Donors & Investors

Identify current gaps in the market and potential opportunities for highest value-for-money investments

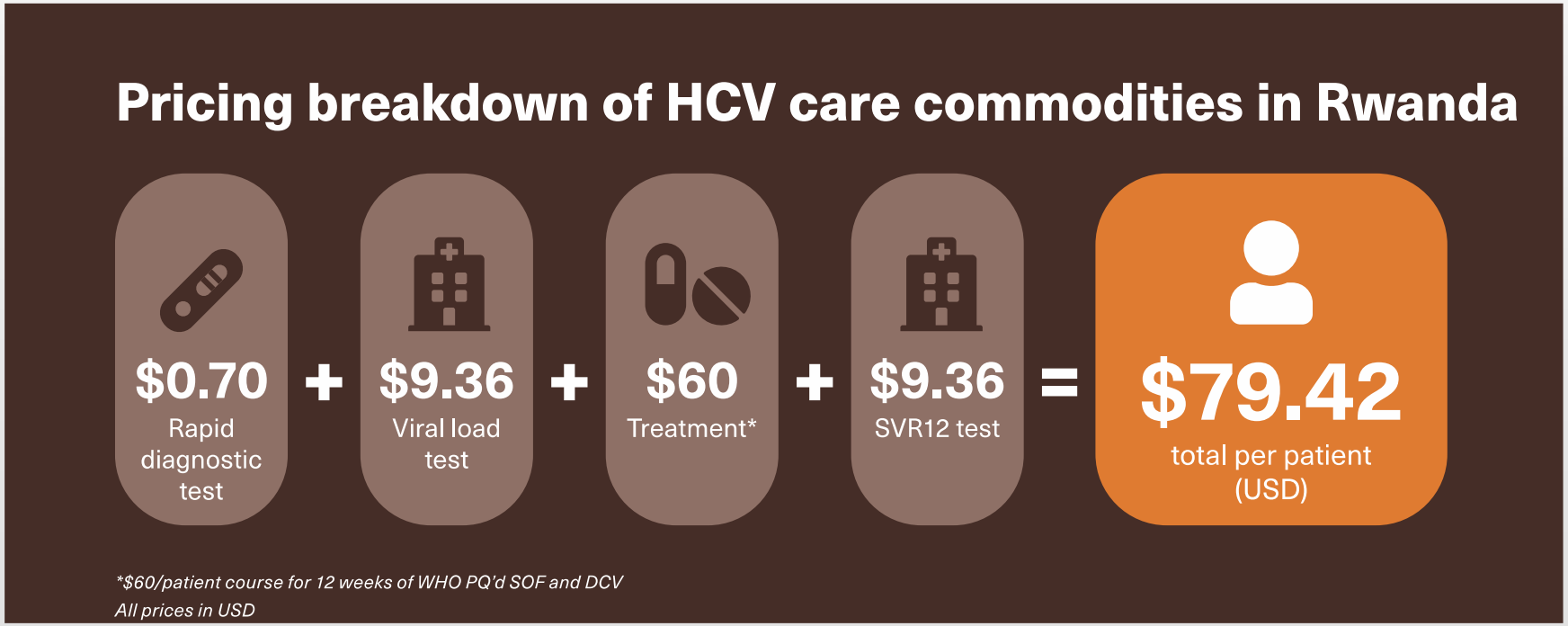
Civil Society & Organizations providing Technical Assistance

Advocate and support implementation of solutions that address current market inefficiencies

Key Market Highlights

HCV care has gained momentum over last few years - number of HCV patients treated globally increased from 1 million by 2016 to 9.4 million by 2019

Pricing for WHO Pre-Qualified products is lowest in Rwanda among high-burden LMICs



COVID-19 impact: Suppliers and HCV programs adapted to ensure momentum for HCV was not lost in 2020

- ❑ Case-finding activities and care-seeking for many diseases, including HCV, decreased across most LMICs as countries responded to limit the spread of COVID-19

- ❑ HCV programs piloted alternate ways of service delivery - multi-month treatment dispensation, online meetings, and virtual trainings

- ❑ Suppliers are mitigating challenges of high lead time and prices of key starting materials import from China by exploring alternate procurement options

The hepatitis community needs to continue adapting to the unpredictability of the COVID-19 situation due to recurring surges in case numbers and the inequitable distribution of vaccines across LMICs

As countries continue to adapt to COVID-19, the hepatitis community needs to sustain efforts to make HCV care more accessible

Strategies to build programs with affordable testing and treatment

Leverage **volume** and **forecast-based pricing**

Access international procurement mechanism **negotiated terms and pricing**

Ensure price transparency and **reduce mark-ups**

Facilitate expedited in-country registrations

Integrate testing across diseases

Public-private partnership

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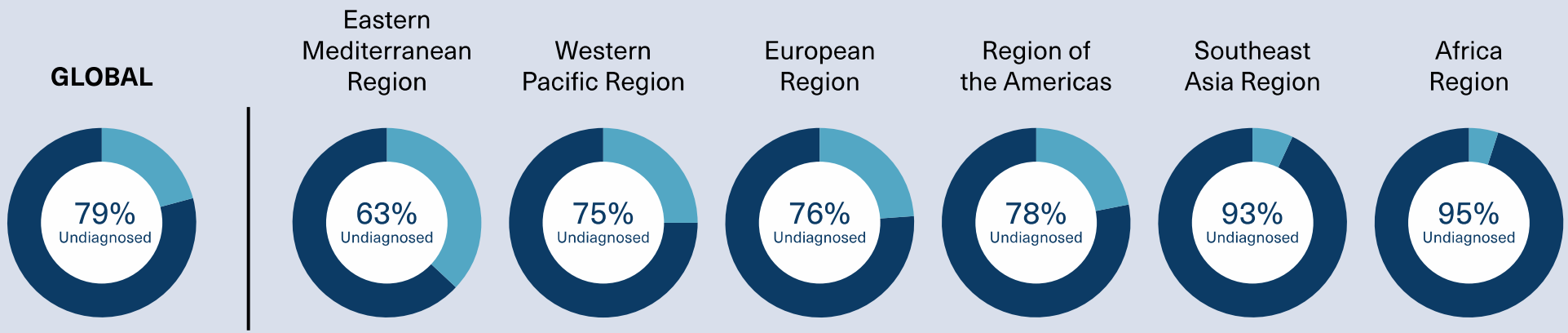
There is significant room for growth in the HCV diagnostics market

Exhibit 2: Percent of HCV positive individuals undiagnosed at the end of 2019



- **Untapped diagnostics market** may be available by reducing the barriers to access through increased awareness, as well as donor and domestic funding for testing and treatment
- This report utilizes public databases of approvals, information from in-country sources on prices paid by public programs, and access pricing deals published or discussed with suppliers
- A public database on global diagnostics approvals, pricing, and volumes could provide more market transparency and help predict diagnostic market trends

Screening: Many quality assured tests are available; rapid diagnostic test (RDT) market share may increase given programmatic value

- As of May 2021, ten HCV antibody tests have received WHO PQ, including four RDTs and six lab-based tests

- Quality-assured HCV antibody RDTs have programmatic benefits over lab-based assays:

enabling decentralization of screening

mitigating challenges of sample collection and transportation

supporting faster turnaround in results

- Self-testing can be an additional approach to screening, however no products have WHO Prequalification yet

Exhibit 3: WHO Prequalified Rapid Tests (RDTs) and Lab-Based HCV Antibody Tests

Rapid HCV Antibody Tests

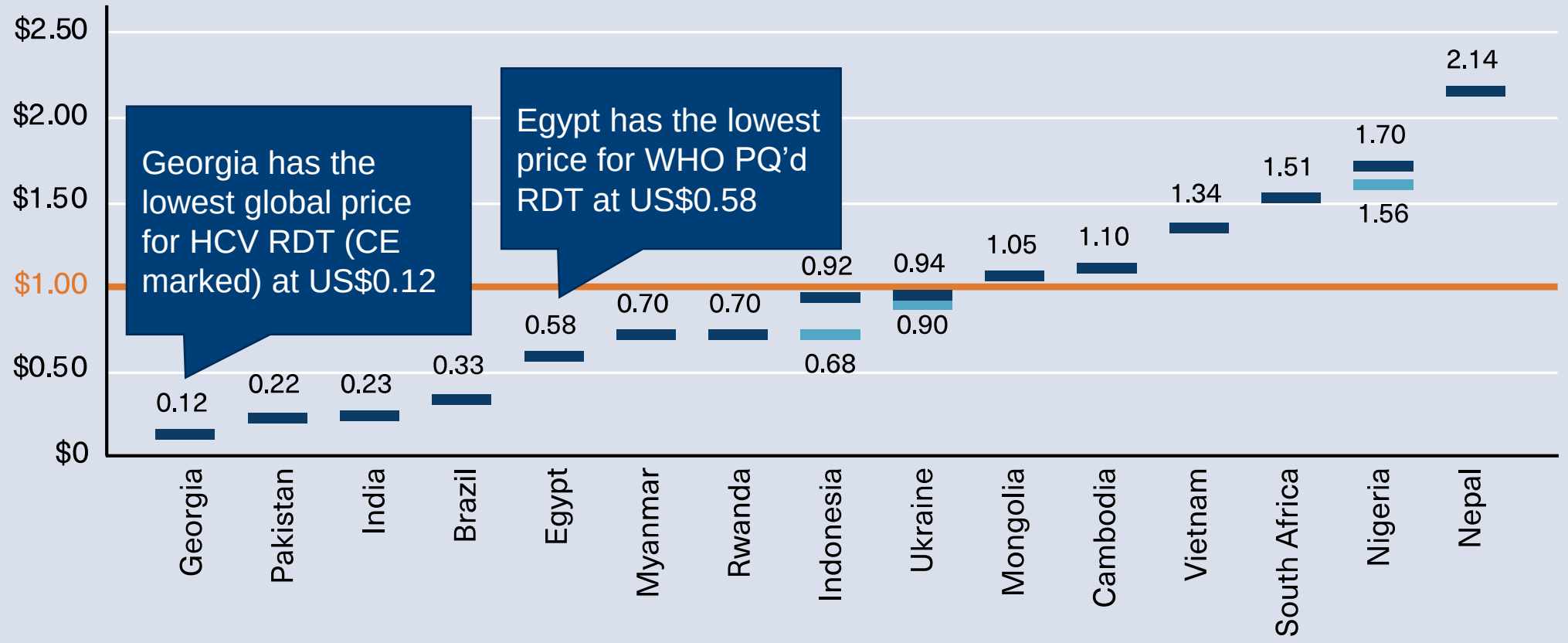
Product Name	Manufacturer	Sample Type
Rapid Anti-HCV	Intec Products	Whole blood, plasma, serum
Bioline HCV*	Abbott Diagnostics Korea	Whole blood, plasma, serum
OraQuick HCV Rapid Antibody	OraSure Technologies	Whole blood
Standard Q HCV Ab	SD Biosensor	Whole blood, plasma, serum

Lab-based HCV Immunoassays

Product Name	Manufacturer	Sample Type
ARCHITECT HCV Ag**	Abbott	Plasma, serum
INNOTEST HCV Ab IV	Fujirebio Europe	Plasma, serum
INNO-LIA HCV Score	Fujirebio Europe	Plasma, serum
Murex Anti-HCV	DiaSorin South Africa	Plasma, serum
Bioelisa HCV 4.0	Biokit South Africa	Plasma, serum
MONOLISA HCV Ag-Ab ULTRA V2	Bio-Rad	Plasma, serum

Screening: Many countries are accessing RDTs at lower than US$ 1, setting a benchmark for other programs to target

Exhibit 5: HCV antibody RDT price per test paid by public programs. Data collected in 2020-2021



Note: The horizontal line is a visual aid to compare prices to $1; all prices in USD.

Liver Staging: Common blood tests that are routinely available and affordable in LMICs can be used for fibrosis assessment.

- WHO guidelines recommend assessment of hepatic fibrosis to determine DAA treatment duration
- Transient elastography, a non-invasive ultrasound technology, is often unavailable or unaffordable in LMICs
- Liver health is frequently assessed using common blood chemistry tests for alanine transaminase (ALT), aspartate transaminase (ALT), and hematology for platelet count.
  - Calculated APRI or Fibrosis-4 (FIB-4) scores indicate the level of fibrosis

Exhibit 7: Example costs for standard liver function tests

	ALT/AST Cost	Platelet Cost
Cambodia	US$2.34	US$2.55
India*	US$0.88	US$2.17
Nigeria	US$3.90	US$2.08

Viral Load: Diagnostic platforms commonly used for HCV viral load have a large global footprint, in part due to HIV and TB programs

Exhibit 4: Cross-disease test menus of platforms commonly used for HCV viral load (non-exhaustive list)

Viral load platforms commonly found in central laboratories (non-exhaustive)

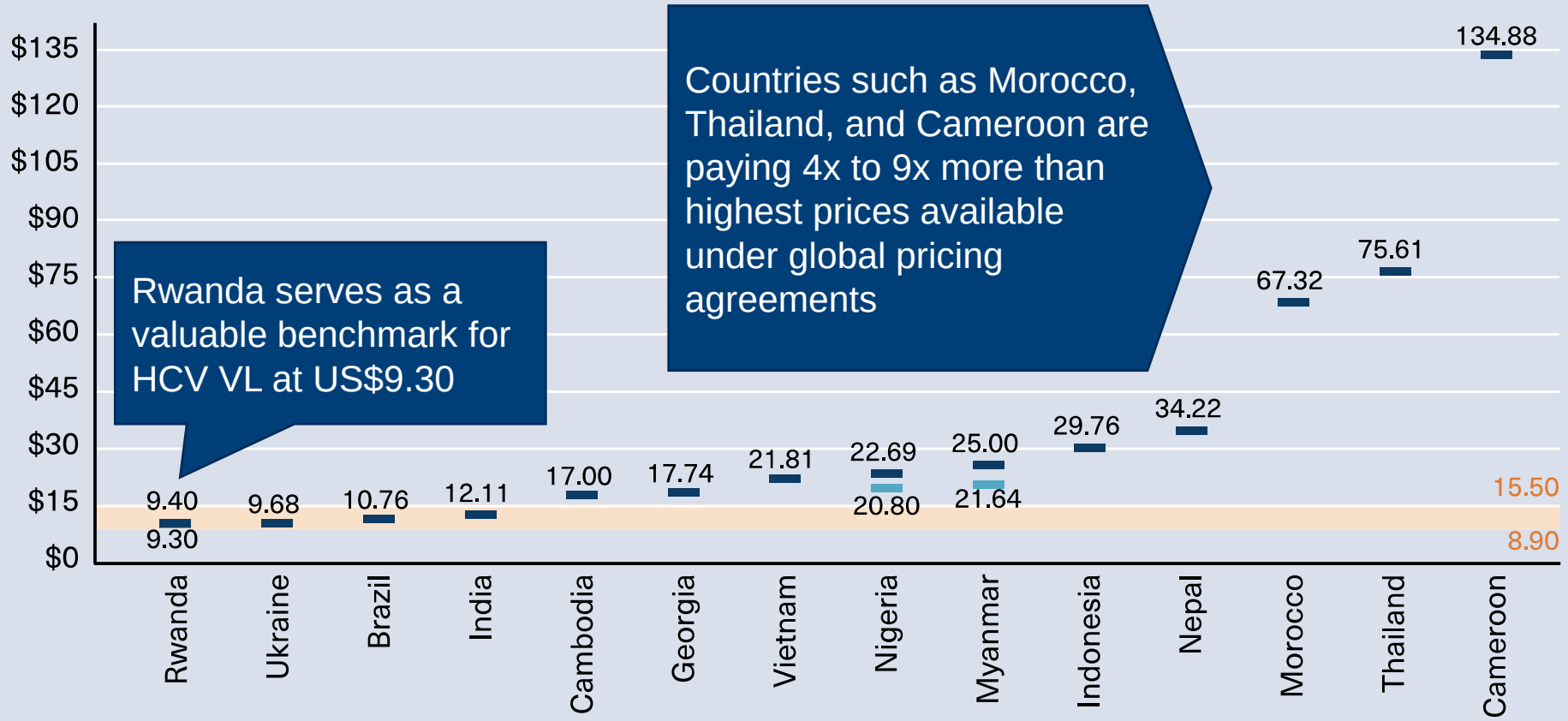
	Roche			Hologic	Qiagen	Cepheid	Abbott	
Platform	COBAS AmpliPrep/ COBAS TaqMan	cobas 4800 System	cobas 6800/ 8800 Systems	Panther	QIAsymphony SP/AS	GeneXpert*	Alinity m	*m*2000
HCV	X	X	X	X	X	X	X	X
HBV	X	X	X	X	X	X	X	X
HIV-1	X	X	X	X	X	X	X	X
HPV		X	X	X		X	X	X
SARS-CoV-2			X	X		X	X	X
MTB			X			X		X
CT/NG, CT, NG		X	X	X		X	X	X

Three additions to the WHO Prequalification list in 2020/2021:

- Roche cobas HCV viral load test (cobas 6800/8800 Systems)
- Abbott RealTime HCV (m2000) for dried blood spot (DBS) samples
  - This represents the first VL assay with PQ for DBS
- Genedrive HCV ID Kit
  - Genedrive offers another option for point-of-care technology

Viral Load: While global pricing for HCV viral load exists, many programs are still paying very high prices for viral load tests

Exhibit 8: HCV viral load price per test paid by public programs. Data collected in 2020-2021



Note: The horizontal band represents the highest and lowest prices (Abbott low test volume and Roche respectively) available under the global pricing agreements in Exhibit 9; all prices in USD.

Viral Load: Leveraging suppliers' global pricing agreements can provide benefits to programs

- Suppliers offer different terms, which are variably inclusive of different cost components
  - These may include instrument placement, service and maintenance, and different incoterms options
- Global pricing may be associated with annual test volume requirements, which may be applicable across disease assays

Exhibit 9: Viral load global pricing

Suppliers	Hologic	Roche[a]	Cepheid[a]		Abbott[a,b]
Platforms	Panther	cobas 4800 System, cobas 6800/8800 Systems and COBAS AmpliPrep / COBAS TaqMan System	GeneXpert (all systems)	GeneXpert (all systems) with GX XVI placement[b]	*m*2000
Corresponding assays	HBV, HCV, HIV (VL and EID), HPV	HBV, HCV, HIV (VL and EID), HPV, MTB/RIF/INH, SARS-CoV-2	HBV, HCV (VL and VL FS), HIV (VL and EID), HPV	HBV, HCV (VL and VL FS), HIV (VL and EID), HPV, SARS-CoV-2	HBV, HCV, HIV
Volume commitment	30,000 tests/yr (avg per instrument)[c]	None	None	10,000 tests/yr for each GX XVI placed[d]	Volume-based pricing 50,000 to >1,000,000 tests/yr (avg per instrument)
Price per test (USD)	$11.28 (ceiling)[e]	~$8.90[f]	~$14.90	$14.90 (ceiling)[g]	Price ranges based on volume:[h] Plasma: ~$9.60 to ~$15.55 DBS: ~$11.10 to ~$17.05

Understanding the net individual costs of differing testing strategies enables the optimization of diagnostics cascades

- ❑ Multiple cost components add to the final cost paid. Visibility to the price breakdown can aid to:
  - Negotiate contract terms
  - Compare costs and services from different suppliers
  - Identify opportunities for cost reductions
  - Assess total budget impacts
- ❑ Open communication with the supplier, distributor, and government import agencies can help achieve cost visibility
- ❑ Implementation factors should be considered including sample collection, sample transport, and platform availability
  - ❑ RDT vs lab-based immunoassays for screening
  - ❑ Point-of-care vs central platforms for viral load
  - ❑ DBS vs plasma samples

Exhibit 12: Example Roche HCV VL cost components from anonymous country

Price Component	Cost %	Incremental Price	Total Price
Test (FOB)			US$8.90
Logistics/clearing fees/handling	15%	US$1.34	US$10.24
Distributor fees	5%	US$0.51	US$10.75
Flat distributor service charge		US$1.00	US$11.75
Cost to facility			US$11.75

Exhibit 13: Example Cepheid HCV VL cost components from anonymous country

Price Component	Cost %	Incremental Price	Total Price
Test (EXW)			US$14.90
Shipping and insurance	8%	US$1.19	US$16.09
Logistics/clearing fees/handling	20%	US$3.22	US$19.31
Cost to facility			US$19.31

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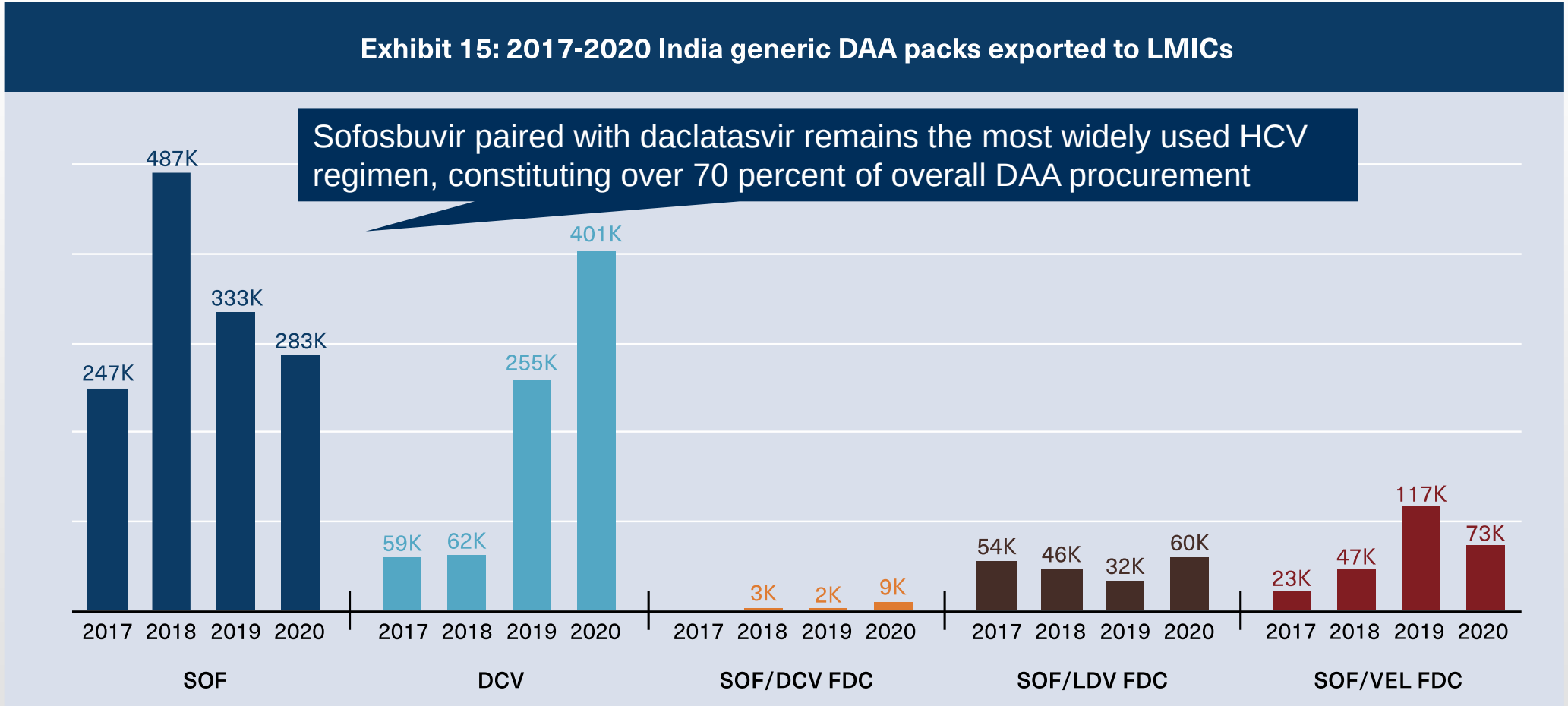
Most WHO-recommended DAA regimens now have at least one WHO prequalified product available

Exhibit 14: Generic supplier quality status (as of July 2021)

DAAs	WHO PQ'd
SOF (400 mg)	Cipla, Hetero, Strides, Viatris, European Egyptian Pharmaceutical Limited (Pharco)*
DCV (30 mg and 60 mg)	Cipla, Hetero, Viatris, **Laurus Labs**
SOF/DCV FDC (400mg/60mg)	**Viatris**
SOF/LDV FDC (400mg/90mg)	**Viatris**
SOF/VEL FDC (400mg/100mg)	**Viatris**
SOF/VEL/VOX FDC	None
G/P (300/120mg)	None

- Viatris received WHO-PQ for SOF/DCV FDC, and SOF/VEL FDC in 2020
- Laurus Labs became the fourth generic to receive WHO-PQ for Daclatasvir

More than one million treatment courses of generic daclatasvir have been procured as of Dec 2020

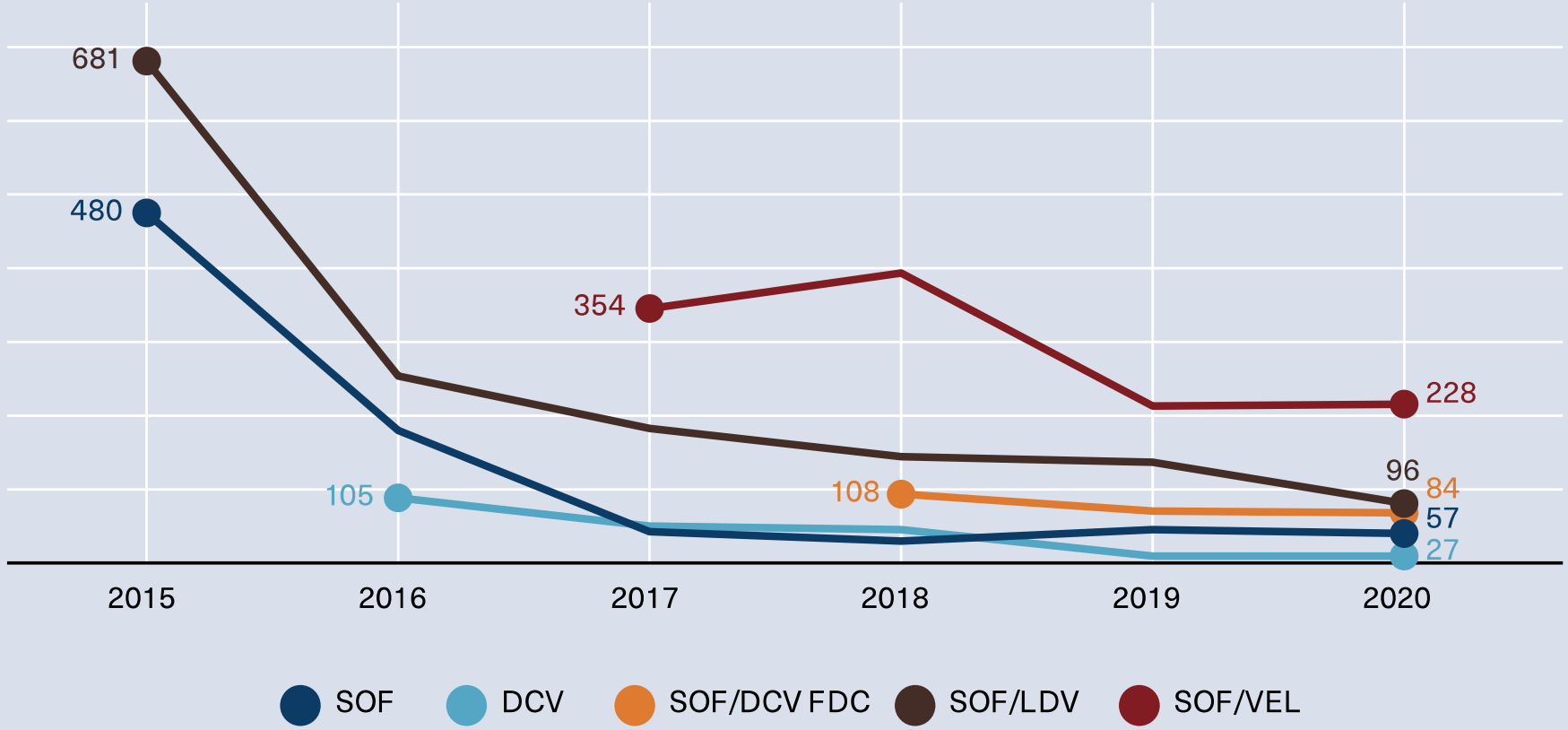


- Only 13 percent of chronic HCV infections are estimated to have been treated worldwide, **more than 50 million patients remain untreated** - a significant opportunity to scale programs

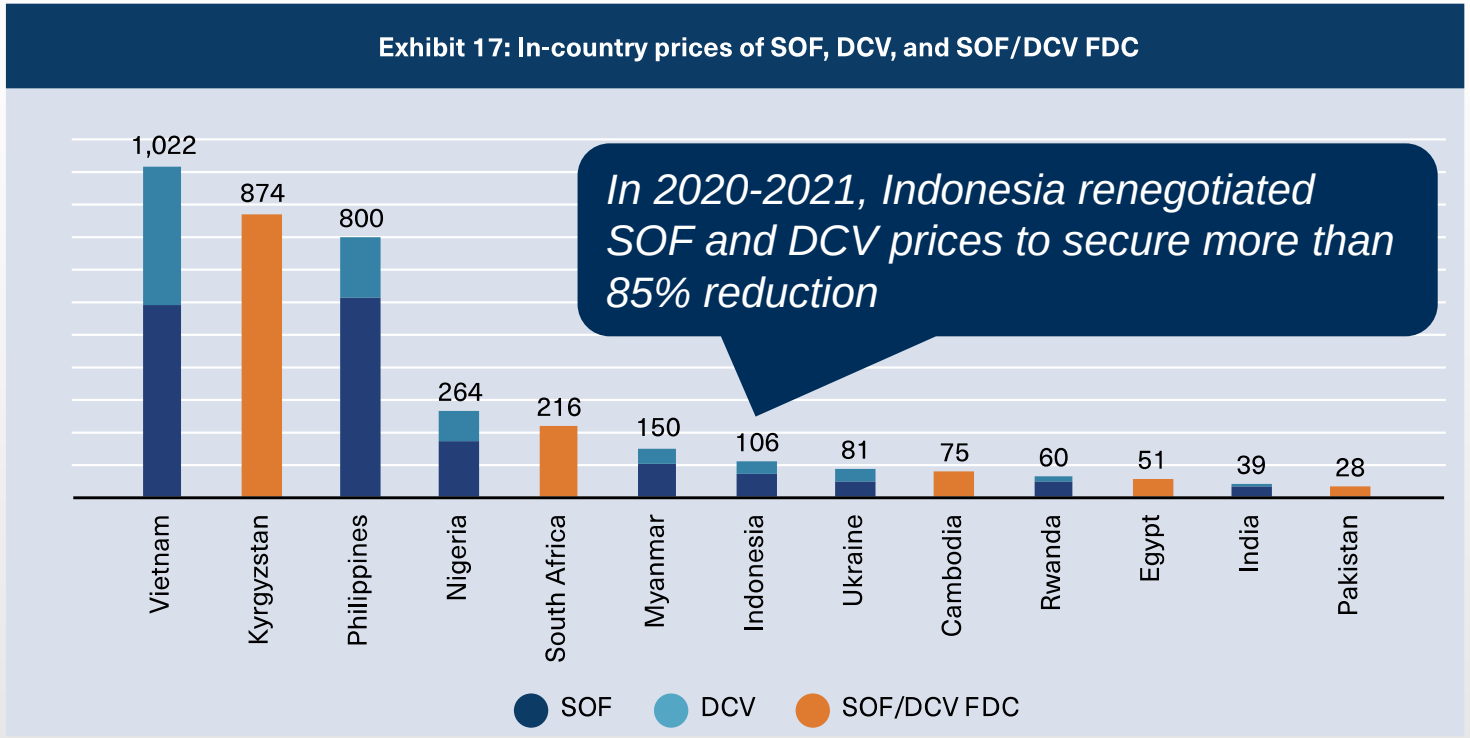
Decreases in DAA prices have slowed after large improvements between 2015 and 2018

- Further decrease in treatment cost can be expected to be driven by supply chain optimization and centralized procurement by countries where the in-country mark-ups are still high

Exhibit 16: Weighted average FOB price for 12 weeks of treatment with DAAs in LMICs

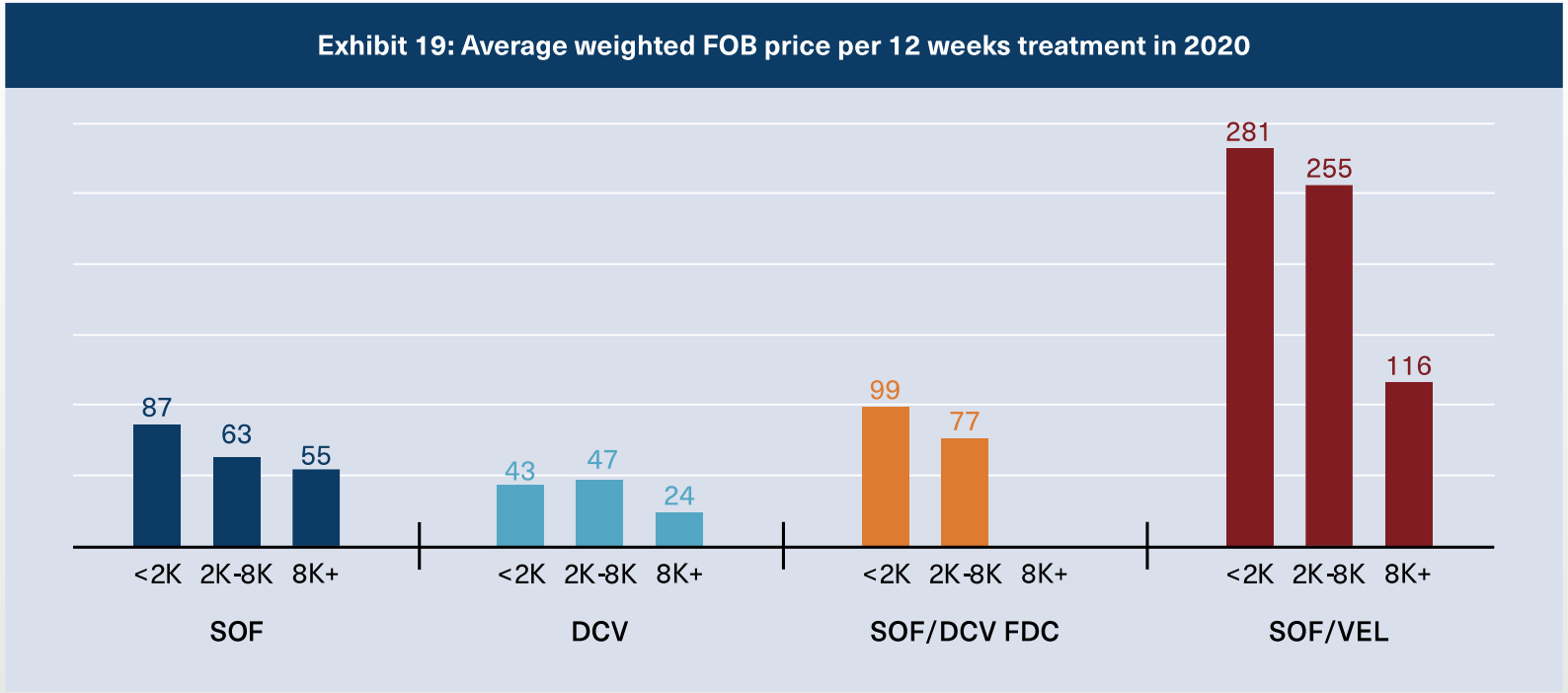


In-country prices remain high in some high burden countries and there is significant variability in prices across countries



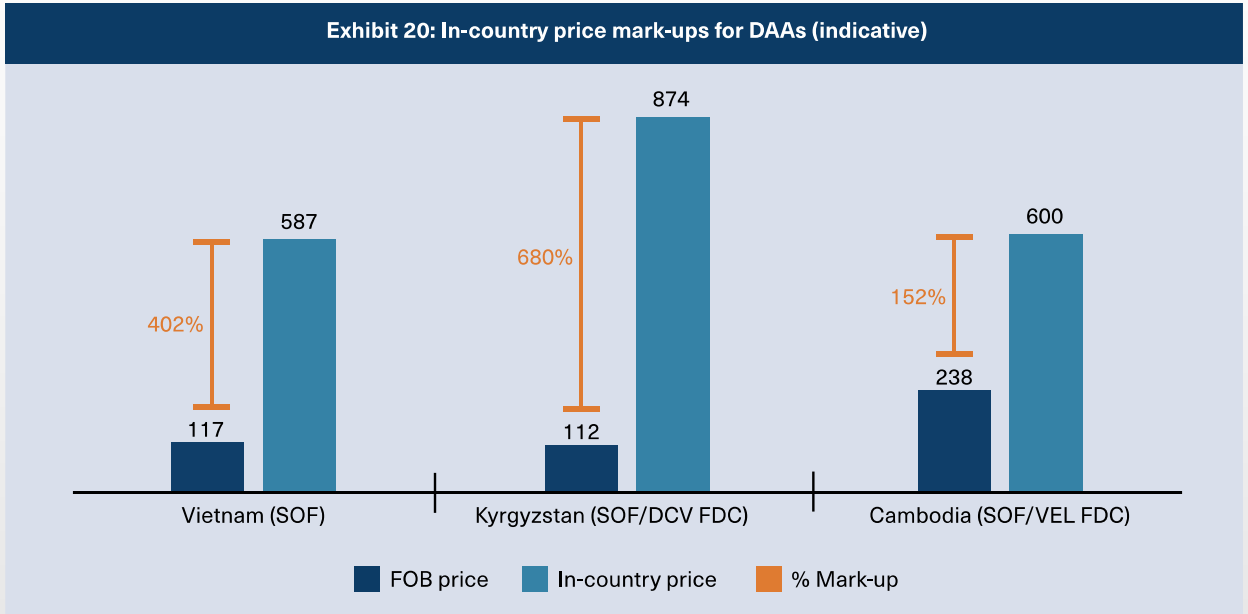
- There is no standardized global price that countries are accessing yet
- Egypt, India, and Pakistan have secured very low prices for DAAs as they are scaling-up public programs; Prices negotiated by GFATM for 12 weeks of HCV treatment are ~US$89 for SOF + DCV singles, and ~US$75 for SOF/DCV FDC
- Similar variation in prices across countries is observed for SOF/VEL

Countries can benefit from lower pricing by planning procurement and ordering DAAs in optimal quantities



- Large orders allow drug suppliers to more efficiently manufacture product, which in turn can lead to lower prices for buyers
- Scaled-up HCV treatment and planned procurement to pool volumes have obtained lower prices for treatment

High mark-ups for shipping, insurance, import duties, and distributor margins continue to contribute to high prices in-country



- Despite a decline in freight-on-board prices of DAAs, in-country prices continue to be high due to high mark-ups
- In-country mark-ups typically include shipping and insurance, import duties and in-country taxes, storage, facility maintenance, and transportation costs, pharmacy charges, distributor margins, and other logistical costs
- In countries lacking a centralized procurement and distribution system managed or contracted by the government, mark-ups are as high as three to six times the FOB cost

A small market and limited quality-approved supply pose an access risk for the HCV retreatment programs

Guidelines

- Current WHO guidelines recommend second-line therapy of SOF/VEL/VOX or extending the initial DAA therapy to 16 or 24 weeks, while reinforcing adherence as an alternative option

- SOF/VEL/VOX is currently only available from the originator Gilead, as generics are not incentivized to enter the small, fragmented market, and are priced out of reach for most LMICs

Current Practice

- A **24-week course of ribavirin (RBV) with either SOF/LDV, SOF/DCV, or SOF/VEL** are the most commonly used second line therapy regimens across LMICs; Assessment of some of these programs are under progress for evidence generation and guidelines consideration

- Currently, there are no WHO PQ'd or ERP-approved suppliers for ribavirin. Only two generics which have US FDA approved ribavirin are supplying in LMICs

- Better quantification of patients needing retreatment, transparency into procurement plans, and pooling of demand across countries could help suppliers plan production capacity, leading to lower lead times and prices

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Upcoming WHO guidelines is expected to include recommendation for HCV treatment of children and adolescents

Guidance Updates

- ❑ Consensus amongst GAP-f on aligning treatment regimens for adults and children
- ❑ Upcoming WHO treatment recommendations expected to include use of all currently recommended pangenotypic DAA regimens among lower age bands

Dosing

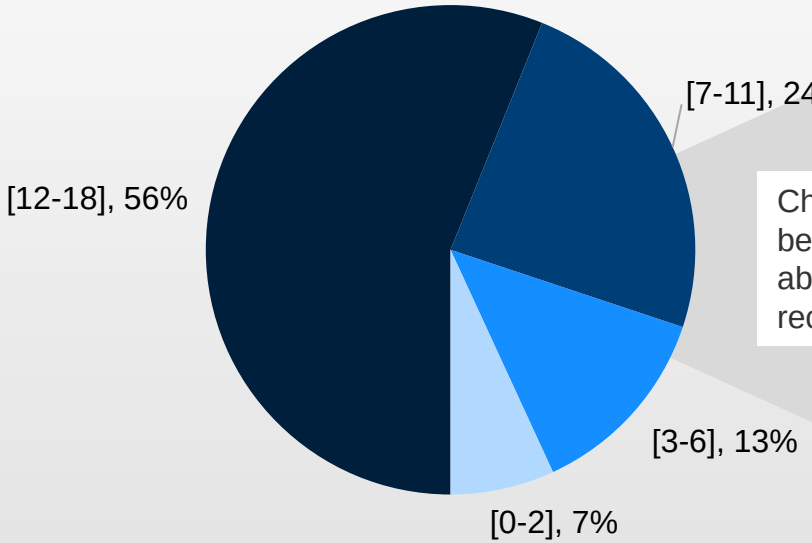
- ❑ Gilead and AbbVie received US FDA approval in Q2 2021 for the use of SOF/VEL and G/P respectively among children down to the age of 3 years
- ❑ Evidence available that DCV 30mg dose will provide appropriate drug exposure amongst younger children

Products

- ❑ WHO PQ'd DCV 30mg is available from multiple generics
- ❑ **SOF 200mg is not yet available as a generic product to pair with DCV**
- ❑ Dossiers for pediatric regimens of SOF singles, DCV singles, SOF/DCV, SOF/VEL, and G/P have been submitted to the WHO Expert Committee for review requesting inclusion on the essential medicines list for children (EMLc)

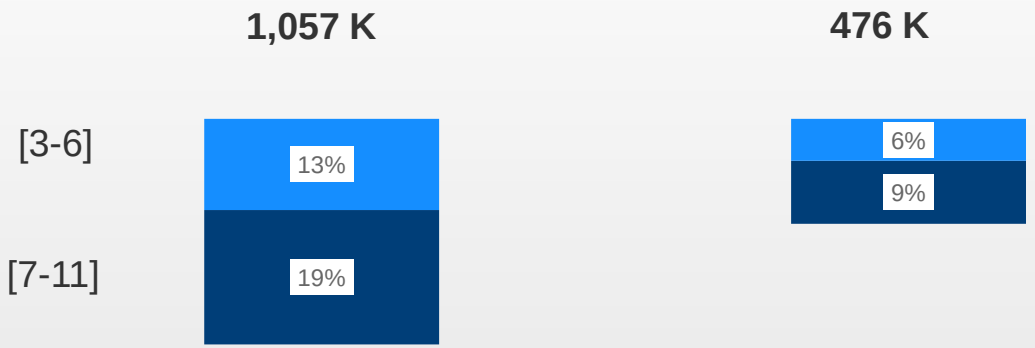
Based on the estimated number of children requiring pediatric dosages in countries with robust adult programs, CHAI estimated the “addressable market” to be nearly 500K children

Age-wise distribution of HCV prevalence estimates amongst children (3,258 K) [1]



Children below 3 are likely to be excluded and children above 12 would be recommended adult dosage

Pediatric HCV and Addressable Market Size Estimates (# of children)



Children requiring pediatric dosage:
100% within the age-group [3-6]
80% within the age-group [7-11]

Addressable market defined as children requiring pediatric dosage across seven countries with robust adult programs – Rwanda, Egypt, India, Mongolia, Pakistan, Georgia, Ukraine

[1.] Schmelzer J, Dugan E, Blach S, et al. Global prevalence of hepatitis C virus in children in 2018: a modelling study. The lancet. Gastroenterology & Hepatology. 2020 Apr;5(4):374-392. DOI: 10.1016/s2468-1253(19)30385-1.

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Progress: Significant room for growth in HBV diagnostic and treatment market

The global target of the Sustainable Development Goals and the global health sector strategy to reduce the incidence of hepatitis B has been met, as measured by the prevalence of hepatitis B surface antigen to less than 1% by 2020 among children younger than five years.

Global HBV Burden

296 million people
living with chronic HBV globally (2019)

820K deaths
from HBV (2019)

1.5 million new HBV infections (2019)

Intervention Coverage

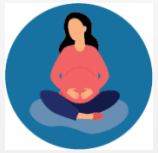
30.4 million people (10%)
know their HBV status (2019)

6.6 million people (2.2%)
received treatment for HBV infection (2019)

43% global coverage for timely HBV birth dose vaccine (2019)

Guidelines: The testing and treatment algorithm for HBV remains complex

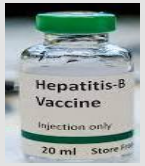
Serological Testing



Assessment for long-term treatment or maternal prophylaxis

Treatment and maternal prophylaxis

Monitoring / assessment of disease progression

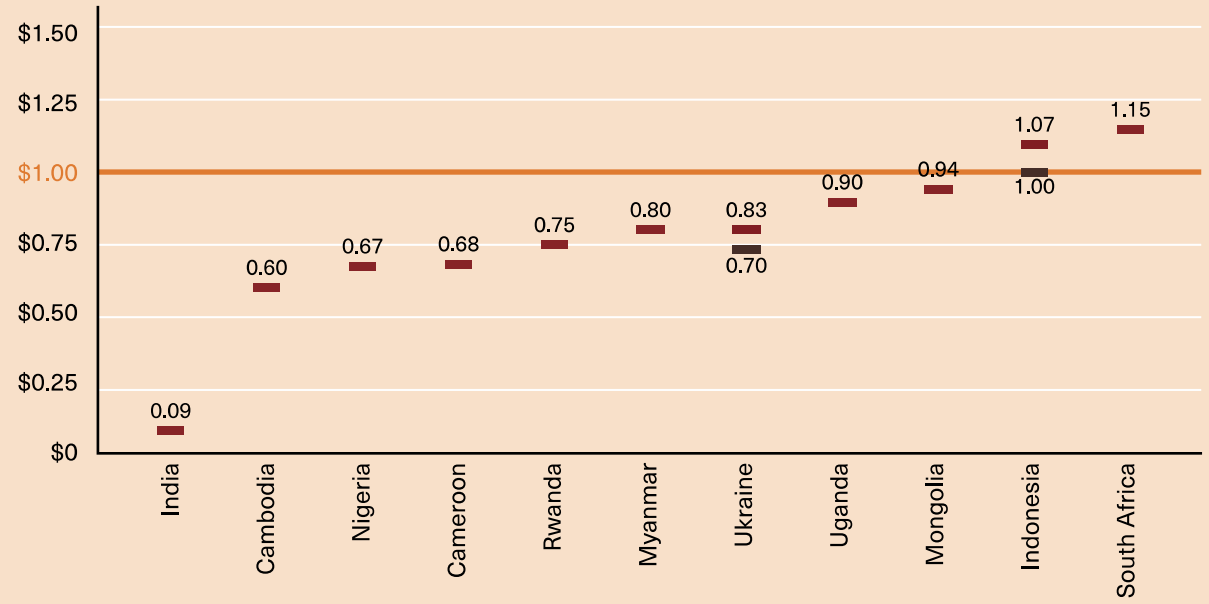


Infant vaccination

Diagnostics Landscape: Availability and pricing of quality-assured HBsAg and HBV viral load tests is similar to HCV diagnostics

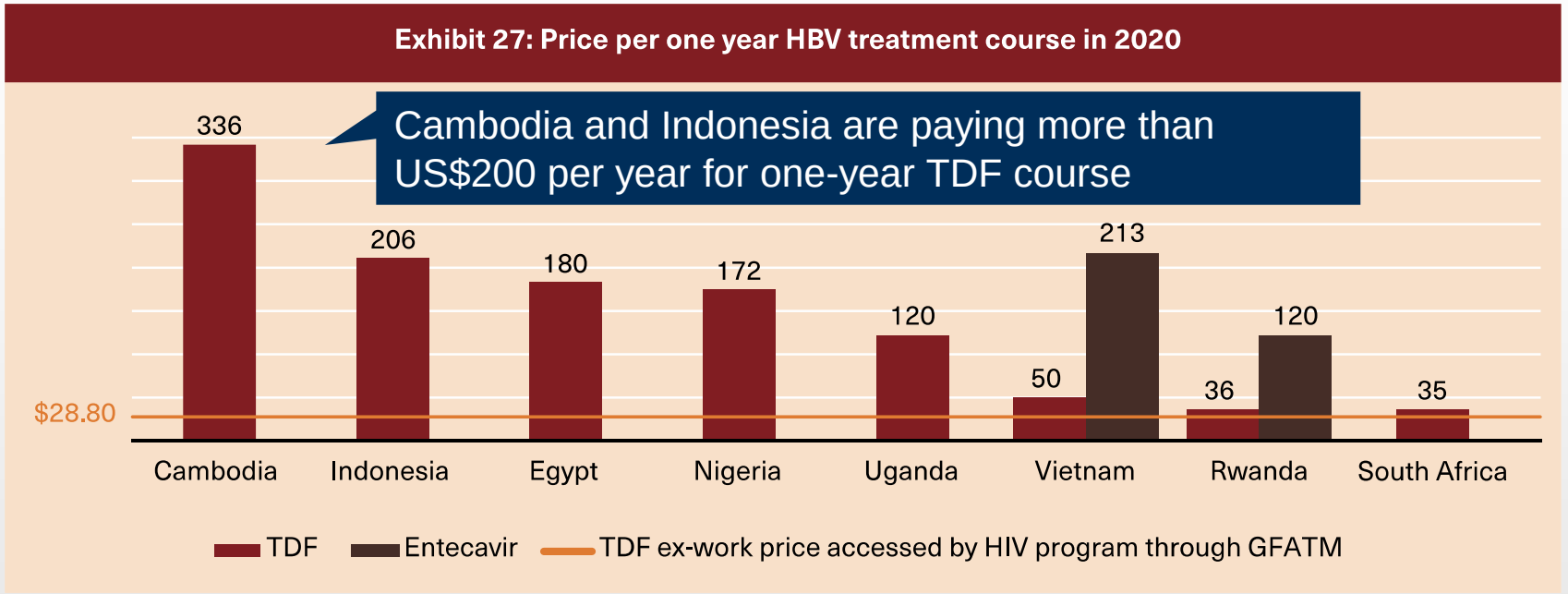
- **Hepatitis B Surface Antigen Tests**
  - There are number of high-quality HBsAg tests available with WHO PQ: three RDT and two lab-based
  - Global prices for HBsAg RDTs are generally comparable with other RDTs; such as HCV antibody RDTs
- **Hepatitis B e Antigen Tests**
  - While both RDT and lab-based HBeAg tests are commercially available, there is currently no WHO PQ process for HBeAg
  - Visibility of global HBeAg pricing and product availability in LMICs is limited at this time
- **Hepatitis B Viral Load Tests**
  - HBV VL is available on most of the platforms being used for HCV VL
  - Supplier's VL global pricing agreements include both hepatitis B and C

Exhibit 26: HBsAg RDT prices per test paid by public programs



Note: The horizontal line is a visual aid to compare prices to $1; all prices in USD.

Treatment Landscape: Though TDF is used as both an HBV and HIV treatment, the prices accessed by the HIV and HBV programs are different



- **Use**: WHO recommends the use of tenofovir disoproxil fumarate (TDF) or entecavir for the treatment of hepatitis B infection in all adults, adolescents, and children aged 12 years or older for whom antiviral therapy is indicated; Only entecavir is recommended for children aged two to 11 years. Both products are off-patent globally
- **Supplier Landscape**: TDF has been a mainstay for HIV treatment and has a broad supplier base of quality-approved generics – six generic suppliers have received WHO PQ. Only one generic has received WHO PQ for entecavir
- **Pricing**: Though TDF is commonly used as both an HBV and HIV treatment, the price paid by HBV programs and patients is often not at parity with the price accessed by HIV programs across LMICs. Entecavir, is costlier than TDF

Looking Forward: Further evidence on the scale-up of innovations for HBV prevention, testing and treatment can help further broaden the HBV market

- **Expanding HBV Testing and Treatment**
  - **Countries like India and Rwanda are expanding HCV infrastructure to screen and treat patients for HBV**
  - Countries working towards the dual elimination of perinatal HIV and syphilis infection are **including elimination of mother-to-child HBV transmission within their programs as part of a triple elimination agenda**
  - **Integrating screening and viral load testing for HBV within antenatal care settings** will support the expansion of HBV programs

- **Innovations in the commodities landscape**
  - **Point-of-care testing for HBV has the potential to broaden testing in low-resource settings**; however, more tests need to be ratified for clinical use by international regulatory bodies to enable uptake
  - **An integrated rapid diagnostic test for HIV, syphilis, and HBV could help improve screening coverage in antenatal care settings**; however, no multiplex product including HBV is commercially available with WHO PQ
  - **New presentations of the HBV birth dose vaccine and control temperature chain could increase coverage and access** to the vaccine at a community level

Agenda

- Introduction *(Craig McClure, CHAI) – 10 mins*
- Welcome Remarks *(David Ripin, CHAI) – 3 mins*
- Message from WHO *(Meg Doherty, WHO) – 15 mins*
- HCV Diagnostics Highlights *(Emi Okamoto, CHAI) – 10 mins*
- HCV Treatment Highlights *(Ritubhan Gautam, CHAI) – 7 mins*
- HCV Pediatrics Market *(Christian Ramers, CHAI) – 10 mins*
- HBV Market Insights *(Oriel Fernandes, CHAI) – 10 mins*
- Country Examples
  - *Nigeria Diagnostic Market Shaping (Chukwuemeka Agwuocha, CHAI) – 5 mins*
  - *Indonesia DAA Price Reduction (Caroline Thomas, Yayasan Peduli Hati Bangsa) – 5 mins*
- Q&A *– 15 mins*

Nigeria Experience: Improving Access to Viral Hepatitis Viral Load Testing

Early Challenges

1. **High cost:** HCV VL offered for over $140 in the private sector, out-of-pocket (OOP) payment
2. **Poor Access:** In certain states, patients had to travel over 850km to access diagnostic testing in the public sector
3. **Limited Services:** Test offered at sites non-standardized processes; limited healthcare worker capacity to manage cases

Strategic Approaches

Stakeholder Engagement/Advocacy
- Identified key stakeholders (MOH, Gastro, etc.) to champion discussions

Optimizing in-country costs and mark-ups
- Negotiated high mark-ups along the value chain and advocated for low facility mark-ups to cover operational costs

Expansion of testing sites
- Integrated testing in the public sector further expanded to atleast 15 facilities
- Trained HCW to adequately manage uncomplicated cases

Market Intel
- Identified trends and opportunities within the global landscape
- Leveraged opportunities to integrate and domesticate these developments

Outcomes

- ❑ Institution of Roche GAP pricing deal resulted in an estimated 40% reduction ($26 to $16) in cost/test and scale-up to 5 additional sites
- ❑ Further achieved a 20% reduction in cost per test on the GeneXpert platform

Agenda

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Registered Sofosbuvir & Daclatasvir

	2016	2018	2019	2020	2021	Total
Sofosbuvir	1	2	1	1	1	6
Daclatasvir	1		2			3

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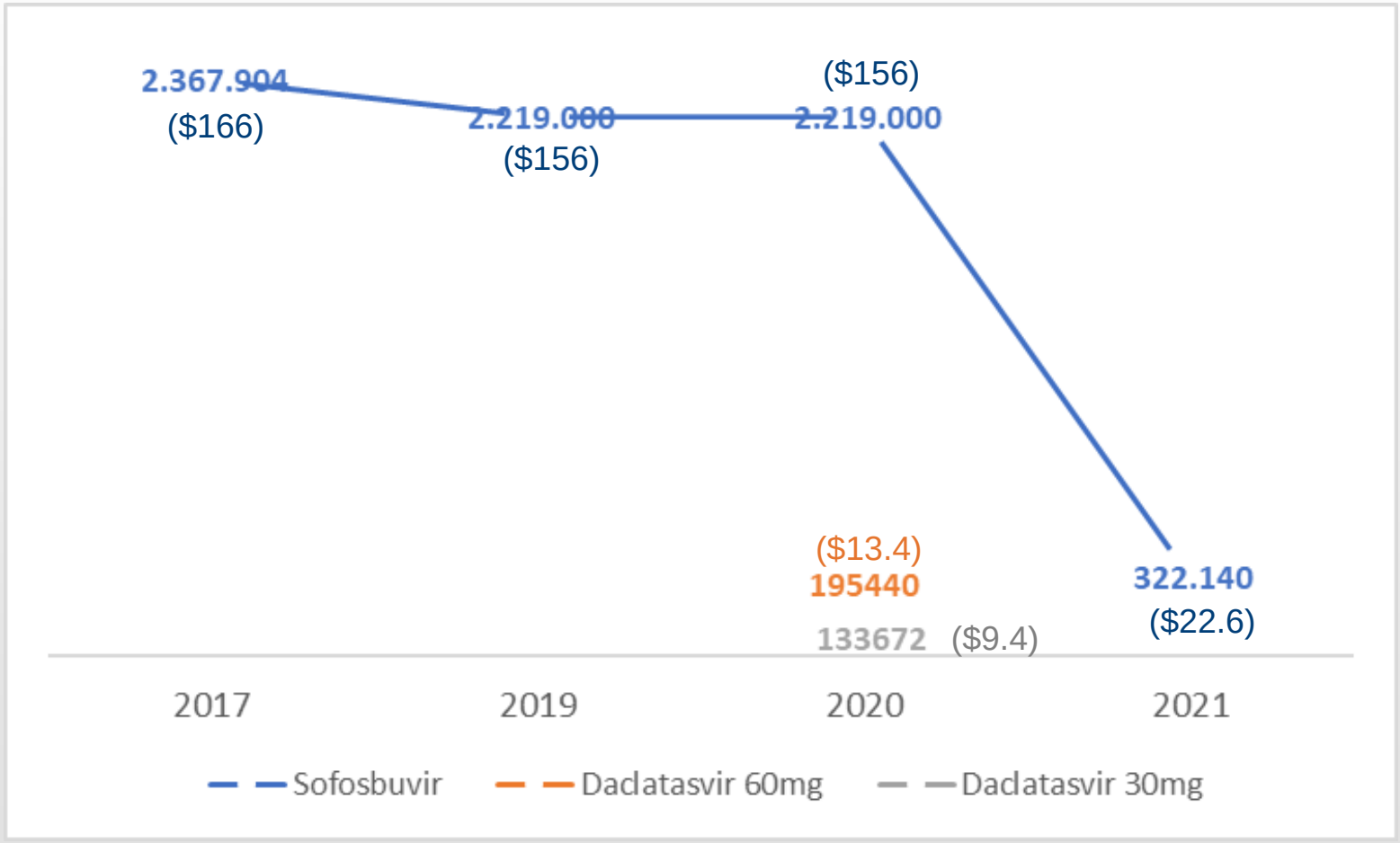
Price of Sofosbuvir and Daclatasvir/bottle (Indonesian Rupiah)-e-catalogue



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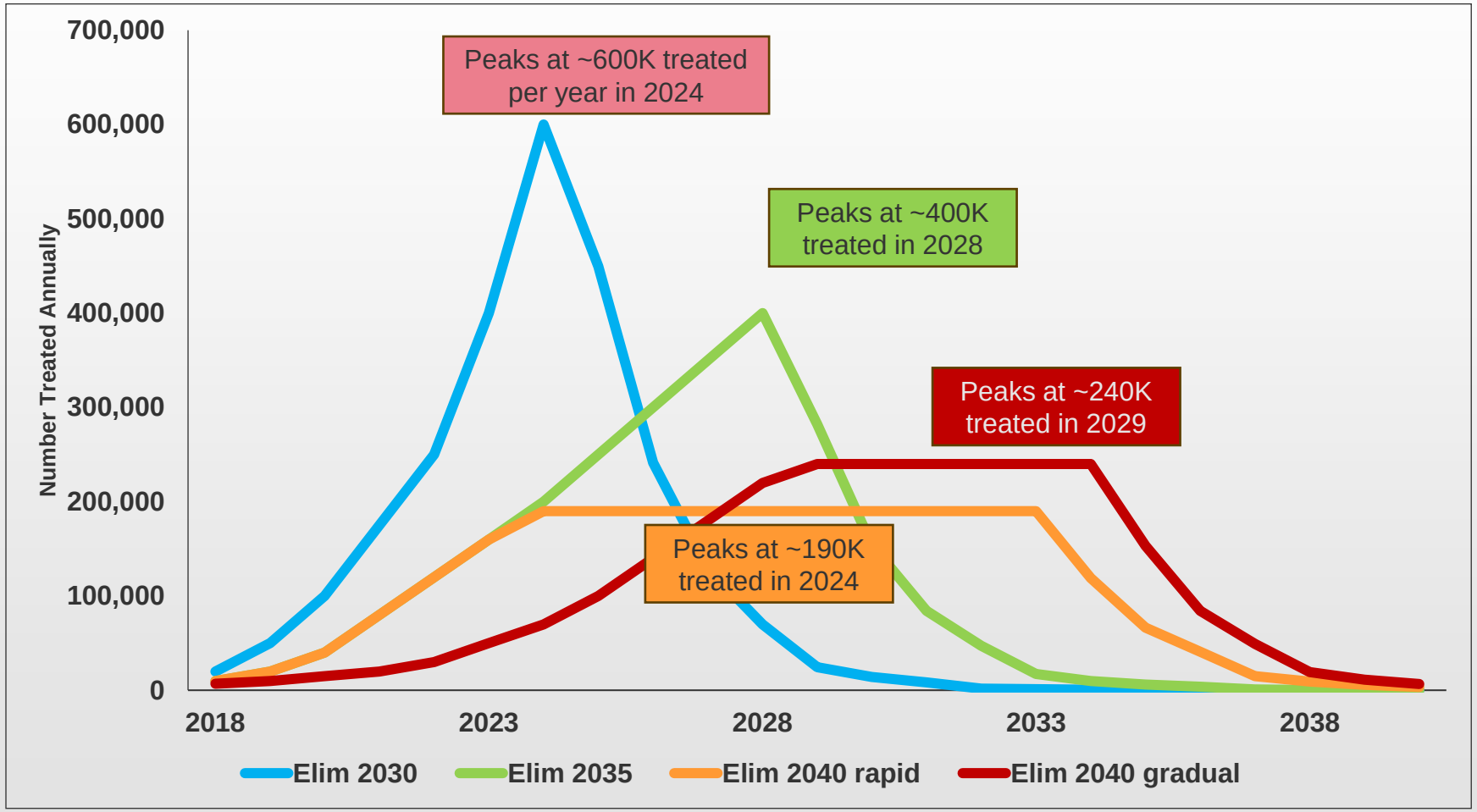
Elimination is possible either by a rapid scale-up to 2030 or by a gradual scale-up to 2040



Trickey, Adam & Hiebert, Lindsey & Perfect, Chase & Thomas, Caroline & Vickerman, Peter & Schùtte, Carl & Hecht, Robert. (2019). Hepatitis C virus elimination in Indonesia: Epidemiological, cost, and cost-effectiveness modelling to advance advocacy and strategic planning. Liver International. 40. 10.1111/liv.14232.

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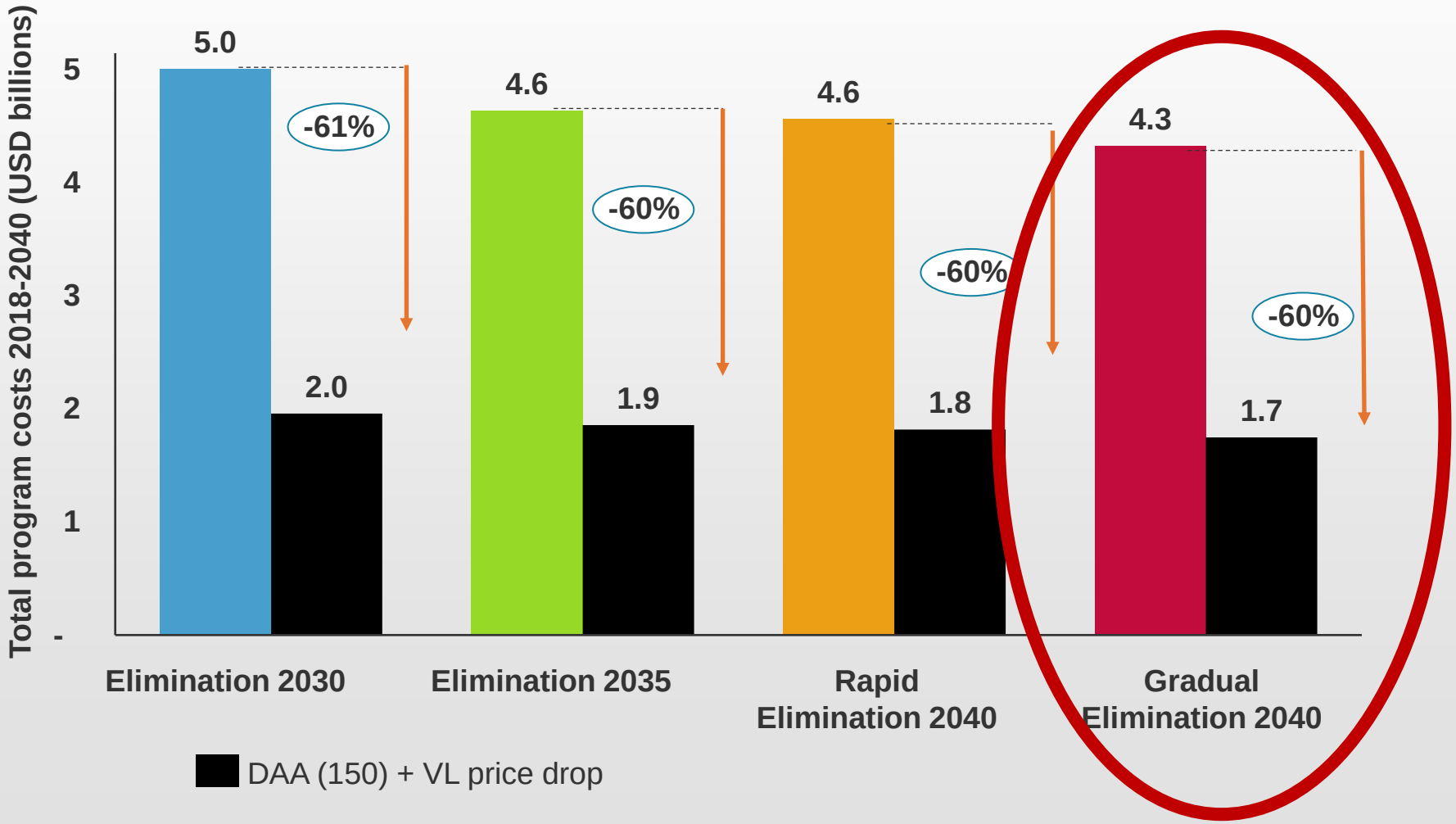
Reduction in DAA prices to USD 150 and VL prices to USD 40 could reduce total program costs by 60% to USD 1.7 B total



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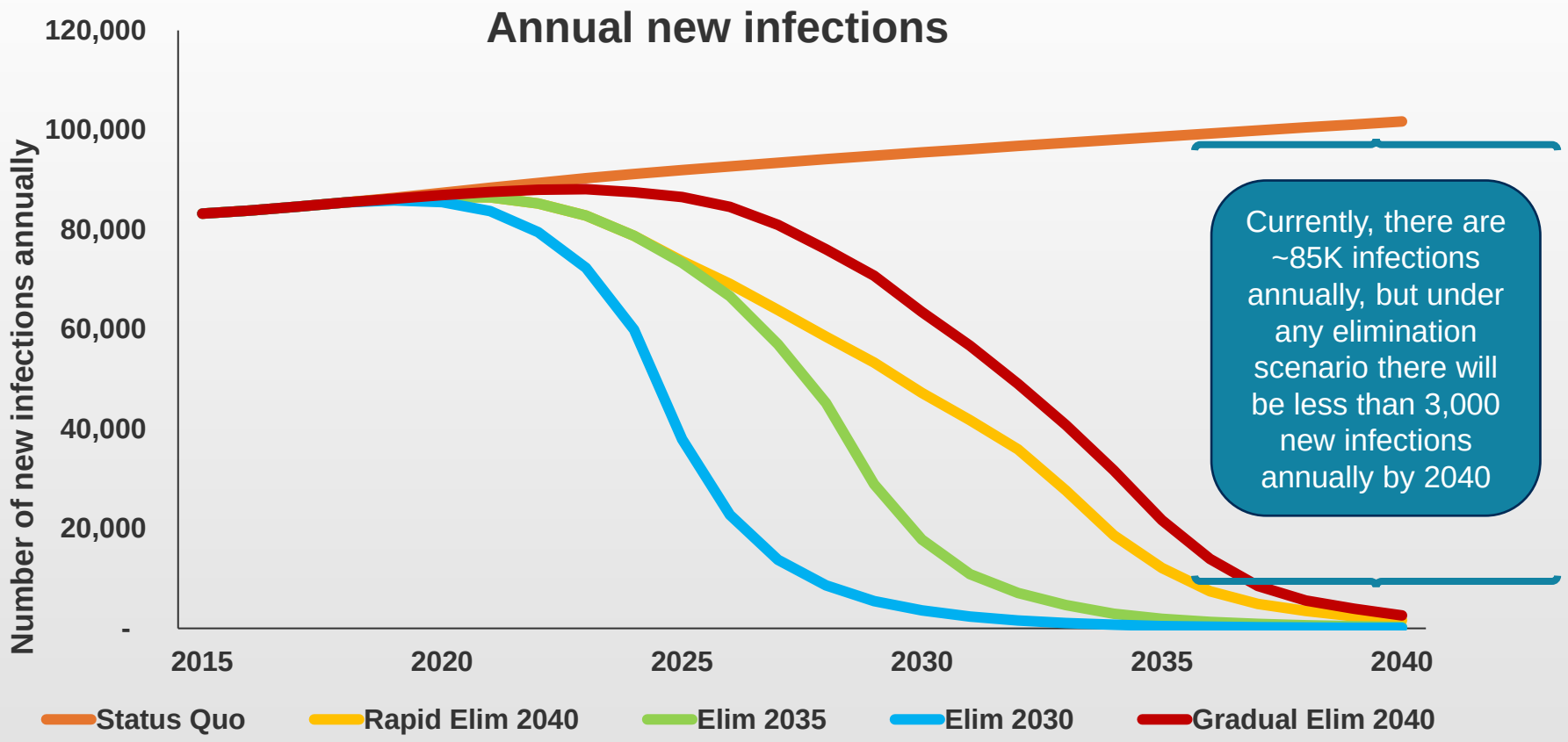
HCV elimination will prevent at least 1 million new infections



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Key messages

- Allow competition
- Competition=lowered price=increased coverage
- Community led monitoring
- Price and procurement transparency
- Investment case study

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Q&A

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HEALTH ACCESS
INITIATIVE